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Zacks Small-Cap Research

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ViewRay Inc (VRAY-NASDAQ)

Solid Q2, FY2018 Guidance Intact. New CEO Outlines Vision for Growth

Based on our 10-year DCF model that uses a 10% discount rate and a 2% terminal growth rate, the target price comes out to roughly $12.50/share. Our assumptions and financial model will be updated based on relevant news.

Current Price (08/10/18)	$9.98
Valuation	**$12.50**

OUTLOOK

ViewRay (VRAY) announced financial results for their second quarter 2018 and provided a business update. In terms of the financials, revenue was well-ahead of our (pre-preannounced Q2) numbers, reflecting one earlier-than-estimated installation (3 A vs 2 E), partially offset by slightly softer than modeled (~15%) average pricing. Both of these differences should dissipate through the end of the year, with management continuing to guide for FY2018 total revenue of $80M - $90M (i.e. inline with our prior and current estimate) and expectations that average ASP, which was somewhat diluted in Q2 due to preferred pricing on a first-in-territory (in China) system installation, firms up. One of the major highlights on the operational front was changes at some of the top leadership positions - including CEO and COO. While not something that we had anticipated, we think the changes may provide a fresh perspective on how best to grow the company. In addition to reducing installation timelines, Scott Drake outlined his key priorities for accelerating growth of the company. Those include providing necessary resources to sales and marketing, continual focus on innovation to remain in front of the competition and to expand the clinical evidence portfolio of MRIdian.

SUMMARY DATA

52-Week High	**$13.21**
52-Week Low	**$5.11**
One-Year Return (%)	**79.63**
Beta	**1.24**
Average Daily Volume (sh)	**1,217,624**
Shares Outstanding (mil)	**75**
Market Capitalization ($mil)	**$749**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**84**
Insider Ownership (%)	**44**
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 2018 Estimate	**-15.9**
P/E using 2019 Estimate	**106.7**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	$1.2 A	$0.7 A	$12.2 A	$19.8 A	$33.9 A
2018	$26.2 A	$16.4 A	$17.5 E	$28.7 E	$88.8 E
2019					$146.0E
2020					$193.6E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.50 A	-$0.15 A	-$0.19 A	-$0.24 A	-$1.24 A
2018	-$0.11 A	-$0.30 A	-$0.21 E	-$0.19 E	-$0.81 E
2019					$0.44 E
2020					$0.24 E

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

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WHAT'S NEW

Q2 Results: Solid Q2, FY2018 Guidance Intact. New CEO Outlines Vision for Growth

ViewRay (VRAY) announced financial results for their second quarter 2018 and provided a business update. In terms of the financials, revenue was well-ahead of our (pre-preannounced Q2) numbers, reflecting one earlier-than-estimated installation (3 A vs 2 E), partially offset by slightly softer than modeled (~15%) average pricing. Both of these differences should dissipate through the end of the year, with management continuing to guide for FY2018 total revenue of $80M - $90M (i.e. inline with our prior and current estimate) and expectations that average ASP, which was somewhat diluted in Q2 due to preferred pricing on a first-in-territory (in China) system installation, firms up.

One of the major highlights on the operational front was changes at some of the top leadership positions - including CEO and COO. While not something that we had anticipated, we think the changes may provide a fresh perspective on how best to grow the company. Certainly that seems to be consistent with comments on the Q2 call by Scott Drake, the newly appointed CEO. Mr. Drake comes with substantive experience in med-tech and what looks to be an overall fairly well-fit background, including as CEO of Spectranetics Corp, a cardiovascular device manufacturer. Impressively, Spectranetics' enterprise value grew 10x under Drake's tutelage until being acquired by Royal Philips in 2017 for over $2B. Scott Drake also assumes the President position as well as a board seat.

Shar Matin was hired as VRAY's COO. He held the same position at Spectranetics' (2014 - acq). And finally, Keith Grossman, joins VRAY's board. Grossman's background, which includes extensive leadership experience in med-tech, also looks like a very good fit for VRAY.

Financials
Product and total revenue were $15.4M and $16.4M in Q2, compared to $0/$698k in Q2 '17 and $25.4M/$26.2M in Q1 '18. Product revenue reflected installation of three new MRIdian systems at an ASP of approximately $5.1M. We look for another three installations in Q3 and four in Q4 - and for ASP in 2H '18 to increase in the high single digit percentages as compared to Q2. Our FY2018 revenue estimate remains largely unchanged at $88.8M.

Product margin, at just 5% in Q2, was negatively impacted by write-off (of $2.7M) of Cobalt-related inventory. Excluding that non-recurring charge, product margin would have been approximately 22% (inline with our 23% estimate). Gross margin was 0% but, again, would have been much healthier if not for the inventory charge. While we think there's potential for future q-to-q volatility in margins (particularly in times and in instances when preferred pricing makes strategic sense) we expect GM to continue to grow over the longer-term. Importantly, with expectations of volume-related economies of scale and other efficiencies, management continues to guide for gross margins to approach 30% by current year-end and 40% in 2019.

Operating expenses ticked up on both a yoy and qoq basis. At least a portion of that appears to be related to some headcount additions. We expect operating expenses will continue to trend higher over time as additional resources are brought into the sales/marketing functions and as VRAY expands new product development. But, on percentage if sales basis, we think opex contracts as sales grow and results in greater operating leverage. And, coupled with expanding product margins, we think operating loss begins to improve in 2019.

Cash position was $66M at Q2 quarter-end. VRAY used $11.4M and $48.8M ($17.3M and $27.6M, ex-changes in working capital) in cash for operating activities in the three and six months ending 6/30/18, compared to $11.9M and $23.9M ($12.2M and $22.9M, ex-changes in working capital) in the comparable prior year periods. The company used a total $73M of cash in 2017 and is now guiding for total cash usage of $90M - $100M in 2018.

Business Update:
As of June 30th, 17 MRIdian systems (7 Cobalt-60 and 10 Linac) have been installed at 15 cancer centers, including eight in the U.S. and seven OUS. VRAY's backlog remains robust. While some relatively old orders slipped off the backlog during Q2, that was more than offset by the value of new orders which came online. VRAY ended Q2 with a backlog of $200M, up from $195M at the close of Q1 '18 and $182M at the end of Q2 '17.

During Q2 VRAY received new MRIdian orders of more than $34M. Importantly, management continues to guide for full-year revenue in the range of $80M to $90M (implying yoy growth of at least 135%), representing an anticipated 13 to 15 system. With seven installations made through the first six months of the year, this implies another six to eight will occur by the end of 2018.

VRAY has wind at their back following a strong ending to 2017 and a similarly rapid start to 2018. Certain catalysts should either make an initial impact or more significant impact during 2018. This includes Shonin approval for the MRIdian Linac system, which came in March, clearing it for marketing in Japan. Japan is one of the world's largest medical device markets. VRAY, which already has two Cobalt systems in the country (including one at the National Cancer Center), has collaborated with ITOCHU Corporation as their Japan-based representative for commercialization. JASTRO (Japan Society of Radiation Oncology) in October should be another awareness-building opportunity for VRAY.

New Linac system installations in leading research institutions and cancer centers in Europe, the U.S. and Japan as well as continued participation at key industry conferences should also significantly benefit awareness-building efforts. A key French tender was among the latest sales-related highlights. The tender, announced in July, is from UNICANCER, a 19-hospital network and currently includes three systems - with potentially more to follow.

Another milestone of-sorts was set in July when the first community hospital in the U.S. installed a MRIdian Linac system. The installation at Palos Health South Campus in Orland Park, IL is a significant event for VRAY as community hospitals have been a target focus for the company. The expectation is that this is just the first of many to come.

Leading university and cancer research hospitals have also been a key part of VRAY's expansion strategy. Recent installations in that target market include University Medical Center in Amsterdam, University Clinic Heidelberg in Germany Product and Miami Cancer Institute at Baptist Health. Adoption and use of MRIdian among high profile cancer centers should undoubtedly facilitate VRAY's awareness building efforts and further validate the superiority of the technology. VRAY also recently announced that the University of Wisconsin Carbone Cancer Center (Madison) and Washington University School of Medicine (St. Louis) began treating with their first and second MRIdian Linac systems, respectively.

In terms of industry events, MRIdian was featured in 55 abstracts selected for presentation at AAPM (July 29 - August 2). VRAY's pipeline, represent additional potential catalysts to growth, was also highlighted - including SmartVISION, which improves tissue visualization and is available in Europe (and for which 510(k) FDA clearance has been filed). The AAPM presentations follow 16 presentations and posters in which MRIdian was featured at ESTRO in April. Other awareness-building events this year included a day-long global symposium at VU Medical Center which was attended by 200 oncology experts and which featured several speakers including those with experience with MRIdian.

A regular flow of clinical data could be particularly key in driving uptake of MRIdian. Lower radiation exposure, improved cosmetic outcomes, lower recurrence rates and overall better patient outcomes are examples of potentially potent endpoints that could facilitate steepening adoption of MRIdian. As the MRIdian installed base expands and utilization and clinical experience grows, so should the opportunity for more evidence-based studies.

Installation times are expected to continue to shorten, which further facilitate growth in product revenue recognition. Installation time of the MRIdian system has been reduced from about 100 to roughly 60-75 days. Noteworthy is that management mentioned on the Q2 call that the last installation done in Q2 was completed in "well under 60 days" - which may indicate that progress continues towards reducing installation timelines.

While lengthy installation times have been an obstacle, reducing the time to commission the system and increasing installation capacity remain priorities and are something that management expects will continually improve throughout 2018. As the installed base ramps up, we also expect maintenance contracts to increase, which would benefit the firm with a steady stream of recurring revenue.

Changing of the guard brings updated strategy…

In addition to reducing installation timelines, Scott Drake outlined his key priorities for accelerating growth of the company. Those include providing necessary resources to sales and marketing, continual focus on innovation to remain in front of the competition and to expand the clinical evidence portfolio of MRIdian.

INVESTMENT THESIS

Radiation oncology is one of the major approaches besides chemotherapy and surgery to treat cancer, precisely and accurately, with ionizing radiation while sparing adjacent, healthy tissue. While Computed Tomography (CT) is traditionally used in radiotherapy (RT) procedures, recent advances in technology have several firms developing systems that use Magnetic Resonance Imaging (MRI). While cone beam CT (CBCT) has been useful for localizing target areas in radiation treatments, it is not the best technology for visualizing soft-tissue anatomy. MRI provides an unparalleled view of soft-tissue structures and is therefore considered the gold standard in such applications. MRI has several advantages over CT:

- It provides superior soft-tissue contrast as compared to CT.
- Unlike CBCT, MRI does not produce ionizing radiation.
- CBCT imaging systems currently in the market are relatively slow taking about one minute to acquire a volumetric image set. MRI, on the other hand, offers very fast volume acquisitions and can image biologic as well as physiologic activity.

The MRIdian was developed by VRAY in collaboration with Siemens Healthcare, which integrates a Cobalt therapy unit with a low field MRI scanner. VRAY's MRIdian-Cobalt is the first and only MRI-guided radiation therapy system in the market. It allows clinicians to simultaneously image and treat patients suffering from cancer.

ViewRay's research efforts have established a series of industry firsts in product design such as:

- First patient treated with MRI-guided RT
  - First and only FDA-cleared MRI-guided RT system
  - First and only CE-marked MRI-guided RT system
  - First on-table adaptive RT system
  - First system to provide direct soft tissue tracking
  - First system to exclusively use Monte Carlo Treatment Planning System (TPS)
  - First MRI-guided system to fit in standard vaults

Currently, innovators at ViewRay have met the challenge of combining the proven cancer treatment capabilities of a Linac with the soft tissue imaging capabilities of MRI. The firm has developed radio frequency (RF) "cloaking" technology to prevent RF emitted by the Linac from destroying the MR image quality as well as magnetic shielding technology to enable undistorted delivery of radiation. The firm's double-focused multi-leaf collimator (MLC) technology allows delivery of sharp radiation beams. Further, the magnet is designed such that it can be easily incorporated into existing vaults. Real-time MRI radiotherapy is a potentially disruptive technology that non-invasively allows anatomical and physiological targeting resulting in the potential to improve cancer outcomes. VRAY's proprietary technology is an emerging disruptive technology that allows the potential to provide targeted dose using 3D image guidance during the treatment.

ViewRay's fast on-table adaptive RT (ART) treatment planning system (TPS) is capable of delineating structures of interest as well as computing a priori Monte Carlo dose to support 3D-CRT, IMRT and SBRT that are clinically equivalent to those produced on the most advanced linear accelerators available today, yet can be done during treatment while the patient is still on the table. Allowing clinicians to re-optimize and reshape dose distributions to adapt to a patients changing anatomy at each treatment, a capability that other systems do not provide. ViewRay's MRIdian system provides positioning accuracy of soft tissues which can be verified visually and is updated four times a second during beam delivery.

The rise in cancer prevalence, coupled with the increase in sophistication of new treatment regimen has created demand for technologically sound systems that can be integrated into clinical practice to make treatments more rapid and cost effective. While growth of radiotherapy

in developed nations is stunted as the market is mature with RT systems, there is a positive trend in growth that is associated with replacement purchases. Growth in emerging markets is expected to be robust given that they are under-equipped. This demand in emerging markets, coupled with the replacement market in developed nations, and the ever- increasing incidence of cancer globally, provides a substantial growth opportunity to disruptive technologies such as ViewRay's.

A paradigm shift is occurring in the approach to RT therapies from invasive and radiation-exposing techniques using CT to non-invasive and non-radiation based MRI procedures. MRI guided procedures such as those provided by MRIdian make it possible to improve visualization and reduce dose fractions, consequently decreasing healthcare costs. Clinical data using the MRIdian system has demonstrated the same. We expect there may be an uptick in the use of MRIdian as clinical documentation as well as publications help highlight benefits over conventional RT procedures.

We believe that MRIdian may be used more frequently for complex cancer cases to address tumors that may be difficult to treat on a conventional Linac due to its location in relation to the surrounding soft tissues. Further, we think the MRIdian can be used to treat a broad spectrum of diseases.

MRIdian Cobalt-60: VRAY's promise to shrink the (cancer) risk!

ViewRay's split-magnet MRI system is used for pre-treatment imaging, real-time and adaptive radiotherapy. The imaging and radiation delivery systems are designed to operate in tandem for accurate, targeted administration of radiation dose. The MRIdian system records patient information, treatment protocols, amount of dose administered with every fraction, the accumulated dose, MR imaging data and system performance during treatment. The system can be disassembled (pop-apart design) for installation to allows easy transportation through existing hospital entryways.

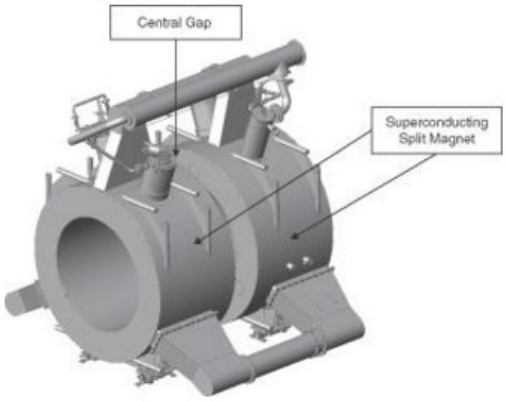
MRIdian



1. Split Superconducting Magnet
2. Gantry
3. Patient Handling System
4. Source Heads
5. Split Gradient Coil

The MRI System: The MRIdian radiotherapy system is designed to fit in a conventional radiotherapy bunker. The MRIdian system utilizes a split, superconducting low field strength (0.35T) magnet that helps minimize distortions to the radiation beam and the image so that a precise dose of radiation can be accurately delivered. Volumetric scans are acquired in about twenty to ninety seconds prior to commencing treatment in order to localize the region of interest. Radiofrequency (RF) surface coils are designed to be thin and uniformly attenuating. They are covered in low-density foam and positioned on the patient to prevent increased surface dose as well as for improved patient comfort. 3D-CRT, IMRT and SBRT can be performed using MRIdian, which delivers clinically equivalent results to those produced by the most advanced linear accelerators currently in the market.

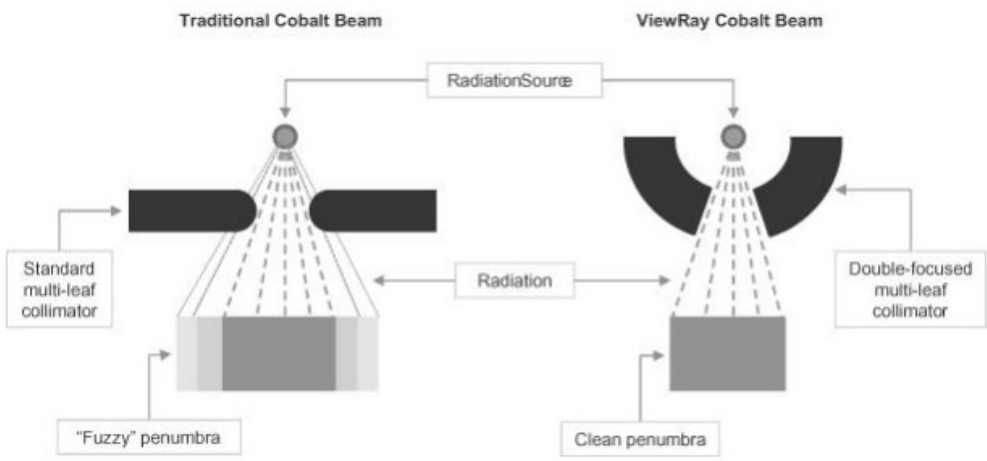
MRI System



(Source: www.viewray.com)

Radiation Source: Cobalt generates gamma rays, which offer many of the same benefits as X-ray photons without interfering with the operation of the MRI unit. Radiation is delivered from three Cobalt-60 radiation therapy heads (15,000 curies per source) symmetrically mounted (120° apart) on a rotating ring gantry between the gap in the MR magnets (allows unobstructed beam path) and provides full 360 degree coverage. The Cobalt sources share a common isocenter with the magnet thereby enabling simultaneous and continuous MRI during radiation delivery.

Each radiation source is equipped with a double-focused Multi-Leaf Collimator (MLC), with 1.05cm leaf width and a maximum field size of 27.3cm x 27.3cm at the isocenter distance of 105cm, resulting in minimal beam penumbra for precision. It is well accepted that X-ray radiation techniques can control many cancers if the radiation beam can be adequately controlled to target the cancerous tissue. MRIdian's MLCs help in defining the irradiation beam precisely to target cancerous cells. A pneumatic drive moves the sources in and out of the depleted Uranium shield. The system design enables axial radiation beam access to the patient with minimal attenuation. During treatment, tissue/organ structures are observable in continuous and simultaneous fast planar images; in one sagittal plane at four frames per second or in three parallel sagittal planes at two frames per second. The gantry containing the sources is positioned between two superconducting magnets. Patient bore diameter is 70cm and accommodates large patients.



Imaging takes place in a 50cm diameter spherical volume.

(Source: www.viewray.com)

Software: The MRIdian software possesses the capability to track the soft-tissue continuously in MRI images. Using this software, the on-table ART process can be implemented in less than two minutes, and includes: auto-contouring, dose prediction and treatment plan optimization. For

contouring, the software will automatically delineate the tumor border. This process allows the clinician to make refinements to the region of interest before delivering treatment, if necessary. Dose prediction can be calculated immediately following auto-contouring. The software then generates a treatment plan in about one minute, allowing time to re-plan while the patient is on the table. While the radiation dose is being delivered, the software analyzes the acquired images to determine the tumor's or organ's location relative to set boundaries. If the targeted tumor or a critical organ moves outside the defined boundary, which can occur due to physiological motions such as respiration, cough or digestion, the treatment beams will automatically pause and will automatically resume when the tumor moves back into the target zone. Physicians can set both spatial and time thresholds for pausing treatment delivery. This enables the system to account for tumor and patient motion during treatment.

The software records all details pertaining to the treatment and builds a database of patient-specific planning, delivery and imaging data. It also includes a review tool which provides clinicians with a visual comparison of the delivered versus planned treatment. At the end of each treatment, the software determines the delivered dose by combining the recorded actions of the radiation delivery system with the daily image and auto-contouring of the patient. With this information, clinicians can fine-tune prescriptions based on the actual dose delivered. In addition, it provides a MRIdian Movie™ of each delivered treatment, which can be evaluated by the physician or exported and shared with the patient.

Safety and Control System: In addition to complying with the FDA and Nuclear Regulatory Commission (NRC) requirements, the MRIdian system is additionally equipped with redundant safety systems. If any two components in the radiation delivery subsystem fail simultaneously, such as power and pneumatics, the system reverts to a safe state. MRIdian also contains redundant computer control for safety and system logging and double encoders on all axes of motion for safety. The control system continuously monitors performance to ensure all systems are performing and communicating appropriately.

MRIdian Linac: A technically challenging but bold move!

A Linac is a device that accelerates electrons to high speeds through a waveguide. The equipment is most commonly used to irradiate cancer cells (EBRT). The high-energy photos released from the system are made to conform to the shape of the tumor and can be delivered from many angles by rotating the gantry and/or moving the treatment couch.

In March 2016, the firm announced the development of a system that combines the Linac technology onto the existing MRIdian platform, eliminating the need for cobalt. What's interesting about this revolutionary system is that it delivers radiation beams in a magnetic field using a linear accelerator and modifies the MRI system to incorporate Linac technology. The MRIdian-Linac upgrade maintains the footprint of the legacy system; the pop-apart model allows replacing the Cobalt with the Linac gantry.

Linacs utilize high-powered microwave generators that generate noise, which can corrupt the delicate signals emitted from the patient's body to generate MR images. ViewRay solved this problem by introducing a technology similar to that used in stealth aircraft. Stealth aircraft can hide from radar by using a coating that reflects and absorbs microwaves, thus preventing radar beams that strike the aircraft from bouncing back to the radar station. In a similar manner, the system reflects and absorbs the output of the Linac's RF waves thereby hiding it from the MRI, producing noise-free MRI images.

MRIs utilize high-powered superconducting magnets that are required to image the patient's tissues. Many Linac components will not operate properly when placed close to or inside these strong magnetic fields. ViewRay overcame this challenge by creating magnetic shielding shells that create voids in the magnetic field without significantly disturbing the magnetic field used for imaging. This allows for a compact system like the MRIdian-Linac, which integrates the Linac to operate on the MRIdian gantry as if there were no magnetic field present.

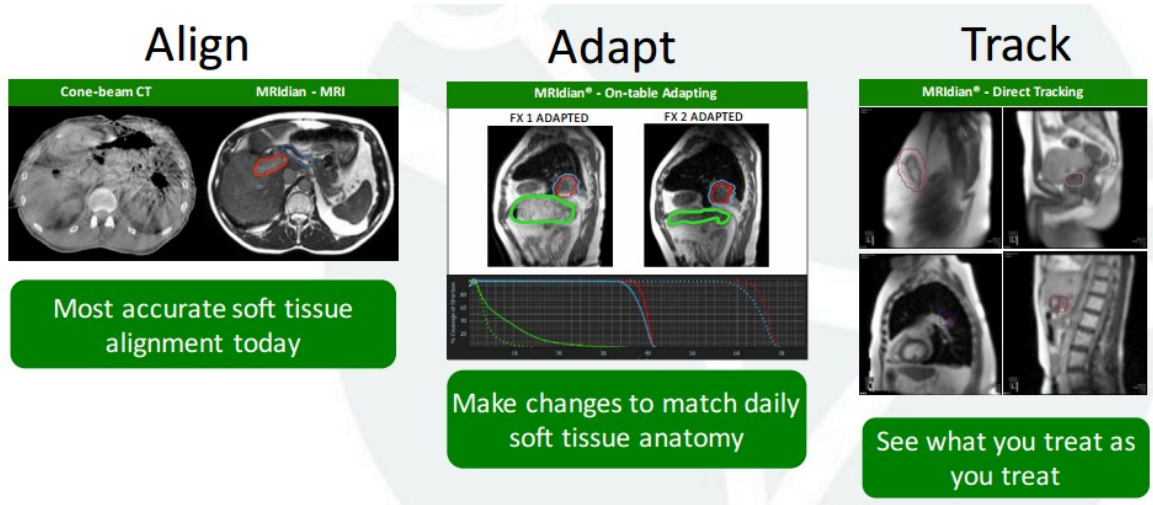
Early Cobalt-60 systems (developed in 1970) versus the Linac

Comparison of various parameters for radiation sources of photon beams

S. No	Physical and other Parameters	^{60}Co machines	6 MV x-rays	15 MV/18 MV x-rays
1	Build up	Equivalent to 4MV Build-up 5 mm	Emean ~ 2 MeV Build up 15 mm	Emean ~ 6 MeV Build up 28-35 mm
2	Skin dose	40-50%	~ 25%	~ 15-25%
3	Penumbra	90-10% is 1.5 cm Field definition 50%	Sharp beam field definition 80%	Sharp beam field definition 80%
4	Penetration	54% (10 cm)	67% (10 cm)	77% (10 cm)
5	Source distance	80 cm	100 cm	100 cm
6	Shape of isodose curves	Rounded beyond central zone (correctable)[9]	Flattened with special filter	Flattened with special filter
7	Side scatter	Less	Less	Less
8	Integral dose/tumor dose ratio	More for non-optimal plans. Manageable with good plans.	Less with simple fields	Less with simple fields
9	Absorption in bone	No differential absorption	No differential absorption	No differential absorption
10	Beam collimation	Asymmetric collimator (Yes)	Asymmetric collimators	Assymetric collimators
		MLC being tried	MLC, IMRT, SRT	MLC, IMRT
11	Irregular fields	Achievable with blocks. MLC being tried[10].	MLC, mMLC	MLC
12	Patients Registration	Possible	Networking yes	Networking yes
13	Computerized control console	Yes	Yes	Yes
14	Clinical acceptability	Yes (WHO,[2,4]	Yes	Yes
		Van Dyk,[6] Podgarsak,[7])		
15	Provision of performing tomotherapy	Feasibility reported'[11]	Dedicated machine	----

(Source: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2805891/)

APPLICATIONS



(Source: www.viewray.com)

IMRT is an advanced form of EBRT in which the shape, angle and intensity of the radiation beam are varied for precise, targeted therapy. This form of radiotherapy allows physicians to deliver higher doses of radiation to the target region as compared to conventional radiation treatments. IMRT allows for clinicians to personalize treatment plans for each patient. IMRT is used to treat complicated, cancerous anatomic sites such as head and neck, prostate, gynecological and central nervous system (CNS). IMRT has become a well-accepted standard of treatment for cancer.

IGRT is another advanced form of EBRT that complements IMRT to enhance treatment efficacy. While IMRT allows for precisely shaping the beam, IGRT goes further to accommodate for a tumor moving or shrinking thereby improving accuracy. IGRT technologies provide dynamic,

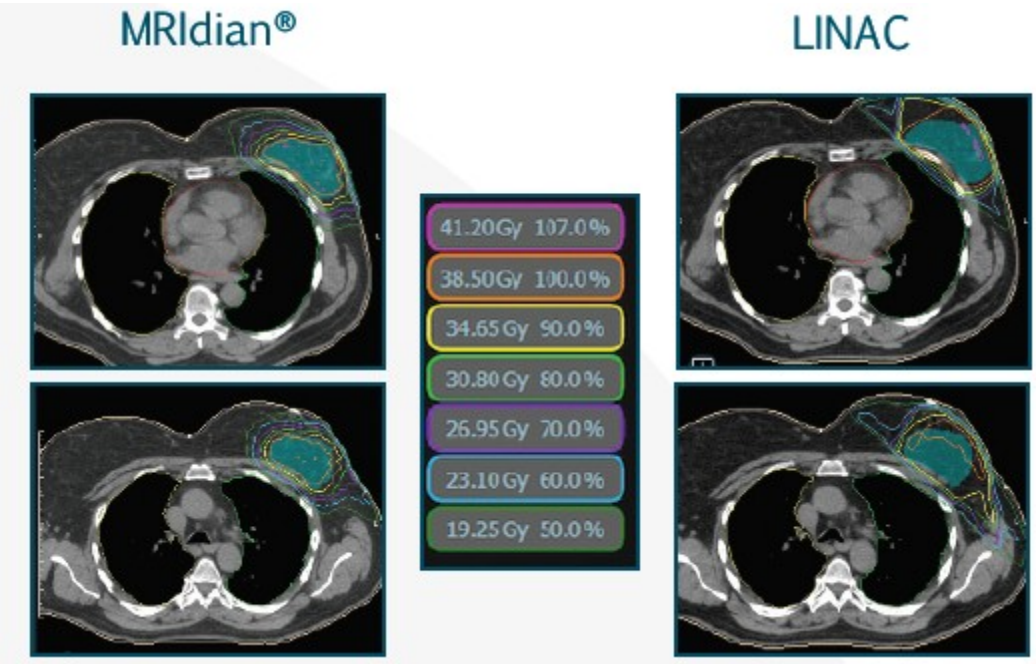
real-time visualization enabling precise treatment of small, moving and changing tumors, which allows clinicians to deliver higher doses of radiation to tumors with the goal of sparing more of the surrounding healthy tissue and potentially improving outcomes. IGRT has also become an accepted standard for treatment in the radiation oncology community.

SBRT and SRS, referred to as radiosurgery, are advanced ablative radiation treatment procedures performed with high doses of ionizing radiation. Radiosurgery uses precise stereotactic image-guidance, which maximizes dose to the target and minimizes dose to surrounding normal tissues. A drawback to SRS/SBRT technique is that it is suitable only for small, well-defined tumors and the amount of radiation that may be safely delivered is limited if the cancer is located close to a sensitive normal structure, such as the spinal cord or bowel. On-table MRI guidance has the potential to improve it use in such cases.

3D-CRT employs CT technique to generate a 3D volume of the target anatomy. The treatment planning software uses this information to design radiation beams that conform to the shape of the tumor. The radiation beams are focused precisely on the tumor to irradiate it while sparing surrounding normal tissues. 3D-CRT is used extensively for treating several cancerous anatomical sites.

Clinical Studies: Instead of relying on existing bones or implanted fiducial markers, the MRIdian system's real-time imaging enables the physician to track the movement of the tumor and the surrounding healthy tissue directly. With better soft tissue imaging provide by MRI, the patient can be aligned more accurately for treatment. When the tissues have changed and the treatment plan is no longer acceptable, on-table ART allows for the reshaping of the dose to maximize target coverage and healthy tissue sparing without moving the patient. During beam delivery, the treatment beam automatically pauses in situations where a tumor is in close proximity to a critical organ, such as the heart during lung and breast cancer treatments or the rectum during prostate cancer treatments. The real-time tracking of tissues has enabled physicians to treat patients who would not have been considered for radiation therapy.

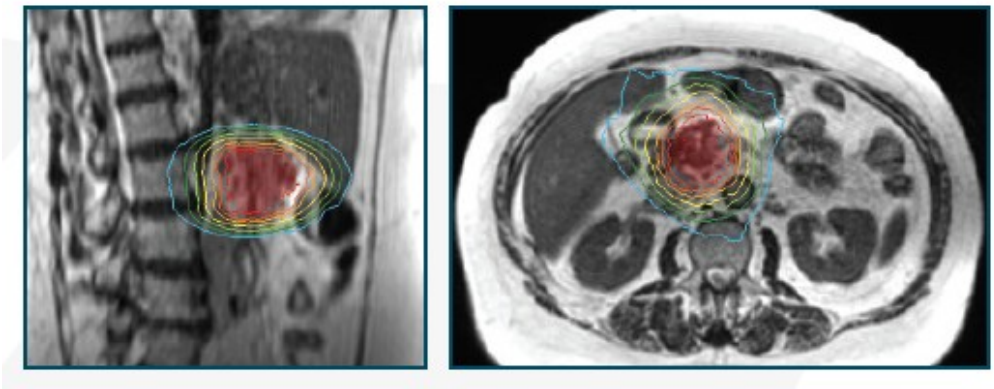
Breast: Breast position and shape differs widely and is further exasperated when treating the left breast as it is close to the heart. With MRIdian, a highly conformal dose can be delivered to the target with minimized dose to the healthy breast tissue and sensitive structures.



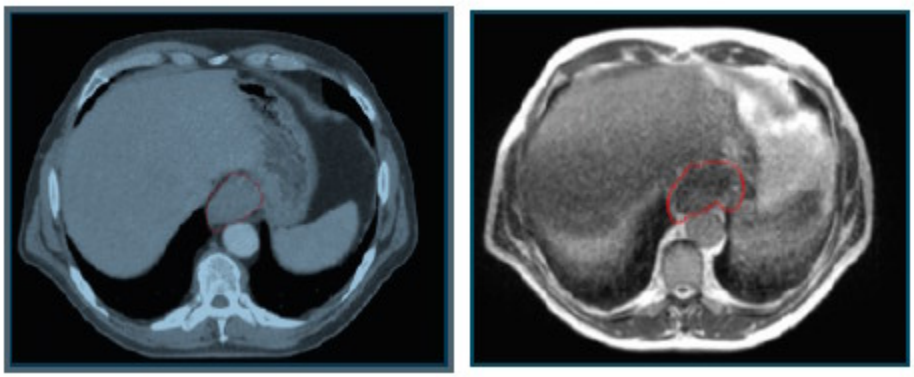
(Source: www.viewray.com)

Pancreas: Most pancreatic cancers are difficult to resect due to the organ's proximal location to the celiac and superior mesenteric arteries along with the portal vein in the abdominal cavity. The head of the pancreas is located within the curve of the duodenum. It is important to track the portal vein or pancreatic head during treatment because the duodenum is very sensitive to radiation. MRIdian allows you to continuously monitor the target area with a gated breathing technique.

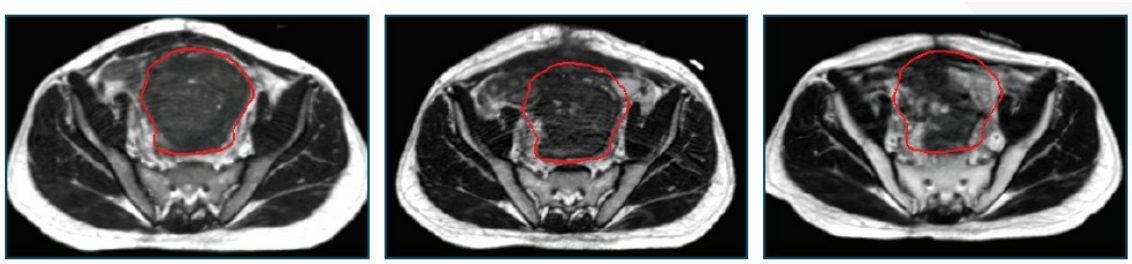
Adenocarcinoma of Distal Esophagus: The image above left shows the GTV delineated by the physician from the



CT simulation. The image above right from the MRIdian® simulation shows the updated GTV. A large area of this target was not visible on the CT and therefore could have been missed without the MRI



Sigmoid Colon Cancer with Bladder Invasion; A large sigmoid tumor that was invading the bladder could be located and accurately tracked despite its motion using the MRIdian system.



(Source: www.viewray.com)

The ability of MRIdian to simultaneously image while treating not only enables clinicians to treat cancers that would be difficult to treat using other radiotherapy systems, it also enables the clinicians to hit the tumor "hard", with larger doses in less sessions. Using CBCT guided radiotherapy systems, doses of radiation are often fractionated and standard radiation therapy is often given once a day (five times a week) for up to eight weeks. The ability to view the tumor during treatment and the enhanced ability to avoid nearby healthy tissues, potentially allows clinicians to give more intense doses in a single or a few sessions and reduce the significantly reduce the duration of treatment. The reduced duration of treatment is going to be embraced enthusiastically by both patients and healthcare systems.

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COMPETITORS

Varian Medical Systems, Inc. (NASDAQ:VAR), Elekta AB (Sweden, EKTA-B.ST), Accuray Incorporated (NASDAQ:ARAY), Thermo Fisher Scientific (NASDAQ:TMO), C. R. Bard, Inc. (NASDAQ:BCR), IsoRay Medical, Inc. (NYSE:ISR), Ion Beam Applications SA (Belgium), Nordion, Inc. (Canada), RaySearch Laboratories AB (Sweden), Mevion Medical Systems, Inc. (U.S.), and Mitsubishi Electric Corporation (Japan) are the key players in the global RT sector. Other competitors in the internal and external radiation therapy market include Brainlab, Theragenics, GE Oncura, Best Medical, Eckert & Ziegler BEBIG and IsoAid among others. VRAY also faces competition from alternative cancer treatment methods, such as traditional surgery, chemotherapy, robotic surgery and drug therapies.

VRAY versus Competitors:

The observed and reported potential clinical benefits of the MRIdian system over competitors' systems include:

- better visualization of soft tissues as the system uses MR imaging
- treatment of patients previously untreatable with RT
- target tracking in head and neck regions which are prone to physiologic motion
- dose escalation for certain anatomic sites
- better control of dose (if tumor is near critical structures)
- reduction in the number of treatment fractions for certain tumor sites.

Technology: ViewRay is ahead of the game with an innovative product design that

- allows real-time visualization using MRI during radiotherapy
- allows on-table adaptive therapy
- allows direct soft tissue tracking
- has in-built exclusive Monte Carlo Treatment Planning System (TPS)
- is FDA-cleared and CE-marked and
- fits in existing, standard-sized vaults.

Competitors' products use X-rays/CT, which falls flat in comparison to MRI's ability to image soft tissue structures embedded deep within the body. X-rays also expose the patient to unnecessary additional radiation. Since target regions could move due to physiologic motions (respiratory or peristaltic movements or cardiac pulsations), there is immense uncertainty when using X-rays/CT in accurately defining the region of interest to deliver radiation doses in fractions. MRIdian circumvents all of the aforementioned issues efficiently.

Magnetic field strength: While competitors propose the use higher field strength (1.5T) magnets in systems under development that both distort soft tissue images, by up to approximately 6mm, and dose distribution, MRIdian uses low field (0.35T) magnets to avoid the image and dose distortion as well as to prevent heating of tissue within the patient. MRIdian uses TRUFI (true fast gradient echo imaging with steady state precession) sequence, which is known to provide the best signal-to-noise ratio equivalent to 4T magnets at very high speed. The 0.35T field strength allows to continuously track the tumors without violating radiation dose limits set by the FDA.

Field of view: The sharp Cobalt beam resulting from the double focused MLCs can target a region of size 27.3cmx27.3cm which is comparable to the TrueBeam (Varian) that has a field of view of 30.1cm x 40.1cm at isocenter. When available, the MRIdian Linac system will apply double focused MLCs to the linac producing even sharper beams than now available.

Target Localizing: Instead of relying on existing bones or invasive implanted fiducial markers as in other RT systems, the MRIdian system's real-time imaging enables the physician to track the movement of the tumor and the surrounding healthy tissue directly. In this system, the tumor *is* the visualized target making fiducial markers obsolete.

Dose delivery: Treatment verification is of prime importance to avoid large deviations in delivered dose. The traditional clinical practice is to correlate the internal target motion with some external reference (e.g., skin surface, abdominal pressure, tidal lung volume from a spirometer.) and control the on/off status of the radiation beam on the external reference's signal. However, the internal target motion and external surface signal is variable and exhibits both inter- and intra-fractionally. It is therefore important to verify that the moving tumor stays inside the planning target volume (PTV) whenever the beam is enabled during treatment delivery.

Since MRI does not provide radio density information that is required for optimal dose treatment planning, the MRIdian is designed to accommodate deformable registration of images and allows transfer of CT density to MRI for dose calculation using Monte Carlo (MC) algorithm. Further, the MRIdian allows real-time tracking of the target tumor, which helps physicians treat it with higher doses over fewer fractions. The software also allows for intrafractional corrections during treatment.

Frame rate: MRIdian allows for MRI acquired in four frames per second in one plane or two frames per second for three planes. The company announced at ASTRO in September 2015 an upgrade to eight frames per sec.

Pricing: Acquiring radiotherapy equipment involves high initial capital costs for the hospitals. ViewRay's MRIdian system, priced around $5.5 million is set at a higher price point than competitor's radiotherapy systems. Varian's systems are priced in the range of $3-$5.5 million; the higher price reflects the purchase of supplemental options and technologies.

Ease of Installation/Upgrade: The ViewRay system is designed to fit in an existing radiotherapy vault unlike its competitors that require renovations to an existing radiotherapy unit for retrofitting their system.

VALUATION

While we think that the MRIdian system has surpassed its competitors based on technology as well as treatment regimen, the underlying question of whether ViewRay's system will become the system of choice depends on whether the firm can penetrate developing markets and/or replace the current systems in mature markets with MRIdian's products.

We calculate the potential addressable market for radiotherapy, including the number of treatable patients as well as consequently, the number of RT systems that are needed to satisfy this demand. According to WHO/GLOBOCAN, there were ~14 million cancer patients in 2012, and this prevalence is rising at the rate of 2% annually. Of this number, 57% are in the developing nations[1]. There is anecdotal evidence that about 60% of those patients are suitable for radiotherapy (currently more than two-thirds of cancer patients in the U.S. receive RT), of whom 88% are eligible for treatment using Linacs[2]. This brings the total eligible patient population to roughly eight million who could potentially receive external beam radiation therapy using Linacs. Currently, as per the IAEA, approximately 13,000 machines are installed globally of which 3,300 RT units are in developing countries, primarily Cobalt therapy units.

If we assume that radiation therapy is given once a day, six times a week, for six weeks on average, with each treatment lasting between ten to fifteen minutes, one machine can treat an average of 624 patients annually. Knowing that the global cancer population treatable by RT systems is about eight million annually, the total potential demand for global LINAC systems could be as much as around 13,500 units, of which 10,000 are required in the emerging markets and the remaining in established markets.

The RT market is divided into two parts: replacement segment and new installation segment. Both markets offer their own unique advantages and challenges. Developed countries such as the U.S. have the infrastructure and financial resources to indulge in new technology. Such markets are already mature and home to significant portion of the installed base globally. Varian, and Elekta, account for the lion's share of new installations.

According to IAEA Human Health Campus, there are 11,000 Linacs installed at over 7,500 centers worldwide. In the U.S., there are ~4000 Linacs installed at over 2,500 centers. The annual market for Linacs is estimated to be 1,100 units per year globally, the majority of which are replacement units. When organizations are ready to replace

[1] http://www.npr.org/sections/goatsandsoda/2015/12/15/459827058/most-of-the-worlds-cancer-cases-are-now-in-developing-countries
[2] http://www.rtanswers.org/statistics/aboutradiationtherapy/

aging equipment with new counterparts, it opens a market segment for VRAY that had been exclusive to RT market leaders. VRAY's systems being disruptive have a good chance of being adopted into mature markets. Further, since 76% of the RT sector is the replacement market, which we think is mostly in the industrialized countries, VRAY will be able to grow its installed base here as systems come up for replacement. VRAY's units offer technological advantages over competitors and can fit into existing bunkers and offer "pop-apart" design that allows installation within existing vaults without the need for extensive restructuring. This should help with faster adoption of VRAY's technology in the U.S. and other advanced markets such as Europe.

Based on the above factors we have modeled modest revenue growth of the installed base globally for the next couple of years. This is based on our assumption that in order to gain entry into these markets, and expand geographic reach, management continues to invest in creating awareness of the product, price the unit attractively for emerging markets and continues to make headway by increasing the number of distributors and direct sales and support personnel as well as by further penetrating established international markets. As the installed base continues to rise, consequently we expect the number of maintenance contracts to increase throughout the forecast period. This will help the firm in generating a steady stream of recurring revenue.

ViewRay has two main sources of revenues. The system costs around $5.5 - $6.0 million and the annual service and maintenance costs amount to $300k. VRAY warrants their system for parts and labor for one year, and offers a variety of post-warranty equipment service contracts and software support contracts to suit customers' requirements.

As VRAY's systems are cost-intensive to manufacture, the low volume of current sales has not been sufficient to fully absorb certain fixed overhead costs, resulting in a relative low gross margin. But, as sales continue to grow and the company is able to achieve economies of scale, we expect an expansion in gross margin. We model gross margin to widen to 30% by Q4 2018, benefiting from economies of scale from higher production volumes. We expect operating expenses will continue to trend higher over time as additional resources are brought into the sales/marketing functions and as VRAY expands new product development. But, on percentage of sales basis, we think opex contracts as sales grow and results in greater operating leverage. And, coupled with expanding product margins, we think operating loss begins to improve in 2019.

We use a 10-year DCF model to value ViewRay Inc. The majority of our revenue forecast for the out years are based on the sales of the MRIdian-Linac system since we expect RT to transition towards this technology globally. We expect revenue to continue to ramp through 2H 2018. We currently model total revenue of $89M in 2018 and $146M in 2019. We think, perhaps conservatively, that VRAY can reach a level of sales of $750M by the year 2028, the new out-year in our 10-year DCF model.

Inclusion of 2028 as the new out-year in our 10-year DCF, which also incorporates a 10% discount rate and 2% terminal growth rate, has moved our price target to $12.50/share. Our outlook is subject to change depending on the progress with expanding installed base and regulatory approvals.

PROJECTED INCOM E STATEMENT

VIEWRAY Inc.	2017A	Q1A	Q2A	Q3E	Q4E	2018E	2019E	2020E
Total revenue	**$34.0**	**$26.2**	**$16.4**	**$17.5**	**$28.7**	**$88.8**	**$146.0**	**$193.6**
Y-o-Y Growth	*53%*	*2034%*	*2256%*	*43%*	*44%*	*161%*	*64%*	*33%*
Total cost of revenue	$27.7	$20.6	$16.4	$12.7	$20.0	$69.7	$87.6	$106.5
Gross Income	**$6.3**	**$5.6**	**$0.1**	**$4.8**	**$8.7**	**$19.1**	**$58.4**	**$87.1**
Gross Margin	*19%*	*21%*	*0%*	*27%*	*30%*	*22%*	*40%*	*45%*
Product Margin	*16.3%*	*22.3%*	*4.6%*	*27.0%*	*30.0%*	*22.5%*	*37.7%*	*41.4%*
Research and development	$14.7	$3.8	$4.4	$4.2	$4.2	$16.6	$19.4	$23.5
% R&D	*43%*	*14%*	*27%*	*24%*	*15%*	*19%*	*13%*	*12%*
Selling and marketing	$8.4	$3.2	$3.4	$4.0	$5.7	$16.3	$23.4	$26.9
%S&M	*25%*	*12%*	*21%*	*23%*	*20%*	*18%*	*16%*	*14%*
General and administrative	$31.4	$9.8	$10.5	$10.7	$11.0	$42.0	$48.2	$54.7
%G&A	*92%*	*38%*	*64%*	*61%*	*38%*	*47%*	*33%*	*28%*
Total operating expenses	$54.5	$16.9	$18.3	$18.9	$20.9	$74.9	$92.0	$106.4
Operating Income	**($48.2)**	**($11.3)**	**($18.2)**	**($14.1)**	**($12.2)**	**($55.8)**	**($33.6)**	**($19.3)**
Operating Margin	-	-	-	-	-	-	-	-
Interest income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest expense	($7.22)	($1.87)	($1.92)	($1.95)	($1.96)	($7.7)	($7.7)	($7.7)
Other income (expense), net	($16.8)	$8.3	($01.9)	$0.0	$0.0	$6.5	$0.0	$0.0
Loss before provision for income taxes	($72.2)	($04.8)	($22.0)	($16.1)	($14.2)	($57.0)	($41.3)	($26.9)
Provision for income taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($72.2)**	**($07.5)**	**($22.0)**	**($16.1)**	**($14.2)**	**($59.8)**	**($41.3)**	**($26.9)**
Net Margin	-	-	-	-	-	-	-	-
EPS	**($01.23)**	**($00.11)**	**($00.30)**	**($00.21)**	**($00.19)**	**($00.81)**	**($00.44)**	**($00.24)**
	-	-	-	-	-	-	-	-
Shares O/ S	58	69	75	75	76	74	94	110

Source: Zack Source: Zacks Investment Research,

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