Part 1: "Elevator" Introduction

SalutarisMD® is a near-revenue medical device company, anticipating first sales revenue in 2017. We have developed a novel, minimally invasive, ophthalmic technology for the treatment of wet age-related macular degeneration ("Wet AMD"), a leading cause of vision loss worldwide. There are 500,000 new onsets of Wet AMD per year in the US and Europe and in the future, Asia will represent a larger market.

Current therapies are only ~40% effective and cost >$8 billion. The macula provides sharp, central vision. Wet AMD is caused by the development of choroidal neovascularization and occurs when abnormal blood vessels grow under the retina at the back of the eye (macula). If untreated, this leakage quickly leads to vision loss and blindness.

The disease is currently treated by chronic, expensive pharmaceutical that only restore vision in <40% of patients, leaving a large patient population with an unmet need. Results of our human clinical study produced very encouraging patient outcomes, including case reports of durable response, or colloquially stated: "patients cured of their blindness".

The SalutarisMD technology delivers a single dose of brachytherapy (radiation) and is designed for use in an outpatient setting in as little as 15 minutes. Results of a small Phase I/II human study produced very encouraging patient outcomes, including case reports of durable response (or colloquially stated: "patients cured of their blindness"). The SalutarisMD technology was developed in conjunction with faculty at The University of Arizona and other institutions, and has the potential to provide greater efficacy (>50% versus 34-40%), reduce or eliminate the need for expensive monthly pharmaceutical injections, and result in significant cost-savings over emerging and current treatment choices.

In December 2016 the FDA cleared a 510(k) on the SalutarisMD's device, a significant commercial milestone.

As of today HOYA Corp (7741:Tokyo, $4.5B in annual sales, $17B Market Cap) has invested $5 million. HOYA's due diligence and ophthalmic market knowledge, we believe, substantively endorses the technology and market potential.

Part 2: Market and Industry Analysis

The current market for treating Wet AMD is $8 billion in direct pharmaceutical sales in the USA and EU markets with over 500,000 new cases of Wet AMD diagnosed each year.

Pricing for SalutarisMD's 2nd generation commercial device SMD-DA is forecast at $5,000 per use, compared with total lifetime drug costs for Lucentis® treatment exceeding $200,000, SalutarisMD's pricing structure creates a strong value proposition. 10% market share goal is a conservative estimate of achievable market penetration. The SalutarisMD technology represents a paradigm-shift from chronic medical treatment to definitive one-and-done treatment, and could become the next standard of care by improving patient outcomes and reducing treatment burden and costs.

SalutarisMD manufacturing partners have a long history of efficient and reliable distribution chains for ophthalmology applications and regulated radiation devices.

We are currently in discussions with leading ophthalmic sales distributors for certain Asian countries. We are also in discussions with EU distributors. Ultimately our exit partner will acquire/control distribution.

Competitors:

Medical Device Companies: Oraya Therapeutics' iRay device (x-ray therapy) , recently acquired by Carl Zeiss AG.

Current Pharmaceuticals: anti-VEGF drugs such as Roche Pharma (Lucentis, Avastin) and Bayer Pharma (Eylea). However, the SalutarisMD solution meets an unmet need of over 60% of the patients not responding to current anti-VEGF therapy.

SalutarisMD has a unique therapy with extensive worldwide patent protection. We have small yet successful human clinical study data. We have a hard to source nuclear materials supply chain secured as well as NRC (Nuclear Regulatory Commission) approval. Retina surgeon Key Opinion Leader backing. Leading medical center associations including a contract with UK NHS Trust Moorfields Eye Hospital.

Part 3: Go-to-Market Plan

SalutarisMD customers are retina specialists who treat Wet AMD. There are about 2,500 retina specialists in the US and 1,500 in the EU. SalutarisMD's first market is the UK's National Health Service (NHS) and Europe, as medical therapy choices are explicitly decided on a cost-benefit basis consistent with the benefits of our product. SalutarisMD is building awareness among retina specialists through presentations and publications by members of its Scientific Advisory Board (SAB).

Retina specialists will target using the SalutarisMD technology directed towards: 1) those 60% patients who do not fully respond to anti-VEGF therapy and 2) treat in a one-and-done procedure those 40% of patients responding to anti-VEGF that requires on average 6 to 12 intra-ocular injections per year.

In the UK, we have met with the National Institute for Clinical Evidence (NICE).

SalutarisMD's go-to-market development plan involves the production and manufacture of SMD-DA devices, subsequent testing in a clinical study first at the University of Arizona, then at Moorfields Eye Hospital in London, and early adopter commercialization in Europe (UK and Germany) in 2017. To successfully capture market share, we are in discussions with leading ophthalmology device sales companies to distribute the device globally.

A large pivotal study to support UK approval and FDA clearance needed for broader market adoption. To support the product roll-out, SalutarisMD has incorporated a UK subsidiary in London.

Part 4: Technical Product Description and Plan

The **SMD device is a brachytherapy medical device** intended to treat wet-AMD in an outpatient setting in approximately 15 minutes. The technology delivers a one-time treatment of highly localized therapeutic radiation to the Wet AMD lesion. Substantial **published data** demonstrate radiation's efficacy. **SMD's Phase I/II clinical trial** treated a small cohort of patients and successfully showed the feasibility and safety of the device and surgical approach with **very encouraging patient outcomes**: durable response, return of vision, no additional interventions required as of two years, and absence of pathologic lesion. SMD data has been **peer reviewed** and presented at a number of international meetings. SMD plans to continue device testing in collaboration with UA, Moorfields Eye Hospital, Duke University, etc. **Results of clinical trials** inform the use of existing imaging modalities to calculate and deliver an optimal dose for therapeutic benefit based on individual patient needs. **Input from clinical experience, technical and surgical end-users** also inform the user-friendly, ergonomic device design are incorporated into SMD-DA. **Other radiation therapy efforts:** Oraya Therapeutics Inc, commercializes a complex externally delivered x-ray therapy in Fee for Service clinics in the UK, Germany and Switzerland, proving the market for radiation therapy of wet-AMD. The Oraya product is limited by high capital costs and maintenance issues. SMD has **strong IP protection** with a total of 57 issued patents and 23 patents pending, ideally positioning the SMD technology in key global markets.
Non-IP barriers to entry for developing a competitive radiation therapy are supply chain and regulatory hurdles. SMD has contracted with the leading radioisotope manufacturers. To market and distribute the SMD device, we are in discussions with leading ophthalmic channel marketers. They will provide additional expertise and experience to ensure compliance with all regulatory requirements. SMD received a FDA 510(k) in December 2016. We also expect to receive a CE Mark in Q1 2017. SMD has received a Sealed Source and Device Registration (SSDR) certificate in compliance with the Nuclear Regulatory Commission (NRC) requirements.

Part 5: Risk vs. Talent Narrative

The company has addressed the main risks associated with medical device development. They include the ability to develop the device, proving that it works, establishing physician buy-in, protecting intellectual property created and obtaining funding for the venture. We have previously developed and produced our first generation device (SMD-I) and tested it in a first into man US clinical trial, demonstrating that SalutarisMD can successfully manage the design, development, build and testing of a clinical brachytherapy device. We have shown physician willingness to embrace this technology based on significant endorsement from key opinion leaders within both medical physics and retina surgery. These endorsements come from world leaders in their respective fields at Moorfields Eye Hospital, Duke University Eye Center, Doheny Eye Institute at the Keck School of Medicine (USC) and University of Arizona.
Built around patented technology from a University of Arizona professor, the Company completely retooled the technology and procedure and filed additional IP. To date, the company has raised a total amount of $15.9MM
Briefly list and describe your key team members.
The SalutarisMD leadership team is composed of experienced executives, medical doctors, and PhDs highly accomplished in their respective disciplines, bringing robust experience and complementary skills in crucial areas such as health care, medicine, medical devices, and with proven records in regulatory affairs, new ventures, marketing and commercialization of new technologies. These scientists are associated with the University of Arizona, NIH, Harvard, Sloan Kettering, Stanford, Wills Eye Center (PA) and Moorfields Eye Hospital (London, UK), and other institutions.
SalutarisMD management is led by Dr. Laurence Marsteller, a physician and physicist with experience in finance and medical devices, who transitioned from the role of COO to CEO in June 2014. (http://salutarismd.com/laurence-j-marsteller-md/). Director of Engineering brings 10 years of engineering, medical product design, and management experience. Manager of Clinical Operations has several years of experience organizing clinical trials. Russell Hamilton PhD, co-founder: Professor, Physics Section Head, The U Arizona, Dept of Radiation Oncology. Previously: U Chicago; PhD Stanford.
The prime contractor for the second generation brachytherapy seed/device one of the world's leading developers and distributors of sealed radiation sources. The manufacturer of the sterile applicator is Arizona-based.
As the company grows in the future, it will recruit additional resources in engineering, program management, marketing and finance to support the development effort and commercialization of the device. The company is already identifying and recruiting from the existing biotech talent base within the State of Arizona and in the UK as discussed above.
Briefly describe any holes in your leadership team. What are your plans to address any recruiting needs in the next 18 mos?
SalutarisMD plans to recruit additional expertise in the next 18 months in marketing, sales, and finance to support development and commercialization of the SMD-DA commercial device.
Briefly list and describe your key advisors, and their contributions to date.
SalutarisMD's Scientific Advisory Board (SAB) is composed of key opinion leaders who are experts in the fields of ophthalmology, retina surgery, medical physics and radiation oncology with backgrounds from NIH, Harvard, Sloan Kettering, Stanford, Wills Eye Center (PA) and Moorfields Eye Hospital (London, UK)
Members include department heads at major research universities with experience in clinical trials, including trials sponsored by the NIH. Please see http://salutarismd.com/company/scientific-advisors/ for additional information.