Aurora Plasmonics

Providing non-invasive methods for blood clot treatment.

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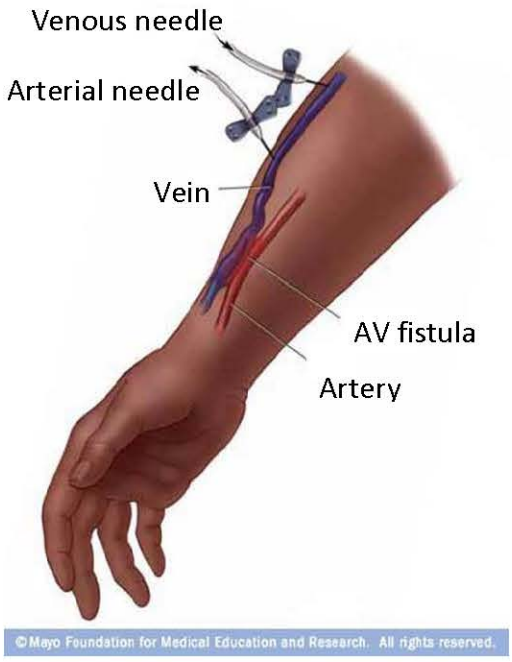
The Problem

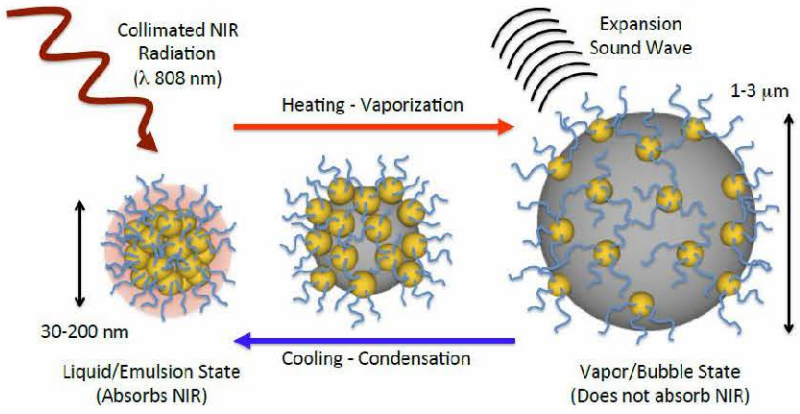
In the United States more than 10% of the adult population has some degree of chronic kidney disease (CKD).[1] Of the more than 20 million adults with CKD, 871,000 were diagnosed with end-stage renal disease (ESRD) in 2009 and 400,000 were being treated with some form of dialysis, costing the United States over $40 billion.[2] During dialysis, vascular access is typically obtained through an arteriovenous (AV) graft or AV fistula (right). Fistulas are becoming increasingly popular due to their ability to mitigate complications. Unfortunately, thrombosis (blood-clotting) is prevalent in both AV grafts and fistulas, leading to about 300,000 de-clotting procedures per year. Once a blood clot forms, either mechanical (e.g. angioplasty and stent) or chemical (e.g. thrombolytic drugs) techniques are used for de-clotting. Unfortunately, these methods are risky and invasive, often requiring long and costly hospital stays. There is currently no commercially available product that can non-invasively de-clot AV grafts or fistulas without the use of thrombolytics.



An AV fistula being used for dialysis.[3]

The Solution

Aurora Plasmonics is developing a new, cost-effective, theranostic (diagnostic and therapeutic) agent for use in non-invasive de-clotting procedures. This agent is based on patented nanoparticle emulsion technology utilizing the unique optical properties of plasmonic nanoparticles. These properties allow Aurora Plasmonics to combine photoacoustic and ultrasound techniques to simultaneously break up and image clots. The major benefits of this technology include the low cost, non-invasive nature, and elimination of dangerous hemorrhaging and stroke risks associated with thrombolytics. Due to the non-invasive nature of the procedure with our particles (requiring a device very similar to a standard ultrasound machine), our technology can take de-clotting out of intensive care rooms, drastically reducing the financial burden on the hospital. Additionally, our technology



Aurora Plasmonics' patented theranostic emulsion techlnology.[4]

lowers procedure times by avoiding the "lyse and wait" approach used with thrombolytics. Unlike current techniques, our agent can be used to visualize the clot and monitor the treatment. In these ways, Aurora Plasmonics provides a technology that increases treatment effectiveness, ultimately saving time, money, and improving outcomes.

Market

Market Overview

The worldwide dialysis industry is a $77 billion business with an average 6% growth rate.[5] In 2007, there were 2.2 million patients worldwide who received dialysis treatment.[5] The dialysis industry is segmented into medical devices (hemodialysis machines, catheters, etc.) and healthcare services, of which healthcare services constitutes the larger portion. The United States is the biggest player in the worldwide industry, providing 61% of the total service market.[5]

Initial Target Market: Declotting in AV fistulas and grafts.

Declotting procedures fall under the healthcare services section of the total dialysis market. In the United States, the average cost of declotting is $3,000.[6] With roughly 300,000 declotting procedures done annually in the US, Aurora Plasmonics is addressing an initial target market close to **$1 billion** in the US alone. Aurora Plasmonics will target this market initially due to the greater competitive advantage provided by the non-invasive nature of our technology. If regulatory hurdles prove to be limiting in the US, Aurora Plasmonics plans to address the foreign market, which is typically easier to enter and still provides a $600 million initial target market. Ultimately, both markets will be served.

Future Market: Deep Vein Thrombosis (DVT)

Due to the ease of integration with current catheter technology, Aurora Plasmonics will enter DVT market after establishment in the initial target market. Around 600,000 people in the United States are affected by DVT.[7] Of these, 100,000 will likely die from the associated pulmonary embolism and about 300,000 will have long term complications. DVT patients are currently treated with anticoagulant drugs such as heparin and Warfarin, which usually require nearly a week of treatment.[8] The associated costs with this type of drug therapy ranges from $2394 to $3369.[8] Therefore, the calculated DVT market is approximately **$1.8 billion**.

Competition

Aurora Plasmonics offers a product that takes advantage of the unique properties of nanoparticles. With the addition of an infra-red laser light source to a traditional ultrasound set-up, our product uses an oil emulsion decorated by gold nanoparticles to improve imaging and perform therapy. Any imaging facility that possesses an ultrasound machine could easily be adapted to use our technology. Aurora Plasmonics offers the **only diagnostic and therapeutic** system that is both **non-invasive** and does **not use thrombolytic drugs**.

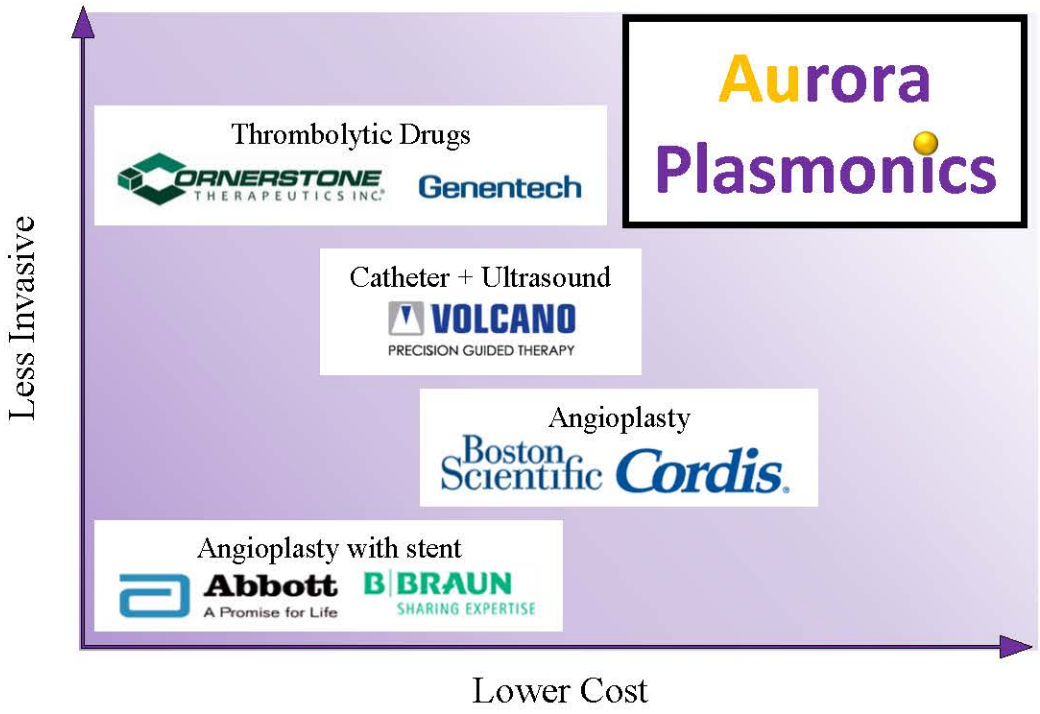
Summary of Benefits

- **Non-invasive**
  - Treatment can be done outside of intensive care facilities, improving allocation of rooms and resources, and **reducing costly in-patient care**
  - Invasive techniques can cause damage to vessel walls and may need to be repeated or replaced due to narrowing of the vessels
- Treatment of clots with **no need for thrombolytic drugs**
- Simultaneous **treatment and imaging**
- **Versatility** in therapeutic and diagnostic applications (for example, could be studied for enhancing contrast for the imaging of targeted tumor tissue, via a targeting agent functionalized onto the nanoparticle)

A main competitor would be Volcano Corporation, a specialist in precision guided therapy for endovascular imaging, stenting, and angioplasty.[9] Volcano Corporation has a product which combines intravascular ultrasound with an invasive angioplasty balloon catheter.[10] Aurora Plasmonics offers a product that will combine ultrasound with **non-invasive** destruction of clots.

Other competitors provide thrombolytic drugs and materials for invasive angioplasty treatments. For thrombolytic drugs the patients must be treated and monitored over multiple hours (and sometimes days). Potentially life-threatening hemorrhaging or bleeding can occur during the use of thrombolytic drugs. The drugs may not be effective against older clots, in which case mechanical force may be needed for clot removal. The use of catheters and stents in angioplasty can result in infection, additional thrombosis, hemorrhaging, and injury to the vessel wall.[11]

Competitive Space



Go To Market Strategy

Aurora Plasmonics' go-to-market strategy will proceed in three major stages.

Stage 1: Product optimization pre-clinical trials
In stage 1, Aurora Plasmonics will further develop our product at the University of Washington. This product development phase is necessary to refine and optimize our technology for stage 2 and to begin the needed testing for the FDA approval process (pre-clinical testing). In stage 1, funding will be acquired internally to the University of Washington such as from the Center for Commercialization, SBIR and STTR grants from the federal government, as well as other funding sources. Stage 1 will last between 1-3 years and will minimize product development costs through the use of university facilities. The determination of appropriate dosage size from this and later phases, and the cost of raw materials, will elucidate the pricing of our product.

Stage 2: FDA phase I clinical trials
In stage 2, Aurora Plasmonics will move into the FDA approval process. Because Aurora Plasmonics has created an entirely new type of technology, there is no predicate device on the market and premarket approval (PMA) is required by the FDA. Funding for Phase I clinical trials will be obtained from additional grants, left over funding from stage 1, and angel investors. Phase I clinical trials can cost between $200,000 and $1,000,000 and last about 2 years. Due to the bio-safe materials used by Aurora Plasmonics, we expect the cost to remain at the lower end of this range. In this stage, Aurora Plasmonics will utilize connections to the UW Medical Center and users such as interventional radiologist Dr. Wayne Monsky, who has already expressed a great need for our product and desire to use it, to improve our presence in the market.

Stage 3: FDA Phase II clinical trials and beyond
Aurora Plasmonics will require large financial assistance to complete the remainder of the FDA approval process. Due to the nature of medical devices and the regulatory hurdles, an additional hundreds of millions of dollars will be needed to complete clinical trials. With highly successful Phase I trials, it is possible to entice a VC firm or medical device company to invest or partner with a company. Additionally, an early acquisition exit at this stage is possible with the appropriate results from stage 1. With the proper investment and/or industrial partner, Aurora Plasmonics will complete phase II and III clinical trials in 3-5 years. With FDA approval, Aurora Plasmonics will move into the declotting market, which will be primed due to the support from interventionalists who have vetted our technology and will stand behind it. Aurora Plasmonics will sell directly to hospitals and medical facilities, initially with a contracted marketing and sales force. Ultimately, Aurora Plasmonics will branch out into the DVT market, by integrating our technology into the current ultrasound catheters.

Traction

Aurora Plasmonics has achieved numerous of traction gaining milestones. In the early stages of product development, optimizing parameters is crucial and several have already been achieved

by the research team. These results will be presented at the Undergraduate Research Symposium in the spring at the University of Washington. Additional fundamental research behind this technology has been published several peer reviewed journal articles and has been presented at several international conferences. Due to the promising nature of our technology, Aurora Plasmonics has filed a full international patent on our technology (PTC/US13/62896 on October 1, 2013). In addition to the technical traction, Aurora Plasmonics has contacted the Center for Commercialization at the University of Washington and has met with future users to discuss the need that our technology addresses and the willingness of interventionists to support and use our product.

Financials

Aurora Plasmonics' financial projections are built around stages I and II of the go to market strategy. To decrease initial burn rate, pre-clinical R&D will be conducted in lab space rented from Department of Chemical Engineering at the University of Washington. Assuming a total cost for FDA clinical trials of $300 million, Aurora Plasmonics will be able to make it through both pre-clinical trials and Phase I of FDA clinical trials with current funding. Funding for the first 4 years will come from an NSF grant, Small Business Innovation Research (SBIR), a Lawrence Award, and other funding for senior capstone design projects, totaling around $1 million. In year 3, Aurora Plasmonics plans to seek $53 thousand in additional funding through early stage investment.

In order to complete phases II and III of FDA clinical trials, Aurora Plasmonics will require around $27 million and $273 million, spread out over 2 and 3 years, respectively. The actual cost will vary, depending on the success of the testing process. Aurora Plasmonics plans to address these needs through a strategic partnership with a medical device company, such as Volcano Corporation, as well as funding from angel investors who specialize in biomedical devices. Successfully completing Phase I of clinical trials should de-risk Aurora Plasmonics enough to make this possible. Ultimately, Aurora Plasmonics aims to be a stand-alone company or become acquired by a large medical device company. Should phase II and III clinical trial tests prove too expensive to complete, Aurora Plasmonics could liquidate its assets and license patents for continued R&D.

Financial Projections (in thousands of dollars)

	2014	2015	2016	2017
Funding	$60.00	$220.00	$250.00	$500.00
Total R&D Expenses	$57.50	$104.00	$303.00	$303.00
Gross Income	$2.50	$116.00	($53.00)	$197.00
				Net Gross Income **$262.50**

Management Team

Jess Little is a senior in UW Chemical Engineering with a passion for collaboration, business, and change. He is conducting research on how to control the size the nanoparticle-decorated emulsions that make up our product. Additionally, he is the lead outreach coordinator with the professional community.

Michael Lombardo is a graduate student in the Department of Chemical Engineering at the University of Washington. His research focuses primarily on the self-assembly of plasmonic nanoparticles for biological applications. Michael is leading this undergraduate research team to commercialize his research as a part of his 2013 GAANN Fellowship in collaboration with the O'Donnell lab in Bioengineering and the Applied Physics Lab at the University of Washington. He has applied for and received $5,000 dollars in funding towards this commercialization project.

Rainie Nelson is a senior at the University of Washington. She is majoring in Chemical Engineering with a focus on Nanoscience and Molecular Engineering. She is interested in research in colloidal and surface science as well as fundamental polymer science. Her current research involves the functionalization of gold nanoparticles with cationic thiols and the use of these nanoparticles to create oil emulsions.

Sim Yee Chen is a UW undergraduate majoring in Chemical Engineering with Nanoscience and Molecular Engineering emphasis. She is interested in research related to synthesize metal nanoparticle in order to develop effective synthesis method of nanoparticles with controlled dispersity.

Advisors:

Dr. Lilo D. Pozzo is an associate professor of Chemical Engineering at UW. A large portion of her research revolves around the characterization of nanoscale structural and morphological changes and their effects on material properties. She also serves on the advisory board for PolyDrop, winners of the 2013 EIC at UW.

Dr. Matthew O'Donnell is a professor of Bioengineering at UW. His lab is conducting research that supplements Aurora Plasmonics' product. He has commercialized a number of biomedical technologies out of his lab and sits on a number of company boards in the local Seattle area. Additionally, he uses his experiences in biomedical entrepreneurship to teach a course on technology commercialization.

Dr. Wayne Monsky is a specialist in vascular and interventional radiology, and is well-acquainted with the current state and needs of the target market. He has already commercialized a catheter-based declotting device and is interested in creating devices that are less invasive, cheaper, and more effective.

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