Zacks Small-Cap Research

May 17, 2016

Anita Dushyanth, PhD
312-265-9434/adushyanth@zacks.com
Brian Marckx, CFA
312-265-9474/bmarckx@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Hansen Medical (HNSN-NASDAQ)

HNSN: Q1 2016 Financial Results

We use a 10-year DCF model to value Hansen Medical. We model revenue to be $17 million in 2016, $58 million in 2019 and rise to $480 million by 2025. Based on the recent buyout announcement we expect the stock to trade near $4.00/share.

Current Price (05/17/16)	$4.01
Valuation	**$4.00**

OUTLOOK

Hansen Medical Inc. (NASDAQ:HNSN) based in Mountain View, CA develops robotically steerable catheters for electrophysiological (EP) and peripheral vascular procedures. Hansen's flagship products, the Sensei® X and Magellan Robotic Navigation Systems have been adopted into clinical practice in a few centers across the U.S. and Europe, as well as other global regions.

The acquisition of Hansen Medical by Auris Surgical Robotics, Inc for an equity value of roughly $80 million was announced on April 20, 2016 and is subject to closing conditions including Hansen Medical shareholders' approval. The deal is expected to close by mid-2016.

SUMMARY DATA

52-Week High	**$10.70**
52-Week Low	**$1.30**
One-Year Return (%)	**-62.43**
Beta	**0.33**
Average Daily Volume (sh)	**252,064**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$76**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**29**
Insider Ownership (%)	**22**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**-2.1**
P/E using 2017 Estimate	**-2.5**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	$5.79 A	$3.09 A	$3.18 A	$4.00 A	$16.07A
2016	$3.04 A	$3.9 E	$4.2 E	$4.5 E	$15.64E
2017					$25.17E
2018					$39.10E

Price/Sales Ratio (Industry = 2.5x)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.90 A	-$3.00 A	-$0.54 A	-$0.61 A	-$4.89 A
2016	-$0.51 A	-$0.49 E	-$0.41 E	-$0.34 E	-$1.72E
2017					-$1.51 E
2018					-$1.05 E

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

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

HNSN: Q1 2016 Financial Results

Financial Update: Hansen Medical reported financial results for Q1 2016 on May 16, 2016.

Total revenue came in at $3 million, product revenue was ~$1.6 million from the sale of 870 catheters and revenue from service was ~$1.4 million. Product revenue decreased 47% from Q1 2016. No systems were sold during this period. Two customers accounted for 15% and 10% of total revenues. The U.S. region accounted for 52% of revenues and Belgium accounted for 14% of total revenues.

Revenue between sequential quarters has been choppy and the fluctuations can be attributed to several factors including general economic and capital market conditions and uncertainty created by the Patient Protection and Affordable Care Act (PPACA). Capital expenditures were routine in healthcare centers and usually authorized by specialists but are now heavily scrutinized requiring approval from the healthcare board. Further, PPACA is driving hospitals to provide value-based care while keeping costs down. The current state of flux in the healthcare sector puts immense financial pressure on hospitals. Consequently, hospitals find it challenging to purchase high-cost technology equipment such as Hansen's robotic systems.

OpEx came in at ~$9 million (~$3 million in R&D and ~$6 million in SG&A) and was mostly in line with our estimates. Management noted in their first quarter earnings report that they plan to expand utility of their robotic platforms and therefore will be making substantial investments in R&D.

Net loss and EPS for the quarter were almost $10 million which equates of an EPS of $(0.51). Hansen exited the first quarter 2016 with $12.5 million in cash and cash equivalents.

Business Update: In February 2016, the FDA cleared the Magellan™ Robotic Catheter eKit (MRC eKit) for sale in the U.S. The MRC eKit allows physicians to use third party microcatheters with the existing Magellan Robotic Catheter 6Fr architecture. Shortly after receiving approval in the U.S., interventional radiologist, Dr. Ripal Gandhi, successfully performed the transarterial chemoembolization (TACE) procedure using the MRC eKit at Miami Cardiac & Vascular Institute (MCVI) in Miami, FL.

As anticipated, Hansen Medical submitted a 510(k) application to the FDA for peripheral vascular as well as neurological indications for the Magellan Robotic System on April 26, 2016.

The acquisition of Hansen Medical by Auris Surgical Robotics, Inc for an equity value of roughly $80 million was announced on April 20, 2016 and is subject to closing conditions including Hansen Medical shareholders' approval. The deal is expected to close by mid-2016. Holders of approximately 65.4% of Hansen Medical's outstanding shares have agreed to vote in favor of this transaction. Additionally, certain significant stockholders of HNSN have agreed to invest about $49 million into Auris at the closing of the transaction.

Shareholders of HNSN will receive $4.00 in cash for each share of common stock they own, which is a 40% premium to the company's six-month average trading price. HNSN's stock has traded as high as $8.50/share on April 27, 2015. The lowest price the stock traded at was $1.28/share on January 14, 2016 and since then has traded at an average price of $2.40/share. Since the merger announcement, the share price has largely remained at around $4.00/share.

In connection with the transaction, Perella Weinberg Partners LP is serving as financial advisor to a Special Committee of the Board of Directors of Hansen Medical, Sidley Austin LLP is serving as legal advisor to Hansen Medical and Morris, Nichols, Arsht & Tunnell LLP is serving as legal advisor to the Special Committee of the Board of Directors of Hansen Medical.

Valuation: We have updated our financial model to reflect Q1 2016 numbers. Based on the recent buyout announcement we expect the stock to trade near $4.00/share.

Hansen Medical: Revolutionizing Physicians' Capabilities With Robotics!

Hansen Medical Inc. (NASDAQ:HNSN) based in Mountain View, CA develops robotically steerable catheters for electrophysiological (EP) and peripheral vascular procedures. Navigating the labyrinthine vasculature with a catheter is challenging and complex. Stability is of prime importance in interventional procedures employing catheters since vessel walls are narrow and can be punctured easily. Robotic catheterization was introduced to facilitate and enhance the performance of minimally invasive procedures (endovascular procedures using catheters). Hansen's systems are intuitive, have six degrees of freedom of movement and offer 3D live views of the internal vasculature during catheter navigation. Robot steered catheters may offer benefits such as short procedure times, decrease in forces exerted by the catheter tip on the vessels, enhanced accuracy in positioning of the catheter and remote operation that spares the operator from heavy radiation doses. Hansen's robotic system provides an ergonomic design, which allows the operator to sit comfortably while maneuvering the catheter. Tactile feedback enhances dexterity and further scales movements such that large movements of the hand are translated to micro movements within the anatomy. Further, the 3D visualization provides enhanced magnification and resolution as compared to conventional systems. Hansen system's user interface is intuitive, in that, as the orientation on the control console changes, the catheter movements are harmonized with the map's orientation, thus accurately reflecting the directional translational movements. The system's robotic arm is attached to the patient's bed and works with Ensite NaVx, CARTO, as well as standard mapping and ablation catheters.

The company's flagship products, the Sensei® X and Magellan Robotic-Assisted EP Navigation Systems operate as a flexible, robotic platform. The Artisan is a guide catheter inside a steerable sheath that transmits the operator's movements to direct the catheter in three dimensions. Hansen's systems have been adopted into clinical practice in a few centers across the U.S. and Europe, as well as other global regions. Early preclinical and preliminary clinical data from using Hansen's systems indicate evidence of safety, efficacy, convenience of operation, and decreased radiation dose to the operator. The Sensei X system is used in cardiac ablation procedures in the treatment of atrial fibrillation (AF). The Magellan system has been used for interventions associated with renal and lower extremity arteries as well as in the treatment of enlarged prostrate, uterine fibroids and liver cancer.

The Sensei Robotic Catheter System and the Artisan Control Catheter received FDA 510(k) clearance for mapping and the CE mark approval for mapping and ablation procedures in 2007. Currently, the company is conducting a clinical study to support an IDE application for performing EP procedures using the Sensei system in the U.S. The FDA cleared the Magellan robotic system and catheter for use in peripheral vasculature procedures in 2012. Hansen's products are used in a wide variety of endovascular applications in the few sites where they have been installed around the globe. Thus far, more than 110 systems have been installed globally. Over 14,000 procedures have been performed in 26 studies and close to 3,000 patients have undergone the procedure. The device is covered by 125 issued U.S. patents and 89 pending U.S. patent applications, 37 granted foreign patents and over 53 pending foreign patent applications.

Medicare does not offer additional reimbursement for robot-assisted procedures. Additionally, reimbursement rates vary widely among national private payers depending on the procedure performed and contract terms. This scenario has resulted in a slower diffusion of the product into the market. We suspect that if and when Hansen obtains clearance from the regulatory agencies for expanded labeling of their product for multidisciplinary use beyond the current indications, there could occur an uptick in utilization. Clinical data could then be gathered from these additional cases and submitted as evidence of effectiveness to the insurance agencies. Consequently, insurance payers may raise the reimbursement rate to cover the cost of using innovative system like Hansen's.
Based on our in-depth research we believe that EP procedures comprise a large market and robotics in the healthcare sector is disruptive but still in a nascent stage. Hansen's systems are a part of this rapidly growing industry. Despite the advantages offered by Hansen's robotic catheters, the adoption rate has been slow. However, as the technology matures and more surgeons embrace Hansen's products we should see an increase in sales in the long-term. Despite

these short-term challenges, we think Hansen offers an investment opportunity considering the large endovascular market that the company is addressing. By demonstrating the key benefits of the Sensei and Magellan systems, the company could establish their systems as the preferred procedure for cardio and peripheral catheterization procedures.

With the current cash balance of $20 million, and at a cash burn rate of roughly $11 million per quarter we believe Hansen would require additional capital until they can turn cash flow positive. Based on the recent buyout announcement we expect the stock to trade near $4.00/share.

TECHNOLOGY

EP procedures are used in diagnosis and treatment of the electrical activities within the body. Traditionally, EP procedures were tedious and time intensive. Endovascular procedures are catheter-based procedures done in the arterial and venous vasculatures. The introduction of catheters in endovascular procedures brought about a noteworthy change in the way such procedures were performed. The advantage of catheterized procedures is smaller incisions, reduced length of stay in hospitals and reduction in risk of infection. The limitation of catheterized procedures was mainly associated with the technical aspects of the equipment. The hand is known to have seven degrees of motion, which was not replicated in these instruments. Some models did not offer haptic feedback, which as a result did not mimic the sense of touch, resulting in the absence of natural hand-eye coordination. Consequently, the systems were unable to mimic hand dexterity. Since endovascular procedures additionally require precise and frequent movement of the catheter, it increased procedure times. As device manipulation within the patient depended heavily on visualizing more than feeling the anatomy, delicate procedures were often difficult to perform. Further, visualization was rendered in 2D through fluoroscopy, which demanded the clinician wear a lead apron while performing the procedure. Additionally, the operator had to perform this procedure while standing.

More recently, robot assisted catheterized systems were introduced to improve efficacy in minimally invasive procedures. Hansen Medical has developed a class of robots to semi-autonomously navigate catheters within the body. By increasing the tool's dexterity inside the patient's anatomy, navigation is made easy and the operator is able to reach locations that are otherwise difficult to reach manually. Further, shrinking the tool size has minimized the difficulty in working with robotic systems in the hospital room. Targeted applications of Hansen's equipment are in manipulation, positioning, and control of catheters (diagnostic, therapeutic, and mapping) in cardiac and peripheral vasculature.

PRODUCTS

Indication – Cardiovascular Disease (Atrial Fibrillation)

AF, which is the most common form of arrhythmia, results from abnormal electrical impulses that cause a rapid irregular heartbeat within the upper chambers (atria) of the heart. The irregularity of the heartbeat results in ineffective pumping of the blood and complications that increase the risk of a cardiac arrest. Patients with AF are especially at high risk of developing blood clots that can lead to stroke. The risk of AF increases with age, high blood pressure, and coronary artery disease (CAD), hyperthyroidism, obesity, diabetes, lung disease, and other unknown factors.

The ideal management of AF involves restoring the heart's natural sinus rhythm, a procedure termed as cardioversion. This can be performed in two ways; by electrically shocking the heart so it stops momentarily and resumes beating with normal rhythm or using oral medications to restore the natural rhythm. Anti-arrhythmic medications are given to prevent future episodes of AF. In occasions where there is a limited success of shock and/or anti-arrhythmia drugs in the treatment of AF, catheter ablation is performed wherein the region from which the abnormal signals originate are destroyed using either RF energy or extreme heat or cold.

Although cardiac ablation has become the mainstay for treating AF in the past decade, the primary challenge has been in ensuring adequate ablation to cause a long-lasting electrical isolation that will prevent future episodes of AF. Injury at the ablation site often occurs due to improper positioning and handling of the catheter. Factors affecting catheter positioning are stability, catheter tip size, tip-tissue interface, and the contact force at the ablation site. In order to have a successful ablation procedure the physician needs to be able to create an electrical isolation of the rebel sites that induce atrial flutter. Further, catheter contact with the tissue is a necessary requirement for scarring the tissue in order to block stray electrical signals effectively.

Sensei X Robotic System

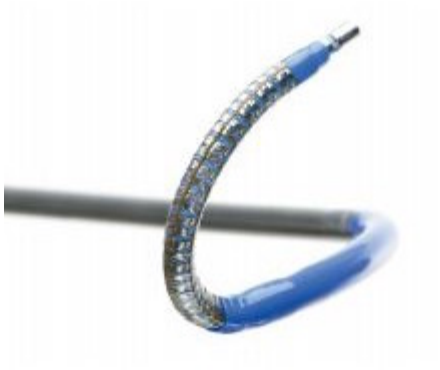


(Source: www.HansenMedical.com)

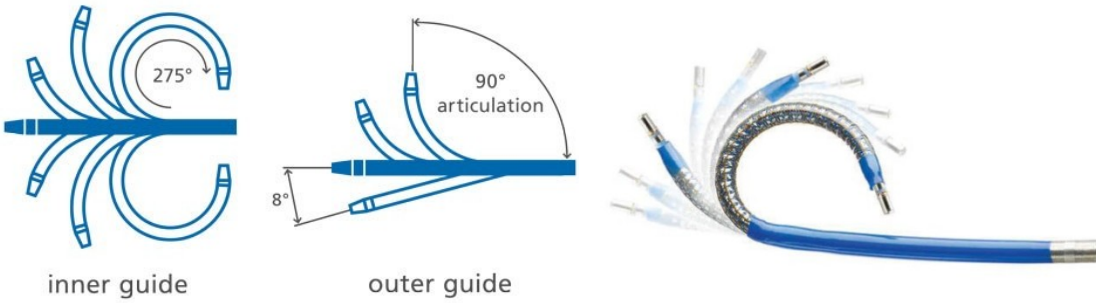
In a traditional setup of cardiac ablation procedures using X-rays, the physician wears a lead vest (for protection from x-rays) and manually threads the catheter through the femoral vein to the heart. Within the heart, various probes are inserted through the catheter's annulus to monitor and measure signals from the heart, obtain biopsy, perform ablation for atrial fibrillation and angioplasty for obstructed blood vessels. Hansen's Sensei robotic navigation system uses specially designed sheaths with multiple pull wires that are connected to a robotic arm. The robotic arm is controlled by an intuitive user interface that is synchronized to either fluoroscopy, EKG, or a 3D mapping system for visualization.

The robotic arm manipulates the pull wires to flex the sheath in three dimensions thereby simplifying the movement of the catheter.

The Sensei system including the Sensei X and Sensei X2 generations of systems is primarily comprised of three components: the physician control console, robotic catheter manipulator (RCM) and the electronics rack. The control console has three imaging monitors that integrate data from the EKG, image source and catheter navigation. The RCM is attached to the operating table and electromechanically controls the Artisan Extend catheter in response to the physician's hand movement.



Artisan Extend® Control Catheter



(Source: www.HansenMedical.com)

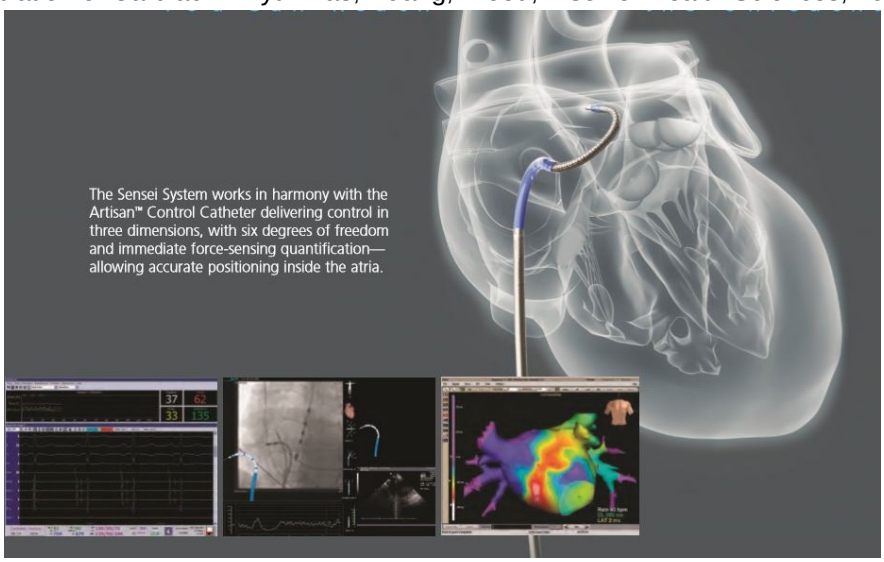
The Artisan catheter is a hollow robotically steered sheath that houses any commercially available mapping or ablation catheters. The Artisan catheter has a flexible cable driven tip (two steerable sheaths, one inside the other) that can be extended. The inner guide is flexible and multidirectional while the outer guide sheath provides stability and allows the entire system to rotate. These catheters are actuated by pull wires that manipulate a curve up to 270 degrees at the distal end of the catheter and can therefore attain c-shaped curves – a key differentiating characteristic as compared to the traditional systems. The catheter tip offers maneuverability with six degrees of freedom in position (flexion, insertion depth) and rotation (pitch, yaw, and roll). The sheaths are steered via a remotely operated system of pulleys. The steerable sheath is used similar to a conventional sheath with various mapping/ablation catheters inserted through the guide lumen so that only the tip protrudes just outside the navigable catheter.
The IntelliSense Fine Force Technology Interface offers a pressure sensing mechanism. It provides the operator with a handle that constantly estimates the contact forces. This technology offers an immediate tactile feedback mechanism for the user when using the Instinctive Motion Controller (IMC), a joystick, on the Sensei X system. As the forces increase on the IntelliSense, the scaling ratio is adjusted such that the catheter tip moves by a smaller distance. It has been shown from studies that contact force mapping could further increase efficacy and safety of the procedure. The contact force technology is improved by the use of the steerable sheath. When used in combination they aim at optimizing the pressure applied to the catheter-tip.

Hansen's systems have the capability to integrate with the CoHesion 3D Visualization Module, a software interface that provides physicians with a three dimensional view of the anatomy. This enhances the operator's ability to maneuver and position the catheter in specific locations within the atria. CoHesion allows importing the 3D anatomical model from the Ensite system directly into the Sensei system. Further, the system integrates the fluoroscopy images as well as a

model of the catheter position within the heart in either the antero-posterior or the lateral view, which is helpful to the operator instead of him/her having to mentally orient the images in a particular view.



(Source: Catheter Ablation of Cardiac Arrhythmias, Huang, Wood, Elsevier Health Sciences, 2014)



(Source: www.HansenMedical.com)

When inserted into a blood vessel, the IMC accurately translates the physician's hand movements to the robotically controlled steerable catheter using fluoroscopy for image guidance. The physician applies force and changes the curvature in order to maneuver the catheter tip to the target site within the heart. The IMC can also be programmed to vibrate when excessive pressure is made during contact. Consequently, the tactile feedback from the system lowers the risk of cardiac perforation and esophageal lesions.

Any image-guided procedure is a leading source of radiation exposure for the physician as well as the patient. Interventional procedures often require the operator to stay close to the patient, which also results in being at a close proximity to the radiation source. Acute exposure is typically within regulatory limits. However, exposure times are cumulative over a physician's career and may result in adverse health effects. With Hansen's systems, the remote operation has shown to reduce radiation levels for the physician while the ergonomic design allows them to operate while seated.

There is a steep learning curve associated with regard to using the system. During this process, procedure times can be prolonged. However, once the physician is comfortable with the system there is significant improvement in procedure throughputs with reduction in radiation exposure to the patient and reduced operator strain.

Marketing Approvals: In 2007, the Sensei Robotic Catheter System and the Artisan Control Catheter received FDA 510(k) clearance (mapping only) as a regulatory Class II device and CE mark (mapping and ablation) approval. The predicate device cited in the 510(k) filing was the Niobe Magnetic Navigation System from Stereotaxis, Inc. (K021555). Regulatory clearance for the newer generation of Sensei X and Artisan Extend was received in 2009. In August 2014, the FDA cleared the Sensei X2 System for sale in the U.S. The Sensei X catheter system is intended to help in manipulating, positioning, and controlling Hansen's robotically steerable catheters for collecting EP data within the atrium of the heart using the PolarisDx™ Steerable Diagnostic catheters made by Boston Scientific Corporation and the

Livewire™ Electrophysiology catheters made by St. Jude Medical. Over 14,000 procedures have been performed in 26 studies and close to 3,000 patients have undergone the procedure. The device is covered by 125 issued U.S. patents and 89 pending U.S. patent applications, 37 granted foreign patents and over 53 pending foreign patent applications. The safety and effectiveness of the Sensei X System in the treatment of cardiac arrhythmias, including atrial fibrillation, have been established only outside the U.S. In the E.U., Sensei X System, Artisan, and Artisan Extend Control catheters are cleared for the treatment of AF.

The ongoing clinical study in the US is investigating the technical characteristics and outcomes of robotic AF ablation using the Sensei system. The robotic navigation system significantly reduced the strain on the operator due to its ergonomic design. The operators were also exposed to a lower amount of radiation.[1]

The company recently completed enrollment of 148 patients (total of 150 patients) for a prospective single-arm study to assess the safety and performance of the Sensei system and Artisan catheters for the treatment of paroxysmal atrial fibrillation. This clinical study is designed to support an IDE application for the expansion of current labeling of the system in the U.S. beyond mapping. The study includes a seven-day follow up for safety and a one-year follow-up for efficacy at intervals of 30, 90, 180, and 365 days. This clinical trial follows an adaptive design during which an interim analysis is performed to evaluate the data from the trial and decide whether to terminate/continue the study with existing or modified trial parameters. The trial is being conducted in nine locations in the U.S., three in Europe and one in U.K. Management expects the trial to be completed in Q4 2016.

Indication – Peripheral Vascular Disease

Peripheral vascular disease results from narrowing of vessels outside the heart/brain that carry blood to the internal organs, legs, or arms. It is a progressive disease resulting from arteriosclerosis (plaque buildup), which decreases the amount of oxygen supplied to those organs. Complications arising from peripheral vascular diseases may include blood clots, heart attack, impotence, pain that restricts mobility and wounds in the internal organs. Hansen's robotic catheter technology has been used in the treatment of peripheral vascular diseases. The most common conditions treated with Hansen's Magellan Robotic system include peripheral arterial disease, liver cancers, enlarged uterine fibroids and enlarged prostates.

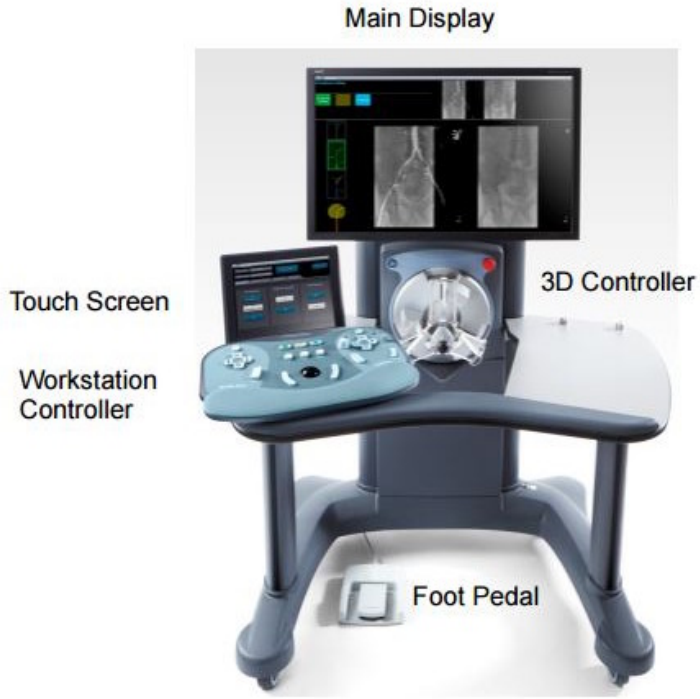
Magellan Robotic System

Hansen Medical's Magellan Robotic System was developed to facilitate navigation in the peripheral vasculature and provide a channel for manual placement of therapeutic devices. The Magellan Robotic System is based on the technology incorporated in the Sensei-X robotic catheter system. Additionally, it preserves the open architecture featured in the Sensei X system.

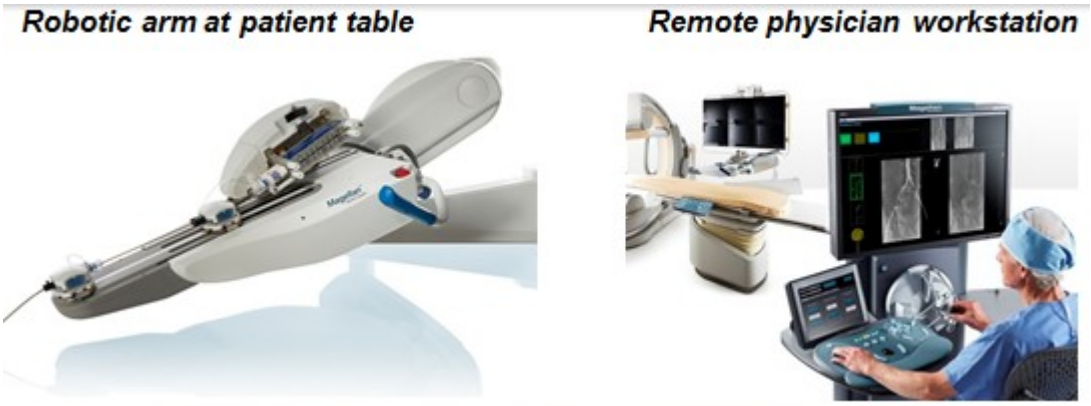
The Magellan robotic system and catheter are designed to remotely manipulate robotically steerable catheters and standard guidewires with precision. The 6Fr, 9Fr, and 10Fr robotic catheters are used for navigating within vasculature during embolization and other complex vascular procedures. The ability of the guide catheter to rotate 360º and turn 180º makes it possible to treat visceral arteries from the groin region. The Magellan 9Fr and 10Fr robotic catheters allow for robotic manipulation of standard guide wires and independent control of two telescoping catheters. The 10Fr is the largest Magellan catheter and enables delivery of therapeutic devices, such as stents and balloons in endovascular aneurysm repairs and lower extremity arterial revascularizations. The 6Fr catheter can be independently controlled at two separate bend sites on a single catheter.

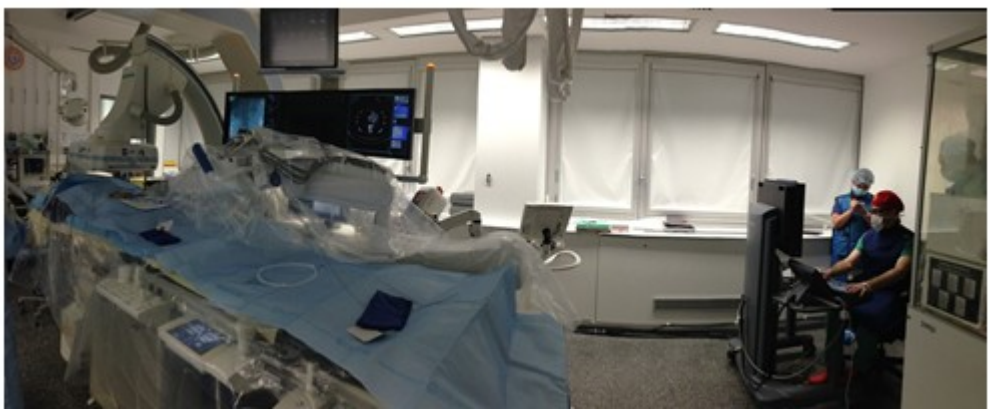
The FDA cleared the Magellan robotic system and catheter in 2012 as a Class II device. The predicate devices cited in the filing were the Terumo Pinnacle Destination System (K080415) from Terumo Medical Corp. and the Sensei X Catheter Control System and Artisan Control Catheter (K102168). The Magellan robotic system and the NorthStar robotic catheter's intended use is in navigating to target anatomy within the peripheral vasculature and provide a passage for manual placement of therapeutic devices. The Magellan 9Fr catheter has both CE mark and 510(k) clearance. The Magellan 6Fr Robotic Catheter obtained 510(k) clearance in the U.S. in Feb 2014. In August 2014, the FDA cleared the Magellan Transport System for sale in the U.S. The device received the CE mark in 2011. In April 2015, the Magellan 10Fr robotic catheter received CE Mark approval for use in the peripheral vasculature and has been used in procedures in Australia, Germany, and the U.K. In July 2015, the 10Fr catheter won FDA 510(k) clearance, which has allowed the company to initiate its clinical use in the U.S. Management submitted a 510(k) to the FDA in April 2016 for using the Magellan system to address a neurological indication.

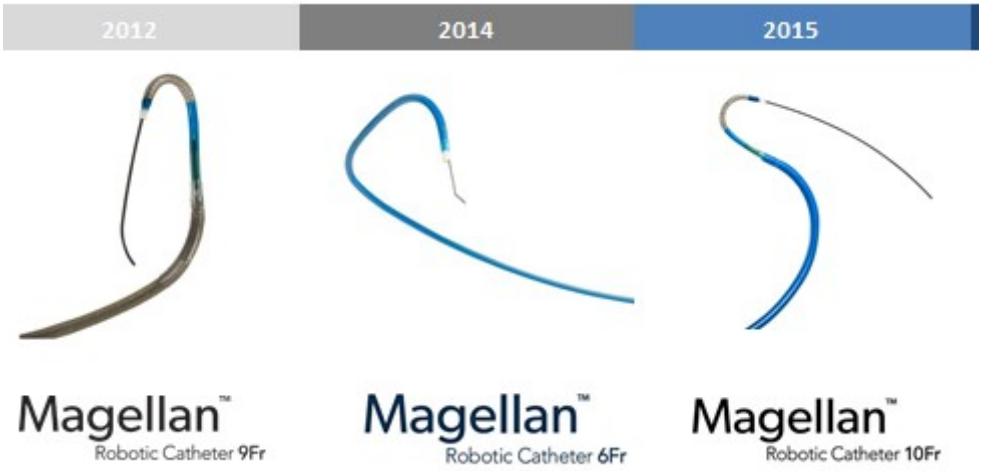
[1] Cardiovasc J Afr. 2012 Jun; 23(5): 274–280.



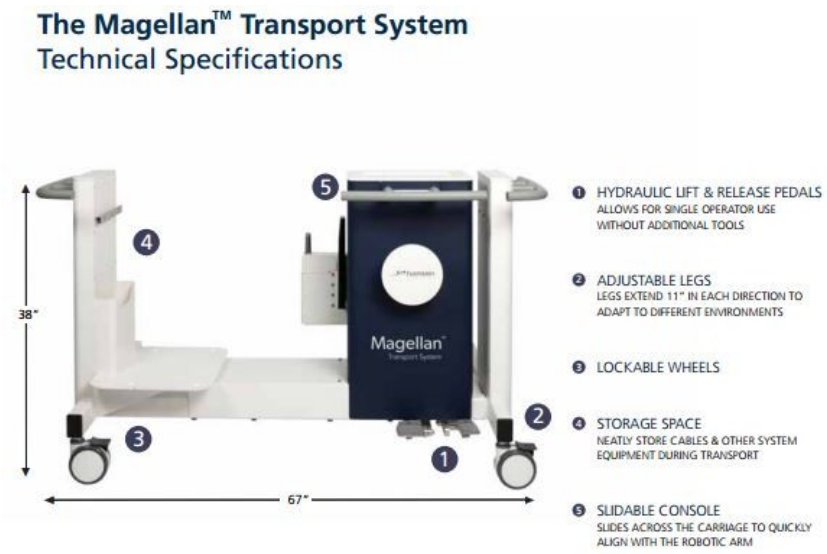
(Source: www.HansenMedical.com)







(Source: www.HansenMedical.com)

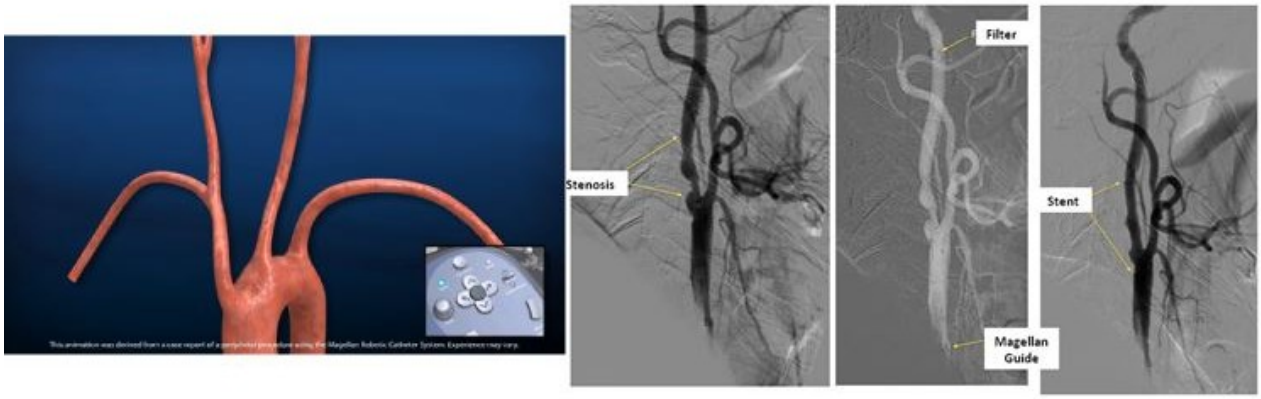


(Source: www.HansenMedical.com)

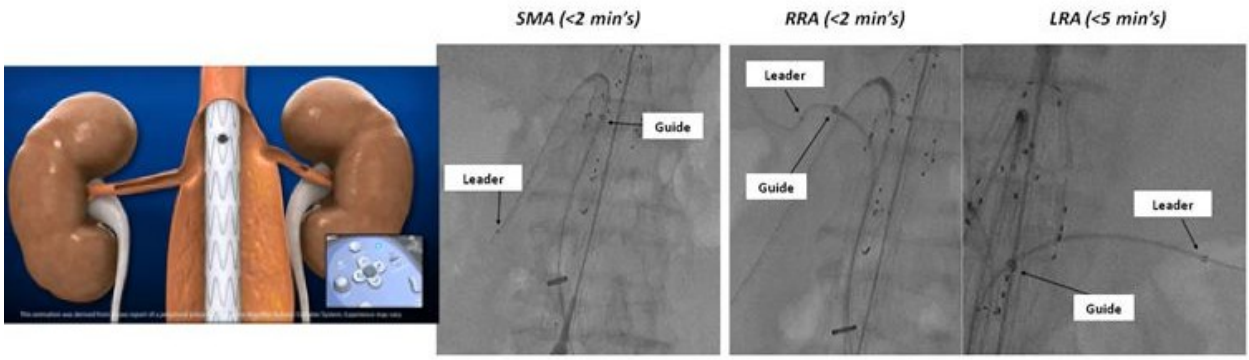
Supporting evidence of use of Magellan System in endovascular procedures:



Magellan guide catheter enables crossing of lesion in presence of significant calcification and subsequent balloon inflation within the superficial femoral artery.



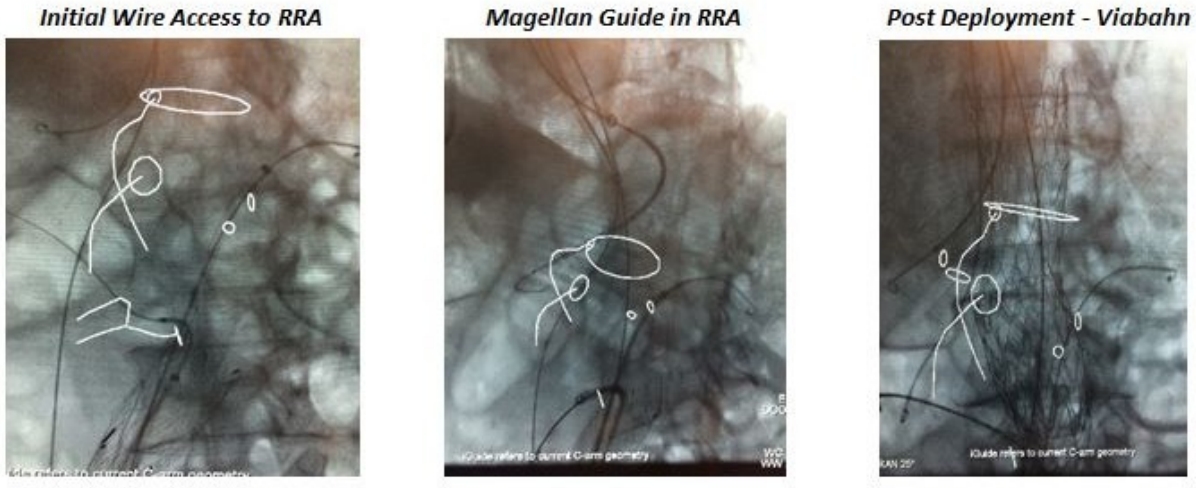
Magellan system used to navigate through the aortic arch to the internal carotid artery for placing a stent to reduce emboli and prevent stroke[2].



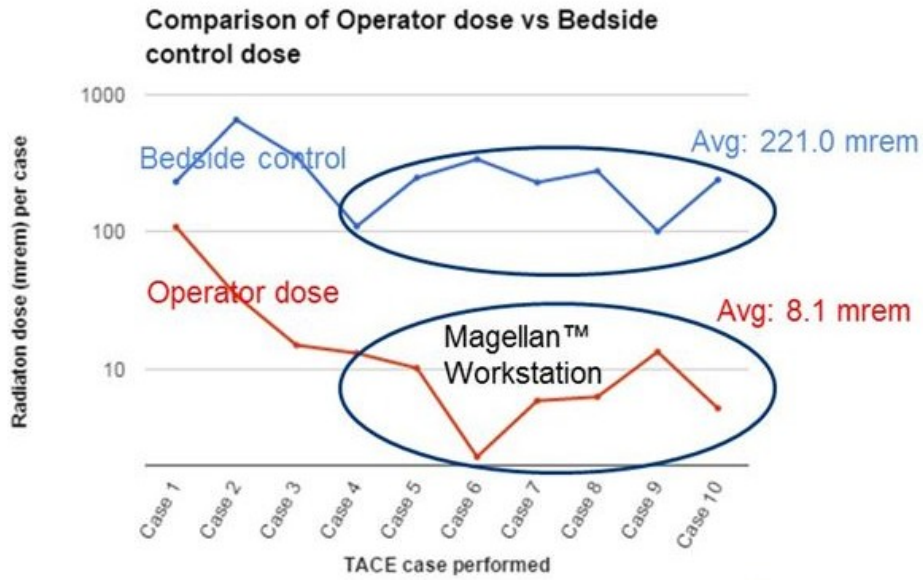
For a Fenestrated Endovascular Aneurysm Repair (FEVAR) procedure, Magellan catheters enable cannulation of three fenestrations in roughly 8 minutes of total navigation time.

[2] The Magellan system is not approved in the U.S. for this indication

An article published in the Journal of Vascular and Interventional Radiology in 2013 detailed a robot-assisted FEVAR procedure on a 67-year-old man having a 7.3-cm juxta renal aneurysm. Hansen's Magellan system was used along with the 6F robotic catheter. The time to setup the system time took five minutes and robotic cannulation of the left renal artery was achieved within three minutes. No postoperative complications were reported. Computed tomography angiography performed at discharge and at 4-month follow-up revealed the vessel was unobstructed and showed no evidence of blood flow in the aneurysm cavity[3].



Magellan catheter used to successfully cannulate right renal artery within about six minutes.



(Source: www.HansenMedical.com)

Dr. Rao and Dr. Katzen, from Sierra Medical Center, TX, collected data over a 5-month period and reviewed the results of seven patients treated undergoing TACE procedure using the Magellan 6Fr robotic catheter at Sierra Medical Center in El Paso, Texas. Average radiation exposure to the operator was measured using RaySafe radiation monitoring. Both investigators experienced more than 90% reduction in radiation from using remote robotic catheter navigation with the Magellan system when compared with the control site at the patient's bedside.

[3] JVIR 2013, Volume 24 (2): 191–196

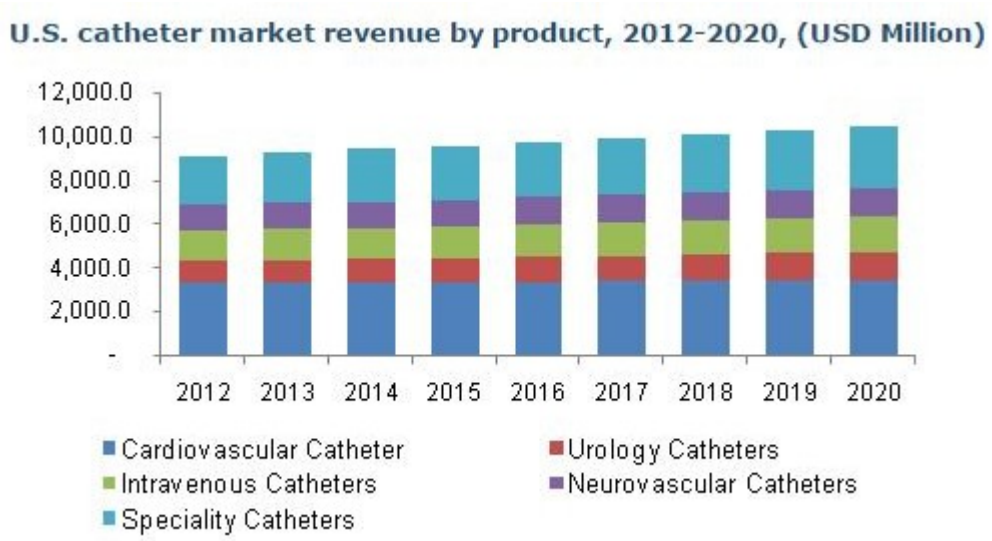
Versatility of Hansen's systems: Hansen's robotic systems have been designed to translate operator's hand movements such that the operator's large movements are scaled into micro motions inside the patient's body. Hansen's robotic catheters provide the operator with improved control to navigate within tortuous blood vessels. Hansen's systems offer 3D views, with tactile feedback. Reduction in radiation exposure was successfully demonstrated. Hansen's robotic systems are comfortable to use and ergonomically designed for the operator to perform the surgery while seated. Although initially, procedure times increased when using the robotic systems, setup times may be decreased as the operator becomes familiar with this equipment.

MARKET OPPORTUNITY

Robot assisted catheterization procedures, such as Hansen's systems, have been successful in eliminating a number of drawbacks associated with conventional procedures. The operator can perform the procedure comfortably seated, with the robot mimicking the hand dexterity in an intuitive manner while providing real-time 3D visualization of the endovascular catheter movement. Hansen's catheters have been designed to address vasculature that resides deeply within anatomy that would be otherwise impossible to reach. Such remote robotic catheter navigation has been shown to achieve stable and precise movement within the visceral vessels, thereby decreasing the risk of vessel trauma, which could have serious consequences[4,5,6]. Hansen's systems are easily portable between hospital rooms. Hansen has designed their systems as an open platform architecture, which enables interfacing with existing and emerging technologies. The primary reason for adopting remote procedure is the decrease in radiation to the operator and assisting staff. For an operator early in his career, performing several procedures while seated and with less radiation could potentially increase his/her throughput without compromising personal health. Although catheterized endovascular procedures are becoming increasingly popular in modern medicine, robot-assisted catheterized procedures are not as popular because they demand acquisition of new skills in operating the systems. There is a learning curve associated with such procedures due to their complexity that can be time consuming and challenging for the surgeon. The efficiency of robotic procedures is largely determined by the operator's skill who is accustomed to conventional/manually steerable catheters that have limited flexibility and maneuverability. However, since Hansen's systems have been designed to be intuitive, the learning curve may be shortened and operators may acquire this advanced skill quickly.

The high upfront cost might have a negative impact on an organization's decision to purchase robotic catheterized systems. Setting robot-assisted endovascular procedures as standard of care may take time. The lack of studies demonstrating the cost effectiveness and outcome data from Hansen's systems might make it challenging for care centers to justify investing in the robotic platform. By extending the spectrum of indications for robotic catheterized procedures Hansen may improve their applicability and potentially gain market share in the long-term.

[4] J. Vasc. Surg. 53, 493–499 (2011)
[5] J. Cardiovasc. Surg. 52, 353–362 (2011)
[6] J. Endovasc. Ther. 16, 149–153 (2009)



(Source: Grand View Research: Catheters Market Analysis By Product And Segment)

As per Grand View Research, there has been an increase in incidence rates of cardiovascular diseases, which in turn is supporting the growth of catheterized EP procedures in cardiovascular space. Further, the ablation catheters market in the U.S. is forecasted to grow at a CAGR of roughly 12% from 2014-2019 by a market research company called Technavio. An increase in demand for catheter ablation procedures could spur a broader trend towards the practice of robot-assisted practices.

Cardiac Vasculature Market: The CDC estimates that more than 2.5 million people in the U.S. have AF. The rising life expectancy within the older population as well as increase in the aging population with cardiovascular disease could potentially increase the prevalence of AF in the U.S. According to the CDC, strokes resulting from AF complications tend to be more severe than strokes resulting from other causes. With the increased risk of stroke, there is significant mortality associated with AF. Healthcare costs associated with management of AF and its related complications are estimated to be roughly $6 billion annually. This is because patients with AF have other comorbidities including non-cardiovascular problems, which are known to be exacerbated by AF. Direct costs related to atrial fibrillation comprise of medical therapy, related hospitalizations, and imaging procedures while the indirect costs are management of related conditions, as well as disability and loss in quality of life.

Cardiac catheter ablation in patients with AF has shown to reduce hospitalization and its associated costs. In the U.S., management is pursuing an IDE for using the Sensei system in cardiac ablation procedures in patients with AF.

Peripheral Vasculature Market: According to CDC, approximately 8 million people in the U.S. have Peripheral Arterial Disease (PAD). PAD has been found to affect roughly 27 million people in North America and Europe and accounts for more than 400,000 hospitalizations annually[7]. PAD is prevalent in 12–15% of the elderly aged over 65 years and also in individuals with diabetes[8].

Enlarged prostate, or Benign Prostatic Hyperplasia (BPH), leads to conditions associated with the bladder and difficulty in urination due to full or partial blocking of the arteries. In an embolization procedure, the arteries feeding the prostate are blocked which results in shrinking the gland. This procedure has been found to improve symptoms resulting from erectile dysfunction, urine leakage, or incontinence with minimal risk. In recent years, in the U.S., robotic prostatectomy has become the most popular approach to treat BPH. In the U.S. BPH accounted for $1 billion in direct health-care expenditures, and estimated annual costs for the treatment totaled $4 billion[9] in 2000.

Uterine fibroids are known to be the most common form of benign tumors in women. They can cause heavy menstrual bleeding, pain, and pressure on the bladder or bowel. Physicians position catheters precisely to block the blood supply and estrogen feeding these fibroids resolving symptoms and avoiding a total hysterectomy. Annual direct health care costs for uterine fibroids exceed $2 billion[10].

[7] Curr Probl Cardiol. 2009 Sep;34(9):359-476
[8] Vascular Medicine 2008; 13: 209–215
[9] Indian J Urol. 2014 Apr-Jun; 30(2): 170–176
[10] http://report.nih.gov/nihfactsheets/viewfactsheet.aspx?csid=50

Liver cancer can be treated with procedures like transarterial chemoembolization (TACE). TACE is a minimally invasive, image-guided procedure using catheters. Small embolic materials are delivered using catheters into selected arteries in order to cut off the blood supply feeding tumors in the liver. TACE is most often performed in patients with Hepatocellular Carcinoma (HCC), the 5th most common cancer and the 3rd leading cause of cancer deaths in the U.S. The survival rate of person with liver cancer is roughly 15% and drastically improves when the cancer is removed[11].

Many patients require repeated TACE procedures due to disease recurrence, which exposes both patients and clinical staff to high doses of radiation. As per Millennium Research Group's 2014 report titled 'U.S. Markets for Transcatheter Embolization and Occlusion Devices', an operator performing TACE procedure acquires a radiation dose of roughly four times more than when performing a cardiac procedure since the imaging field of view is larger.

Marketing Strategy: Currently, Hansen sells its products through direct sales force in the U.S., through distributors primarily in EU, and a combination of both for international markets. Hansen's partners include St. Jude Medical Inc. (NYSE: STJ), Philips Healthcare (NYSE: PHG), Siemens Healthcare (OTC: SIEGY, GR: SIE) and GE Healthcare (NYSE: GE). As part of the global expansion strategy, Hansen has signed agreements with large device companies to expand their geographic reach and raise awareness of their systems among the end users. The partnerships have helped Hansen understand the end user's needs that in turn helps them in designing their devices.

In April 2007, Hansen entered into a distribution agreement with St. Jude Medical, Inc. to integrate the Sensei system with St. Jude's Ensite system and to co-market the integrated product in France. In August 2010, Hansen inked another agreement with St. Jude to integrate the CoHesion 3D Visualization Module and the EnSite System for EP procedures.

In May 2009, Hansen entered into a joint development agreement with Siemens Healthcare to co-develop products to help simplify complex cardiac procedures.

In late 2009, Hansen inked a development agreement with Philips. Under the terms of the agreement, Hansen has developed a vascular robotics platform and associated catheters. As per the agreement, Hansen will pay Philips royalties based on the number of Magellan Robotic Systems and Magellan Robotic Catheters that are sold through October 2017. In February 2011, Hansen signed a patent and technology license with Philips Healthcare that allows Phillips to develop and commercialize the non-robotic applications (vascular, endoluminal and orthopedic domains) of Hansen Medical's Fiber Optic Shape Sensing and Localization (FOSSL) technology.

Management has also developed the Magellan 3Fr robotic micro-catheter, which is appreciably smaller and may help physicians navigate in small, tortuous visceral and cerebral arteries. This addition may open up larger market opportunities such as neural, abdominal, and thoracic aortic aneurysm repair as well as for embolization procedures. Hansen also provides technology support, marketing, and education materials to the hospitals as well as to patients to maximize opportunities for raising public awareness about their technology.

COMPETITION

Hansen has a number of competitors in the remote catheter navigation space. Foremost among them are Stereotaxis, Catheter Robotics, Aeon Scientific and Corindus. While all these companies compete with Hansen for similar procedures, there are significant differences in their technology and application.

The Niobe (Stereotaxis, CE mark: 2008, FDA clearance: 2009) remote magnetic navigation system uses a magnetic field, generated by two permanent magnets, to guide the catheter tip. The magnetic field is contained within a housing on either side of the patient's table. The surgeon uses one joystick to manipulate the catheter tip by controlling the magnetic field and another to control the four axes of motion including advancement/retraction, rotation, and deflection. The Niobe only works with the CARTO electroanatomic mapping system and Biosense Webster mapping and ablation catheters. People who have a pacemaker or ICD cannot undergo a Niobe procedure as the proper functioning of the pacemaker would be affected by the magnets. On using the Niobe system physicians had a learning curve of eighty patients.

[11] http://www.cancer.org/cancer/livercancer/detailedguide/liver-cancer-survival-rates

The Amigo Remote Catheter System (Catheter Robotics, CE mark: 2010, FDA clearance: 2012) replicates manual movements to manipulate the catheter, but there is no built-in force contact sensor to provide force feedback. Contact force is detected using catheters manufactured by Biosense Webster, Inc., or by measuring tissue interface temperature with Boston Scientific's non-irrigated large tip ablation catheter. The setup time for using the Amigo system is roughly fifteen minutes. The Amigo system can be mounted on a procedure table. During the U.S. clinical trial Amigo was shown to have a learning curve of three patients. By using the Amigo system, radiation exposure to the operator reduces by about 60%. The Amigo system is comparatively less expensive system than the Niobe and Sensei systems.

The CorPath Vascular Robotic System (Corindus, FDA clearance: 2012) is used to navigate coronary guidewires and in the placement of balloon/stent devices during percutaneous coronary intervention (PCI) remotely. Clinical trials using the CorPath have demonstrated safety and efficacy profiles as well as reduction in radiation exposure by roughly 95%. Additionally, the average procedure time using CorPath 200 is about 25 minutes and boasts a learning curve of three coronary intervention procedures.

Aeon Scientific in Switzerland has developed Aeon Phocus, an electromagnetic catheter steering system for treating cardiac arrhythmias. CE mark approval of the Aeon Phocus was obtained in July 2015.

The Catheter Guidance Control and Imaging (CGCI) system (Magnetecs) is a remote magnetic navigation system in which an array of electromagnets surrounds the patient in a semi-spherical arrangement. The structure is encased in a magnetic shield that does not require any special arrangement in the hospital room. The system works with a 7Fr irrigated ablation catheter. The system can be controlled either using a joystick that uses magnetic attraction or operated in automated mode. The system integrates with the EnSite mapping system. Currently, the CGCI system is in clinical trials involving humans.

	Amigo (Catheter Robotics)	Niobe (Stereotaxis)	CGCI (Magnetecs)	Sensei (Hansen Medical)
Remote Operation	√	√	√	√
Compatibility w/ other catheters	√	**X**	**X**	√
Catheter manipulation	√	√	√	√
Lab redesign required	**X**	√	√	**X**
User Interface	Easy	Training required	Training required	Training required
Learning Curve	Low	Steep	Steep	Steep
Disposable part	none	steering tip	steering tip	long sheath
Cost	Less expensive	Very expensive	Very expensive	Moderately expensive

Hansen's Systems versus their competitors:

In a manual procedure, feedback is received through the sense of touch and the catheter is manipulated using fluoroscopic 2D visualization. Amigo's system does not incorporate this type of haptic feedback. Therefore, with this system physicians must rely heavily on the visuals for navigation. Instead of providing a visible graph on the monitor that displays the tissue contact force, the Sensei X uses IntelliSense Fine Force Technology that offers tactile vibration as feedback. Hansen's Artisan catheters use the IntelliSense pressure sensing mechanism, which mitigates the risk arising from absence of haptic feedback. The tactile feedback makes the controller vibrate when contact force exceeds the preprogrammed limit. Niobe and Magnetecs systems do not offer the direct sensor but uses properties of magnetism to control the catheter movement.

The user interface of these systems is different and the physicians need to learn the various navigation techniques. Integration of robotic catheters to 3D visualization and mapping systems help perform complex procedures. The Amigo system does not integrate with the commercially available mapping system. Hansen's systems integrate with CoHesion software and EnSite mapping system to make manipulation intuitive. All catheter movements are performed relative to the orientation map. Niobe system integrates with CARTO (Biosense Webster) mapping system and makes the catheter manipulation intuitive similar to the Hansen system. Magnetecs system also integrates with the EnSite system and a fluoroscopic unit. Niobe and Magnetecs systems use a mouse to direct the magnetic vector to control catheter movements. Therefore, this is not very intuitive and requires some practice.

A study conducted to assess the learning curve associated with the use of conventional, manually steerable, and robotic endovascular catheters (Sensei X system) on a silicone phantom with a 5-week training program demonstrated that physicians using remote catheters significantly showed superior performance with a shorter learning curve. Remote catheters seemed to be very intuitive to use, and the ability to acquire the advanced skill occurred with minimal training. The results indicated the enhanced ease of movement and accurate navigational capabilities associated with Hansen's robotic catheters. This allows the possibility of more physicians adopting this technology to address complex endovascular procedures[12]. In low volume centers, there appeared to be a learning curve of approximately 50 procedures using Hansen's systems[13].

All of the systems involve high initial capital costs for the hospitals. While Hansen's systems do not require specific redesign of the laboratory, Niobe and Magnetecs systems do and that adds to the cost of initial capital investment. Hansen's system, priced at roughly $625,000 is more expensive than the Amigo (~$400,000) but cheaper than the Niobe (~$2.8 million) system. However, the disposables for the Niobe system (~$1,200) are priced cheaper than that of Hansen's (~$1,600). Since the Amigo system differs in functionality and utility from Hansen's systems, we are not including it in our cost analysis in the table below. Assuming a total life of 10 years for the systems, we get a wide range of cost per procedure as shown in the table below depending on the number of procedures performed per system per year. At low utilization rates, purchasing the Hansen system is clearly the cheaper option. The Niobe system becomes a better option from a cost perspective if utilization increases over 215 procedures/system/year.

The Niobe system began commercialization in 2003 and is intended for navigating through tissue to the anatomical region of interest in the right and left heart, coronary vasculature, neuro vasculature and peripheral vasculature. Currently, we estimate that the Niobe system is being utilized at a rate of 200 procedures per system per year while Hansen's system has a utilization rate of only 25 procedures per system per year. If Hansen is able to expand the intended use of the device for multiple indications, we expect utilization to increase significantly. Even at a utilization rate of 200 procedures performed per system per year, purchasing a Hansen system is economically viable for the hospital.

	Hansen	**Niobe**
Upfront cost	$625,000	$2,800,000
cost/disposable	$2,000	$1,200
Annual Servicing Cost	$150,000	$104,000
Useful Life (years)	10	10

	Total Cost per Procedure	
Procedures/system/yr	**Hansen**	**Niobe**
25	$10,500	$16,560
50	$6,250	$8,880
75	$4,833	$6,320
100	$4,125	$5,040
200	$3,063	$3,120
215	$2,988	$2,986

[12] European Journal of Vascular and Endovascular Surgery, 2011, 42(4): 531–8
[13] (J Cardiovasc Electrophysiol, Vol. 23, pp. 820-826, August 2012)

MEDICAL REIMBURSEMENT

According to CMS and HIPAA defined code-sets, coders must first report the primary procedure with the appropriate ICD-9-CM Volume 3 procedure code followed by the appropriate procedure code for the robotic assistance. In October 2008, CMS and NCHS issued a new family of ICD-9-CM procedure codes for "robotically assisted procedures":

17.41: open robotic-assisted procedure
17.42: laparoscopic robotic-assisted procedure
17.43: percutaneous robotic-assisted procedure
17.44: endoscopic robotic-assisted procedure
17.45: thoracoscopic robotic-assisted procedure
17.49: other and unspecified robotic-assisted procedure

Codes in category 17.4x (robotic-assisted procedures) also include computer-assisted, computer-enhanced, and surgeon-controlled robotic surgery.

The hospital cost per endovascular procedure increases if the healthcare facility uses robotic technology. In order to include Hansen's systems for reimbursement the company must build evidence to position it as a standard of care in robotic vascular procedures. Currently, robot assisted procedures are considered to be a matter of choice for the surgeon. The reimbursement under the ICT and CPT coding practices for catheterized procedures remains the same and does not change just because an operator choses to use a robot-assisted device.

Since Medicare does not offer additional payment for robot-assisted procedures and national private payers generally follow Medicare policy, adoption of Hansen's technology could be slow. Reimbursement rates also vary widely between private companies and depends on the procedure performed, contract terms, and several other factors. For instance, Medicare reimburses roughly $10,000 for an ablation procedure that mostly covers the cost of hospitalizations and tests and probably a small percentage of the cost of disposables. In the previous section, we noted that the costs associated with robot-assisted procedures could vary depending on the utilization rate of the system. Even at a utilization rate of 200 procedures per system per year, the average cost (system + disposable + servicing) is roughly $3,000 per procedure. At lower utilization rates, the cost of using Hansen's system can be prohibitively high. For instance, at the current utilization rate of 25 procedures per system per year, the cost per procedure amounts to roughly $10,000, which is about the total amount received from reimbursement. Obviously, this is insufficient to cover costs incurred when purchasing Hansen's system. We can surmise that unless Hansen is able to obtain clearance for expanding their device use in multiple indications, we may not see an uptick in utilization and that could hamper their growth potential. The same procedure costs roughly between $6,000 - $12,000 when performed manually[14] which is lower than when performed using robotically steered catheters and falls within Medicare reimbursement amount.

Further, the Budget Control Act of 2011 has recommended proposals to the government for reducing expenditures associated with healthcare. In lieu of this there has been a reduction to Medicare payments of up to 2% per annum to providers including hospitals and imaging centers. Consequently, there is increasing demands by private payers and CMS to show comparative effectiveness as an evidence for potential coverage. Since Hansen's systems are yet to offer robust clinical evidence, reimbursements for unapproved uses may be delayed or unavailable.

FINANCIAL POSITION

Hansen Medical reported financial results for Q1 2016 on May 16, 2016.

Total revenue came in at $3 million, product revenue was ~$1.6 million from the sale of 870 catheters and revenue from service was ~$1.4 million. Product revenue decreased 47% from Q1 2016. No systems were sold during this period. Two customers accounted for 15% and 10% of total revenues. The U.S. region accounted for 52% of revenues and Belgium accounted for 14% of total revenues.

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

Revenue between sequential quarters has been choppy and the fluctuations can be attributed to several factors including general economic and capital market conditions and uncertainty created by the Patient Protection and Affordable Care Act (PPACA). Capital expenditures were routine in healthcare centers and usually authorized by specialists but are now heavily scrutinized requiring approval from the healthcare board. Further, PPACA is driving hospitals to provide value-based care while keeping costs down. The current state of flux in the healthcare sector puts immense financial pressure on hospitals. Consequently, hospitals find it challenging to purchase high-cost technology equipment such as Hansen's robotic systems.

OpEx came in at ~$9 million (~$3 million in R&D and ~$6 million in SG&A) and was mostly in line with our estimates. Management noted in their first quarter earnings report that they plan to expand utility of their robotic platforms and therefore will be making substantial investments in R&D.

Net loss and EPS for the quarter were almost $10 million which equates of an EPS of $(0.51). Hansen exited the first quarter 2016 with $12.5 million in cash and cash equivalents.

Debt: In August 2013, Hansen closed a $33 million, long-term debt agreement with White Oak Global Advisors. The amended and restated senior secured loan agreement requires quarterly interest-only payments based on an annual interest rate of 11.0%. An additional interest of 3.0% per annum will accrue to the loan balance every quarter and will be payable, along with the entire principal amount, at the end of the loan term on December 30, 2017. No warrants were issued as part of the debt facility.

MANAGEMENT

Cary Vance
President and Chief Executive Officer
Cary G. Vance was appointed as President and Chief Executive Officer on May 23, 2014. Mr. Vance served as President of the Anesthesia & Respiratory global business at Teleflex Incorporated for three years and as their Executive Vice President North America in 2010. Before joining Teleflex, Mr. Vance was an executive at Covidien, and served as Vice President & General Manager of Interventional Oncology – Americas, and was the Vice President & General Manager for their Energy-based Devices unit since 2007. Mr. Vance served in a series of roles with progressive responsibility at GE Healthcare from 1997 to 2007, principally in diagnostic imaging sales, sales and marketing management and executive leadership. Mr. Vance holds a B.A. in Economics and an M.B.A from Marquette University.

Christopher P. Lowe
Interim Chief Financial Officer
Christopher P. Lowe has served as a Director of Hansen since September 2006 and previously served as interim Chief Executive Officer of Hansen from February 2014 to May 2014. Mr. Lowe served as Chief Financial Officer of Anthera Pharmaceuticals, Inc., a drug development company, since November 2007, and has additionally served as its Chief Business Officer since January 2011. Mr. Lowe served as Vice President, Finance and Administration of Asthmatx, Inc., a medical device company acquired by Boston Scientific, since September 2005 and as its Chief Financial Officer from January 2006 to November 2007. Mr. Lowe served with Peninsula Pharmaceuticals, Inc., a pharmaceutical company, as Corporate Controller from June 2004 to October 2004 and Chief Accounting Officer from October 2004 until its acquisition by Johnson & Johnson in June 2005. From January 2003 to June 2004, Mr. Lowe served as Global Divisional Controller — Trane Division with American Standard Corporation, a producer of bathroom and kitchen fixtures and fittings. Mr. Lowe holds a B.S. from California Polytechnic State University, San Luis Obispo and an M.B.A. from Saint Mary's University, Texas.

Robert Cathcart
Senior Vice President of Global Sales
Robert Cathcart joined Hansen Medical in January of 2013 as Senior Vice President of Global Sales. He brings nearly 30 years of increasingly senior sales management experience in both domestic and international roles in the medical technology industry with large and small companies.

[14] J Interv Card Electrophysiol. 2013 Mar; 36(2): 157–165

Prior to joining Hansen Medical, Mr. Cathcart served as the Chief Commercial Officer of surgical medical device start-up, HyperBranch Medical Technology. Earlier, he served as the President and CEO of FlowCo, Inc./3DT Holdings, a privately held medical device company focused on interventional cardiology. From 2001 to 2009, Mr. Cathcart worked at Datascope Corporation (acquired by Maquet); where he served as the Division President and Vice President of Sales in the Cardiac Assist Division, and later the President of the Interventional Products Division.
Mr. Cathcart has also led the sales functions of Promedix Inc., Bard Access Systems and MedChem Products. He began his career at Davis and Geck, where he served as a sales representative, global training manager, regional manager, and eventually area director of the endo-surgery division.
Cathcart holds a Bachelor of Arts degree from DePauw University.

Joe Guido
Senior Vice President of Marketing & Business Development
Joe Guido joined Hansen in April 2012 as Vice President of Marketing & Business Development and was named a Senior Vice President in January 2015. He brings over 20 years of medical device experience including domestic and international marketing, sales and business development for large public companies and start-ups. Prior to joining Hansen Medical, Joe spent five years as Vice President of Sales and Marketing at Novare Surgical Systems, Inc., a privately held medical device company that developed innovative products for minimally invasive surgery. Previous to Novare, he was the Director of Global Strategic Marketing for Abbott Vascular Devices' vessel closure business, and Vice President of Global Marketing at Intuitive Surgical, a public medical device company specializing in surgical robotic systems.
Guido has a Bachelor of Science degree in Business Administration from Villanova University and a Masters degree in Business Administration from Pepperdine University.

Brian Sheahan
Vice President of Clinical, Regulatory and Quality Affairs
Brian Sheahan was appointed Vice President of Clinical, Regulatory and Quality Affairs on October 20, 2014. Mr. Sheahan joins Hansen with more than 25 years of experience in the medical device field. Previously, Mr. Sheahan served as Senior Vice President of Clinical and Regulatory Affairs and Quality Assurance for Direct Flow Medical, where he was responsible for all U.S. and E.U. field and in-house clinical operations, regulatory affairs and quality assurance matters. Prior to Direct Flow Medical, he also held similar roles at TriVascular, Medtronic, Arterial Vascular Engineering and PS Medical, Inc. Mr. Sheahan holds a Bachelor of Science from Saint Joseph's University in Philadelphia.

VALUATION AND RECOMMENDATION

Since commercialization commencing in 2007, Hansen encountered several unanticipated hiccups in their sales. The reasons are manifold. The reasons are manifold and encompass a host of issues that the medical device industry has faced, including;

- pricing concerns
- procedural volume pressures
- global economic downturn in 2009
- Health Care Affordability Act in 2010 forced providers into reduced reimbursement

Hansen's systems may be subject to prolonged purchase orders as hospitals and healthcare centers undergo capital budgeting and approval processes that tend to be intensely scrutinized.

Rate of reimbursement from CMS and third party insurers probably unintentionally influence investment decision-making in disruptive, yet cost-intensive, technologies. Insurance coverage can depend on analysis of comparable technologies and/or evidence-based technology. Hansen's robotic catheters fall into the space where the technology is still in a nascent stage and there are no comparative studies that have been done between competing systems. As there is a certain level of uncertainty regarding the rates of reimbursement and volume of procedures, hospitals might be reluctant to invest heavily in such innovative technology. Further, there is the potential for federal budget cutbacks that could adversely affect the reimbursement scenario.

Despite these headwinds, we believe there are multiple reasons that may help the company achieve sustainable growth in the out years. A paradigm shift occurred in the approach to endovascular surgical procedures from invasive techniques in open surgery to minimally invasive catheter based procedures. However, physicians faced several limitations both in viewing and in being able to feel the anatomical region of interest. Robot-assisted procedures such as Hansen's have made it possible to improve navigation, dexterity, control, and stability of catheterized endovascular procedures. Clinical data from using Hansen's systems has demonstrated less vessel wall trauma from using robot-assisted catheters, and the physicians are able to perform the procedures with high efficiency. An institution might be recognized as providing treatment options using state of the art technology and might be able to attract patients if it invests in Hansen's systems. We expect there may be an uptick in the use of robotic-catheterized procedures as Hansen's systems have some documented clinical benefits over conventional EP procedures.

We expect utilization to increase over time as Hansen is able to expand the number of indications. The company is also introducing new features to help increase utilization such as the Magellan Mobility, a package that consists of the Magellan transport system in addition to the physician workstation and centralized control system. This system can be transported between different catheter labs and shared by more than one physician.

Hansen systems have three main sources of revenues. The system costs around $650,000 and the catheter costs roughly $1,600. The annual service and maintenance costs amount to $150,000. The company has been selling their devices since 2007 but revenue has declined since then. Until there is more clarity on reimbursement and expanded indications of use, we model modest revenue growth of the installed base globally for the next couple of years. This is based on our assumption that management continues to invest in physician training programs, hospitals renew the service maintenance contracts, and reimbursement remains at current levels. We will update our model if and when the reimbursement scenario improves. Although the current reimbursement scenario is not favorable, the benefits offered by the system such as lower radiation dose, intuitive navigation and better visualization could increase physicians' interest in this system and help drive revenues higher in the long-term. Hansen expects to submit an IDE application to the FDA in the first half of 2016 for the Sensei system. Pending approval, with supplemental clinical data to support sales and an aggressive marketing strategy we think Hansen can increase their installed base to about 20 to 45 systems per year by 2025. In addition, we believe that management's flexibility in allowing lease options as compared to one-time upfront payment for their systems may translate to a larger installed base.

The major portion of our estimated revenue comes purely from increase in catheter utilization. With approximately 110 sites committed to their technology, we expect Hansen to regain momentum in recurring revenue stream from catheter sales as the technology gets widely adopted for multidisciplinary use over time. Management expects to receive CE Mark and FDA clearance for the micro catheter driver in early 2016. The driver's design provides control of a wide variety of third party micro catheters and expands the application of the Magellan system to several endovascular procedures that could help Hansen gain additional revenue.

Since Hansen's systems are comprised of expensive materials that are also cost-intensive to manufacture, low volume of sales do not absorb these overhead costs. Therefore, Hansen's gross margin remains relatively low (~20%) and can be attributed to the continued weak demand of robotic systems across the market, and high manufacturing overhead expense. We expect sales to grow considerably in the U.S. market and help absorb the manufacturing overhead expense and consequently expand gross margin. We have modeled gross margin to be 32% by 2025 and suspect this may expand further with evolvement of the reimbursement scenario in favor of robot-assisted procedures. Management continues to be focused on controlling operating expenses which should additionally benefit operating margins. The company has active R&D programs underway to develop complementary devices for use in EP procedures. We anticipate R&D expenses to increase moderately during the next couple of years as the company continues to explore other potential applications in the EP market. We also expect the sales and marketing team to implement an aggressive sales strategy to build awareness and drive utilization of Hansen's products. We are guiding Op-Ex to have an average run rate of about $40 million over the next couple of years.

We use a 10-year DCF model to value Hansen Medical. We model revenue to be $17 million in 2016, $58 million in 2019 and rise to $480 million by 2025. Other inputs to our DCF model are 16.5% discount rate and 2% terminal growth rate. Based on the recent buyout announcement we expect the stock to trade near $4.00/share. Our outlook is subject to change depending on the progress with expanding installed base, reimbursement scenario and regulatory approvals.

RISKS

- ***Adoption of Hansen's technology:*** Robotic catheter ablation technology is relatively new and in the nascent stages of adoption. The size of the system and costs associated with purchase and maintenance are high, although comparable in price to the other competing systems. It could be a long period of time before robotic procedures become widely accepted as the standard of care. This could lead to reduced revenues and low margins for an extended period of time leading to high cash burn.

- **Reimbursement:** Insurance companies consider robot-assisted procedures as merely an option for physicians. Additionally, there is inadequate comparative evidence of its superiority over existing methods. Further, although positive effects were found from studies, it was not clear whether the positive result achieved was large enough to replace traditional manual EP procedures. If the lack of reimbursement for such procedures continues, sales of Hansen systems could be negatively impacted.

- **Model-based assumptions are prone to large variations:** Our projected revenue growth from the sales of Sensei and Magellan systems from the current year and beyond is largely best guesses based on healthcare centers adopting Hansen's technology as well as growth in the customer base. Revenue could underperform relative to our model if the customer base does not grow at our assumed forecast or is less correlated to revenue growth than what we are assuming. Achieving our price objective includes regulatory, competitive, reimbursement and financial risks. Hansen may require substantial funding which could be dilutive to current shareholders.

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

PROJECTED INCOME STATEMENT & BALANCE SHEET

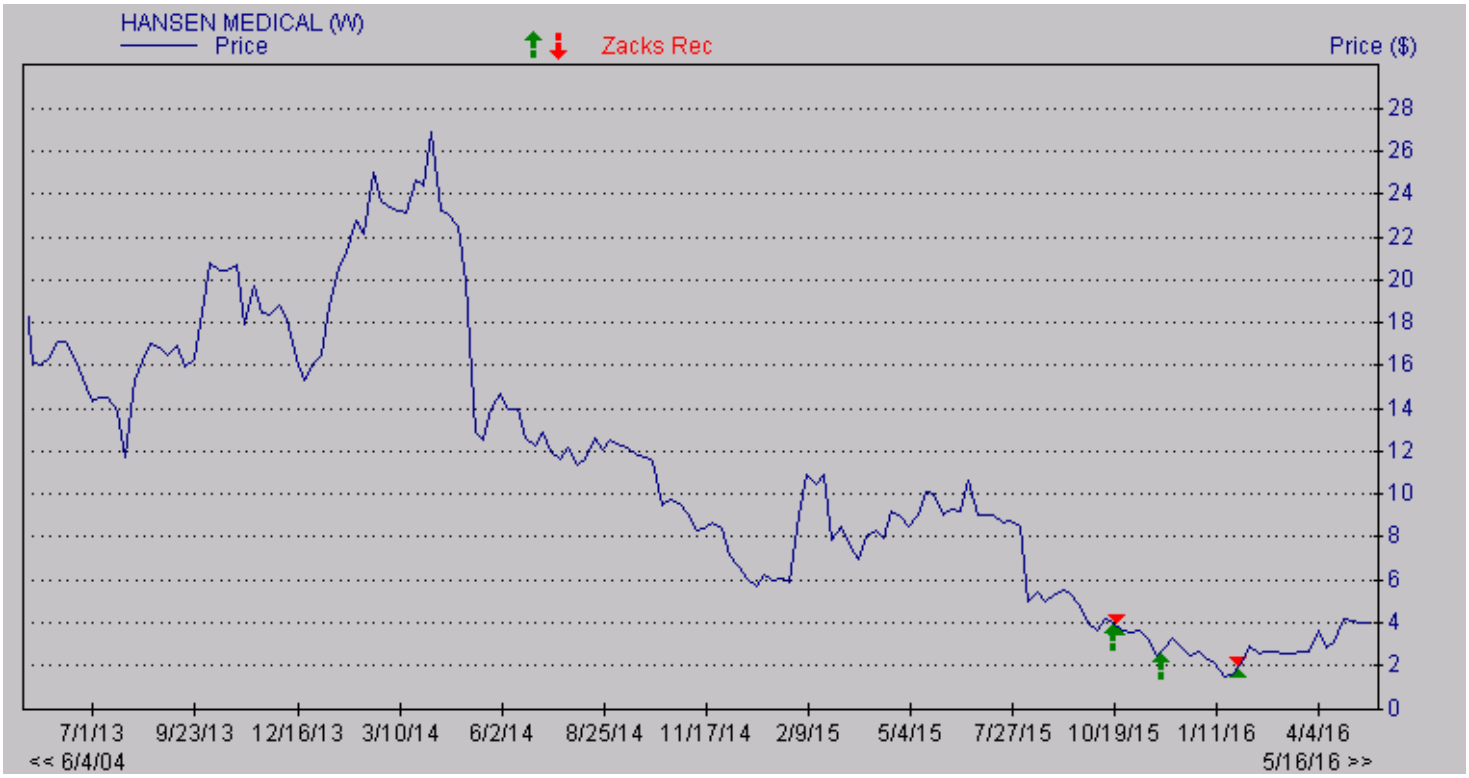
Hansen Medical Inc.
Income Statement

Hansen Medical HNSN	2015 A	Q1 A	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E	2019 E
Total Revenues	**16.07**	**3.04**	**3.90**	**4.20**	**4.50**	**15.64**	**25.17**	**39.10**	**57.98**
YOY Growth	-18%	-48%	26%	32%	12%	-3%	61%	55%	48%
Total COGS	15.07	2.08	2.72	2.93	3.15	$10.88	20.14	30.89	45.22
Gross Profit	**1.01**	**0.96**	**1.18**	**1.27**	**1.35**	**4.76**	**5.03**	**8.21**	**12.75**
Gross Margin	6%	32%	30%	30%	30%	30%	20%	21%	22%
R&D	13.81	3.05	3.80	3.70	3.22	$13.77	14.18	14.61	15.05
% R&D	86%	100%	97%	88%	72%	88%	56%	37%	26%
SG&A	23.50	5.87	6.30	5.90	5.60	$23.67	24.38	25.11	25.86
%SG&A	146%	193%	162%	140%	124%	151%	97%	64%	45%
Loss from Operations	**(37.85)**	**(7.96)**	**(8.92)**	**(8.33)**	**(7.47)**	**(32.68)**	**(33.53)**	**(31.51)**	**(28.16)**
Interest income	0.02	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Loss on Extinguishment of debt	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Interest Expense	5.29	(1.72)	1.40	1.45	1.50	$2.63	5.80	0.00	0.00
Warrant exchange	2.99	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Other Expenses	0.06	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
non-cash expense	36.30	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EBIT	**(82.50)**	**(9.68)**	**(10.32)**	**(9.78)**	**(8.97)**	**(38.75)**	**(39.33)**	**(31.51)**	**(28.16)**
Tax Rate	35%	35%	35%	35%	35%	35%	35%	35%	35%
Taxes	0.05	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net Loss	**(82.46)**	**(9.68)**	**(10.32)**	**(9.78)**	**(8.97)**	**(38.75)**	**(39.33)**	**(31.51)**	**(28.16)**
Net Margin	-	-	-	-	-	-	-	-	-
Shares	17	19	21	24	26	22	26	30	32
EPS	**(4.89)**	**(0.51)**	**(0.49)**	**(0.41)**	**(0.34)**	**(1.72)**	**(1.51)**	**(1.05)**	**(0.88)**

Source: Zacks Investment Research *Anita Dushyanth, PhD*

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2016, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Anita Dushyanth, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.