Ra Medical Systems™
Life-Changing Laser Innovation

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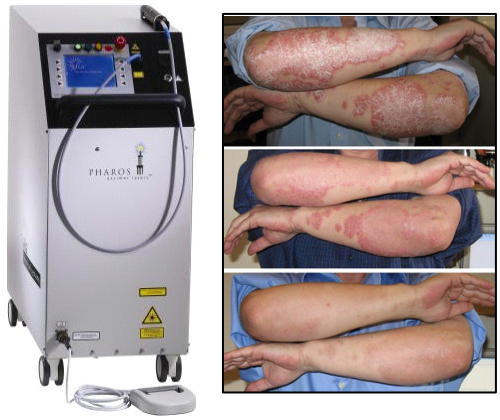
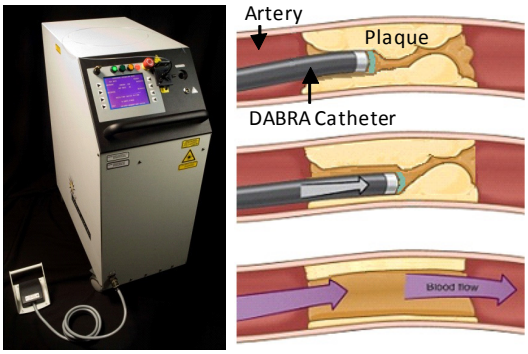
PHAROS EX-308 for Skin Diseases and Conditions



RA-308 and DABRA Catheters for Vascular Diseases and Conditions



Company Description

Ra Medical Systems, Inc. ("Ra Medical" or "the Company") is a medical device company commercializing laser therapies for a number of dermatology and vascular diseases. The Company has had over a decade of past success creating and marketing the PHAROS brand **excimer laser†** to treat **psoriasis**, **vitiligo**, **atopic dermatitis**, and **leukoderma**. Today, Ra Medical is poised to launch a novel laser and catheter system for minimally invasive endovascular treatments that center on the safe, efficacious, and efficient removal of plaque deposits from inside blood vessels. The Company's patent-pending DABRA catheter design has shown to achieve faster **ablation** and a higher quality **lumen** than is currently available. Further, it can be manufactured at a lower cost and uses a powerful, more portable, and more intuitive laser platform than competing products. A U.S. clinical study for the DABRA catheter is presently ongoing, which Ra Medical believes can support a **510(k)** medical device clearance leading to the start of sales later in 2016.

Key Points

- Ra Medical reported revenue of over $7 million in 2015. Future sales growth is expected to be driven by the launch of the Company's endovascular laser products.
- Receiving FDA medical device clearance for the DABRA catheters and laser could be a value driver leading to a potential acquisition or strategic partnership for the Company.
- Growth in the global **atherectomy** devices market is driven in part by an aging population disproportionately affected by arterial disease, an increase in the prevalence of risk factors for blocked arteries, and a shift toward new technologies that can perform well in cost-sensitive, outpatient settings.
- Ra Medical is led by individuals who helped pioneer excimer lasers for the medical arena, including CEO Dean Irwin and R&D director, Dr. James Laudenslager. Management has extensive experience in medical device development as well as 14 years of making Ra Medical a capital-efficient business.
- The Company's patent portfolio includes provisional and utility patent applications filed in the U.S. and overseas.
- As of March 31, 2016, Ra Medical reported that it held cash and cash equivalents of $218,509, and recorded first quarter 2016 sales of nearly $2.3 million.

Table of Contents

Executive Overview 3

Growth Strategy 5

Milestones 6

Intellectual Property 7

Company Leadership 8

Core Story 11

- Excimer Laser Technology and Market 11
- PHAROS EX-308 for Dermatology 15
- RA-308 and DABRA Catheters for Vascular Disease 22

Competition 34

Key Points 37

Historical Financial Results 38

Risks and Disclosures 41

Glossary 53

Executive Overview

Ra Medical Systems, Inc. ("Ra Medical" or "the Company") develops, manufactures, and markets medical devices targeting the dermatology and endovascular specialties. The Company's product development centers on proprietary applications of its excimer laser technology to treat psoriasis, vitiligo, atopic dermatitis, leukoderma, **peripheral artery disease (PAD)**, **coronary artery disease (CAD)**, **in-stent restenosis**, atherectomy for drug-eluting balloons and stents, and other dermatological and vascular procedures. Since their earliest commercial launch in 2004 (for psoriasis and vitiligo treatment), Ra Medical's excimer lasers have been successfully used around the world. The Company has been in a process of continual refinement of its core laser product for dermatologists, and as a result, has received subsequent FDA clearances for the use of its lasers in multiple skin diseases.

The Company's research and development (R&D) has been focused on identifying and developing new indications where its laser therapy can be safe and efficacious. One market in particular where Ra Medical is presently focused on introducing new therapeutic solutions is in vascular disease. Use of excimer lasers for endovascular surgery—a minimally invasive approach for treating problems in blood vessels—has historically been limited by an inability to get laser energy to the blockage in the blood vessel (e.g., a blocked artery). Ra Medical believes that, after nearly a decade of R&D and over $65 million spent on development, it has created an innovative method for improving the treatment of vascular disease using excimer laser therapy. The Company's potential competitive advantages in this arena center on its newly developed, proprietary DABRA catheters (detailed on pages 27-33) and novel use of a liquid transmission medium (as opposed to conventional glass mediums) for delivering laser energy to a blockage.

Today, Ra Medical holds four FDA medical device clearances and multiple quality certifications for its production facilities, employs a staff of 37 individuals with deep experience in the development and marketing of excimer laser treatments (including CEO and cofounder, Mr. Dean Irwin, who pioneered the technology at Harvard Medical School in the late 1990s [biography on page 8]), and is profitable with an installed base of over 1,000 lasers in 18 countries, including the U.S. Going forward, Ra Medical intends to introduce a new laser system for endovascular procedures in 2016, following the completion of a confirmatory clinical study (currently in progress) and FDA approval of the Company's 510(k) application.

The RA-308 Excimer Laser and DABRA Single-use Catheters

An excimer laser emits nanosecond pulses of concentrated ultraviolet (UV) light that can be used as a minimally invasive surgical instrument. It focuses very accurately on tiny areas, enabling precise surgical work or for cutting through tissue. These lasers are routinely used in ophthalmology and dermatology practices, and are widely employed in LASIK procedures. Ra Medical builds xenon chloride (XeCl) excimer lasers that deliver concentrated, high-dose, monochromatic 308 nm ultraviolet B (UVB) light. The monochromatic laser beam is narrow, high-intensity, highly directional, and suited for use in a number of clinical applications.

The Company's newest excimer laser for vascular disease indications entails a lightweight, portable XeCl 308 nm excimer laser system combined with proprietary, single-use (disposable) catheters. This product development capitalizes on the knowledge and skill that Ra Medical has gained from over a decade developing, manufacturing, testing, marketing, and servicing the PHAROS excimer laser system for dermatological diseases.

The RA-308 is intended to serve as a laser atherectomy adjunct to balloon angioplasty and stents—two procedures commonly used in the treatment of peripheral and coronary artery diseases and conditions, but that are limited in their effectiveness. Up to 15% of patients need to have repeat procedures to reopen their arteries, even after having a stent placed, and many more have complications from the procedure as a result of trauma to the artery from balloon inflation or other causes. Atherectomy in conjunction with angioplasty or stenting has shown to improve patient outcomes. It entails a process of removing plaque deposits from inside arteries in order to restore blood flow to the limbs (peripheral artery disease) or heart (coronary artery disease). It is reimbursed by insurance carriers over and above angioplasty/stents. The global atherectomy devices market is forecast to expand at a CAGR of over 5% from 2016 to 2020. Laser atherectomy is one of the key developments in this space enabling greater efficiencies with fewer complications.

The RA-308 and DABRA catheter products are applicable to multiple endovascular applications, including crossing **chronic total occlusions** ([CTOs] totally blocked arteries) in the peripherals, specifically below the knee; in-stent restenosis; other atherectomy needs; coronary artery disease; and lead removal.

Ra Medical plans to drive adoption of its laser atherectomy solution by enabling improved economics for cardiac centers and office-based procedures via a catheter product priced well below current tools and a laser light source that can be installed without a capital expense. This pricing strategy, when combined with a demonstration of utility and efficacy of the platform, are expected to promote and accelerate sales. Greater specifics of the economics are provided on pages 32-33 of the Core Story.

Globally, the market for medical laser systems was reported to total nearly $3.7 billion as of 2013 (Source: BCC Research's *Global Markets and Technologies for Medical Lasers*, February 2015). Forecasts for growth in this market place its value at between $7.8 billion by 2019 and $12.5 billion by 2022, fueled by expanding customer demand and improved price points as well as better performance driven by technological advancements.

PHAROS EX-308 in Dermatology

Ra Medical's PHAROS laser delivers only monochromatic 308 nm, known to be an efficacious wavelength for treating psoriasis, vitiligo, atopic dermatitis, and leukoderma. The XeCl wavelength is well documented in scientific literature and is a key advancement in selective **phototherapy**—meaning that the emitted light is capable of selectively treating the target lesion while sparing surrounding healthy skin.

The manner by which the PHAROS EX-308 delivers a high-intensity beam of UVB light to affected skin has shown to clear psoriasis faster, produce longer remissions, and require fewer treatments per week to produce the desired effect than traditional phototherapy—which is one of the reason insurance companies reimburse at a higher rate for laser phototherapy versus phototherapy from other light sources.

XeCl laser treatments are sold both directly to physicians and through distributors around the world. The therapy is covered by Medicare and most private insurance carriers.

Headquarters and Employees

Figure 1
HEADQUARTERS

Source: Ra Medical Systems, Inc.

Ra Medical is a California corporation founded in 2002. It is headquartered in Carlsbad, California, in between Los Angeles and San Diego. The Company leases 17,000 square feet in Carlsbad (shown in Figure 1) that is used for research and development (R&D), product design, assembly, and testing. The manufacturing operations of this facility have been inspected by the FDA and the State of California's Food and Drug Branch, and the Company is permitted to manufacture medical devices that include lasers and sterile catheters. The facility is also compliant with **ISO 9001** and **ISO 13485** quality control standards and current **Good Manufacturing Practices (cGMP)**.

Ra Medical employs roughly 37 individuals and provides incentives aimed at retaining key personnel, including an employee stock option plan, healthcare benefits, and semi-annual merit-based cash bonuses for non-executive personnel. The Company is closely held.

Growth Strategy

Ra Medical's primary growth objective at present is the commercial launch of its new laser atherectomy solution: the RA-308 excimer laser with DABRA disposable catheters. The Company believes achieving this near-term milestone can lead to the following positive outcomes:

- Add high-profit recurring revenue from the disposable catheters for PAD treatment;
- Present the Company for acquisition or a strategic partnership; and/or
- Make a market for Ra Medical's stock.

In the meantime, the Company continues to explore new indications and pursue new markets for its PHAROS EX-308 laser to treat skin diseases.

Endovascular Laser

Ra Medical reported GAAP revenue of over $7 million in 2015. The Company expects a major driver of future sales growth to be the launch of its endovascular laser atherectomy products. Upon receiving an FDA medical device clearance (anticipated during 2016), Ra Medical aims to target the PAD market either by partnering with a larger medical device company or by using a sales staff responsible for placing lasers in experienced and prominent facilities where physicians and surgeons perform crossing of CTOs, among other endovascular procedures. The Company may also utilize a national distributor. After first placing lasers in well-known, expert clinics, Ra Medical intends to work closely with physicians on their initial PAD cases and subsequently expand its roll-out to the office-based market. The Company expects to receive a CE mark for the vascular system in the third quarter of 2016, enabling sales in Europe, Saudi Arabia, and India.

The value proposition expected to drive adoption of the Company's devices centers on an ability to improve patient outcomes with minimal capital outlay, as the laser light source can be provided at no cost to the customer and the catheters are extremely cost effective compared to competitive devices. Greater details on the economic benefits for Ra Medical and healthcare providers are presented on pages 32-33.

PHAROS Dermatology Laser

With regard to its PHAROS excimer lasers in dermatology applications, Ra Medical has regulatory approvals and has installed lasers around the world, including in Korea, China, Egypt, Saudi Arabia, South Africa, India, Malaysia, Bahrain, Kuwait, Thailand, and in nearly every U.S. state. The Company's U.S. sales force is supplemented by independent representatives and regional distributors, all of which target new customers at trade shows (more than 25 trade shows in 2014/2015), workshops, and office demonstrations, as well as by direct outreach.

At current sales levels, the Company believes its existing manufacturing facility can meet needs through 2018 for both of its laser solutions and accessory products.

Potential Future Corporate Events

A potential acquisition, a strategic partnership with a larger medical device company, or moving the stock to the public markets are all potential long-term corporate strategies for Ra Medical. The Company is currently pursuing these routes and believes that receiving FDA clearance for its endovascular product is the main gating factor in reaching such a liquidity event.

Milestones

Recent Milestones

- Exhibited at over 25 trade shows in 2014 and 2015, including showcasing the endovascular products at two major endovascular interventional conferences in 2015
- Completed the successful treatment of five patients in the pilot study of the laser atherectomy catheters with no adverse events, and 20 patients in the pivotal study, also without an adverse event
- Received FDA approval to commence human study of the DABRA system arterial laser and catheter in the U.S.
- Received approval from the Institutional Review Boards (IRBs) of two hospitals where the U.S. clinical study is underway, and received CMS authorization for Medicare reimbursement for patients in the study
- Commenced the U.S. clinical study with the treatment of the first patients at the Cardiovascular Clinic of Hattiesburg, Wesley Medical Center, in Hattiesburg, Mississippi, and at the University of California, San Diego (UCSD)
- Invested in capital equipment and staff for the manufacturing facility, including more than doubling the size of the controlled environment (clean room) work areas to create more space for fabricating catheters and laser chamber systems

Potential Milestones

- Complete the ongoing clinical study of the DABRA catheters, adding up to three additional sites
- Obtain FDA clearance for treating CTOs in the peripherals, and a CE mark for Europe
- Build a clinical database
- Prepare and submit FDA submissions for general atherectomy (510k application) and in-stent restenosis (510k application)
- Launch the laser system for the treatment of vascular disease, including PAD
- Consider future FDA submissions for the treatment of coronary artery disease (PMA application) and lead removal (PMA application)
- Partner with a larger medical device company or build a targeted sales force
- Achieve a liquidity event through the sale of the Company, a strategic partnership, or listing the stock on a public exchange

Intellectual Property

Ra Medical pursues patents, copyrights, trademarks, trade secret laws, confidentiality agreements, and invention assignment agreements where necessary to protect its intellectual property (IP) rights. The Company's current IP portfolio consists of provisional and utility patent applications in the U.S. related specifically to its endovascular technology. Ra Medical has also filed for certain patent protections globally. A provisional application is an interim patent application that provides one year for product development. A provisional patent application is not examined but can establish a filing date to serve as priority for an application filed later. In contrast, a utility patent application covers inventions producing a new and useful result. If granted, it aims to prevent anyone else from making, selling, using, or importing a said invention.

The PHAROS platform in dermatology applications has previously had patent coverage that was challenged by a competitor and successfully defended by Ra Medical. That patent has now expired and the excimer laser technology used in the PHAROS laser is believed to be in the public domain. Between that and the Company's published patent applications for its endovascular excimer laser technology, Ra Medical operates under the notion that it has freedom to operate for both its dermatology and vascular products.

Figure 2 provides a snapshot of some of the Company's relevant IP.

Figure 2

INTELLECTUAL PROPERTY SNAPSHOT

Title Application Number	Filing Date
RMS-1002-CN Small Flexible Liquid Core Catheter For Laser Ablation In Body Lumens And Methods For Use 201280061080	10/12/12
RMS-1002-EP Small Flexible Liquid Core Catheter For Laser Ablation In Body Lumens And Methods For Use 12840010.8	10/12/12
RMS-1002-PC Small Flexible Liquid Core Catheter For Laser Ablation In Body Lumens And Methods For Use PCT/US2012/060065	10/12/12
RMS-1002-PV Small Flexible Liquid Core Catheter For Laser Ablation And Method For Use 61/547,435	10/14/11
RMS-1002-UT Small Flexible Liquid Core Catheter For Laser Ablation In Body Lumens And Methods For Use 13/651,070	10/12/12
RMS-1003-PV Methods And Devices For Treatment Of Stenosis Of Arteriovenous Fistula Shunts 61/891,830	10/16/13
RMS-1003-UT Methods And Devices For Treatment Of Stenosis Of Arteriovenous Fistula Shunts 14/515,435	10/15/14
RMS-1004-PV Enlarged Shaped Distal Window Tips For Laser Ablation Catheters 62/258,836	11/23/15

Source: Ra Medical Systems, Inc.

Company Leadership

Ra Medical is led by a team with considerable expertise in medical device manufacturing and sales, especially for high-tech medical laser systems. Its management comes to Ra Medical from major medical device companies and leading science and engineering institutions, including Eli Lilly and Co. (LLY-NYSE), PhotoMedex, Inc. (PHMD-NASDAQ), the Plasma Research Center at the Massachusetts Institute of Technology (MIT), the Institute of Plasma Physics at Nagoya University in Japan, Caltech's Jet Propulsion Laboratory, Intel Corp. (INTC-NASDAQ), the Kellogg Company (K-NYSE), Solta Medical (a division of Valeant Pharmaceuticals International, Inc. [VRX-NYSE]), and the U.S. Navy and Marine Corp, among other notable entities. Ra Medical's well-rounded leadership team further includes individuals skilled in key aspects of regulatory and quality affairs, as the Company is focused on both the development and commercialization of novel products in the medical device space.

Ra Medical further benefits from the expertise of a panel of scientific advisors (listed in Figure 4 [page 10]) who are recognized as thought leaders in their fields, having both professional and clinical expertise in Ra Medical's target markets.

Executive Management and Board of Directors

Figure 3 summarizes the Company's executive leadership, followed by brief biographies. Mr. Dean Irwin, chief executive officer (CEO) of Ra Medical; Ms. Melissa Burstein, the Company's executive vice president; and Misters Martin Burstein, Qiushi Ren, and Richard Heymann together also comprise Ra Medical's Board of Directors, which oversees the conduct of and supervises the Company's management.

Figure 3
LEADERSHIP

Dean Irwin	Executive Chairman, Chief Executive Officer, and Chief Technology Officer
Melissa Burstein, MBA	Executive Vice President and a Director
Kevin Gertsman	Vice President of Domestic Sales
James B. Laudenslager, Ph.D., MBA	Director of Research and Development
Daniel Sanchez	Chief Financial Officer
Vicki Chester	Vice President of Regulatory Affairs and Quality Assurance
William (Bill) L. Schmidt	Vice President of Operations
Kevin Moyles	Purchasing Manager
Matt Bonjean	Service Manager
Martin Burstein, MBA	Director
Qiushi Ren, Ph.D.	Director
Richard Heymann	Director

Source: Ra Medical Systems, Inc.

Dean Irwin, Executive Chairman, Chief Executive Officer, and Chief Technology Officer

Mr. Irwin brings over 35 years of management and product development experience to the founding team. Prior to forming Ra Medical, Mr. Irwin was vice president of research, development, and engineering for PhotoMedex, Inc., where he developed laser systems for cardiovascular surgery and dermatology. Prior to his tenure at PhotoMedex, Mr. Irwin was vice president of engineering and general manager at SpatiaLight, Inc., where he developed award-winning electro-optical components and systems. Mr. Irwin was also a founder and chief scientist of DIR Corp. and has held various engineering positions with Acculase, Inc. (acquired by PhotoMedex), General Atomics, and Universal Voltronics Corp. In addition, he has consulted for the Plasma Research Center at MIT, the Institute of Plasma Physics at Nagoya University in Japan, Borland International, and Intel Corp. Mr. Irwin has been issued 12 patents in the field of electro-optics and has published numerous engineering and scientific papers.

Melissa Burstein, MBA, Executive Vice President and a Director

Ms. Burstein brings innovative marketing and sales experience to the medical laser market from the pharmaceutical, consumer products, and telecommunications industries. Prior to co-founding Ra Medical, Ms. Burstein held various sales and marketing positions with Eli Lilly and Co., the Kellogg Company, and Sprint International. At Lilly, Ms. Burstein was responsible for the market launch of the pharmaceutical Cialis in Asia, Middle East/Africa, and Eastern Europe. Ms. Burstein holds an MBA specializing in international management from Thunderbird, the American Graduate School of International Management, and a B.S. from Georgetown University, School of Foreign Service.

Kevin Gertsman, Vice President of Domestic Sales

Mr. Gertsman brings more than 20 years of entrepreneurial, first-to-market start-up medical device experience, spanning specialties from orthopedics and neurorehabilitation to plastic surgery and dermatology. His background includes sales and sales management roles with Solta Medical (a division of Valeant Pharmaceuticals International, Inc.), venture-backed Eleme Medical, and PhotoMedex. Mr. Gertsman led the launch of excimer laser technology for PhotoMedex as western regional manager and was a sales leader at Solta. In addition, he served as director of sales at Eleme Medical for the launch of two innovative, laser body-shaping technologies. Mr. Gertsman holds a B.S. in business from the University of South Carolina.

James B. Laudenslager, Ph.D., MBA, Director of Research and Development (R&D)

Dr. Laudenslager has over 33 years of experience in excimer laser development and manufacturing. Prior to joining Ra Medical, Dr. Laudenslager was the co-founder and vice president for laser R&D for Advanced Interventional Systems, specializing in the development and marketing of excimer laser systems for angioplasty. He was also the supervisor of the Laser Physics and Applications Group at Caltech's Jet Propulsion Laboratory. He has authored numerous papers and articles and holds five issued patents. Dr. Laudenslager holds a Ph.D. from the University of California, Santa Barbara (UCSB) and an MBA from the University of California, Irvine (UCI).

Daniel Sanchez, Chief Financial Officer (CFO)

Mr. Sanchez joined the Company in 2010 and was appointed to the CFO position in 2011. Prior to joining Ra Medical, he was an accountant for AMN Healthcare Services Inc. (AHS-NYSE), an accountant for Spy Optic, and an accountant for No Fear, Inc. Mr. Sanchez holds a degree in accounting from California State University San Marcos.

Vicki Chester, Vice President of Regulatory Affairs and Quality Assurance

Ms. Chester has over 15 years of experience in the high-tech medical device industry, including extensive experience with medical lasers and light-based systems. Prior to joining Ra Medical, she was the regulatory affairs manager for Epitope Diagnostics Inc., and served in increasing capacities in the regulatory group at PhotoMedex. Ms. Chester has a B.S. in chemistry from Bradley University.

William (Bill) L. Schmidt, Vice President of Operations

Mr. Schmidt has over 20 years of experience in medical device manufacturing. He began his career at Mentor Corp. as a medical device manufacturing engineer. He has held positions at Safeskin Corp. and was the production manager at PhotoMedex. Mr. Schmidt has a B.S. in chemical engineering from the University of California, Santa Barbara.

Kevin Moyles, Purchasing Manager

Mr. Moyles joined Ra Medical in 2003 to spearhead materials acquisition for the PHAROS EX-308 excimer laser. His 25 years of experience in high-tech purchasing, including three years as purchasing manager for PhotoMedex, have contributed to Ra Medical's success in manufacturing cost-effective, high-quality laser systems.

Matt Bonjean, Service Manager

Mr. Bonjean joined Ra Medical in 2005 and now heads the Company's Service Department. His customer-focused approach sets the standard for the Company's service technicians located in six metro areas across the U.S. as well as for Ra Medical's international service technicians. Prior to joining Ra Medical, Mr. Bonjean held test and service positions for the U.S. Marine Corps and United Parcel Service, Inc. (UPS-NYSE).

Martin Burstein, MBA, Director

Mr. Burstein has over 25 years of executive and senior management experience in the consumer electronic and high technology industries with companies such as Sybase, Motorola (MSI-NYSE), and Intel (INTC-NASDAQ). He is currently vice president of administration for a business unit of Matsushita Electric Industrial Co (Panasonic). Mr. Burstein holds an MBA from the University of Missouri.

Qiushi Ren, Ph.D., Director

Professor Ren graduated from the Hua-zhong University of Science and Technology (Wuhan, China) with a Ph.D. in optical science. During his Ph.D. study, Dr. Ren worked as a research assistant at Wellman Laboratories of Photo-Medicine of Massachusetts General Hospital and the Laser Research Laboratory of Massachusetts Eye and Ear Infirmary of Harvard Medical School. After receiving his Ph.D., Dr. Ren joined the faculty of the Department of Biomedical Engineering as an assistant professor, with adjunct appointment at the Department of Ophthalmology and Bascom Palmer Eye Institute of the University of Miami, where he worked on innovative laser therapies for medical applications. In 1995, he joined the faculty of the Department of Ophthalmology at UCI, where he worked on excimer laser refractive surgery and new laser therapies in ophthalmology. In 2002, Dr. Ren joined the faculty of the Department of Biomedical Engineering at Shanghai Jiao Tong University as a full professor and served as the director of the Institute for Laser Medicine and Bio-Photonics. In 2009, Dr. Ren joined the College of Engineering at Peking University as the COE Endowed Chair Professor and served as the chairman of the Department of Biomedical Engineering. Professor Ren has published over 100 journal papers, co-edited three proceedings books, and is a U.S. patent holder. Professor Ren is currently the chair of the Biomedical Engineering Department of Peking University and associate dean, Faculty of Engineering.

Richard Heymann, Director

Mr. Heymann brings over 25 years of sales, marketing, executive management, and investment skills to the Board. Prior to his current position as president and CEO of Noteworthy Advisors beginning in 1997, he served as president of Security Financial Bancorp from 1992 to 1997. Mr. Heymann has been successful in real estate debt and equity investment since 1997 and holds a B.A. from Idaho State University.

Scientific Advisors

Figure 4 lists the individuals who provide scientific, R&D, and clinical guidance to the Company as it develops, enhances, and places its products worldwide.

Figure 4
SCIENTIFIC ADVISORS

Raghotham R. Patlola, M.D.	Cardiologist and Medical Director at Cardiovascular Clinic of Hattiesburg
David Goldberg, M.D., J.D.	Professor and Director of Laser Research at the Mount Sinai School of Medicine
Ehtisham Mahmud, M.D., FACC	Chief of Cardiovascular Medicine at UCSD and Professor of Medicine at UCSD
John Seelig, M.D.	Assistant Professor of Neurosurgery at the UCSD Medical Center
Antone Salel, M.D., FACC, FACP, FAHA	Associate Clinical Professor of Medicine at UCSD

Source: Ra Medical Systems, Inc.

Core Story

Ra Medical Systems, Inc. ("Ra Medical" or "the Company") develops, manufactures, and markets medical devices targeting the dermatology and endovascular specialties. The Company's product development centers on proprietary applications of its excimer laser technology to treat psoriasis, vitiligo, atopic dermatitis, leukoderma, crossing chronic total occlusions (CTOs) in the peripherals, peripheral and coronary atherectomy, peripheral and coronary in-stent restenosis, atherectomy for drug-eluting balloons and stents, and other dermatological and vascular procedures. Since their earliest commercial launch in 2004 (for psoriasis and vitiligo treatment), Ra Medical's excimer lasers have been successfully used around the world for over 12 years. The Company has been in a process of continual refinement of its core laser product for dermatologists, and as a result, has received subsequent FDA clearances for the use of its lasers in an array of skin diseases.

Research and development (R&D) is a major focus area for Ra Medical, as the Company seeks new indications where laser therapy can be safe and efficacious. One market in particular where Ra Medical is presently focused on introducing new therapeutic solutions is in vascular disease. Using excimer lasers for endovascular surgery—a minimally invasive approach for treating blockages in blood vessels—has historically been limited by an inability to get laser energy to the blockage in the blood vessel (e.g., arterial plaque). Ra Medical believes that, after nearly a decade of R&D and over $65 million spent on development, it has created an innovative method for improving the treatment of vascular disease using excimer laser therapy. The Company's potential competitive advantages in this arena center on its newly developed, proprietary DABRA catheters (detailed on pages 27-33) and novel use of a liquid transmission medium (as opposed to conventional glass mediums) for delivering laser energy to a blockage.

Today, Ra Medical holds four FDA medical device clearances and multiple quality certifications for its production facilities, employs a staff with deep experience in the development of excimer laser treatments (including CEO and cofounder, Mr. Dean Irwin, who pioneered the technology at Harvard Medical School in the late 1990s [biography on page 8]), and is profitable with an installed base of over 1,000 lasers in 18 countries. Going forward, Ra Medical is poised to introduce a new laser system for endovascular procedures in 2016 following the completion of a confirmatory clinical study (currently in progress) and FDA approval of the Company's 510(k) application.

The accompanying pages describe excimer laser technology and its accepted uses, followed by details of Ra Medical's marketed PHAROS EX-308 laser system for dermatological disorders and the Company's development of a PAD laser system, including its clinical and regulatory status, competitive landscape, and market opportunities.

EXCIMER LASER TECHNOLOGY AND MARKET

An excimer laser emits nanosecond pulses of concentrated ultraviolet (UV) light that can be used in a therapeutic manner and as a minimally invasive surgical instrument. These lasers are routinely used in ophthalmology and dermatology practices, as illustrated in Figure 6 (page 12). The term "excimer" refers to "excited **dimer**," which is a molecule of two atoms bound in an excited electronic state. Typically, this is a **noble gas**, such as argon, kypton, or xenon, and a **halogen**, such as fluorine or chlorine. Figure 5 (page 12) lists several types of excimers that can be used in a laser light source. Ra Medical, specifically, builds xenon chloride (XeCl) lasers that deliver concentrated, high-dose, monochromatic 308 nm ultraviolet B (UVB) light.

"Monochromatic" means "one color" and alludes to a key property of laser radiation, which is that it has a very specific wavelength and phase that is focused in a narrow and high-intensity beam of light (Source: the *International Journal of Advances in Pharmacy, Biology and Chemistry*, 2013 Jul-Sep; 2[3]). This is in contrast to ordinary white light, such as from a light bulb, which is composed of an array of colors in varying wavelengths that spread in all directions instead of being focused in one direction. The divergence of colors can be understood by viewing ordinary white light through a prism, an effect which allows the viewer to see a rainbow of colors emanating from the prism. Ra Medical's excimer laser UV light does not do this. Rather, the Company's lasers produce a monochromatic laser beam that is narrow, high-intensity, highly directional, and suited for use in a number of clinical applications.

Figure 5
EXCIMER WAVELENGTH

Excimer	Wavelength
F2 (fluorine)	157 nm
ArF (argon fluoride)	193 nm
KrF (krypton fluoride)	248 nm
XeBr (xenon bromide)	282 nm
XeCl (xenon chloride)	**308 nm**
XeF (xenon fluoride)	351 nm

Source: RP Photonics Consulting GmbH.

As summarized in Figure 5, excimer lasers typically emit light at wavelengths between 157 and 351 nm. Within this range, conventional UVB phototherapy systems emit wavelengths that vary from 290 to 320 nm.

Ra Medical's XeCl lasers deliver only monochromatic 308 nm, known to be an efficacious wavelength for treating psoriasis, vitiligo, atopic dermatitis, and leukoderma. The XeCl wavelength is well documented in scientific literature and is among the latest advancements in selective phototherapy—meaning that the emitted light is capable of selectively treating the target lesion while sparing surrounding healthy skin (Source: *Clinics in Dermatology*, 2006 Jan-Feb; 24[1]:33-42).

The ability of lasers to focus very accurately on tiny areas enables their use for very precise surgical work or for cutting through tissue (in place of a scalpel) (Source: FDA).

Applications

Excimer lasers have been cleared for use in the U.S. since the mid-1990s, when they were initially targeted for laser eye surgery (correcting nearsightedness) (Figure 6). The application to eye surgery, which today includes correcting farsightedness and astigmatism in LASIK procedures as well, illustrates the accuracy and selectivity achievable with an excimer laser. To date, the FDA has approved more than 30 excimer lasers for LASIK surgery alone (Source: FDA). Ophthalmologists use these lasers to reshape the cornea without damaging surrounding eye tissue. They are also used in ablation, general and plastic surgery, dermatology treatments, and a variety of non-medical applications, such as semiconductor chip production and microstructuring of glasses and plastics.

Figure 6
EXCIMER LASERS HAVE BEEN USED CLINICALLY FOR DECADES

Sources: Lehigh Valley Dermatology Associates, Clinical Skin Center (http://www.clinicalskincenter.com/), Anne Arundel Dermatology, and Crystal Research Associates, LLC.

Regulatory Pathway in the U.S.

Excimer lasers are generally classified as a **Class II medical device** in the U.S. Under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, manufacturers of medical devices (such as Ra Medical) must notify the FDA at least 90 days in advance of marketing a medical device. This is known as a "510(k) application" or a "Premarket Notification," through which the manufacturer must demonstrate to the FDA that the new device is substantially equivalent (meaning that it is at least as safe and effective) as a device already on the market before the FDA will clear the new device for sale (Source: FDA). There are three classes of medical devices, which vary in how stringently they are regulated for safety and effectiveness, as overviewed below. General controls to be satisfied by all device classes involve listing the medical device with the FDA, manufacturing in accordance with Good Manufacturing Practices (GMP), and labeling in accordance with labeling regulations.

- Class I Medical Device: Subject to the least regulatory control, these devices are often simple in design with minimal potential for harm to the user. The FDA reports that 47% of medical devices are considered Class I, which include items such as elastic bandages, examination gloves, and handheld surgical instruments.

- Class II Medical Device: Ra Medical's excimer lasers are classified as Class II medical devices. In addition to complying with general controls, Class II devices are also subject to special controls, such as special labeling requirements, mandatory performance standards, and postmarket surveillance. Examples of Class II devices, which represent approximately 43% of all medical devices, include powered wheelchairs, some pregnancy test kits, and surgical drapes (Source: FDA).

- Class III Medical Device: A Class III device is usually one that sustains or supports life, is implanted, or bears a high risk of illness or injury; thus, these are the most closely regulated. Examples of such products include pacemakers and breast implants.

In addition to medical device regulations, manufacturers of laser products sold in the U.S. must comply with other federal laws and controls as listed in the Federal Food, Drug and Cosmetic Act's Chapter V, Subchapter C (Electronic Product Radiation Control) and Title 21 Code of Federal Regulations' Subchapter J (Radiological Health).

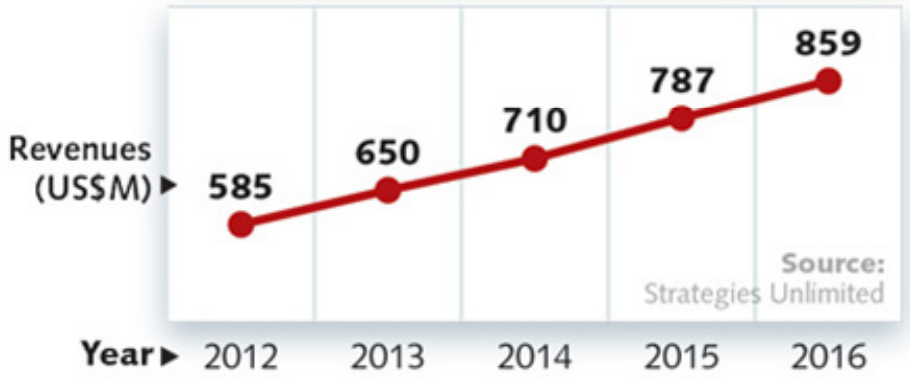
Market Growth of Medical Lasers

In early 2016, *LaserFocusWorld* (a provider of laser technology and optics research and news for the photonics industry) forecast that sales of medical and aesthetic lasers could expand to $859 million during the year, representing a consistent increase over prior years (as shown in Figure 7).

Figure 7

MEDICAL AND AESTHETIC LASER MARKET (Estimated)

Includes all lasers used for ophthalmology, surgical, dental, therapeutic, skin, hair, and other cosmetic applications.



Source: LaserFocusWorld's "Annual Laser Market Review & Forecast: Can laser markets trump a global slowdown?" February 1, 2016.

Globally, the market for medical laser systems was reported to total nearly $3.7 billion as of 2013 (Source: BCC Research's *Global Markets and Technologies for Medical Lasers*, February 2015). Forecasts for growth in this market place its value at between $7.8 billion by 2019 and $12.5 billion by 2022 (Sources: BCC Research [the 2019 estimate] and Grand View Research, Inc.'s November 9, 2015, report, *Medical Laser Systems Market Analysis, By Product (Diode, Solid State, Gas and Dye Laser), By Application (Ophthalmology, Dermatology, Gynecology, Urology, Dentistry, Cardiology, Gastroenterology) And Segment Forecasts To 2022* [the 2022 estimate]).

Expansion in the medical use of excimer lasers is being driven by a combination of factors, including customer demand and improved price points and performance driven by technological advancements. Ra Medical anticipates significant growth of excimer laser markets in both the dermatology and PAD markets over the next few years, as these products have already been accepted for use in these specialties and are becoming more attractive to providers and patients alike.

The leading sectors for medical and aesthetic lasers in 2015 were believed to be cosmetology and dermatology, followed closely by surgical lasers (Source: *LaserFocusWorld*, February 2016). There are a number of factors contributing to market growth for medical lasers, including excimer lasers, as outlined below.

- Economics. It is only recently that technological advancements in lasers have made them sufficient for use in smaller medical offices at a reasonable cost, without needing excessive servicing. As the healthcare industry continues to face pressure to cut costs while improving outcomes, efficacious devices with favorable economics may see greater adoption.

- The Developing World. The developing world's middle class population is growing and is increasingly accounting for a larger portion of medical laser revenues. The Asia-Pacific region in particular may represent one-quarter of the global medical laser market by 2022 as a result of rising disposable income, an increasing awareness and volume of cosmetic surgeries, and greater prevalence of diseases/disorders treatable by laser.

- Aging Population. Today, roughly one in three U.S. citizens is over age 50. Globally, there are over 841 million people past age 60 in the world, accounting for 11.7% of the global population as of 2013. By 2050, this age group is forecast to more than double—totaling over two billion people who make up 21.1% of the world's population (Source: the United Nations' *World Population Ageing* 2013). As the world ages, there is generally an increasing prevalence of diseases, such as PAD and other vascular conditions, that disproportionately affect older adults.

- Demand for Minimally Invasive and Non-invasive Procedures. Desire for less invasive therapies may be one of the most impactful trends in this market. Minimally invasive or non-invasive treatments typically offer patients a number of benefits, including less pain and quicker recoveries. These features offer convenience and ease of therapy to patients who receive multiple treatments a week over an extended period of time (as for dermatological conditions). Moreover, technological advancements are bringing the high surgical precision of laser beams to new indications in cardiology, cardiovascular disease, and vascular disease—areas where the patient population may be already infirmed, elderly, or otherwise vulnerable to surgical complications and thus a less invasive approach could be beneficial. Grand View Research cites statistics from the World Health Organization that over 17.5 million people annually have chronic cardiovascular disorders that require surgical follow-up.

As detailed on the accompanying pages, Ra Medical believes that it possesses the necessary infrastructure to capitalize on this market growth.

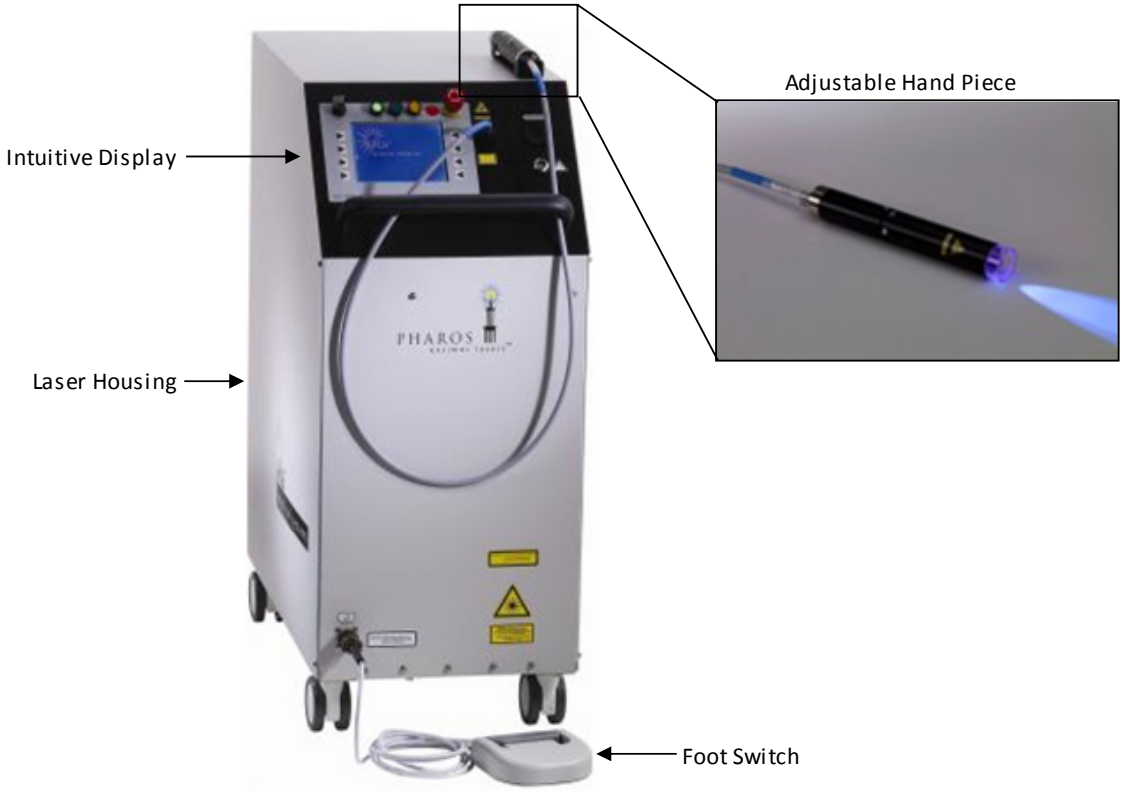
PHAROS EX-308 FOR DERMATOLOGY

Ra Medical's excimer laser-based system for dermatology applications is called the PHAROS EX-308. The Company has been manufacturing its XeCl lasers since 2002 and launched the PHAROS EX-308 commercially in the U.S. in 2004. Today, the FDA has cleared the PHAROS EX-308 laser to treat four exceedingly common skin disorders: psoriasis (raised, scaly lesions), vitiligo (whitish patches of depigmented skin), atopic dermatitis (eczema), and leukoderma (white stretch marks and scars).

Figure 8 illustrates the PHAROS EX-308, which is essentially a self-contained UV laser light source that uses a XeCl gas mixture to emit a UVB wavelength of 308 nm. The console housing contains the laser operation. The "laser dose," or amount of emitted therapeutic radiation, is controlled by the machine operator (e.g., a physician or clinician) via a footswitch. The UVB phototherapy is then administered with a handheld device, as shown in Figure 8, which incorporates a brightly lit aiming beam to guide the operator in aiming the laser precisely at the targeted area. The proprietary optical design of the hand piece is intended to reduce surface scatter and increase penetration of the concentrated UVB laser light on psoriatic and depigmented lesions.

Figure 8

THE PHAROS EX-308 EXCIMER LASER PHOTOTHERAPY SYSTEM



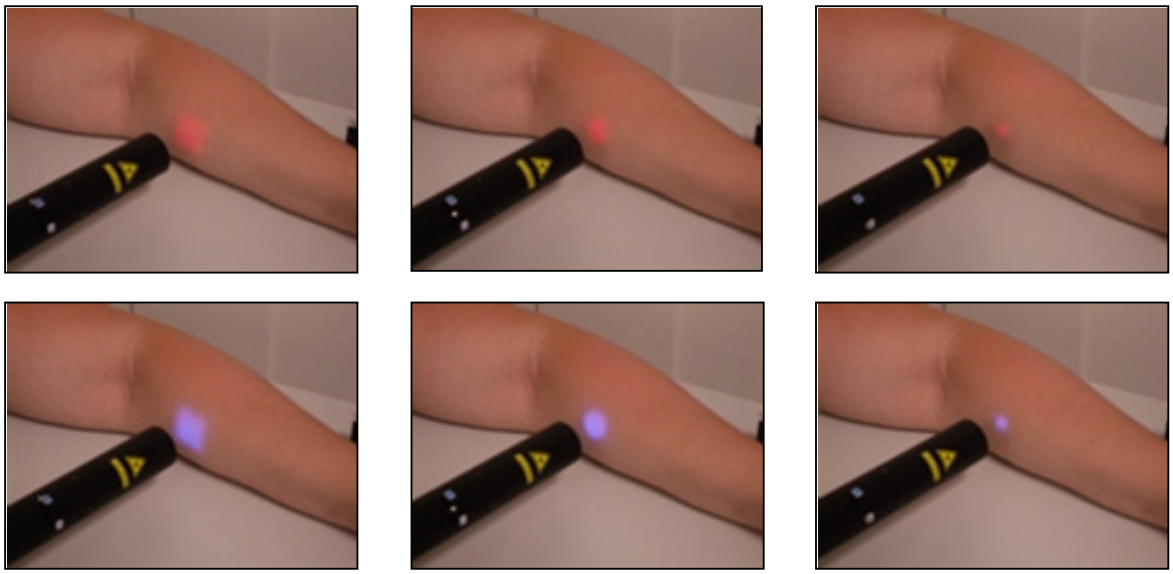
Source: Ra Medical Systems, Inc.

As shown in Figure 9, the laser beam can be sized as needed using PHAROS' variable spot size hand piece. The hand piece is lightweight and features a sliding finger switch for gentle contouring of the laser beam to match the size of the lesion being treated.

Figure 9

TARGETED UVB PHOTOTHERAPY

The PHAROS EX-308's novel lightweight handpiece features an integrated adjustable spot size and corresponding brightly lit aiming beam.

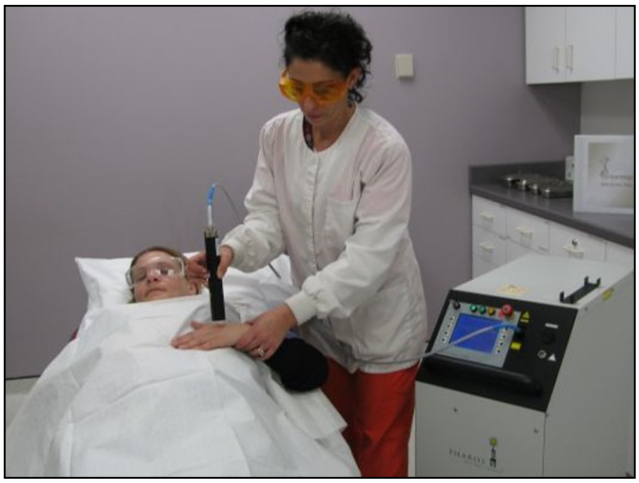


Source: Ra Medical Systems, Inc.

As the operator can customize the desired dose and make continuous adjustments to the aiming beam, PHAROS enables targeted and rapid treatment of affected tissue while limiting healthy skin's exposure to the UVB radiation. The device design is stated to produce a uniform dose delivery with no "hot spots," in order to achieve optimal outcomes and patient comfort. The operator-dependent dose can range from as low as 10 mJ/cm^2 to a powerful 5,000 mJ/cm^2.

Figure 10

A PATIENT RECEIVING TREATMENT WITH THE PHAROS EX-308



Source: Dermatology Services (dsiderm.com).

In addition to dose customization, the PHAROS EX-308 provides dermatologists with operational versatility. The entire system weighs only approximately 100 lbs and is smaller than many competitive laser consoles. The small and light size increases the system's portability and makes it well suited for virtually any size treatment room. The treatment process is also relatively quick, enabling high patient throughput.

To see a video demonstration of the PHAROS EX-308 in action at Pennsylvania's Lehigh Valley Dermatology Associates, Ltd., visit this URL: https://www.youtube.com/watch?v=bvamhctEP6g or http://www.ramed.com/.

Regulatory and Insurance Reimbursement Status

XeCl laser treatments are covered by most private insurance carriers today, as well as by Medicare, and are becoming the **standard of care** for psoriasis and vitiligo treatment. Figure 11 summarizes the 510(k) medical device clearances that have been granted to Ra Medical for marketing its PHAROS excimer laser in the U.S. The Company has also received clearances in China and Korea.

XeCl excimer laser phototherapy for inflammatory skin diseases is covered under healthcare insurance plans from Medicare and many private insurance carriers, such as those listed in Figure 11.

Figure 11

CLEARANCES AND APPROVALS FOR THE PHAROS EX-308

510(k) Medical Device Clearances from the FDA	
Indication	Year Granted
Psoriasis	2003
Vitiligo	2003
Leukoderma	2007
Atopic Dermatitis	2007

Off-label Uses in Other Skin Disorders*	
Alopecia areata	**These indications have not been cleared by the FDA.*
Lichen planus	
Acne	

Insurance Reimbursement Approvals	
CPT® Codes	Description
96920	Laser treatment for inflammatory skin diseases (psoriasis); total area less than 250 cm2
96921	Laser treatment for inflammatory skin diseases (psoriasis); total area 250 to 500 cm2
96922	Laser treatment for inflammatory skin diseases (psoriasis); total area over 500 cm2

A selection of insurers that have coverage for XeCl excimer laser dermatology treatments:
Centers for Medicare and Medicaid Services (CMS), Aetna, Cigna, UnitedHealthcare, Anthem, Blue Cross Blue Shield Plans of WellPoint, CareFirst, Regence, Empire, Independence, Highmark, Horizon, Premera, and many other private insurers

Sources: Ra Medical Systems, Inc. and Crystal Research Associates, LLC.

Manufacturing

Figure 12 contains pictures of Ra Medical's production facilities at its headquarters in Carlsbad, California. In all, the Company uses a 17,000 square foot site that includes 6,000 square feet of space for research and development (R&D). Product design, assembly, and testing for all of Ra Medical's products (both the PHAROS laser and the new PAD lasers/catheters [detailed on pages 22-33]) is performed here. In 2015, Ra Medical invested in upgrades for its clean room space—increasing the total square footage from 500 sq. ft. to 1,200 sq. ft.—in order to have an adequate work area for fabricating sterile, high quality catheters for the PAD laser systems and high-reliability laser pump chambers to support both the dermatology and the vascular markets.

The Company has further recently invested in capital equipment and staff, and believes that its current manufacturing capacity is sufficient to produce over 250 lasers per year and up to 5,000 catheters per month.

Figure 12

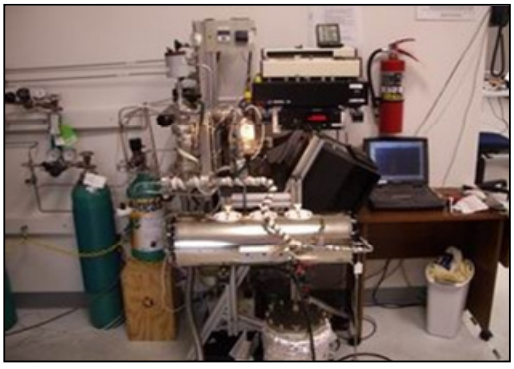
SNAPSHOTS OF RA MEDICAL'S MANUFACTURING FACILITIES

- Licensed to manufacture medical devices, including lasers and sterile catheters
- ISO9001 and ISO13485 certified
- Inspected by the FDA and the State of California's Food and Drug Branch
- Compliant with current Good Manufacturing Practice (cGMP)

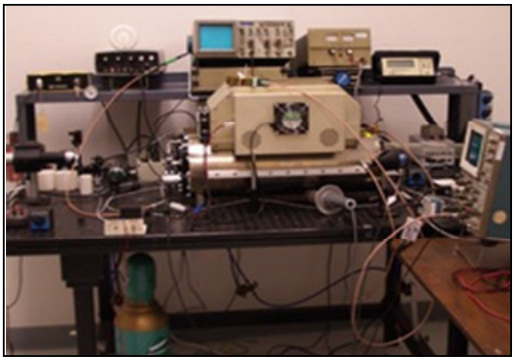
Over 1,200 sq. ft. Clean Room

Laser Assembly

Metrology and Turbo Pump Stations



Development Stations



Sources: Ra Medical Systems, Inc. and Crystal Research Associates, LLC.

Distribution and Sales

Ra Medical sells its laser systems both directly to physicians and through distributors. The Company's products are presently in use in nearly every U.S. state and in 18 countries, including but not limited to the U.S., Korea, China, Egypt, Saudi Arabia, South Africa, India, Malaysia, Bahrain, Kuwait, and Thailand.

Customers often learn about Ra Medical's XeCl excimer lasers from trade show exhibits, workshops, direct mail outreach, and in-office demonstrations. The portable and lightweight size of the laser systems makes it convenient for the Company's sales force to transport the devices in the back of an SUV for in-person demonstrations in hospitals, physicians' offices, and clinics. Ra Medical believes this to be a significant competitive advantage that often results in sales. As of December 2013, the Company had announced that it has shipped 1,000 laser devices to customers around the world.

There are several factors contributing to physicians' adoption of Ra Medical's XeCl excimer lasers. For one, the Company believes that the PHAROS EX-308 is financially appealing to providers due to the large patient populations that can be treated with the laser, the high dollar reimbursements, and high patient demand for laser phototherapy. The PHAROS system retails for approximately $64,900, for which financing via payment plans, third-party leasing, or rental programs is available. Treatments are reimbursed at roughly $150 to $250 per session under the CPT® codes listed in Figure 11 (page 17). This is a higher insurance reimbursement rate than non-laser phototherapy, which is covered at a cost closer to $25 using the CPT® code 96900 for actinotherapy procedures (UV light therapy) as an example (Source: PGM Billing's CPT® Codes Look-up Tool: http://www.pgmbilling.com/test-cpt-codes).

As detailed on pages 32-33, the Company's new atherectomy laser system expected to launch during 2016 may also benefit from favorable economics versus competitive devices, which too could spur its adoption in the marketplace.

Service and Support

Ra Medical continues to service its equipment after its sale to the customer, and prides itself on a typical response time of within 48 hours for service calls. The Company employs both in-house and contract service technicians and engineers. In addition to responding to service requests, Ra Medical performs periodic device maintenance and emphasizes continuous training for its service and sales staff—activities geared toward maintaining the Company's reputation in the industry through high product reliability and customer satisfaction.

Target Markets

Psoriasis

Psoriasis is a genetic autoimmune disease affecting the skin and joints. The condition most commonly manifests as raised, red lesions on the skin covered by whitish scales, as shown in Figure 13 (page 20), but can also progress to psoriatic arthritis in the joints. It often begins appearing between the ages of 15 and 25 but can affect people of all ages. The incidence of psoriasis increases as people age. The severity of psoriasis typically depends on the extent of skin affected by the disease: more than 10% of skin showing lesions is considered to be a severe case. As one of the most common inflammatory dermatoses in the U.S., psoriasis affects approximately 7.5 million people, which accounts for over 2% of the domestic population (Source: National Psoriasis Foundation). Globally, this skin condition is estimated to afflict over 125 million people. For these people, psoriasis is a chronic condition for which there is no cure to date—only treatments for flare-ups.

There are essentially three main types of psoriasis treatments, as listed below and on page 20.

- Topical Therapies. These can include corticosteroids, vitamin D3 derivatives, coal tar, anthralin, and retinoids, among others, that are sold as a cream, gel, liquid, spray, or ointment. The efficacy of topical agents varies from person to person, although these products are commonly associated with a loss of potency over time as people develop resistance (Source: WebMD, Inc.).

- Phototherapy. This is the area where Ra Medical operates. Phototherapy alone or in combination with medications can be used to improve skin appearance in the midst of a psoriatic outbreak. There are many different forms of phototherapy being performed by dermatologists, aestheticians, and other clinicians, but most typically entail exposing the skin to artificial ultraviolet light. UVB light (which is what Ra Medical's devices deliver to patients' skin lesions) is present in natural sunlight and is an accepted psoriasis treatment that penetrates the skin to slow the growth of damaged skin cells (Source: National Psoriasis Foundation). UVB therapy takes place as patients expose their affected skin to a UVB light source for a set length of time on a regular schedule. The manner by which the PHAROS EX-308 delivers a high-intensity beam of UVB light to affected skin has shown to clear psoriasis faster, produce longer remissions, and require fewer treatments per week to produce the desired effect than traditional phototherapy—which is one of the reasons insurance companies reimburse at a higher rate for laser phototherapy versus phototherapy from other light sources (e.g., lamp-based systems).

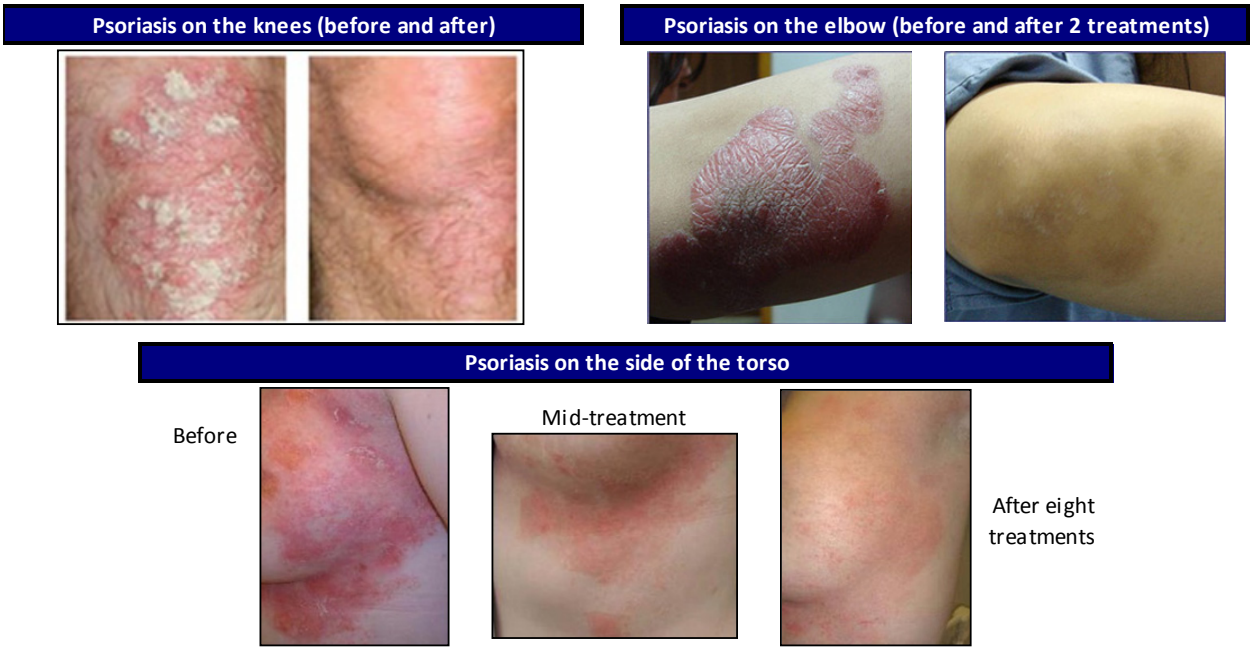
- Systemic Medications. There are a number of prescription medications available for psoriasis, which are given either by mouth or as an injection. Generally, these drugs are administered only after both topical treatments and phototherapy have failed, or for people who have severe disease or active psoriatic arthritis.

The National Psoriasis Foundation reports that direct and indirect healthcare costs related to psoriasis in the U.S. alone are roughly $11.25 billion annually, based on a 2008 study published in the *Journal of the American Academy of Dermatology*. Lost time from work accounts for 40% of these costs, as the majority of psoriasis patients miss an average of 26 days of work a year due to their disease.

The National Psoriasis Foundation recommends that patients receive two phototherapy treatments per week with a minimum of 48 hours between treatments. The PHAROS EX-308 can lead to several months of treatment-free remission for patients, which encourages patient compliance and enhances satisfaction (Source: *Journal of Cosmetic and Laser Therapy*, 2011; 13:47-19). Laser sessions are painless and relatively quick, only requiring a few minutes, twice a week. PHAROS EX-308 is intended for mild to moderate psoriasis, with particular utility at treating traditionally hard-to-reach areas on the knees, elbows, and scalp and stubborn plaque psoriasis that has not responded to other treatments. The number of sessions required may vary based on each patient's extent, thickness, and location of lesions. Figure 13 illustrates some results of using PHAROS EX-308 for psoriasis patients.

Figure 13

RESULTS OF USING THE PHAROS EX-308 EXCIMER LASER FOR PSORIASIS



Sources: www.kesseldermatology.com, Dermatology & Laser Institute of Southwest Florida, and Crystal Research Associates, LLC.

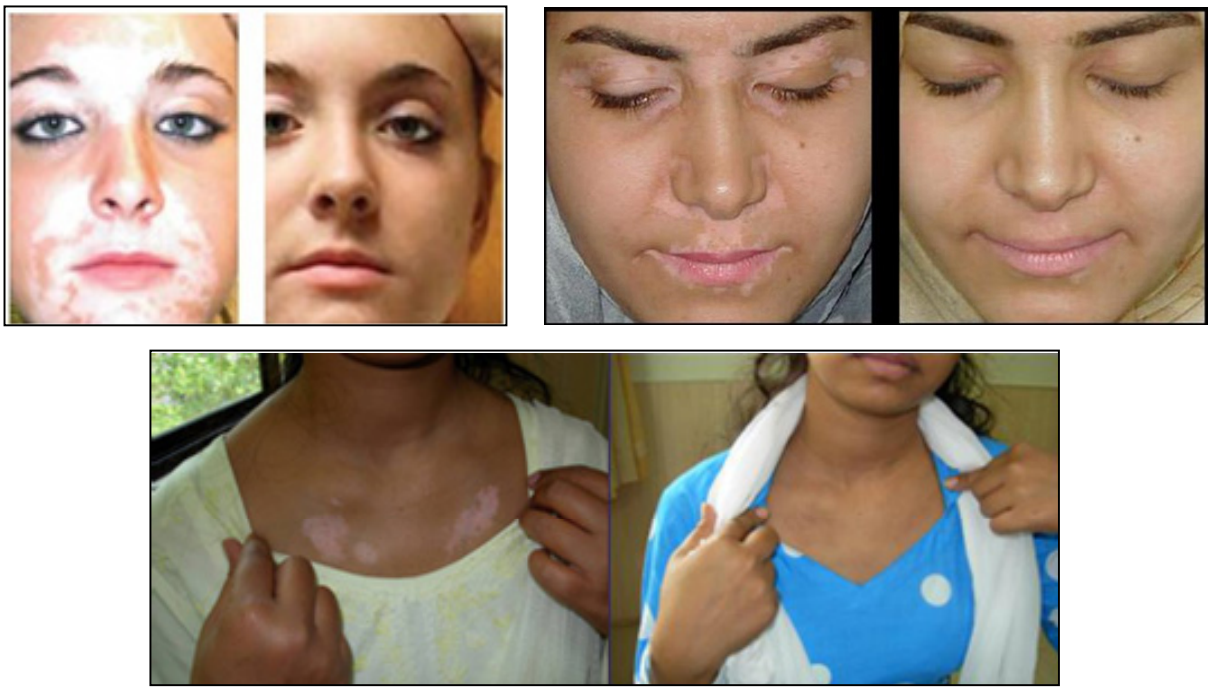
Vitiligo

Vitiligo is a pigmentation disorder that affects 1% to 2% of the population. It occurs when pigment-producing cells in skin stop functioning, leading to a loss of skin color creating whitish patches on the body. The loss of skin color can affect any part of the body, and to date, is incurable, though treatment can help improve appearance. With more than 200,000 cases in the U.S. alone each year, vitiligo is the fourth most common skin disorder.

Ra Medical has been able to show that its XeCl excimer laser can not only put vitiligo into remission but also reverse the effect—selectively re-pigmenting areas that were devoid of pigmentation. Other treatments for vitiligo include medicines (e.g., steroid creams), lamp-based phototherapy (which has serious drawbacks since it may expose healthy skin to high doses of unnecessary radiation), and surgery (e.g., skin grafts). Excimer lasers have shown to be safe and efficacious in vitiligo treatment and offer numerous benefits over other options, such as convenience, reduced UV exposure, and targeted and non-invasive treatment. Re-pigmentation may begin to occur after as few as six PHAROS laser phototherapy sessions, though some patients require between 15 and 30 sessions on a twice-weekly basis. With the high-intensity and variable size hand piece of the PHAROS laser system, dermatologists can treat localized depigmented skin patches on the face, neck, and torso as well as hard-to-reach areas on the underarms, hands, and feet and stubborn patches that have not responded to other treatments. Figure 14 illustrates the impact of the PHAROS EX-308 laser on vitiligo patients.

Figure 14

RESULTS OF USING THE PHAROS EX-308 EXCIMER LASER FOR VITILIGO (Before and Afters)



Sources: www.kesseldermatology.com, milfordmd.com, Dermatology & Laser Institute of Southwest Florida, and Crystal Research Associates, LLC.

Atopic Dermatitis (Eczema) and Leukoderma

Atopic dermatitis, or as it is better known, eczema, is a red, scaly, and very itchy rash that occurs on patches of inflamed skin. While it can appear anywhere on the body, it is most common on the arms and behind the knees. There are more than three million cases of atopic dermatitis annually in the U.S., making it one of the most common inflammatory skin diseases. Topical antiseptics, antihistamines, and steroid creams can be used for mild cases, while more serious outbreaks can be treated with UV light therapy or other medications. The ability of the PHAROS laser to selectively target only the affected area, in a painless and noninvasive manner, is well suited for patients, especially children, for whom steroids and full-body booth UV phototherapy may not be desirable treatment options.

Leukoderma is a localized loss of skin pigmentation that occurs after an inflammatory skin condition, such as a burn, intralesional steroid injection, or post dermabrasion. The term "leukoderma" is used to describe any depigmented skin, such as white stretch marks or scars, which is not caused by vitiligo. As with treating vitiligo, UV phototherapy is an accepted therapy for re-pigmenting leukoderma, functioning by means of stimulating any residual or peripheral melanocytes for re-pigmentation. Melanocytes are melanin-producing cells responsible for skin color.

RA-308 AND DABRA CATHETERS FOR VASCULAR DISEASE

Based on the Company's core 308 nm excimer laser technology, Ra Medical is poised to launch its newest XeCl laser system for vascular and cardiovascular disease indications. Cardiovascular diseases are the number one cause of death worldwide, with an estimated 17.5 million deaths in 2012 attributable to diseases affecting the heart and/or blood vessels. The mortality burden of cardiovascular diseases today represent roughly 31% of all deaths globally (Source: World Health Organization).

The RA-308 device in development entails a lightweight, portable XeCl 308 nm excimer laser system combined with proprietary, single-use catheters that, together, may represent a competitive atherectomy solution for the minimally invasive treatment of blocked arteries. This product development capitalizes on the knowledge and skill that Ra Medical has gained from over a decade of experience developing, manufacturing, testing, marketing, and servicing the PHAROS excimer laser system for dermatological diseases.

Ra Medical's vascular device has been cleared by the FDA for investigational use, and the Company is currently conducting a confirmatory clinical study as part of its pending 510(k) application for the product. The RA-308 laser with innovative DABRA catheters seeks to address unmet needs in multiple vascular and cardiovascular conditions, including peripheral artery disease (PAD), crossing chronic total occlusions (CTOs), in-stent restenosis, and more.

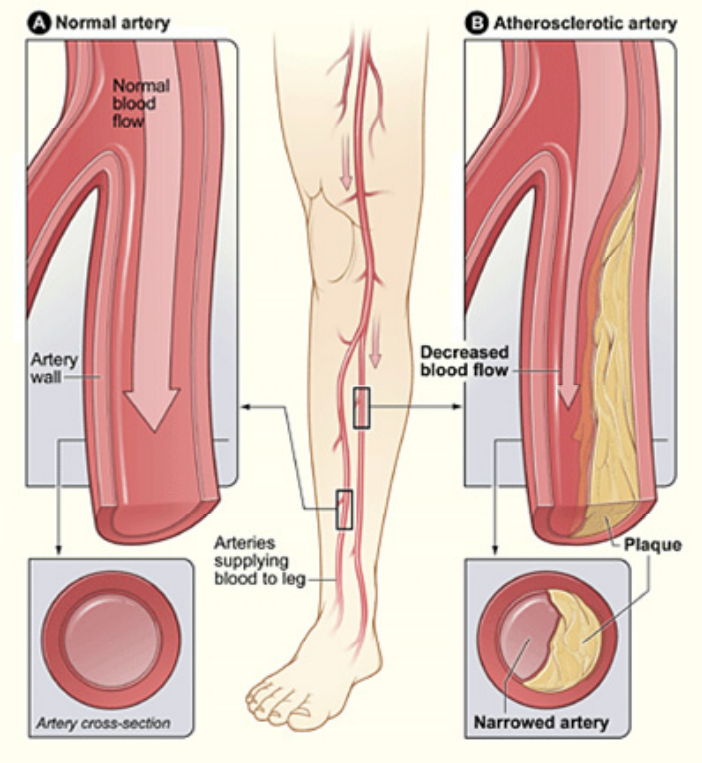
Peripheral Artery Disease (PAD), Coronary Artery Disease (CAD), and Arterial Plaque Deposits

People who are diagnosed with PAD have a build-up of plaque in their arteries that carry blood to the head, organs, and limbs. These plaque deposits contain fat, cholesterol, fibrous tissue, and other substances in and along the arterial wall that harden over time. Plaque build-up has the effect of progressively narrowing and blocking the arteries, as illustrated in Figure 15 (page 23), which then limits the flow of oxygen-rich blood to the patient's organs and limbs. Atherosclerotic plaque is one of the main underlying causes of severe cardiovascular diseases, including PAD, coronary artery disease (CAD), heart attack, and stroke. "Atherosclerosis" is the term for hardening of the arteries due to plaque. PAD is diagnosed based on the extent of the patient's atherosclerotic burden.

PAD affects at least 12 million people in the U.S., with a far greater prevalence among older adults (Source: the Cleveland Clinic Foundation, January 2009). It is thought that 12% to 20% of adults over age 65 currently have PAD. By 2050, research from the Cleveland Clinic suggests that 19 million people of all ages will likely be afflicted with the disease, including up to 16 million older adults over age 65. PAD, and other conditions stemming from the hardening of the arteries, are primarily associated with the overall aging process but may also result from high blood cholesterol levels at any age, a history of chronic kidney disease or organ transplant, or an unhealthy lifestyle, such as a diet that is high in fat, heavy alcohol use, lack of exercise, smoking, or being overweight.

Figure 15

NORMAL ARTERY AND ARTERY WITH PLAQUE BUILDUP



Source: the National Heart, Lung, and Blood Institute.

PAD can be very difficult to treat since it forms inside the wall of the blood vessel. Plaque deposits are usually calcified and have a thick fibrous cap made of smooth muscle cells. In addition to being hard to reach, unstable plaque may be dangerous since it the fibrous cap can rupture and release plaque into the bloodstream. Regardless of the type of plaque, blocked arteries starve tissues of blood and oxygen, which can result in damage or tissue death (necrosis) and ultimately cause a heart attack or stroke.

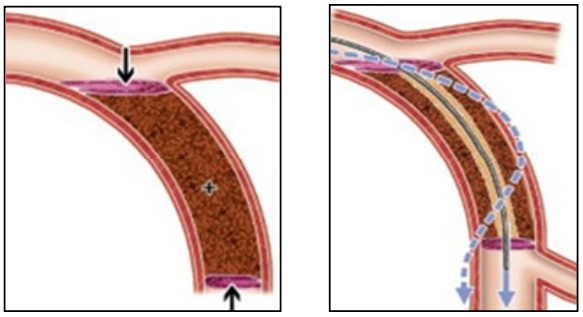
Chronic Total Occlusions (CTOs)

In both the coronary and peripheral arteries, it is possible for atherosclerotic plaque to accumulate to such an extent that the artery is completely or nearly completely blocked. When this event persists for 30 or more days, it is referred to as a chronic total occlusion (CTO). CTOs are frequently found in patients with advanced PAD (narrowing of the peripheral arteries) or CAD (narrowing of the arteries leading to the heart). Up to 50% of patients treated for PAD are estimated to present CTO, generally in the superficial femoral artery of the thigh, and the incidence of CTO in patients who have had coronary **angiography** is as high as 15% to 30% (Source: *Circulation*, 2011; 123:1780-1784). The goal of treatment for CTOs is revascularization, or opening up a path through the occlusion in order to restore blood flow, known as "crossing" (as illustrated in Figure 16).

Figure 16

AN EXAMPLE OF CROSSING CHRONIC TOTAL OCCLUSIONS (CTOs)

Diagram of a CTO with fibrotic plaque and calcified lesions	"Crossing" or creating an opening to restore blood flow through the entire occlusion



Source: The Journal of the American College of Cardiology: Cardiovascular Interventions, 2011; 4[9]:941-951.

Treatment Options

The fibrous cap that covers the plaque accumulation makes it challenging to reach whether via drug therapy or mechanical therapy device. Addressing plaque is a critical unmet need since the current standard of care, administering statin pharmaceuticals, reduces cholesterol to inhibit the formation of plaque but does not reduce existing plaque. Other available treatments, such as drug-eluting stents and balloon angioplasty, have not proven completely effective at either stabilizing or reducing plaque in the arteries.

Treatment of CTOs is particularly challenging due to their length and often heavily calcified or extremely fibrotic nature. Whereas medication and lifestyle modification might be sufficient for mild to moderate PAD patients, CTOs and dangerously narrowed blood vessels require endovascular therapy or bypass surgery. Without treatment, patients may experience anything from severe chest pain to a fatal heart attack, or may face the potential for limb amputation.

Bypass surgery entails a complex, highly invasive, inpatient procedure where a surgeon manually redirects blood flow around the blocked artery, which may require using blood vessels from another part of the patient's body. Data from the CDC show that there are 395,000 bypass surgeries performed annually in the U.S. (listed in Figure 17). An alternative to the bypass surgery is balloon angioplasty, where a small balloon attached to a tube is threaded into the artery and inflated to widen the opening. A stent—a small mesh scaffold (depicted in Figure 18)—is typically left in place in the artery to keep it from narrowing again. The stent may be bare metal, or more often than not, it will be coated with a drug that slowly releases medication to prevent scar tissue from growing into the artery. This is known as a "drug-eluting stent." Balloon angioplasty is preferred to bypass surgery in many instances because it is less risky (having only approximately a 10% rate of complications), though it is not as effective (Source: American Heart Association). A repeat procedure is needed to restore the arterial opening in 10% to 15% of patients who have stents (Source: the *New York Times'* data from ADAM, Inc.). This is known as in-stent restenosis, where the artery narrows again after a stent has been inserted.

Figure 17

COMMON INPATIENT SURGERIES IN THE U.S. (annual)

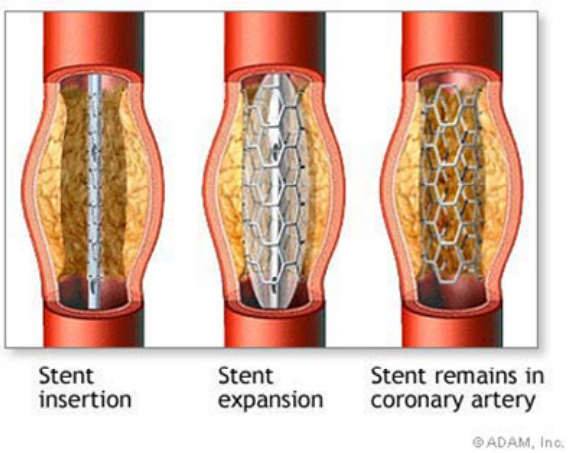
Total inpatient surgical procedures performed: 51.4 million

- Cesarean section: 1.3 million
- Diagnostic ultrasound: 1.1 million
- Cardiac catheterizations: 1.0 million
- Total knee replacement: 719,000
- **Balloon angioplasty of coronary artery or coronary atherectomy: 500,000**
- Hysterectomy: 498,000
- **Insertion of coronary artery stent: 454,000**
- **Coronary artery bypass graft: 395,000**
- Total hip replacement: 332,000

Source: the CDC's National Hospital Discharge Survey: 2010 table, Procedures by selected patient characteristics - Number by procedure category and age.

Figure 18

PLACING A STENT IN ANGIOPLASTY



Source: ADAM, Inc.

Angioplasty, stents, and atherectomy (described on page 25) are forms of endovascular therapy, as opposed to bypass surgery. Endovascular therapies are minimally invasive techniques for revascularization of blocked arteries that may reduce the need for bypass surgery or amputations altogether. In an endovascular approach, such as what Ra Medical seeks to commercialize with its laser atherectomy solution, the surgeon gains access to the arteries via a single puncture site on the body and carefully threads a catheter through the arterial vasculature to the site of the blockage. There, the treatment may take several forms, depending on which procedure is being performed. For crossing CTOs, the catheter must be able to successfully transverse the entire occlusion. A balloon or stent may be placed, or as detailed on page 25, the plaque may be ablated via an atherectomy.

Atherectomy

Atherectomy devices are used for many procedures related to PAD and CAD, from crossing occluded lesions to debulking lesions before inserting drug-eluting stents or balloons (drugs cannot pass through the plaque, so the removal of the plaque enhances the efficacy of the drug-eluting device) to lead removal. (A "lead" is a special wire delivering energy from a pacemaker or other implanted device to the heart muscle. These wires occasionally need to be removed through an endovascular approach if the lead has become damaged, infected, or too much scar tissue has formed, impeding the function of the lead or blocking the blood flow of the vein.) Atherectomy can also be used as an adjunct to improve patient outcomes in angioplasty and stenting, which is one of Ra Medical's goals for its laser atherectomy solution detailed on the accompanying pages.

In an atherectomy procedure, the physician uses a catheter to navigate through the arteries to the blocked area. The end of the catheter is outfitted with a tiny cutting device that works to shave off or cut away hardened, calcified plaque. Some catheters are designed to capture the bits of plaque and remove them from the body, while others allow the plaque to wash away in the bloodstream if they are small enough. A well-known atherectomy device is the Rotablator System from Boston Scientific Corp. (BSX-NYSE). The Rotablator has a spinning, diamond-tipped burr for ablation (cutting and removing body tissue or plaque). Its mechanical ablation approach is associated with perforation (tearing) and arterial spasms, along with other complications, that are more likely to occur when treating lesions and occlusions located on bends or in lengthy, overly twisty vessels.

Atherectomy can also be performed using an excimer laser that delivers high-intensity UVB radiation to dissolve the blockage without exposing the blood vessel to traumatic cutting or heat. Excimer laser ablation uses "photo-ablation," or the use of light to break down and vaporize the unwanted matter. Greater details on this technique are provided in the accompanying section, with a description of existing atherectomy technologies—directional, orbital, rotational, and laser—and their manufacturers provided in the Competition section on pages 34-36.

Ra Medical's Laser Atherectomy Solution

Ra Medical has nearly completed the optimization of its excimer laser technology for vascular disease. The Company expects that its initial indication for the RA-308 laser atherectomy system will likely be crossing CTOs in the legs (peripherals), followed by in-stent restenosis and other atherectomy procedures. Figure 19 shows the RA-308 laser light source. Although the RA-308 is very similar to the PHAROS EX-308 (described on pages 15-22), these are technically two different systems, and only the RA-308 is compatible with Ra Medical's novel DABRA catheters.

Figure 19

RA MEDICAL'S LASER ATHERECTOMY SYSTEM

RA-308

DABRA Catheter and Packaging

Source: Ra Medical Systems, Inc.

Some of the advantages of Ra Medical's excimer laser photoablation system are that it is portable (weighing only roughly 100 lbs.) and it plugs directly into the wall, unlike competitive systems. The RA-308 was further designed with an intuitive, user-friendly interface that is similar to the interface on an Automated Teller Machine (ATM), so surgeons, cardiologists, interventionists, and technicians can use the device right away without having to worry about codes and so on, which is a particularly important feature in a device that providers might not use every day. In addition to the practical, simple-to-use console, the DABRA catheters may represent a considerable advancement in the performance of laser ablation today. Their design and function is detailed on pages 27-31, but it is worth noting that this disposable catheter solution may also create a high-margin, recurring revenue stream associated with sales of the RA-308 and physician reimbursement of the procedure. Figure 20 summarizes many of the other key characteristics of the RA-308.

Figure 20

SYSTEM ADVANTAGES

• Safely and rapidly ablates all lesion types, including: ○ Soft thrombus ○ Hard, calcified plaque, including total occlusions
• May be used throughout the body, including: ○ Peripheral and coronary vasculature ○ Chronic total inclusions ○ In-stent restenosis
• Produces a high quality lumen for better clinical outcomes
• Easy to use portable system with short learning curve
• 115VAC – Plug and play in any catheter lab with no special connections
• Revenue generated from sale of high-margin consumable catheter product with improved economics for hospitals and office-based centers

Source: Ra Medical Systems, Inc.

Figure 21

RA-308 AND CVX-300 SIDE BY SIDE

Source: Ra Medical Systems, Inc.

In comparison to what may be Ra Medical's primary competition in the endovascular laser space, Spectranetics Corp.'s (SPNC-NASDAQ) CVX-300® Excimer Laser, Ra Medical believes its design offers several key advantages. One of these is size, as evidenced in Figure 21. As with its PHAROS laser, Ra Medical's RA-308 can be easily transported for on-site demonstrations, which the Company does not believe is achievable with the 650-pound CVX-300. In addition to its small footprint, the plug-and-play RA-308 has a fast warm-up time unlike the CVX-300, which may require special connections in each catheter lab for its 230VAC plug and has a slow warm-up time as it takes several minutes to calibrate. The quality of the ablation achievable between the machines may become one of the largest differentiators, as Ra Medical's solid-fill catheter offers a much faster ablation rate than the competing glass fiber laser light transmission medium that degrades with each use.

*The DABRA Catheter: **D**estruction of **A**rteriosclerotic **B**lockages by Laser **R**adiation **A**blation*

Ra Medical has spent over $65 million since 2008 developing its single-use DABRA catheter for delivering laser energy to the target blood vessel that is capable of photo-ablating arterial plaque and buildup. The Company believes the DABRA catheter is a key innovation that will likely distinguish its laser atherectomy product from existing options (e.g., Spectranetics' excimer laser). It uses a liquid transmission medium instead of a glass fiber bundle, which is a complete turnaround from other types of laser catheters.

One of the historical problems with excimer laser atherectomy has been delivering the laser energy to the blockage. Historically glass has been used as the transmitting medium, although glass is not a very good conductor of the energy. It is also quite stiff. Ra Medical's scientists have developed a liquid transmission system. The liquid is inside a plastic tube and it conducts the laser energy from the light source directly to the blockage. It is very flexible and highly transmissive.

The Company's R&D team knew that the scientific approach to using a liquid transmission medium was sound, so there were not any development issues related to the transmission medium other than how to make it feasible and practical. While the concept of the liquid-filled catheter has been around since the mid-1970s, Ra Medical believes that it may be among the first to effectively put the concept into practice.

Figure 22
DABRA CATHETER AND PACKAGING

Source: Ra Medical Systems, Inc.

This advanced transmission medium in the DABRA catheter has been shown to achieve precise energy delivery, and is functional for partially or wholly blocked arteries and stubborn, calcified lesions. With its laser atherectomy solution, Ra Medical aims to ablate all types of plaque, including **thrombus**, calcified plaque, total occlusions (CTOs), and **atheroma**. The applications possible entail both peripheral and coronary blockages, crossing CTOs, and in-stent restenosis (when a stent clogs up with plaque after a previous treatment).

Moreover, because the method of ablation is not thermal, it spares the surrounding tissue from trauma. Trauma occurring through other means of ablation is thought to actually contribute to **restenosis** (the re-narrowing of the artery) as a result of the body's healing response. DABRA ablates vascular obstructions by applying non-thermal light energy to break molecular bonds. In fact, Ra Medical's patent-pending light delivery system (shown in Figure 23 [page 28]) is key to a highly effective ablation procedure.

Figure 23 illustrates the difference in function and appearance of the light delivery system between Ra Medical's RA-308 versus Spectranetics' product. Looking at these images helps highlight how the light delivery from Ra Medical's fiber-optic–like catheter may be enhanced (stronger and thus faster-working) versus competing options.

Figure 23

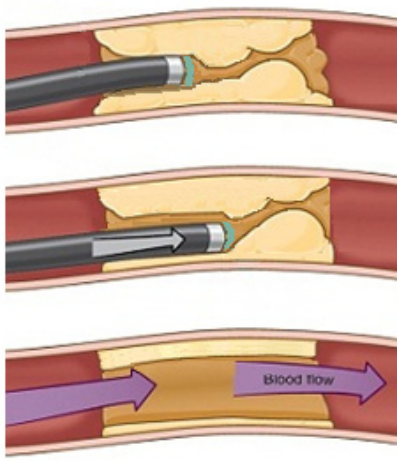
LIGHT DELIVERY SYSTEM

RA-308	Spectranetics
	
▪ Solid fill factor means that the catheter can ablate completely, passing through thrombus, soft, or hard calcium cleanly without releasing particulate matter into the bloodstream	▪ Incomplete fill factor means the catheter may not ablate completely, slowing the procedure down and releasing troublesome particulates
▪ Short pulse and solid fill produce high advance rates of .5cm/sec to 1cm/sec, depending on the material	▪ Long pulse means much greater energy/pulse and contributes to the slow advance rate (.05cm/sec), resulting in long procedure times of 35 min or more
▪ Advanced technology transmission medium allows short pulse energy delivery but production costs are low – gross margins at 80%-90%	▪ Glass fibers degrade with every use and transmit light less efficiently, contributing to slow procedure times and increasing the cost of ownership

Source: Ra Medical Systems, Inc.

Figure 24

PHOTO-ABLATION OF PLAQUE



Source: Ra Medical Systems, Inc.

In addition to representing an advancement over other excimer laser products, the Company's laser atherectomy solution seeks to further become a preferred alternative to other ablation technologies altogether. Unlike products that have a thermal mechanism of action (causing heat), an excimer laser radiates energy without giving off heat. It directly breaks down molecular bond, breaking the material down into its constituent components. In the case of arterial plaque, laser light breaks the plaque down into lipids, proteins, minerals, and water, and these are molecules, not particles, that are native to the bloodstream. Thus, there is not a concern over the ablated particles being mechanically shaved or cut off of the plaque and then left to circulate dangerously in the bloodstream, as laser energy manages to convert the target lesion from one chemical compound to another.

The light energy emitted from Ra Medical's "solid-fill" catheter ablates only approximately 50 microns in front of the catheter tip, which essentially makes it a contact cutter, as illustrated in Figure 24. The system gives off only a small amount of energy to cut only directly in front of the catheter tip but, in turn, the laser energy is extremely efficient. Ra Medical estimates that it uses approximately 1/50th to 1/1000th of the energy of top atherectomy systems, as such systems are typically mechanical in nature, which requires a greater amount of energy to break up plaque.

Ra Medical states that the small amount of focused energy emitted by its DABRA catheter is sufficient to clear blockages or debulk occlusions as both a monotherapy or as an adjunct to angioplasty and stenting.

The DABRA catheter design comes in multiple diameters and length sizes, enabling its use for minimally invasive endovascular surgeries throughout the body—in large vessels as well as in the small vasculature below the knee. It is also quick and easy for the physician to use, and it reduces time under the **fluoroscope**. Ra Medical reports that its ablation rate is faster than competing devices so the physician spends less time under fluoroscopic guidance and under fluoroscopy than with existing products. Figure 25 highlights a procedure where the Company's technology was able to cross a nearly wholly occluded lesion with a lasing time of less than 10 seconds.

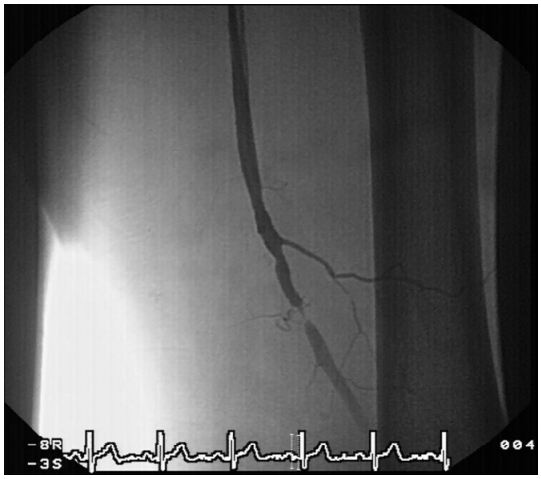
Figure 25

RESULTS OF LASER ATHERECTOMY USING THE DABRA SYSTEM

Total lasing time less than 10 seconds

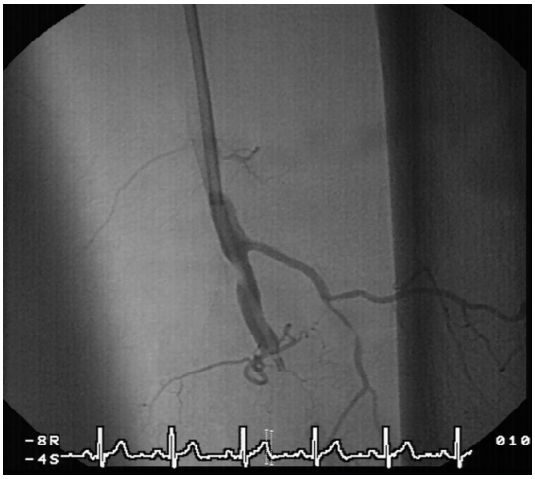
Before

Superficial Femoral Artery with near total occlusion



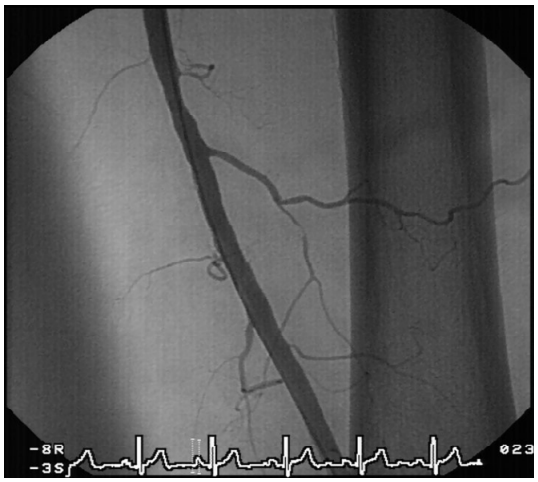
During

7Fr Support catheter visible above
5Fr Ra Med laser catheter crossing lesion



After

Excellent final result--lesion was not stented

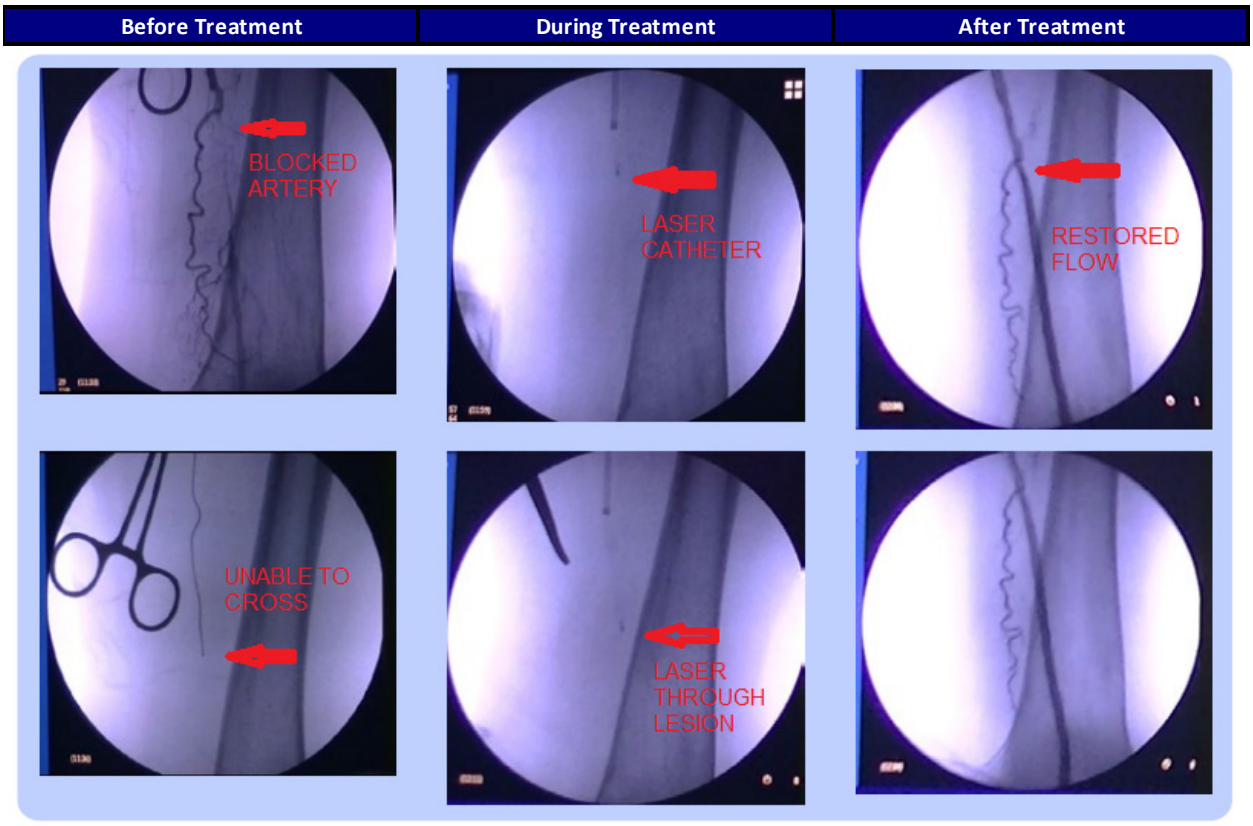


Source: Ra Medical Systems, Inc.

Figure 26 shows the breadth of the Company's laser atherectomy solution, as used for ablation of CTOs and in-stent lesions.

Figure 26

FAST ABLATION THROUGH CTOS AND IN-STENT LESIONS USING THE DABRA SYSTEM



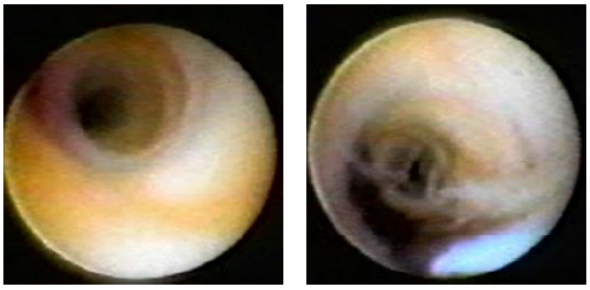
Source: Ra Medical Systems, Inc.

In addition to a fast and quick ablation of all different lesion types, the DABRA catheter produces a high quality lumen, particularly in comparison to mechanical ablation. The lumen is the interior cavity of the vessel through which blood flows. Figure 27 (page 31) compares the inside of a blood vessel ablated in a mechanical atherectomy versus a laser atherectomy. Mechanical cutting can be another cause of trauma to the blood vessels (leading to pain and possibly perforation), which understandably reduces patient satisfaction as well as increases the possibility of restenosis since trauma in the vessel stimulates the body's healing response—a negative outcome in this procedure. Another complication from mechanical cutting is turbulence in the blood vessel, damaging the lumen and potentially causing blood clots, restenosis, and **embolism**. In contrast, laser atherectomy essentially remodels the plaque, creating a smooth channel in the vessel for blood to flow, without turbulence or trauma. When used with angioplasty, it allows for a much lower balloon inflation, reducing the barrel trauma. As such, Ra Medical's device may improve patient outcomes in crossing CTOs as well as when used as an adjunct to balloon angioplasty.

Figure 27

LASER ATHERECTOMY OFFERS CLINICAL ADVANTAGES VERSUS MECHANICAL ATHERECTOMY

Mechanical Atherectomy

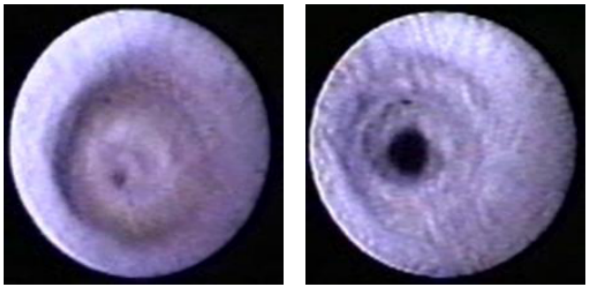


BEFORE AFTER

Mechanical Atherectomy

- Turbulence promotes blood clotting because of damage to the lumen
- Trauma promotes healing response leading to restenosis

Laser Atherectomy



BEFORE AFTER

Laser Atherectomy

- Crosses tough totally occluded lesions
- Re-models plaque for low balloon inflation pressure
- Smooth result for improved blood flow and less material for embolism

Source: Ra Medical Systems, Inc.

Summary of Potential Competitive Advantages of the DABRA Catheter Design

The DABRA catheter design offers numerous competitive advantages in the atherectomy market, including but not limited to the following:

- a novel transmission medium and light delivery system for stronger, faster, and more complete ablation;
- shorter procedure times;
- an ability to cleanly treat thrombus, soft, or hard calcium deposits without releasing particulate matter into the bloodstream;
- a non-thermal and non-mechanical mechanism of action;
- a reduced energy requirement;
- suitability for large and small vasculature;
- production of a high-quality lumen; and
- an ability to work as a monotherapy or an adjunct device to complement the performance of angioplasty and stents.

Favorable Economics for the RA-308 and DABRA Catheter Solution

Ra Medical's platform provides favorable economics to hospitals and office-based laboratories. The DABRA catheter is a "consumable" product, meaning that it is a single-use item, intended for only one patient/procedure and then to be disposed of after its use. Ra Medical has designed the catheter to have low production costs, potentially enabling high-margin sales as well as a recurring revenue stream from routine catheter purchases. In order to help drive adoption of its disposable catheters, the Company is able to provide its excimer laser energy source—the RA-308—to users at no cost, as the light source is inexpensive to produce. Under this arrangement, Ra Medical would retain ownership of the capital equipment and the customer would be scheduled to purchase a predetermined minimum number of catheters per a unit of time. Other options include sales or leases of the devices or the purchase of catheters on consignment (no capital outlay for the customer). The DABRA catheter may retail for approximately $1,200 with gross margins over 80% according to Ra Medical.

Ra Medical estimates that, given the same procedural cost for an atherectomy using Cardiovascular Systems Inc.'s (CSII-NASDAQ) Orbital Atherectomy solution, Covidien's (acquired by Medtronic plc) Directional Atherectomy product, Spectranetics' excimer laser atherectomy, or its own excimer laser atherectomy product (the RA-308 with DABRA catheters), the greatest residual (money left to cover costs and provide a profit) is obtained by using Ra Medical's solution. This cost advantage is primarily achieved because of the lower cost of the DABRA catheters versus the consumables required by competing products, as illustrated in Figure 28 using cost assumptions furnished by Ra Medical.

Figure 28
RA MEDICAL'S POTENTIAL ECONOMIC BENEFITS

Procedural Cost Breakdown	CSII Orbital Atherectomy	Covidien (Medtronic) Directional Atherectomy	Spectranetics Excimer Laser	Ra Medical
Surgical Procedure Total	$15,000	$15,000	$15,000	$15,000
Less: Payment to Physician	($3,000)	($3,000)	($3,000)	($3,000)
Less: Payment for Consumable	($3,600)	($2,600)	($2,200)	($1,200)
Residual for Other Costs and Profit	**$8,400**	**$9,400**	**$9,800**	**$10,800**

Source: Ra Medical Systems, Inc.

Insurance Reimbursement

The Company believes its device can enhances practices that are already benefiting from high-value atherectomy reimbursement codes. CPT® codes for laser atherectomy are in place, with research showing the procedure's value, particularly when performed prior to inflating a balloon or placing a drug-eluting balloon or stent inside an artery. Atherectomy is typically a blanket reimbursement over and above angioplasty and stent. Ra Medical believes there are three primary incentives for physicians and surgeons to choose the RA-308 endovascular system: (1) the existing favorable reimbursement landscape for atherectomy (on top of that of balloon angioplasty or stent); (2) the clinical benefit of improving patient outcomes by reducing trauma; and (3) the competitive price of the catheters, which comes in far below the typical retail price for endovascular catheters ($2,200 to $3,600 each [as shown in Figure 28]).

Status of Clinical Development

Ra Medical completed an initial study of its atherectomy procedure in Mexico, in which all five patients were treated successfully without any adverse events. Follow-up found that the patients continued to show favorable safety and efficacy of the vascular device.

In January 2016, the Company received approval from the FDA to commence patient testing of the laser atherectomy in the U.S. under an **Investigational Device Exemption (IDE)**. Since then, Ra Medical also received approval from the Centers for Medicare & Medicaid Services (CMS) to have Medicare patient treatments reimbursed, and received study approval from the Institutional Review Boards (IRBs) of two trial locations: (1) the Cardiovascular Clinic of Hattiesburg, Wesley Medical Center, Hattiesburg, Mississippi, and (2) the University of California, San Diego (UCSD). The study's principal investigator is Dr. Ehtisham Mahmud, M.D., Professor and Chief of Cardiovascular Medicine, Director, Sulpizio Cardiovascular Center-Medicine, Director, Interventional Cardiology and CV **Cath Labs**, University of California, San Diego (UCSD). Dr. Mahmud is also a scientific advisor to Ra Medical and previously performed the first-in-human procedure with the Company's vascular device.

Ra Medical began the study in Hattiesburg and at UCSD in July 2016. The patients enroll as they present, and the study is expected to require approximately 10 weeks with four weeks of follow-up. When the trial is complete, Ra Medical can submit the package to the FDA per the 510(k) pathway for regulatory approval. The Company states that it has had numerous face-to-face meetings with the FDA and believes that it may receive its first medical device clearance in this field during 2016. To date, 25 patients have been treated with over 95% procedural and technical success and a 0% adverse event rate according to results provided by Ra Medical.

Target Markets

Atherectomy procedures are poised for growth as minimally invasive cardiology procedures increase in frequency along with the aging population and a rise in diabetes, heart disease, and other risk factors for artery disease. The migration of treatment procedures to office-based centers may also fuel market growth for minimally invasive endovascular techniques.

The first indication for which Ra Medical is pursuing a medical device clearance in the U.S. is crossing CTOs in the peripherals. The PAD market is served by interventional radiologists, vascular surgeons, and interventional cardiologists. Ra Medical plans to target the PAD market with a sales force in 2016 and may also partner with a national distributor.

Subsequent clearances for in-stent restenosis and other atherectomy indications are expected to have a shorter timeline to marketing approval since the laser and catheter would have both already been approved. Future FDA submissions for the treatment of coronary artery disease and lead removal will likely require the filing of a premarket approval (PMA) application in the U.S. instead of a 510(k) application. A PMA is the FDA's application for approval of Class III devices, which are defined as those that "support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury" (Source: FDA). As it stands now, Ra Medical's devices are considered Class II for the initially targeted indications in the peripheral arteries, and thus only require a 510(k) application. The more stringent PMA is a scientific review to ensure a device's safety and efficacy, in addition to meeting general controls. In the PMA application, the manufacturer must substantiate the device's safety and effectiveness for its intended use. The FDA states its review time for a PMA is 180 days, though it varies on a case-by-case basis.

In these markets, Ra Medical anticipates that it can potentially address over two million U.S. procedures annually, composed of 250,000 to 500,000 procedures to treat in-stent restenosis each year, 1.4 million CAD procedures where the Company's device would be complementary to angioplasty and stenting for improved patient outcomes, and roughly 200,000 surgeries annually to remove leads due to lead age, failure, or recall.

Competition

The following description is not intended to be an exhaustive collection of potential competitors to Ra Medical; however, it is believed to be representative of the type of competition the Company may encounter as it seeks to commercialize its endovascular devices and further market its dermatology laser therapies.

Vascular Disease

The global atherectomy devices market is forecasted to expand at a compound annual growth rate (CAGR) of more than 5% from 2016 to 2020 due in large part to a rise in the incidence of PAD among aging adults worldwide (Source: Technavio's *Global Atherectomy Devices Market 2016-2020*, June 25, 2016). Demand for novel atherectomy devices will likely increase over the next few years, particularly in the market segment for below-the-knee procedures, as more medical facilities include atherectomy procedures in minimally invasive PAD treatment. Importantly, these facilities have been transitioning from traditional atherectomy devices to new products that have technological advancements enabling greater efficiencies with fewer complications. Technavio analysts specifically cite laser atherectomy as being one of the key new developments in this space.

The market for atherectomy devices is highly consolidated, with only a few major device manufacturers representing the bulk of market share: **Medtronic plc**, **Cardiovascular Systems Inc.**, **Boston Scientific Corp.**, and **Spectranetics Corp.** These entities are detailed below on the basis of their technological approach to atherectomy. Notably, a trend in this market at present is significant R&D investment, as each of these companies and potentially new entrants to the space, such as Ra Medical, seek to launch safer, more efficient, and more cost competitive devices.

Directional Atherectomy

There are a host of different atherectomy systems available today. One of the leading classes of atherectomy systems is FoxHollow's SilverHawk® line of directional devices manufactured by Medtronic's Covidien subsidiary (stemming from Covidien's earlier acquisition of the FoxHollow products). Medtronic is currently the market leader and its directional atherectomy devices are believed to sell for roughly $2,500 to $3,000 according to Ra Medical, though analysts expect average selling prices for atherectomy devices in general to decline over the next few years as peripheral atherectomy procedures shift toward more cost-sensitive, outpatient settings (Source: iData Research, December 21, 2015). Covidien's SilverHawk™ and TurboHawk™ Plaque Excision Systems remove hundreds of milligrams of plaque from the body, rather than chopping the plaque into small pieces for circulation or pressing it up against the side of the vessel wall (which Covidien states has a higher risk of trauma to the vessel). However, the constant removal of plaque can mean a tedious and repetitive procedure.

Covidien's most recent directional atherectomy device launch is the HawkOne™, which may be capable of crossing challenging lesions more predictably than its prior devices. HawkOne treats all morphologies, including severely calcified lesions, and was designed to offer increased procedural efficiency due to a simplified process for removing the excised plaque. Covidien estimates that cleaning times are now up to 55% faster, saving lab time.

Orbital and Rotational Atherectomy

Other leading devices that are established in this market include Cardiovascular Systems' Diamondback 360® Peripheral and Coronary Orbital Atherectomy Systems and Boston Scientific's Rotablator System, both of which use a very rapidly spinning, diamond-coated disc or ball that is wound through the artery at a very high revolving speed. The orbital atherectomy, which has been developed for suitability in both peripheral and coronary applications, aims to cut plaque into such small remnants that it can be harmlessly excreted through the circulatory system, reducing the need to tediously and continuously empty captured plaque pieces from the body. However, the mechanical cutting approach may still lead to unnecessary trauma to the blood vessel, decreasing patient comfort and potentially increasing the chance of restenosis, and as well may have difficulty crossing CTOs.

New Approaches

Spectranetics is perhaps Ra Medical's most direct competitor, as this company also markets an excimer laser-based device for vascular disease. Ra Medical estimates that Spectranetics sells approximately $65 million in atherectomy catheters each year, with recent double-digit sales growth. Spectranetics' CVX-300® Excimer Laser is also equipped with a 308nm excimer laser system and disposable catheters, though the mechanism of action of energy delivery in Ra Medical's new catheters differs from that employed in Spectranetics' catheters. Details of the fundamental differences between Ra Medical's DABRA catheters and Spectranetics' are provided in the Core Story of this report. Ra Medical believes that the time it spent developing a portable, low-cost, and improved product over the past several years may lead to a more preferred solution than Spectranetics' large laser console and high-cost catheters that initially went to market in 2004. Spectranetics is also presently developing the Stellarex™ drug coated angioplasty balloon, which received a CE Mark in Europe in 2014 but is not yet approved for use in the U.S.

In another approach, Avinger, Inc. (AVGR-NASDAQ) received FDA clearance in March 2016, and has begun commercialization, for an enhanced version of its Pantheris™ lumivascular image-guided atherectomy system. Pantheris™ is believed to be the first image-guided atherectomy device. It was initially cleared by the FDA in October 2015, with the new version supposed to offer improvements in ergonomics and manufacturability. Pantheris™ uses a directional atherectomy approach but allows physicians to see inside the artery during the procedure using optical coherence tomography (OCT) imaging rather than the standard X-ray imaging.

Ra Medical's Position in the Competitive Landscape

Ra Medical believes one of the reasons laser atherectomy is picking up steam is because of its benefits over directional, orbital, and rotational devices, which are limited in their ability to cross CTOs or function in vessels that contain stents (a required function in order to treat in-stent restenosis). Figure 29 summarizes some of these benefits, noting that the information provided in Figure 29 comes from Ra Medical's internal market analysis.

Figure 29

HOW RA MEDICAL POSITIONS ITS ATHERECTOMY SOLUTION IN THE COMPETITIVE LANDSCAPE

Parameter	Orbital Atherectomy	Directional Atherectomy	Other Excimer Laser	Ra Medical RA-308
Footprint	Medium	Small	Large	Medium
Procedure Time	Short	Long	Long	Short
Cost of Catheter/Procedure	$3,000	$2,600	$2,200	$1,200
Debulking Capability	Hard plaque only	Most plaque types	Not for hard plaque	All plaque types
Able to Cross CTO?	No	No	Yes	Yes
Capable of treating In-Stent Restenosis?	No	No	Yes, but slow	Yes, rapidly
Ease-of-Use Considerations	▪ Multi-parameter procedure with difficult learning curve	▪ Tedious and repetitive procedure	▪ Not portable, slow warm-up, 230VAC power required ▪ Unfriendly code-driven user interface	▪ As easy to use as a guide wire ▪ Portable, fast warm-up, 115VAC power ▪ Intuitive user interface with easy-to-use calibration and energy application
Complication Considerations	▪ Risk of adverse events due to significant mechanical energy ▪ Risk of embolism	▪ Repetition increases risk of adverse events	▪ Low adverse event rate	▪ Low adverse event rate predicted

Source: Ra Medical Systems, Inc.

Dermatology

Ra Medical's PHAROS EX-308 laser to treat psoriasis, vitiligo, atopic dermatitis, and leukoderma may compete with the following companies in the dermatology treatment market, noting that this is not intended to be an exhaustive summation of possible competitors.

STRATA Skin Sciences, Inc. (SSKN-NASDAQ)

STRATA Skin Sciences, formerly MELA Sciences, Inc. (MELA-NASDAQ) as the company changed its name in January 2016, is a medical technology company focused on the dermatology market, with both diagnostic and therapeutic products. It markets two excimer laser and lamp systems that are used to treat psoriasis, vitiligo, and various other skin conditions: the XTRAC® excimer laser and the VTRAC® excimer lamp. XTRAC received an FDA clearance in 2000 and has since become a widely recognized treatment among dermatologists for psoriasis and other skin conditions. The VTRAC lamp is targeted to treat vitiligo patches quickly and effectively. The XTRAC and VTRAC machines deliver 308nm UVB light to affected areas of skin, leading to psoriasis remission in an average of 8 to 12 treatments and of vitiligo after 48 treatments. XTRAC is endorsed by the National Psoriasis Foundation, and its use for psoriasis is covered by nearly all major insurance companies, including Medicare. STRATA Skin Sciences is also focused on the commercialization of its MelaFind® product, a non-invasive point-of-care software driven image analysis instrument to aid in the detection of melanoma. MelaFind® consists of a hand-held component that emits light of multiple wavelengths to capture digital data from clinically atypical pigmented skin lesions. The image is then analyzed utilizing proprietary algorithms to provide physicians with information to assist in the management of the patient's disease, including information useful in the decision of whether to biopsy the lesion. MelaFind® is approved in the U.S. under a PMA and has been granted CE Mark approval for sale in the EU.

National Biological Corp. (Closely held)

Ohio-based National Biological Corp. was founded in 1967. The company's purpose is to commercialize and distribute UV phototherapy products as an alternative treatment to pharmaceuticals and biologics for severe or chronic psoriasis, vitiligo, and other skin conditions. National Biological maintains its own production facility and works to invent its UV phototherapy equipment. Its line of phototherapy equipment is extensive, from home units to full-body phototherapy units (which look akin to a walk-in tanning booth) to replacement UV lamps and goggles/sunglasses to wear during and after treatment. The company's UV light equipment delivers each of UVA, UVB, or narrowband UVB light, and can be installed in a clinic, hospital, or physician's office, or delivered to a patient for home use with a valid prescription and insurance coverage. National Biological approximates that the cost of a home phototherapy unit is significantly less than one 12-week course of biologic treatment. Its products are targeted to treat psoriasis (in roughly 20 to 25 phototherapy treatments), vitiligo, and acne. The company markets a "clinical starter kit" for physicians or clinics looking to start a phototherapy practice. It entails four UV devices, including a full-body phototherapy booth (has 32 lamps delivering UV light), a hand unit and a foot unit mounted on a cart, and a device for scalp or spot treatment, plus technical support and training.

Key Points

- Ra Medical creates and commercializes medical devices targeting the dermatology and endovascular specialties. The Company's core competencies include a deep understanding of the development, manufacture, regulatory pathways, and maintenance of laser systems for medical applications.

- The Company's first product, the PHAROS EX-308 laser for dermatology markets, has received regulatory approval and been sold in 18 countries around the world, and Ra Medical was able to leverage its initial medical device clearances in psoriasis and vitiligo to also include clearances for additional indications in atopic dermatitis and leukoderma. Though the technology is now in the public domain, Ra Medical has also had successful experience defending its patents on the PHAROS laser in court.

- The Company's present product development focuses on markets for vascular and cardiovascular diseases, with the anticipated launch during 2016 of a novel excimer laser and catheter solution for endovascular procedures. Development of its RA-308 laser and DABRA catheters has been underway for roughly eight years, with over $65 million invested in creating a new catheter design that may perform endovascular ablation more efficiently, effectively, safely, and rapidly than existing technologies, and at a lower cost.

- Ra Medical believes there exists a compelling strategic opportunity for its DABRA catheters in a very large market. The Company's newest device is intended to serve as a laser atherectomy adjunct to balloon angioplasty and stents—two procedures commonly used in the treatment of peripheral and coronary artery diseases and conditions, but that are limited in their effectiveness. Up to 15% of patients need to have repeat procedures to reopen their arteries, even after having a stent placed, and many more have complications from the procedure as a result of trauma to the artery from balloon inflation or other causes.

    - Atherectomy in conjunction with angioplasty or stenting has shown to improve patient outcomes. It entails a process of removing plaque deposits from inside arteries in order to restore blood flow to the limbs (peripheral artery disease) or heart (coronary artery disease). It is reimbursed by insurance carriers over and above angioplasty/stents. Ra Medical's laser atherectomy may be used as a monotherapy or as an adjunct to the current standard of care, thus the Company is not trying to supplant an existing product.

    - The global atherectomy devices market is forecast to expand at a CAGR of over 5% from 2016 to 2020. Laser atherectomy is one of the key developments in this space enabling greater efficiencies with fewer complications.

- The RA-308 and DABRA catheter products are applicable to multiple endovascular applications, including crossing chronic total occlusions ([CTOs] totally blocked arteries) in the peripherals, specifically below the knee; in-stent restenosis; other atherectomy needs; coronary artery disease; and lead removal.

- The RA Medical team has over 14 years of experience in building its business with high capital efficiency, and decades of expertise in excimer lasers specifically. Its executive leadership comes from major medical device companies and science and engineering institutions, including Eli Lilly, the Plasma Research Center at MIT, the Institute of Plasma Physics at Nagoya University, Caltech's Jet Propulsion Laboratory, Intel, Kellogg, Solta Medical, and the U.S. Navy and Marine Corp, among other notable entities. There are almost 70 years of experience in excimer laser and medical device development and manufacturing just between CEO Dean Irwin and R&D Director, Dr. James Laudenslager.

- The Company pursues patents, copyrights, trademarks, and confidentiality/invention assignment agreements to protect its intellectual property rights. Its patent portfolio consists of provisional and utility patent applications for the endovascular technology that have been filed in the U.S. and certain foreign jurisdictions.

- As of March 31, 2016, Ra Medical reported that the Company held cash and cash equivalents of $218,509, with total current assets of over $1.5 million and no debt.

Historical Financial Results

Figures 30, 31, and 32 (pages 38-40) provide a summary of Ra Medical's key historical financial statements: its Statement of Operations, Balance Sheet, and Statement of Cash Flows for the first quarter 2016 (ended March 31, 2016), as furnished to Crystal Research Associates by Ra Medical.

Figure 30
STATEMENT OF OPERATIONS
GAAP

	For the Quarter ending March 31, 2016 (Unaudited)
Total Sales	$ 2,257,201
Less: Sales Discounts	(298,450)
Net Sales	1,958,751
Cost of Sales	867,222
Gross Profit	1,091,530
Operating Expenses	
Selling, General and Administrative	851,402
Research and Development	160,055
Total Operating Expenses	1,011,457
Operating Income	80,073
Other Expenses:	
Interest Expense	2,773
Total Other Expenses	2,773
Income/Loss before Income Tax Expenses	77,300
Income Tax Expenses	-
Net Income	$ 77,300

Source: Ra Medical Systems, Inc.

Figure 31
BALANCE SHEETS
GAAP

Assets	For the Quarter ending March 31, 2016 (Unaudited)
Current Assets:	
Cash & cash equivalents	$ 218,509
Accounts Receivable	640,349
Inventories	642,952
Prepaid expenses and other current assets	27,960
Total Current Assets	1,529,770
Property & Equipment, net	303,968
Other Non-Current Assets	42,900
Total Assets	$ 1,876,637
Liabilities and Stockholders' Deficit	
Current Liabilities:	
Account Payable	$ 391,841
Current portion of long-term debt	-
Accrued expenses	300,817
Deferred Rent	13,308
Deferred Revenue	1,424,439
Total current liabilities	2,130,404
Long-Term Liabilities	
Deferred revenue net of current portion	753,484
Long-term debt, net of current portion	-
Other long-term liabilities, net of current portion	60,871
Total Liabilities	2,944,760
Stockholders' Deficit	
Common stock, $0.01 par value, 10,000,000 shares authorized; 6,739,461 oustanding as of December 31, 2015	67,395
Additional paid-in capital	5,829,064
Retained Earnings	(6,964,582)
Total Stockholders' Deficit	(1,068,123)
Total Liabilities and Stockholders' Equity	$ 1,876,637

Source: Ra Medical Systems, Inc.

Figure 32
STATEMENT OF CASH FLOWS
GAAP

	For the Quarter ending March 31, 2016 (Unaudited)
Cash Flows From Operating Activities:	
Net Income / (Loss)	$ 77,300
Adjustments to reconcile net income/(loss) to net cash provided by (used in) operating activities:	
Depreciation and Amortization	21,326
Inventory Reserve	12,055
Bad debt Expense	-
Changes in operating assets and liabilities:	
Accounts Receivable	(351,092)
Inventories	179,471
Prepaid Expenses and Other Assets	1,957
Accounts Payable	(296,849)
Net cash provided by operating activities	(355,832)
Cash Flows From Investing Activities:	
Purchase of property and equipment	(69,803)
Net cash used in from Investing Activities	(69,803)
Cash Flows From Financing Activities:	
Payments on notes payable	-
Proceeds from sale of common stock	-
Net cash provided by (used in) financing activities	-
Net change in Cash	(425,635)
Cash and Cash Equivalents, beginning of quarter	644,144
Cash and Cash Equivalents, end of quarter	$ 218,509
Supplemental Cash Flow Information:	
Cash payments for:	
Interest	$ 520
Taxes	$ 1,044

Source: Ra Medical Systems, Inc.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Ra Medical Systems, Inc. ("Ra Medical" or "the Company") with the assistance of Crystal Research Associates, LLC ("CRA") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in Ra Medical's statements in its corporate materials as well as other forms filed or released from time to time.

The content of this report with respect to Ra Medical has been compiled primarily from information available to the public released by the Company. Ra Medical is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Ra Medical or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, CRA has been compensated by the Company in cash of thirty-five thousand U.S. dollars for its services in creating this report and for updates.

Investors should carefully consider the risks and information about Ra Medical's business, as described below. Investors should not interpret the order in which considerations are presented in this or other materials as an indication of their relative importance. The risks and uncertainties overviewed below are not the only risks that the Company faces, and should not be taken as a complete enumeration or explanation of the risk factors potentially affecting the Company. Additional risks and uncertainties not presently known to Ra Medical or that it currently believes to be immaterial may also adversely affect its business. If any of such risks and uncertainties develops into an actual event, Ra Medical's business, financial condition, and results of operations could be materially and adversely affected, and the Company's shares could decline.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. Additional information about Ra Medical, as well as copies of this report, can be obtained by calling (760) 804-1648.

RISKS RELATED TO THE COMPANY

Ra Medical's quarterly and annual results going forward may fluctuate significantly, may not fully reflect the underlying performance of the Company's business, and may result in decreases in the value of its stock.

Factors that may cause fluctuations in reported results include, without limitation, the following:

- ability to maintain and obtain FDA clearances and approvals from foreign regulatory authorities for products, particularly the EX-308, RA-308, and DABRA catheter, which the Company plans to commercialize in 2016;
- sales of the PHAROS EX-308 and market acceptance of the RA-308 and DABRA system;
- the availability of reimbursement for products;
- ability to attract new customers;
- results of clinical studies and trials;
- timing and success of new product and feature introductions by the Company or its competitors or any other change in the competitive dynamics of the industry, including consolidation among competitors, customers, or strategic partners;

- the amount and timing of costs and expenses related to the maintenance and expansion of business and operations;
- changes in the Company's pricing policies or business model, or those of Ra Medical's competitors;
- general economic, industry, and market conditions;
- the regulatory environment;
- the hiring, training, and retention of key employees, including the Company's ability to expand its sales team;
- litigation or other claims against the Company;
- ability to obtain financing, if needed; and
- advancements and trends in new technologies and industry standards.

Although Ra Medical has a history of funding research and development from operations, the Company may not be able to sustain profitability.

The Company expects its costs and expenses to increase in the future due to anticipated increases in cost of revenues, sales, and marketing expenses, research and development expenses, and general and administrative expenses, and therefore, might incur losses in the future as it develops and expands its business. The Company plans to list its stock on a public market and that might increase legal, accounting and other expenses that it did not incur as a private company. Accordingly, Ra Medical cannot assure investors that it will be profitable in the future or that it will sustain profitability. Ra Medical's failure to operate profitably would negatively impact the value of its stock.

The Company began developing the RA-308 and DABRA product in 2008 and treated the first patient in late 2012. The Company has only treated 25 patients to date. Although the results were encouraging, Ra Medical's limited experience makes it difficult to predict future prospects. The Company has encountered, and will continue to encounter, risks and difficulties frequently experienced by companies in rapidly changing industries. These risks and uncertainties include the risks inherent in clinical studies and increasing and unforeseen expenses as Ra Medical continues to attempt to grow its business.

Ra Medical's success depends in large part on a limited number of products, particularly the PHAROS EX-308. If this product loses market acceptance, business will suffer.

The PHAROS EX-308 is the Company's only product currently cleared for sale in the U.S., and Ra Medical's current revenues are wholly dependent on it. Sales may decline as Ra Medical focuses on the promotion of the RA-308 and DABRA products. In addition, the long-term viability of the Company is largely dependent on the successful commercialization and continued development of catheters and Ra Medical expects that sales of catheters and its other current and future RA-308 and DABRA products in the U.S. will account for a large part of revenues in the future. Accordingly, success depends on the acceptance of the RA-308 and DABRA products by the medical community. Acceptance among physicians of these products may not occur. Ra Medical's ability to successfully market the DABRA will also be limited due to a number of factors, including regulatory restrictions in labeling. The Company cannot assure investors that demand for the EX-308 product will continue to grow and that its RA-308 and DABRA products will penetrate new markets. If demand for the EX-308, RA-308, and DABRA products does not increase as anticipated and Ra Medical cannot sell its products as planned, financial results will be limited. In addition, market acceptance may be hindered if physicians are not presented with compelling data from studies of the safety and efficacy of the RA-308 and DABRA products compared to alternative procedures, such as angioplasty, stenting, bypass surgery, or other atherectomy procedures.

The Company may not be able to secure financing on favorable terms, or at all, to meet potential future capital needs, and a failure to obtain additional financing when needed could force the Company to delay, reduce, or eliminate product development programs and commercialization efforts.

The Company may raise funds in equity or debt financings or enter into credit facilities in order to access funds for capital needs. Any debt financing obtained by the Company in the future would cause it to incur additional debt service expenses and could include restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for the Company to obtain additional capital and pursue business opportunities. If Ra Medical raises additional funds through further issuances of equity or convertible debt securities, existing stockholders could suffer significant dilution in their percentage ownership of the company, and any new equity securities issued could have rights, preferences, and privileges senior to those of holders of the common stock. If Ra Medical is unable to obtain adequate financing or financing on terms satisfactory to the Company when required, the Company may terminate or delay the development of one or more of its products, delay clinical trials necessary to market products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize products. If this were to occur, its ability to continue to grow and support its business and respond to business challenges could be significantly limited.

Ra Medical's ability to compete is highly dependent on demonstrating the benefits of RA-308 and DABRA to physicians, hospitals, and patients.

In order to generate sales, the Company must be able to clearly demonstrate that RA-308 and DABRA is both a more effective treatment system and more cost-effective than the alternatives offered by competitors. If Ra Medical is unable to convince physicians that RA-308 and DABRA leads to significantly lower rates of restenosis, or narrowing of the artery, and leads to fewer adverse events during treatment than those using competing technologies, business will suffer. If the Company is unable to develop robust clinical data to support these claims, it may be unable to convince hospitals and third-party payors of these benefits and business may suffer.

The Company's value proposition to physicians and hospitals is dependent upon its contention that arterial injury is lower when physicians are using its product rather than competing products. If minimizing arterial injury does not significantly impact patient restenosis, then Ra Medical may be unable to demonstrate that the DABRA catheter's benefits are any different than competing technologies. If physicians do not value the benefits of the Company's products during an endovascular intervention as compared to competitors' products, or do not believe that such benefits improve clinical outcomes, the RA-308 and DABRA products may not be widely adopted.

The use, misuse, or off-label use of the products in the RA-308 and DABRA may result in injuries that lead to product liability suits, which could be costly to business.

The expense and potential unavailability of insurance coverage for liabilities resulting from Ra Medical's products could harm the Company and its ability to sell products. The Company may not have sufficient insurance coverage for future product liability claims. The Company may not be able to obtain insurance in amounts or scope sufficient to provide the Company with adequate coverage against all potential liabilities. Any product liability claims brought against the Company, with or without merit, could increase product liability insurance rates or prevent the Company from securing continuing coverage, harm its reputation in the industry, significantly increase expenses, and reduce product sales. Product liability claims in excess of insurance coverage would be paid out of cash reserves, harming its financial condition and operating results.

The Company competes against companies that have longer operating histories, more established products, and greater resources, which may prevent the Company from achieving significant market penetration, increasing revenues, or sustaining profitability.

The market for medical devices in general, and in the PAD market in particular, is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. There are few barriers that would prevent new entrants or existing competitors from developing products that compete directly with Ra Medical's. Demand for the RA-308 and DABRA products could be diminished by equivalent or superior products

and technologies offered by competitors. If Ra Medical is unable to innovate successfully, its RA-308 and DABRA products could become obsolete and revenues would decline as customers purchase competitors' products.

Ra Medical's ability to compete effectively depends on its ability to distinguish the Company and its products from competitors and their products, and includes such factors as procedural safety and efficacy, acute and long-term outcomes, ease of use and short procedure time, price of the product, and third-party reimbursement.

If the Company's clinical studies are unsuccessful or significantly delayed, or if Ra Medical does not complete its clinical studies, its business may be harmed.

The Company may experience numerous unforeseen events during, or because of, the clinical trial process that could delay or prevent the Company from receiving regulatory clearance or approval for new products or modifications to existing products, including new indications for existing products, including the following:

- negative or inconclusive results that may cause the Company to decide, or regulators may require the Company, to conduct additional clinical and/or preclinical testing which may be expensive and time consuming;
- trial results that do not meet the level of statistical significance required by the FDA or other regulatory authorities;
- findings by the FDA or similar foreign regulatory authorities that the product is not sufficiently safe for investigational use in humans;
- delays or failure in obtaining approval of clinical trial protocols from the FDA or other regulatory authorities;
- delays in obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;
- changes in the review policies of the FDA or similar foreign regulatory authorities or the adoption of new regulations that may negatively affect or delay Ra Medical's ability to bring a product to market or receive approvals or clearances to treat new indications;
- trouble in managing multiple clinical sites; and
- the suspension or termination by the Company, or regulators, of clinical trials because the participating patients are being exposed to unacceptable health risks.

From time to time, Ra Medical engages outside parties to perform services related to certain of its clinical studies and trials, and any failure of those parties to fulfill their obligations could increase costs and cause delays. Failures or perceived failures in Ra Medical's clinical trials will delay and may prevent the product development and regulatory approval process, damage business prospects, and negatively affect reputation and competitive position. As well, the Company has no long-term data regarding the safety and efficacy of EX-308 or RA-308 and DABRA products. Any long-term data that is generated by clinical trials may not be positive or consistent with the short-term data, which would harm the Company's ability to obtain clearance to market and sell its products.

If Ra Medical fails to grow its sales and marketing capabilities cost effectively, its growth will be impeded and its business may suffer.

The Company plans to continue to expand and optimize its sales infrastructure in order to grow its customer base and business. Identifying and recruiting qualified personnel and training them in the use of RA-308 and DABRA, and on applicable federal and state laws and regulations and internal policies and procedures, requires significant time, expense, and attention. It could take several months before any new sales representatives are fully trained and productive. Ra Medical's business may be harmed if efforts to expand and train its sales force do not generate a corresponding increase in revenues. In particular, if the Company is unable to hire, develop, and retain talented

sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, the Company may not be able to realize the expected benefits of this investment or increase revenues.

If Ra Medical is unable to manage the anticipated growth of its business, its future revenues and operating results may be harmed.

Any growth that is experienced in the future could provide challenges to Ra Medical's organization, requiring the Company to expand sales personnel and manufacturing operations and general and administrative infrastructure. The Company expects to continue to grow its sales force and manufacturing infrastructure. Rapid expansion in personnel could mean that less experienced people produce and sell its products, which could result in inefficiencies and unanticipated costs and disruptions to operations.

The Company has limited experience manufacturing its RA-308 and DABRA products in commercial quantities. Key components and sub-assemblies of RA-308 and DABRA products are currently provided by a limited number of suppliers, and Ra Medical does not maintain large inventory levels of these components and sub-assemblies. If Ra Medical experiences a shortage in any of these components or sub-assemblies, it would need to identify and qualify new supply sources, which could increase costs and result in manufacturing delays.

The Company may experience a delay in completing validation and verification testing or sterility audits for controlled-environment rooms at its manufacturing facility.

Ra Medical's manufacturing facilities and processes and those of its third-party suppliers are subject to unannounced FDA and state regulatory inspections for compliance with QSR. Developing and maintaining a compliant quality system is time-consuming and expensive. Failure to maintain, or not fully comply with the requirements of, a quality system could result in regulatory authorities initiating enforcement actions against the Company and its third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls and civil and criminal penalties, any one of which could significantly impact manufacturing supply and impair financial results.

The Company currently manufactures and assembles its RA-308 and DABRA products in-house.

Ra Medical's facility and equipment, or those of its suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, terrorism, flooding, and power outages. Further, electronic systems may experience service interruptions, denial-of-service, and other cyber-attacks, computer viruses, or other events. Any of these may render it difficult or impossible for the Company to manufacture products, pursue research and development efforts, or otherwise run its business for some period of time. If Ra Medical's facility is inoperable for even a short period of time, the inability to manufacture current products, and the interruption in research and development of any future products, may result in harm to the Company's reputation, increased costs, lower revenues, and the loss of customers. Furthermore, it could be costly and time-consuming to repair or replace facilities and the equipment used to perform research and development work and manufacture products.

The Company depends on its senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm its business.

Ra Medical's success largely depends upon the continued services of its executive management team and key employees, and the loss of one or more of executive officers or key employees could harm the Company and directly impact financial results. Ra Medical's employees may terminate their employment with the Company at any time. Changes in the executive management team resulting from the hiring or departure of executives could disrupt business. In particular, Ra Medical's founder and executive chairman, Dean Irwin (biography on page 8), is the visionary behind many of the Company's product development activities and he actively supports the clinical trials and physician education and training efforts. If Mr. Irwin was no longer working for the Company, Ra Medical's product development efforts and physician relationships would be harmed. The Company currently maintains a key person life insurance policy on Mr. Irwin, although there can be no assurance that the coverage of $5 million is sufficient to offset the loss.

To execute our growth plan, Ra Medical must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales executives. The Company has, from time to time, experienced, and expects to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which it competes for experienced personnel have greater resources than Ra Medical. If the Company hires employees from competitors or other companies, their former employers may attempt to assert that these employees or Ra Medical has breached legal obligations, resulting in a diversion of time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in southern California, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of the Company's stock is insufficient, it may harm Ra Medical's ability to recruit and retain highly skilled employees. In addition, the Company invests significant time and expense in training employees, which increases their value to competitors that may seek to recruit them. If the Company fails to attract new personnel or fails to retain and motivate current personnel, its business and future growth prospects would be harmed.

The Company will incur additional compensation costs in the event that it decides to pay its executive officers cash compensation closer to that of executive officers of other medical device companies, which would increase general and administrative expense and could harm profitability. Any future equity awards will also increase compensation expense.

The Company does not intend to devote significant resources in the near-term to market the RA-308 and DABRA internationally, which will limit potential revenues from RA-308 and DABRA products in the short term.

Marketing RA-308 and DABRA outside of the U.S. would require substantial additional sales and marketing, regulatory, and personnel expenses. As part of its product development and regulatory strategy, Ra Medical plans to expand into select European markets, but does not currently intend to devote significant additional resources to market the RA-308 and DABRA internationally. Ra Medical's decision to market its products primarily in the U.S. in the near-term will limit its ability to reach all of its potential markets and will limit its potential sources of revenue. In addition, competitors will have an opportunity to further penetrate and achieve market share outside of the U.S. unless Ra Medical devotes significant additional resources to market its RA-308 and DABRA products or other products internationally.

The forecasts of market growth included in this report may prove to be inaccurate. Even if the markets in which Ra Medical competes achieve the forecasted growth, its business may not grow at similar rates, if at all.

The Company may acquire other companies or technologies, which could divert management's attention, resulting in additional dilution to stockholders and disrupt operations and harm operating results.

The Company may in the future seek to acquire or invest in businesses, applications, or technologies that it believes could complement or expand its products, enhance its technical capabilities, or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause the Company to incur various costs and expenses in identifying, investigating, and pursuing suitable acquisitions, whether or not they are consummated. The Company may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, business growth has been organic and Ra Medical has no experience in acquiring other businesses. In any acquisition, it may not be able to successfully integrate acquired personnel, operations, and technologies, or effectively manage the combined business following the acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of available cash, or the incurrence of debt, which could harm operating results. In addition, if an acquired business fails to meet expectations, Ra Medical's operating results, business, and financial condition may suffer.

The Company may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with Ra Medical's ability to sell its products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover Ra Medical's products, or that the Company may be accused of misappropriating third parties' trade secrets. Additionally, its products may include hardware and software components that are purchased from vendors, and may include design components that are outside of Ra Medical's direct control. Ra Medical's competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained or may in the future apply for or obtain patents or trademarks that will prevent, limit, or otherwise interfere with the Company's ability to make, use, sell and/or export its products or to use product names. The Company may become a party to patent or trademark infringement or trade secret claims and litigation as a result of these and other third-party intellectual property rights being asserted against the Company. The defense and prosecution of these matters are both costly and time-consuming. Vendors from whom Ra Medical purchases hardware or software may not indemnify the Company in the event that such hardware or software is accused of infringing a third party's patent or trademark or of misappropriating a third party's trade secret.

Further, if such patents, trademarks, or trade secrets are successfully asserted against the Company, this may harm business and result in injunctions preventing the Company from selling its products, license fees, damages, and the payment of attorney fees and court costs. In addition, if Ra Medical is found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, it could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. The Company may be unable to obtain necessary licenses on satisfactory terms, if at all. If it does not obtain necessary licenses, it may not be able to redesign its RA-308 and DABRA products to avoid infringement.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office (USPTO) may be necessary to determine the priority of inventions or other matters of inventorship with respect to Ra Medical's patents or patent applications. The Company may also become involved in other proceedings before the USPTO or other jurisdictional body relating to its intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent the Company from manufacturing and selling its products or using product names, which would have a significant adverse impact on its business.

Additionally, Ra Medical may need to commence proceedings against others to enforce patents or trademarks, to protect trade secrets or know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. These proceedings would result in substantial expense to the Company and significant diversion of effort by technical and management personnel. The Company may not prevail in any lawsuits that it initiates and the damages or other remedies awarded, if any, may not be commercially meaningful. The Company may not be able to stop a competitor from marketing and selling products that are the same or similar to its products or from using product names that are the same or similar to its product names, and its business may be harmed as a result.

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against the Company more effectively.

In order to remain competitive, Ra Medical must develop and maintain protection of the proprietary aspects of its technologies. The Company relies on a combination of patents, copyrights, trademarks, trade secret laws, and confidentiality and invention assignment agreements to protect its intellectual property rights. As of December 31, 2015, Ra Medical had three U.S. utility patent applications pending. Ra Medical's patent applications may not result in issued patents and its patents may not be sufficiently broad to protect its technology. Any patents issued to the Company may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids Ra Medical's patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar. The Company may not be able to prevent the unauthorized disclosure or use of its technical knowledge or other trade secrets by consultants, vendors, or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of intellectual property is difficult, and Ra Medical does not know whether the steps it has taken to protect its intellectual property will be adequate. In addition, the laws of many foreign countries will not protect intellectual property rights to the same extent as the laws of the U.S. Consequently, Ra Medical may be unable to prevent proprietary technology from being exploited abroad, which could affect its ability to expand to international markets or require costly efforts to protect its technology. To the extent its intellectual property protection is incomplete, the Company is exposed to a greater risk of direct competition. In addition, competitors could purchase its products and attempt to replicate some or all of the competitive advantages Ra Medical derives from its development efforts or design around its protected technology. Ra Medical's failure to secure, protect, and enforce intellectual property rights could substantially harm the value of its products, brand, and business.

Failure to comply with laws and regulations could harm Ra Medical's business.

Ra Medical's business is subject to regulation by various federal, state, local, and foreign governmental agencies, including agencies responsible for monitoring and enforcing employment and labor laws, workplace safety, environmental laws, consumer protection laws, anti-bribery laws, import/export controls, federal securities laws, and tax laws and regulations. Noncompliance with applicable regulations or requirements could subject the Company to investigations, sanctions, mandatory recalls, enforcement actions, adverse publicity, disgorgement of profits, fines, damages, civil and criminal penalties or injunctions and administrative actions. If any governmental sanctions, fines, or penalties are imposed, or if Ra Medical does not prevail in any possible civil or criminal litigation, its business, operating results, and financial condition could be harmed. In addition, responding to any action will likely result in a significant diversion of management's attention and resources and substantial costs.

Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject the Company to significant liability.

Ra Medical's research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. In addition, the Company's research and development and manufacturing operations produce waste solvents, such as isopropyl alcohol. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Compliance with environmental laws and regulations may be expensive and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. The Company cannot assure investors that violations of these laws and regulations will not occur in the future, or have not occurred in the past, as a result of human error, accidents, equipment failure, or other causes. The expense associated with environmental regulation and remediation could harm Ra Medical's financial condition and operating results.

If Ra Medical fails to obtain and maintain necessary regulatory clearances or approvals for its EX-308, RA-308, and DABRA products, or if clearances or approvals for future products and indications are delayed or not issued, its commercial operations would be harmed.

Ra Medical's PHAROS EX-308, RA-308, and DABRA products are medical devices that are subject to extensive regulation by the FDA in the U.S. and by regulatory agencies in other countries where the Company does business. Government regulations specific to medical devices are wide-ranging and govern, among other things, product design, development and manufacture; laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution; pre-market clearance or approval; record keeping; product marketing, promotion and advertising, sales and distribution; and post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing product can be marketed in the U.S., a company must first submit and receive either 510(k) clearance or pre-market approval from FDA, unless an exemption applies. Either process can be expensive, lengthy, and unpredictable. The Company may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm its business. Furthermore, even if it is granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although Ra Medical has obtained 510(k) clearance to market the EX-308, its clearance can be revoked if safety or efficacy problems develop. Delays in obtaining clearance or approval could increase costs and harm revenues and growth.

In addition, Ra Medical is required to timely file various reports with the FDA, including reports required by the Medical Device Reporting regulations which require that the Company report to the regulatory authorities if its devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of its products may suffer, and Ra Medical may be subject to product liability or regulatory enforcement actions, all of which could harm its business. For example, to date, Ra Medical has submitted to the FDA one MDR regarding its EX-308, which was for strong erythema (sunburn).

If Ra Medical initiates a correction or removal for one of its devices to reduce a risk to health posed by the device, it would be required to submit a publicly available Correction and Removal report to the FDA, and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall, which could lead to increased scrutiny by the FDA, other international regulatory agencies, and customers regarding the quality and safety of the Company's devices. Furthermore, the submission of these reports has been and could be used by competitors against the Company in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm Ra Medical's reputation.

The FDA and the Federal Trade Commission (FTC) also regulate the advertising and promotion of Ra Medical's products to ensure that the claims made are consistent with regulatory clearances, that there are adequate and reasonable data to substantiate the claims, and that promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of the Company's advertising or promotional claims are misleading, not substantiated, or not permissible, Ra Medical may be subject to enforcement actions, including Warning Letters, and may be required to revise its promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Ra Medical's failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;

- refusing requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, Ra Medical's business and financial condition would be harmed.

Material modifications to the PHAROS EX-308, RA-308, and DABRA products may require new 510(k) clearances or premarket approvals or may require the Company to recall or cease marketing the products until clearances are obtained.

Material modifications to the intended use or technological characteristics of the PHAROS EX-308 will require new 510(k) clearances or premarket approvals or require the Company to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on published FDA guidelines, the FDA requires device manufacturers to initially make and document whether a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. The Company may not be able to obtain additional 510(k) clearances or premarket approvals for new products, modifications, or additional indications for, its RA-308 and DABRA products in a timely fashion, or at all. Delays in obtaining required future clearances would harm its ability to introduce new or enhanced products in a timely manner, which in turn would harm future growth. The Company has made modifications to its RA-308 and DABRA products in the past and will make additional modifications in the future that it believes do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, Ra Medical may be required to recall and to stop selling or marketing its products as modified, which could harm operating results, require the Company to redesign its products, and subject the Company to significant enforcement actions.

If Ra Medical or its suppliers fail to comply with the FDA's Quality System Regulations, its manufacturing operations could be delayed or shut down and EX-308, RA-308, and DABRA sales could suffer.

The Company has registered with the FDA as a medical device manufacturer and has obtained a manufacturing license from the California Department of Public Health. Ra Medical's manufacturing processes and those of its third-party suppliers are required to comply with the FDA's QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of products. The Company is also subject to similar state requirements and licenses. In addition, it must engage in extensive recordkeeping and reporting and must make available its manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities, and comparable agencies in other countries. If Ra Medical fails a QSR inspection, its operations could be disrupted and manufacturing interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, a shut-down of manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of devices, operating restrictions, and criminal prosecutions, any of which would cause business to suffer. Furthermore, key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for the Company's products and cause its revenues to decline.

Changes in insurance coverage and reimbursement for procedures using Ra Medical's products could affect adoption and future revenues.

Currently, the PHAROS EX-308, RA-308, and DABRA procedure are typically reimbursed by third-party payors, including Medicare and private healthcare insurance companies, under existing reimbursement codes. These payors may change their coverage and reimbursement policies, as well as payment amounts, in a way that would prevent or limit reimbursement for Ra Medical's products, which would significantly harm its business. Also, healthcare reform legislation or regulation may be proposed or enacted in the future, which may adversely affect

such policies and amounts. The Company cannot predict whether and to what extent existing coverage and reimbursement will continue to be available. If physicians, hospitals, and other providers are unable to obtain adequate insurance coverage and or reimbursement for procedures performed using Ra Medical's products, they are significantly less likely to use these products and the Company's business would be limited.

Healthcare reform measures could hinder or prevent Ra Medical's planned products' commercial success. In the U.S., there have been, and the Company expects there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm the Company's future revenues and profitability and the future revenues and profitability of its potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, was enacted in 2010. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, imposed an excise tax of 2.3% on the sale of most medical devices, including Ra Medical's, and any failure to pay this amount could result in the imposition of an injunction on the sale of the Company's products, fines, and penalties. Effective January 1, 2016, the excise tax of 2.3% on the sale of medical devices was suspended for two years.

It remains unclear whether changes will be made to the Affordable Care Act. The Company cannot assure investors that the Affordable Care Act, as currently enacted or as amended in the future, will not harm its business and financial results and cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect business. There will likely continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. The Company cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare may harm Ra Medical's ability to set a price that it believes is fair for its products, its ability to generate revenues and achieve or maintain profitability, and the availability of capital.

Ra Medical's stock price may be volatile, and purchasers of the Company's stock could incur substantial losses.

The market price for Ra Medical's common stock may be influenced by many factors, including the results of clinical trials, changes in investors' perceptions, competitors' results of operations, the Company's failure to meet projections, general market conditions, the loss of key personnel, legislation or regulation of business, lawsuits threatened or filed against the Company, and developments in the industry. Sales of a substantial number of shares of Ra Medical's common stock, or the perception that these sales might occur, could depress the price of the Company's common stock and could impair its ability to raise capital through the sale of additional equity securities. The Company is unable to predict the effect that these sales and others may have on the prevailing market price of its common stock.

Ra Medical's directors, officers, and their affiliates have significant voting power and may take actions that may not be in the best interests of other stockholders.

As of February 29, 2016, Ra Medical's directors, officers, and their affiliates collectively controlled approximately 70% of the Company's outstanding common stock, assuming the exercise of all options and warrants held by such persons. As a result, these stockholders, if they act together, would be able to exert significant influence over the management and affairs of the Company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of Ra Medical's stock and may not be in the best interests of other stockholders.

The Company previously identified and remediated a material weakness in its internal control over financial reporting. If it fails to remediate any material weaknesses or if it fails to establish and maintain effective control over financial reporting, its ability to accurately and timely report financial results could be adversely affected.

Ra Medical's management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles (GAAP). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

The Company is a private company with limited accounting personnel and other resources to address its internal control over financial reporting. Any failure to maintain or implement required new or improved controls, or any difficulties encountered in their implementation, could result in additional material weaknesses or significant deficiencies, cause the Company to fail to meet its periodic reporting obligations or result in material misstatements in its financial statements. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of its internal control over financial reporting. The existence of a material weakness or significant deficiency could result in errors in financial statements that could result in a restatement of financial statements, cause the Company to fail to meet reporting obligations and cause investors to lose confidence in its reported financial information, leading to a decline in stock price.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. The Company intends to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If Ra Medical's efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against the Company and its business may be harmed.

The Company has not paid dividends in the past and does not expect to pay dividends in the future, and any return on investment may be limited to the value of its stock.

Glossary

510(k)—A regulatory application filed in order to gain approval to market medical devices that the FDA has determined to be substantially equivalent to another legally marketed device. A premarket notification, referred to as a 510(k), must be submitted to FDA for clearance. A 510(k) is most often submitted by the medical device manufacturer.

Ablation—The surgical removal of body tissue.

Angiography—A procedure performed to view blood vessels after injecting them with a radio-opaque dye that outlines them on x-ray.

Atherectomy—A minimally invasive endovascular surgery technique for removing atherosclerosis from blood vessels within the body. It is an alternative to angioplasty for the treatment of peripheral artery disease (PAD).

Atheroma—Degeneration of the walls of the arteries caused by accumulated fatty deposits and scar tissue, and leading to restriction of the circulation and a risk of thrombosis.

Atopic Dermatitis—(Eczema) A condition that makes skin red and itchy. It is common in children but can occur at any age. Atopic dermatitis is long lasting (chronic) and tends to flare periodically and then subside. It may be accompanied by asthma or hay fever.

Catheterization Lab—(or "Cath lab") An examination room in a hospital or clinic with diagnostic imaging equipment used to visualize the arteries of the heart and the chambers of the heart and treat any stenosis or abnormality found.

Chronic Total Occlusions (CTOs)—Characterized by heavy atherosclerotic plaque burden within the artery, resulting in complete (or nearly complete) occlusion of the vessel. Duration is typically longer than 30 days.

Class II Medical Device—Under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, there are three classes of medical devices, which vary in how stringently they are regulated for safety and effectiveness. General controls to be satisfied by all device classes involve listing the medical device with the FDA, manufacturing in accordance with Good Manufacturing Practices (GMP), and labeling in accordance with labeling regulations. Class II devices are also subject to special controls, such as special labeling requirements, mandatory performance standards, and postmarket surveillance. Examples of Class II devices, which represent approximately 43% of all medical devices, include powered wheelchairs, some pregnancy test kits, and surgical drapes (Source: FDA).

Coronary Artery Disease (CAD)—When the major blood vessels that supply the heart with blood, oxygen, and nutrients (coronary arteries) become damaged or diseased. Cholesterol-containing deposits (plaque) in the arteries and inflammation are usually to blame for CAD.

Dimer—Any of various chemical compounds made of two smaller identical or similar molecules (called monomers) that are linked together. Dimers are linked by hydrogen bonds, coordinate bonds, or covalent bonds.

Embolism—Obstruction of an artery, typically by a clot of blood or an air bubble.

Excimer Laser—A laser that emits very concentrated light in the ultraviolet (UV) region of the spectrum.

Fluoroscope—An instrument with a fluorescent screen used for viewing X-ray images without taking and developing X-ray photographs.

Good Manufacturing Practices (GMP)—Regulations established by the FDA for all domestic and foreign manufacturers. These require the establishment of a quality system meeting requirements related to the methods, controls, and facilities used for designing, manufacturing, packaging, labeling, storing, installing, and servicing products and medical devices intended for human use.

Halogen—Any of the elements fluorine, chlorine, bromine, iodine, and astatine, occupying group VIIA (17) of the periodic table. They are reactive nonmetallic elements that form strongly acidic compounds with hydrogen, from which simple salts can be made.

In-stent Restenosis—Scar-induced re-closure of a previously stenosed artery, a complication seen in roughly 20% of patients undergoing stent placement for CAD.

Investigational Device Exemption (IDE)—Allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to Food and Drug Administration (FDA). Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)'s require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

ISO 13485—An International Organization for Standardization (ISO) standard, published in 2003, which represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.

ISO 9001—This standard establishes criteria for a quality management system. It can be used by any organization, large or small, regardless of its field of activity. The quality management principles of ISO 9001 include a strong customer focus, the motivation and implication of top management, the process approach, and continual improvement.

Leukoderma—Partial or total loss of skin pigmentation, often occurring in patches.

Lumen—The interior cavity of a blood vessel through which blood flows.

Noble Gas—Any of the gaseous elements helium, neon, argon, krypton, xenon, and radon, occupying Group 0 (18) of the periodic table. They were long believed to be totally unreactive but compounds of xenon, krypton, and radon are now known.

Peripheral Artery Disease (PAD)—A disease of blood vessels outside of the heart. A common circulatory problem in which narrowed arteries reduce blood flow to the limbs.

Phototherapy—The use of light in the treatment of physical or mental illness.

Psoriasis—A skin disease marked by red, itchy, scaly patches.

Restenosis—The recurrence of stenosis, which is an abnormal narrowing of an artery or valve after corrective surgery leading to restricted blood flow.

Standard of Care—A diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance.

Stenosis—The abnormal narrowing of a passage in the body.

Thrombus—A blood clot formed in situ within the vascular system of the body and impeding blood flow.

Vitiligo—A condition in which the pigment is lost from areas of the skin, causing whitish patches, often with no clear cause.

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