NanoFOD:
Assessment of the Technology

I&E 281: Basics of Technology Commercialization

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I. Abstract

Nano-Scintillating Fiber Optic Dosimeter (NanoFOD) is a cutting edge radiation detection technology. NanoFOD consists of radiation detecting nano-materials along with a DAQ system to measure radiation. It operates by quantifying and measuring emitted photons when radiation interacts with the nano-material. Electrons are released and the diode/DAQ system is used to convert the physical response into a digital signal that the computer can read. NanoFOD technology has a sub-millimeter diameter, which allows for minimally invasive insertion into the human body with extreme precision. While the technology has capabilities to contribute to several different fields, the ideal customers are hospitals and cancer treatment centers that perform radiation therapies and have the capital and infrastructure to adopt the new technology. With patent protection and pending 510(k) approval, NanoFOD is equipped to surpass its competition, most of which consists of inferior products incapable of real-time in vivo radiation measurement.

II. Customer Identification and Segmentation

The advantages of NanoFOD, namely its small size and real-time data acquisition capabilities, allow for its implementation in various different industries such as nuclear power plant radiation and food irradiation monitoring. In national defense and border control, radiation detection allows for screening of vehicles, passengers and goods entering and exiting the country. Resulting potential customers, therefore, include various government agencies such as the Department of Homeland Security, the Department of Agriculture, and the Department of Energy. Bureaucratic complexities coupled with the necessity to win government contracts in these segments reduce the appeal of these applications. However, Nano-FOD has tremendous potential in the healthcare industry. Medical applications in radiation therapy drive an anticipated compound annual growth rate of 5.54% in the radiation detection industry in the next four years (TechNavio 17). Therefore, NanoFOD would be best implemented in the healthcare industry, in which the nuclear medicine imaging and therapy treatment market was valued at $16.9 billion in 2015 (TechNavio 17). With patent protection in medical applications and pending 510(k) approval, the healthcare industry is the clear target market for NanoFOD.

Within the healthcare industry, the market can be segmented into doctors, hospitals/cancer treatment centers, patients, and insurance companies. Narrowing the ideal customers to hospitals and cancer treatment centers allows for abundant access to patients and the technical and financial resources to adopt NanoFOD technology. Further segmentation divides the hospitals and treatment centers by type of treatment performed. We've identified internal radiation therapy and the external radiation therapy as target treatments. Brachytherapy is a form of internal radiation therapy where localized radiation is injected into tumor cells. Most treatment centers offer external beam therapy as well, where x-ray beams attack cancer cells through the skin. By targeting hospitals with brachytherapy and external radiation therapy, NanoFOD maximizes its value provided to doctors, patients, hospitals, and insurance companies, alike.

III. Value Proposition

NanoFOD provides value to each of these market segments for both internal and external radiation treatment. Most importantly, patients are able to receive more effective treatment and be healthier as a result. NanoFOD is undergoing 3 clinical trials, one at Duke, one at Wake Forest, and one at UNC. The results have indicated a consistent dose measurement accuracy within 20% of Treatment Planning Software. 50% of the trials had an accuracy within 7%. (Belley 98). For context, in rectal cancer therapy, for example, a study showed that there is greater than 40% variance from the intended radiation dose. (Belley 53). Because no device capable of in vivo real-time radiation measurements for radiation therapy exists on the market, doctors currently don’t know how much radiation they are giving their patients and could be over-radiating them or under-radiating them without any knowledge. Furthermore, “acute symptoms of overexposure might only be showing when it is too late to do something to correct the treatment” (International Atomic Energy Agency). It is unclear how many people are being affected by wrong doses of radiation because there is currently no real-time measurement tool on the market. However, 147 cases of over-radiation were bad enough that they were reported to the Nuclear Regulatory Commission in 2009 and 2010 (Richardson).
Under-radiation would result in less effective treatment and the patient would have to undergo more rounds of radiation therapy, costing hospitals, insurance companies, and patients time and money. Over-radiation causes very drastic effects on patients including nausea, vomiting, headaches, diarrhea, seizures, coma, and even death (CDC). A study showed that between 2 - 12 people per year die due to radiation treatment, with a median number of deaths of 4 per year (Mulcahy). A hospital in New York city killed a tongue cancer patient in 2010. In June of 2009, a Philadelphia hospital gave the wrong radiation dose to more than 90 patients with prostate cancer. In 2005, a hospital in Florida acknowledged that 77 brain cancer patients had received 50% more radiation than prescribed due to incorrect programming. Dr. John J. Feldmeier an expert on the treatment of radiation injuries from the University of Toledo estimates that 1 in 20 patients will suffer injuries due to over-radiation. (Bogdanich). Using NanoFOD in these situations could help reduce error making treatment more effective, alleviating unpleasant side effects, and even saving lives. Naturally, this extreme value to patients provides value to the rest of the parts of the health system. Hospitals and cancer treatment centers will all want to have this product to provide the best care. This will not only positively affect the reputation of the hospital, but also lower liability. Doctors will be able to do their job much more effectively with the live stream of data of exactly how much radiation they are administering to a patient. Insurance companies would also benefit because having healthier patients leads to lower costs. NanoFOD has already demonstrated accuracy and efficacy in clinical trials and it seems to be safe but is awaiting 510(k).

IV. Market Opportunity

The market need and opportunity for radiation measurement technology of this kind cannot be overstated. There is a need for the monitoring radiation dosing accurately and therefore administering safe and effective treatment. There are an estimated 15MM cancer patients in the US and two thirds of them receive radiation therapy. There is a need for accurate targeting and dosing of radiation. Targeting and dosing are directly linked to either positive or negative outcomes in cancer treatment. There is also a need for proper quality assurance and safety that NanoFOD fills. With current treatments, the risk exists for incorrect administration of radiation and the inability to monitor or prevent it. The biggest risks are with human error and equipment malfunction. If radiation is dosed incorrectly, a patient can become very sick and even die. NanoFOD can reduce the risk of improper dosing significantly because of its accurate and effective monitoring of radiation, which can prevent any overdoses before they happen. About 75 radiation therapy accidents severe enough to be reported to the Nuclear Regulatory Commission occur each year, and this number will be reduced by the efficacy of NanoFOD in treatments, as well as prevent any improper dosing because of its real-time monitoring radiation monitoring technology (Richardson 2012).

NanoFOD will compete in the medical radiation detection, monitoring, and dosimeter market. The founders of NanoFOD have identified two prices, a bundle unit price for all of the technology at $17,500 and a disposable sensor, which will be disposed after each radiation treatment, at $25. There are 2,400 radiation therapy centers in the US and 23MM radiation treatments per year. Each center that would purchase the NanoFOD bundle unit technology is expected to purchase 3 units at $17,500 (Bond). If they capture 25% of their available market, the market size would be $175,250,000, at 50% capture the market size would be $350,500,000, and at 75%, $525,750,000. As a point of reference, the founders estimated their market capture at around 72% with a market size of $500MM. NanoFOD is revolutionary in radiation monitoring, detection, and dosimeter markets, and the founders have recognized their potential success with confidence.

V. Regulatory Environment

To enter the health care radiation therapy (RT) market, the first round of regulations which the Nano-FOD must pass are administered by the FDA for medical devices. Per Professor Hallford, medical devices include “any agent designed to diagnose, treat, or prevent disease through any process other than chemical action.” As the Nano-FOD plans to prevent incorrect radiation administration by providing accurate radiation readouts, it is categorized as a medical device, and must follow FDA guidelines for medical use. Medical devices fall into three potential categories - Class I, Class II, or Class III. Since the device “was considered to be a non-significant risk device, when categorized according to the definitions given by an FDA
guidance document” (Belley, 2015) it can be categorized as a Class II device. Furthermore, “non-significant risk rating was arrived at due to (i) no additional surgery or procedures were necessary that could lead to potential harm of the patient, (ii) the device itself did not present a serious health risk to the patient, (iii) the device was not a permanent implant, (iv) the device was not used to support or sustain human life, and (v) the device was not impacting the standard of care via a diagnosis, cure, or treatment of the disease” (Belley, 2015). As the device has been classified as a Class II device, it only requires a 510(k) if it can be deemed “substantially equivalent” to predicate devices.” The 510(k) pathway is significantly easier and less expensive than the alternative approval pathway, labeled a PMA or Pre-Market Approval.

As the device will be classified as a Class II device, it is possible for the device to be brought to market without clinical trials if the creators can prove substantial equivalence to devices already approved by the FDA. However, the device’s current regulatory status is somewhat unique because the device has been developed by a university lab focused on primary research rather than an entrepreneur or medical device company trying to bring a device to market. After speaking directly with Nano-FOD developer William R. Kenan, Jr. Professor of Chemistry, Michael J. Therien, it has become clear that the device is currently in regulatory limbo. This is because rather than attempting to bring this device directly to market, the creators are hoping to prove the device’s efficacy through clinical trials aimed to draw potential investors or buyers before pursuing a 510(k). While pre-510(k) talks with the FDA were initiated in November of 2014, the Nano-FOD has only reached the stage of clinical trials.

Before beginning the clinical trials, the creators submitted an IDE, or Investigational Device Exemption. This exemption provides the creators with the ability to begin performing clinical trials. The Nano-FOD was in 2 clinical trials expected to end in November of 2014. At the time, the creators were also in talks with the FDA to assist in preparing the 510(k) submission. Proposals to the FDA were planned for the summer of 2015. However, the clinical trials were not aimed at receiving FDA approval; rather, the clinical trials were aimed at attracting investors, entrepreneurs, and medical device companies for a potential sale (Interview with Professor Therien). As of April 2017, the device is still undergoing clinical trials at Wake Forest University Hospital, University of North Carolina Chapel Hill University Hospital, and Duke University Hospital. So far, 20 patients have been recruited for clinical trials by lead radiation oncologist, Terry Yoshizumi, and more patients are currently being recruited (Interview with Professor Therien). Once the efficacy of the device has been proven, the creators hope to develop a fully working market prototype before approaching the FDA for 510(k) approval.

While the original creators of the device will likely not bring the device to market, whoever purchases the device should consider the regulatory path for medical devices in the global market. The creators of the device believe that the device will provide significant value to countries with less developed medical systems, so the company bringing the device to market should consider global regulatory pathways (Interview with Professor Therien). Regulatory pathways differ significantly from country to country. However, the US generally has one of the more stringent regulatory pathways, so a device approved in the US will likely be capable of receiving approval in most countries (Interview with Professor Therien). Countries in Western Europe and Eastern Asia generally have regulations of similar severity as the US; however, countries in Eastern Europe, South America, Africa, Eurasia, and South-Southeast Asia will generally have less severe regulations, and it is more likely the device gains regulatory success in these regions.

As of now, while the device is not yet 510(k) approved, the device is well positioned to gain FDA approval should the device end up being brought to market (Interview with Professor Therien). At this point, the future of the device lies more in the hands of the market than with the regulators.

VI. Intellectual Property

The developers of NanoFOD have a patent (WO2016093942A2) that was filed in 2015 and published in 2016. The patent includes an extensive list of claims that thoroughly define the technology. The most critical claims are as follows: Claim #1 outlines that the patented technology is a system comprised of a real-time radiation detector with a controller consisting of a memory and a processor. This detector also determines either the location or the dwell time of the radiation source. Claim #3 and claim #4 discuss the safety interlock
feature that reduces or eliminates the radiation in the case of over radiation being detected. Claim #7 describes the technology as a fiber optic scintillation detector and claim #8 specifies that the device is biocompatible. Finally, claim #23 defines the calibration function which determines the dose that is absorbed.

One concern surrounding the intellectual property is that an extremely similar technology called BrachyFOD published a patent in 2009, seven years prior to NanoFOD. This patent is much more specific about how the technology of the fiber optic scintillator works and about manufacturing methods, while the NanoFOD patent is more focused on specific features and functions of the technology. We believe that since the NanoFOD patent is not claiming to have invented fiber optic scintillation, but rather is utilizing this known technology in a more effective way and with novel features, it differentiates itself enough to not infringe on the existing patent, giving NanoFOD freedom to operate. An additional positive point is that because the patent is new, it will still be valid through 2036.

VII. Competitive Analysis

The key competitors in the space of radiation detectors are ionization chambers, metal oxide semiconductor field effect transistors (MOSFETs), and thermoluminescent dosimeters (TLDs). However, there are crucial problems with each competitor that limit their potential for commercialization. All of the current radiation detectors are either too large, cannot withstand the radiation and therefore do not have enough durability, or the time to produce the needed results is too long. The ion chamber is considered the “gold standard,” of radiation detection because of the accuracy it provides. However the problem with the ion chambers is that it is too large. As Belley describes “Ion chambers may range in size from 0.1 cm$^3$ to in excess of 1800 cm$^3$” (Belley 15). Due to the size of the ion chambers it would be impossible to convert this technology to produce real time results because it would not be feasible to use an ion chamber inside a living body.

The more comparable competitive radiation detectors, MOSFETs and TLDs, have their own problems. Although these alternatives are smaller and therefore would be stronger competitors, they are not small enough to provide safe results during brachytherapy. In addition, another key difference between NanoFOD and these other technologies is the time to produce the desired results. Both MOSFETs and TLDs do not yield the radiation readouts until after the procedure is completed, making them essentially useless in preventing harmful radiation effects. Although the main competitor is the TLDs, they can not produce live results and therefore are an inferior product to the NanoFOD.

NanoFOD solves all three problems: it is small enough to be safely placed inside a living human, the optical fiber can withstand radiation, and since it can be inserted in the body it can relay radiation levels in live time. The fiber system of the NanoFOD allows the product to withstand radiation as well as be small enough to be placed inside the body. Notably there are other competitors attempting to use similar optical fiber systems.

The size difference between the ion chamber, MOSFET, and NanoFOD is extremely significant. The NanoFOD’s small size, coupled with its ability to withstand radiation allows it to be inserted in-vivo during radiation treatment giving it the clear competitive edge over its competitors. The NanoFOD has a dominating advantage in this market and should not seriously worry about their competitors because the NanoFOD is truly a superior product.

VIII. Go-to-Market Strategy and Funding

As a broad outline for our go-to-market strategy, we’ve identified several key value inflection points, or steps that the product should achieve that will increase its value in the market. All of these seem obtainable in 5 to 10 years. The first value inflection point is completing clinical trials to prove the efficacy of the device. Next, is the development of a final, accurate, working prototype. Once seed funding has been acquired, 510(k) approval is the next logical step in the regulatory process so that the technology can be used across the US. The following two steps are important in achieving economies of scale -- developing relationships with manufacturers and establishing DAQ partnerships with external beam companies so that the product is compatible with equipment at every hospital. This will allow for expansion to numerous hospitals. Finally, global regulatory approval is the last step for gaining value, allowing the product to reach millions across the world, especially in less developed countries where demand could be even higher due to inaccuracies in system calibration.
There are several potential sources of funding that this product could attract, and this is a top priority for the team at this time. At the product’s current stage, it would be most appropriate for an angel investor or VC firm to provide seed funding that will allow the technology to gain 510(k) approval and continue to develop, before it is potentially acquired at a later stage by a larger company. Developing a final prototype and getting approved are steps that can be taken with seed funding, but the later value inflection points that involve achieving scale are much easier to accomplish with access to the resources and relationships that larger firms can provide, and an acquisition by a larger medical device company would make the most sense at a later time.

Pricing is an important element of later stage go-to-market strategy. Pricing in this context can be thought of from both the top-down and bottom-up perspectives. Starting from the top, the value of the solution the product provides can be hard to quantify since this technology could potentially save lives. Another method could be starting from the additional procedures or pain and suffering that are avoided as a result of using this product. The probability of losing this value, followed by the probability that this product prevents a person from losing this value could bring us to a potential price that patients and doctors may be willing to pay. This pricing scheme is not realistic because it is impossible to place value on someone’s life, and the team has the best interest of the patients at heart with the ability to create an affordable product. From the bottom-up perspective, starting from the unit cost of materials, this approach builds up other associated costs and whatever premium the firm may desire in order to arrive at profits. This allows for the founders to maintain an affordable product while determining margins and the premium necessary to keep the company profitable. The most likely pricing model that this technology would implement in the market would be the razor/razorblade model. This would involve initial installation followed by perpetual replacement of the fiber and crystal scintillator pieces, allowing for a continuous stream of revenues for whomever is selling the device.

As a part of our go-to-market strategy, we have designed a target product profile (TPP) of our “needs” and “wants” in order for NanoFOD to be viable at launch. In regards to safety, NanoFOD needs to finish the process of obtaining 510(k) approval from the FDA before it can be launched. In regards to accuracy it needs to have consistent dose measurement accuracy within 20% of Treatment Planning Software and an angular insertion dependence of less than 2% in order to be considered better than the current standard of care. Other needs are those that are required for the logistics of launching the product including manufacturing and distribution as well as a partnership with at least one of the companies that produce the external beam machines used in radiation therapy to ensure that our DAQ software is compatible with their machine. A final need in order to ensure that the NanoFOD is effective, is to have sales representatives who can train the hospital employees who will be administering the treatment how to properly use the NanoFOD technology. In order to achieve the developers’ goal of 72% market capture, we have several “wants” that will help to achieve this goal. We want our clinical trials to prove consistent dose measurement accuracy within 7% of Treatment Planning Software. This accuracy within 7% has been demonstrated for 50% of treatments in the early clinical trials and we believe the technology is capable of this high bench mark. If this want is achieved, NanoFOD will be far and away better than the current standard of care and will. Ideally, we would also want to successfully develop partnerships with all three companies that produce external beam machines, rather than just one. Additionally, we would like to obtain global regulatory approval in order to expand into the global market.

IX. Conclusion

After performing a thorough analysis of the NanoFOD technology, our team has decided that if we were a team of investors with a strong background in medical devices and the available funds necessary to take the product to market, we would invest in NanoFod. We have arrived at this conclusion because NanoFOD satisfies an important unmet market need that none of the current technologies can, allowing NanoFOD to dominate the competitive landscape. Additionally, this product is for a large and growing market, with an estimated market capture of over $500M. Also, the product itself is cheap to produce, allowing for large profit margins using a razor-razor blade business model. The product’s IP is already protected with a patent and it is on its way to obtaining the necessary 510(k) approval from the FDA. The current developers believe they would only need an additional $700,000 in funding in order to take the product to market. Because of all of these reasons, we believe that NanoFOD is a worthwhile and profitable investment.
References


