

UltraVision's Proposal for Investment

UltraVision Corporation seeks an equity investment of \$5 million to fund several projects we intend to develop and divest at exceptional valuations.

UltraVision Corporation can be viewed today as having four assets:

- 1) The Company itself, which will continue the research and development of new ultrasound products.
- 2) The royalty stream from Cadwell Industries Inc.
- 3) The Spinal Division, which is designed for divesture.
- 4) The Breast Division, which is designed for divesture.

After divesting these businesses, UltraVision Corporation will continue to innovate new ultrasound technologies when exceptional opportunities occur. UltraVision has a backlog of many new opportunities, with high customer demand, ready for when resources are available.

UltraVision is currently concluding negotiations on the divesture of its manufacturing to Cadwell Industries, a medical manufacturer in the neurodiagnostic space, where Cadwell has been granted an exclusive territory. Cadwell will also become a supplier of products to UltraVision for products outside Cadwell's territory.

The Spinal Division is an exceptional opportunity where we invented an ultrasound product to guide the placement of pedicle screws in the spine. This product we are developing, the PediView, solves a significant problem in a high-cost procedure in a high-volume market where we are the first to invent and patent.

In the Breast Division, we are expanding the use of ultrasound to visualize and discriminate microcalcifications with our proprietary methods. One type of these microscopic particles is an indicator of early breast cancer, and another is not. Until now, there has not been a commercially viable way of discriminating between the two, so hundreds of thousands of unnecessary biopsies are performed in the US annually. We are again developing a robust intellectual property portfolio in a large market.

UltraVision is designing an ultrasound system for sales over the internet exclusively. This specialized Point of Care Ultrasound System covers all the needs of a very profitable and diverse market.

UltraVision Corporation has PowerPoint presentations and other documentation, including financial data, that will be copied to the Data Vault. Interested parties may request printed or emailed documents, however, we strongly prefer to present and demonstrate our capabilities at our facilities in North Palm Beach.

1) About the UltraVision Corporation



UltraVision Corporation is the new name of WinProbe Corporation, which was changed for better commercial recognition. It effectively is the same company just "doing business as," as defined by the states of Florida and Delaware. UltraVision (WinProbe) is a Delaware corporation registered to do business in Florida.

The company was founded by Guy Scott in October 1999 with the innovative idea that an ultrasound system could be built in a large Field Programmable Gate Array (FPGA). The innovation was stalled by the availability of a suitably large FPGA, which finally arrived in 2005. So UltraVision was just a shell for several years.

At this time, Guy was consumed with his other innovations in another company he had founded (called Cross Match Technologies, a fingerprinting company). In 2012, Cross Match was sold for \$240 million, so Guy had sufficient funds to support UltraVision's further development of the scanners selling to many research institutes worldwide.

Guy's efforts moved to UltraVision in 2005, and he won ten grants from the National Institutes of Health over the next five years totaling more than \$4 million to develop the UltraVision scanners. Commercialization began with supplying Original Equipment Manufacturers (OEMs) that needed an ultrasonic scanner in their equipment but did not have the technology. It was also beneficial for these OEMs to utilize UltraVision's regulatory approvals with the Food and Drug Administration (FDA). Some examples of these companies are 1) Sonavex Inc, for a blood flow analysis on transplanted tissue, 2) SonoVol Inc. (now Perkin Elmer), for a mouse scanner for the pharmaceutical industry, and 3) Cadwell Inc, for neuromuscular diagnostics.

The original innovation that an ultrasound system could be made in a large FPGA facilitated an unprecedented platform for algorithm development. The raw ultrasound data can be processed in the gate array, which can be configured on the fly from the PC to perform mathematical algorithms in massive parallel calculations in nanoseconds. This critical feature uniquely allows the algorithms to be performed in the UltraVision products and to be highly cost-competitive.

The UltraVision line of scanners is designed to be manufactured by OEMs, and among its many features has an encrypted key that secures our royalty revenue. We have calculated a pie chart for an ultrasound system's revenue distributions diagram (next page), so we charge 15% of the retail price for engineering design and support.

The low cost of construction and reliability makes UltraVision scanners very conducive to be a retail product sold only over the internet. We have, however, some issues to address before internet sales become a reality in late 2023. The first is weight. The current machined aluminum case has many benefits in precision and strength, but it alone weighs two pounds. Kyle Matheson, our Production Manager, has developed the technology of 3D printing and is perfecting a plastic case that can be printed on a desktop at a rate of one per day with one \$2,000 printer and a materials cost of \$40. Once we achieve volume we can take his perfected Computer-Aided Design straight into injection molding for an even lower price. The goal is for the weight of the scanner will be less than five pounds, including a built-in Microsoft Surface Pro 8. The second issue is cardiology. This is the largest segment, by cost, of the ultrasound market. We have yet to develop experience in cardiology which is part of the general practitioner market. We will gather this knowledge in a project for a Chinese cardiac developer. The world market for all ultrasound scanners today is more than 200,000 scanners per year.

Being constantly bombarded by companies and individuals to build a scanner for their market, we have become very selective in what we spend our time on. A Chinese Company has expended considerable funds copying Oldelft's (a Dutch Company) design of an intervascular cardiac 4D ultrasound transducer catheter. This Chinese company has no ultrasound engine and has approached us to interface and supply 500 scanners per month of the UltraVision-R ultrasound engine. This forecast is possible based on the size of the market and the Chinese production cost and margins compared to the Dutch price, but not probable due to the Chinese company's size. Oldelft supplies these 4D catheter transducers to GE, Siemens, and Philips, who charge approximately \$2,000 per catheter for one-time use. Initially, we see the Chinese company paying us to develop the cardiac requirements for an ultrasound scanner. We can use that knowledge in our UltraVision-C scanner for retail sales over the internet for the general practitioner.

Our UltraVision-C Scanner

The market size for a Point Of Care Ultrasound System (POCUS) is more than 20,000 systems per year in the US. Our UltraVision-C fits in this POCUS segment which has high growth, is well-supported and has excellent user education

Questions Answered by Point-of-Care Ultrasonography That Are Applicable to Family Medicine

Use	Yes/No Question
Abdominal aortic aneurysm screening	Is there an aneurysm?
Cardiac	Is there left ventricular systolic dysfunction? Is there left ventricular hypertrophy? Is there a pericardial effusion? Does the patient still have fluid overload?
Deep venous thrombosis (for a video of this test, see https://youtu.be/ M0JmjOOg10M)	Is there a deep venous thrombosis?
Hepatobiliary	Is there cholelithiasis? Is there cholecystitis? Is there hepatosplenomegaly? Is there steatosis of the liver? Is there ascites?
Musculoskeletal	Is there a fracture? Is there ligament or tendon pathology? Is there a joint effusion? Is the median nerve enlarged, suggesting carpal tunnel syndrome?
Obstetric	Is there an intrauterine pregnancy? What is the fetal presentation? Is there a heartbeat? What is the gestational age?
Ophthalmologic	Is there a retinal detachment? Is there a vitreous hemorrhage? Is the optic nerve enlarged, suggesting increased intracranial pressure?
Procedural guidance	Is the needle/catheter/endotracheal tube in the proper location?
Pulmonary (for a video of this test, see https://youtu. be/WOlz8-km6hE)	Is there a pneumothorax? Is there evidence of pneumonia? Is there a plural effusion? Is there evidence of pulmonary edema?
Skin and soft tissue infections	Is there an abscess?
Thyroid	Is there a lesion on the thyroid?
Urologic	Is there hydronephrosis or evidence of nephrolithiasis? What is the postvoid residual volume?
1	

available. UltraVision-C performs all the applications in the adjacent chart. The scanner has been well-tested and is so reliable that it can easily support a five-year warranty. Selling POCUS ultrasound products over the internet has yet to prove successful but is inevitable due to the alternative high marketing costs.

It will require a significant commitment to providing a website with training and support, but these could be just links to already existing websites.

This complete scanner system will have a cost of goods of under \$9,000 and a retail price of at least \$25,000, so it has a gross margin of 64%.

Being priced under \$30,000, it can be purchased without cumbersome committee approvals in most hospitals for the ER, OB/GYN, ambulances, and patient rounds for common applications like Deep Vein Thrombosis.

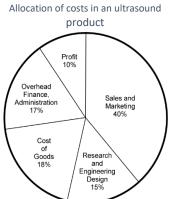
The UltraVision-C has a Microsoft Surface Pro 8 tablet embedded, serving as the user interface/viewing screen, and will utilize our current software suite.

The UltraVision-C would be manufactured at Cadwell's facilities, and arrangements would be made to ship from Cadwell directly to the end user.

As the system can be equipped with unique functionality to support leasing, this has been seen as an excellent source of revenue.

exceptional value. This method may be slow to start, but as

In the latter half of 2023, UltraVision will release the UltraVision-C, complete with three transducers: one cardiac, one abdominal, and one for small parts all included in this \$25,000 price. Internet sales allow the cost of sales and marketing to be reduced to 20%, so the Cost of Goods can increase to 35%, giving the buyer



Note: This is not an exhaustive list, and studies continue to find new applications as the use of point-of-care ultrasonography increases.

references and word of mouth increase about our value, so would the volume.

Selling ultrasonic scanners over the internet has previously failed except for the lowest-cost scanners like Butterfly or Chinese handheld units. The high cost of marketing in producing up-to-date literature and attending symposiums, combined with the high price of selling which includes travel/physician lunch outings/ and loaners, all comes to about 40% of the cost of the product. At some point, the brochures will be replaced by URLs, the visits will become zoom meetings, and demonstrations and training will be on YouTube.

Our vision for the UltraVision-C sales program is that it will eliminate any deficiencies in the sales method by product design. Firstly, if the scanner is to be shipped as a demonstrator with perhaps a small deposit, it must be inexpensive to ship. When a demonstrator looks used, its case must be inexpensive and easy to change. Ideally, if the

physician or sonographer has a problem, the system should be able to run via remote control from a team at the factory. This team must be able to review the images created in the clinic transparently and at any requested time. This need can be contracted to sonographers as long as the scanner has this feature and images are viewed remotely. Lastly, if the physician is in default of his lease or rental agreement, the factory should be able to turn it off until payments are resolved, or the product is returned.

The UltraVision-C will have all these features by November 2023. This will take some product development costs in the case design and software features. Initially, we will work with a leasing company that can run the credit checks and has financial liability. Still, there is a great incentive to run the leasing or rentals internally, as the company is leasing a \$25,000 product with a cost of less than \$9,000.

We would expect minimal sales at the program's start while we build user referrals in a managed net-based system to overcome customer hesitations. This allows us to offer a product for \$25,000 that would be competitive with \$50,000 to \$70,000 products today. As the market itself grows, the UltraVision-C business is likely to grow in time to 20,000 units per year worldwide or a total sales volume of \$500 million.

UltraVision-C Project Budget (All numbers are in thousands of dollars.)

- 1) Case design in plastic and EMC Compliance
- 2) Cardiac software and FDA compliance
- 3) FDA, meetings, consultants, legal, and application
- 4) Construction of commercial websites for credit cards
- 5) Initial inventory





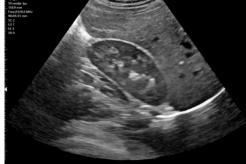
300 Total \$750,000

200

100

100

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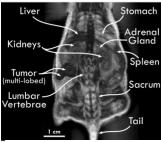


UltraVision-R Kidney and Liver

UltraVision's Future Endeavors

Another typical example of companies approaching us for design and build projects is Aspire, which wants a compartment syndrome product. Compartment syndrome is where a limb is involved in a traumatic accident, and the blood flow is restricted from leaving the limb, so it becomes pressurized and, if not recognized and treated in the ER or ambulance in time, the limb will be lost. We found a unique ultrasound algorithm to measure the pulsatility of the facia of the muscle, and the pulsatility of the artery, to diagnose this condition. It is a litigious issue if not diagnosed and treated in time. This will result in sales to ambulances, emergency rooms, and the military. Here we could partner with a low-cost, hand-carry scanner from China, but for now, the project is in storage, awaiting resources.

Many companies have approached UltraVision to design and develop ultrasound products, and if we see an opportunity and have the resources, we may accept the challenge. We have, for example, accepted a project from Sonovol Inc to design the next-generation scanner. Supply chain issues have embarrassingly delayed this project as it uses the latest components. Still, it is coming together now that Sonovol will get exclusive use for small animal studies where they can better visualize the moving parts in mouse hearts with a 30-megahertz transducer. We will also get the next generation of ultrasonic scanners with the assistance of Sonovol (now Perkin Elmer) funds.

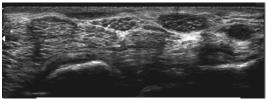


UltraVision-R image of a mouse

2) Cadwell Industries Inc

The first divestiture was a royalty agreement with Cadwell Industries Inc, where Cadwell will manufacture the UltraVision-R scanner. This conforms to our formula: UltraVision receives 15% of the product's retail price. Cadwell will also become a contract manufacturer for products UltraVision sells outside Cadwell's territory of Neuromuscular products.

The forecast for Cadwell becomes 1,400 scanners within three years at today's retail price of just over \$20,000. Further development work for Cadwell is considered out of the scope of previous projects and will be negotiated for compensation for new design efforts by UltraVision but, of course, will increase their sales. We are excited about these, as Cadwell has proven to be an excellent marketer. These projects requested by Cadwell assure their accelerated market growth.



Wrist showing medial nerve, tendons, and vessels

At Cadwell's request, our president and chief software engineer, Charles Scott developed unique software algorithms that diagnose amyotrophic lateral sclerosis (ALS), vastly increasing Cadwell's business competitiveness. Cadwell, which ordered 250 scanners in 2022, will require 500 in 2023 and will grow almost exponentially after that.

This manufacturing demand, coupled with the semiconductor supply chain issues, convinced us that we should allow Cadwell, already a manufacturing company of several hundred million in sales, to be licensed to manufacture the UltraVision-C scanners themselves. We will then purchase from Cadwell our other scanner sales needs. As we have the PediView, the Microcalcification projects, and the next generation of scanners in the final tests, our resources are strained. We find it more rewarding to conduct research and development, than product manufacturing, since innovation is our main strength.





The UltraVision-C

3) Spine - The Pediview

The second divesture opportunity is the PediView spinal navigation system, which is in development and is planned for completion in July 2026. From the beginning, this project was designed to be acquired by one of the world's ten largest medical device companies.

A comparison acquisition was Medtronic's purchase of Mazor Robotics which has the same function as Pediview. Medtronics paid \$1.6 billion for a robotic navigation system that costs the hospital \$850,000 per system plus \$1,500 of disposables. This Mazor system can be developed into other robotic surgery applications like the brain or general surgery and is being adopted by the "major medical centers." However, most of the 352,000 spinal fusions performed in the US annually are performed in surgical centers, which do not have a budget to add a million-dollar surgical robot to their capabilities.

The PediView transducer is aimed solely at reducing the misplacement of pedicle screws. The Pediview could become part of the recommended standard of care and may be used in its one-time disposable form in most spinal fusion procedures worldwide. The Pediview is projected to cost the hospital \$1,500, which is trivial compared to the \$40,000 to \$300,000 cost of the procedure.

We have been evaluating multiple methods of implementing the conceived functionality of the PediView and filing provisional patents every two months. We are extensively patenting the PediView because once seen by competitors, it could be copied, given the market size and value. In about six months, these provisional patents will start to be turned into nonprovisional patents pending, and our patent costs will escalate.

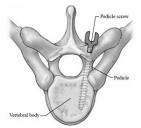
After a well-negotiated sale, we estimate the acquisition value of the spinal division to be well over \$100 million. A partial list of potential acquirers for the Spinal Division includes: Medtronics, Johnson and Johnson, Stryker, Globus, Boston Scientific, Zimmer Biomet, Alphatec Spine, and NuVasive. All have a history of acquiring technology in the \$1 billion range.

We have been approached by several spine surgeons asking for a small interoperative transducer to assess the

surgical field during spinal surgery and to look for debris like bone chips. In discussions with Dr. Charles Theofilos, now a board member, we have conceived a product called the PediView, which addresses the problem of awl navigation. The awl is used to push into a pedicle bone's marrow creating a hole for the screw to follow into the vertebrae.

The accuracy of the placement of this hole is at the forefront of all spine surgery supply companies' concerns. A misplaced pedicle screw is the most common and significant cause of surgery failure and, the largest cause of litigation, patient discontent, and pain. All these multibillion-dollar companies are looking at using MRI and CAT with robots to guide with fluoroscopy and surgical tools in a 3D rendering with price tags of around \$1 million per installation. These robots (like the Mazor) take significant time to set up each patient, involve





more X-Ray radiation, and if a fiducial marker falls off, the setup requires a total reset. The Pediview has none of these deficiencies and provides a real-time image for the navigation of the awl.

The PediView is exciting as our developments have determined its low manufacturing cost (<\$300) and provides an 80% gross margin. The PediView is designed to be disposable, and its one-time use is justified as there is a requirement for sterility and the possibility of spreading *Creutzfeldt-Jakob disease* cannot be sterilized.

A spinal fusion requires a scaffold that prevents motion between the vertebrae. The frame is secured to the vertebra with screws through the pedicle bone. Placement of the hole for the pedicle screw has been an art as the screws are most commonly 5 to 7mm in diameter, and the Pedicle bone can be less than 8 mm across in parts. Any misplacement of the pedicle screw too near to a wall can result in the screw breaking through the cortical wall (hard outer shell of the bone) of the pedicle bone and touching the nerves, which causes the patient severe pain and potentially severed nerves, and then a loss of functionality for life. The hole that aligns the pedicle screw is usually created free hand with an awl. The surgery, especially for scoliosis, can involve more than 20 vertebrae with a screw on each side, totaling 40 screws. The failure rate for placement of the screws varies between 4 to 6 percent if done well. It's generally recommended by all to avoid spinal fusion whenever possible, yet there are these 352,000 surgeries per year performed in the US.

Robotic pedicle placement devices vastly improve accuracy but at a cost \$850,000 and uses X-rays. Today most spinal fusion surgeries are done in surgery centers, not hospitals, where the robotic cost is prohibitive.

UltraVision is developing a titanium awl with a piezoelectric element at the proximal end connected to an ultrasound system pictured to the right. A motor rotates the awl, so when the tip

of the awl is in the pedicle bone, the surgeon can view the walls of the bone from inside the bone in real time. Our device is called the PediView and is supplied sterile for a one-time use for a projected \$1,500. PediView's projected production cost is less than \$300. The average spinal fusion procedure costs between \$40,000 and \$300,000, so the safety, improvement, and liability assurance from using the PediView is well justified.

Being ultrasonic and not emitting radiation, the Pediview inherently does no harm to the patients, the surgeons, or the operating staff. The Pediview, having a 3mm shaft, will be used with all the vertebrae that one patient's procedure needs, and then it will be discarded.

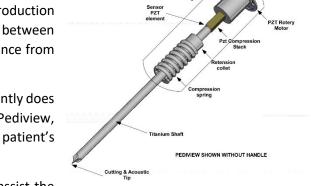
The UltraVision Scanner can record the entire operation and assist the surgeon by documenting the procedure, where litigation often arises.

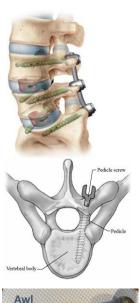
UltraVision aims to develop this product, attain FDA approval, attain a positive key opinion leader consensus, and then sell the division to a large company already in the business. The companies that have become aware of the project already have a very positive view of the PediView.

The product's market is the number of spinal fusions performed each year without navigation. At least ten large companies are committed to this market and have a high capability of supplying PediViews for the market's needs. The surgeons see the benefit of the radiation-free operation and the real-time quality of the images provided.

Faced with limited alternatives, there is a controversy over the free-hand placing of pedicle screws (which is today the majority of operations), where studies find this 4-6% of mispositioned pedicle screws. The implications of a mispositioned pedicle screw are patient pain, incapacitation, and subsequent litigation. Spinal surgery is among the highest litigated specialties due to the possibility of permanent disability. There is a risk posed by instrumentation placed near vital neurovascular structures, and the unforgiving nature of the spinal cord and nerve roots can lead to traumatic injury caused by medical procedures.

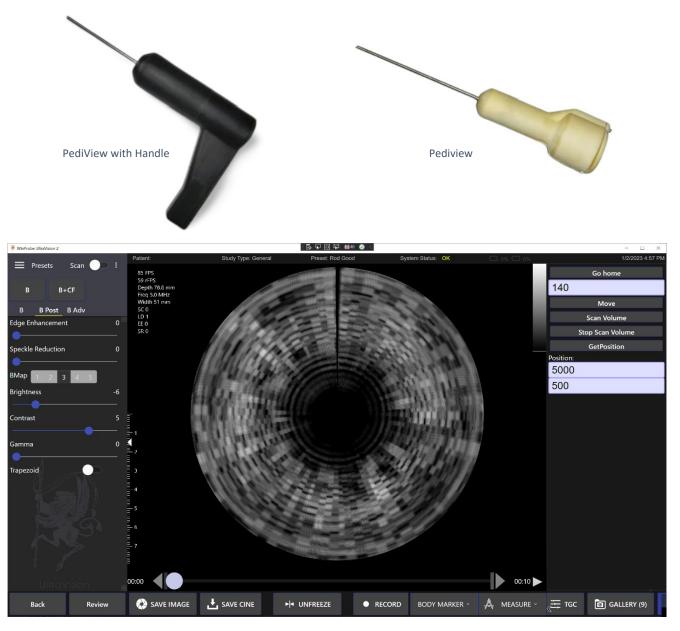
The original task of looking for debris and now locating the best place to start the pedicle screw hole will be met with a miniature phased array courtesy of our Chinese project.





Going back to 2014, we find a comparable acquisition to the PediView, where Philips acquired the company Volcano for \$1.2 billion for its specialized transducer intervascular product line (similar to our Chinese Project). The total US market size with competitor products included is \$600 million. The PediView addresses a larger market, and its patent protection should ensure its dominance.

The world needs an affordable solution to pedicle screw placement. As we have stressed, the consequence of misplacement is significant. UltraVision plans to develop the PediView through FDA compliance and Key Opinion Leader referrals and then sell the division. This Spinal Division should be valued at well over \$100 million within three years with a suitable investment today.



PediView Engineering image of inside a cow bone

The PediView has been an engineering challenge, which is why it is in such an open field for intellectual property. The physics of sending ultrasonic pulses down a titanium rod and then at the distal end into tissue and having the echoes return from the tissue into the rod and back to the piezo sensor at the proximal end is exceptionally challenging. The efficiency of moving acoustic energy between titanium and tissue is approximately 10%, which must occur twice in the PediView, so we gather the image with 1% efficiency mixed with reverberation from the 90% reflection energy internally in the rod. We have explored many methods to increase this efficacy and have finally found elegant mathematical algorithms to separate the small signals from the ever-present but repeatable reverberations and noise. We will continue researching methods to improve the efficiency for the product's long-term success so that some costs will be incurred in this further research.

Tecomet Inc., a surgical tool supplier to the spine market, has a factory locally in Rivera Beach, where it specializes in machining titanium for surgical instruments for all the major spinal surgical companies we see as targets for this division's acquisition. It also helps that this factory was sold to Tecomet by the Davis family, who are members of our Board. Having Tecomet build the initial PediViews is a considerable advantage, as our acquirer will already have qualified Tecomet through all their regulatory requirements.

We will complete the PediView in its current form within months, and the next step will be submitting it for FDA approval. Technically it is just another transducer, so usually, the FDA only wants us to document the transducer's acoustic power outputs, which we can conduct in-house, but as a scanner, we have changed its "use case." It is also similar to an awl that was used before 1976, so it is potentially grandfathered in. Our functionality claims then become an issue with the FDA, so they should be minimal. Once we secure FDA approval, we can move to field tests on patients, which should be more of a promotional effort with a small design effort. We will request an initial meeting with the FDA to discuss the route to approval, as electrical safety, sterility, and operator manuals with warnings will be examined. We will also need to seek legal advice to insulate liability exposure in the user instructions in the operator manual.

The current plan is to select ten Key Opinion Leader (KOL) surgeons and supply them with everything needed to conduct the tests. We are budgeting 300 PediViews, as they are disposable onetime use devices, so that most surgeons would be allocated 30 operations. The surgeons would be selected and supervised by Dr. Charles Theofilos.

The initial concept of the PediView was to include a piezo stack for cutting through the cortical bones so we could cut with the tip (distal end) of the rod through the cortical outer skin of the pedicle bone and thus save one more instrument in operation. This feature is included in the provisional patent, and we chose not to have it in the initial product to simplify the engineering and approvals effort. To start, we can build many of the components of the PediView with printed parts, but when we get to the 300 PediViews for the KOLs, we will change them to machined titanium so they can support the forces produced by a stack. The stack can provide a "hit" of 200 pounds at a frequency of 50,000 hertz so it will have more safety considerations.

We started development with a \$200 piezo stepper motor, then moved to an \$80 electro-magnetic stepper motor, and are now working with a \$14 geared and encoded direct current motor. Our initial production budget was \$300, using off-the-shelf titanium rods and printed parts, which is now estimated to be under \$100. We have yet to discuss with Tecomet their production needs as they have a unique cleaning process for titanium and can sterilize the product in an operation room-ready plastic sterile tray. For the first 300 PediViews, I have budgeted \$1,000 each due to the low volume and first article preparations that Tecomet will need.

If necessary, Dr. Theofilos will perform tests on pork pedicles and possibly cadavers to write the operator manuals, which may have associated costs. We will also need to supply up to 10 UltraVisions for the KOLs to perform their tests, but these systems would be on a short-duration loans. We will have multiple review meetings with the KOLs that may lead to product design changes. Travel will also be needed to demonstrate and install systems with the KOLs. We have an agreement with Dr. Theofilos that he will get 30% of the selling price of the spinal division.

Most of our target acquirers will hear about the PediView in the upcoming months. Still, we also plan on demonstrating it at a few spine symposiums to attain excitement for the highest acquisition price for the division.

Spine Project Budget

All numbers are in thousands of dollars.

1)	Acoustic efficiency research in the titanium rod	200
2)	Patenting and securing intellectual property	50
3)	Tecomet interface, custom design, cleaning, sterilizing, and packaging design	300
4)	FDA, meetings, consultants, legal, and application	100
5)	Preproduction PediViews	300
6)	Installation training, travel, meetings, reviews, and changes	300
7)	Symposiums, meetings, consultants, legal, and marketing	<u>300</u>

Total \$1.55 million

4) Breast Division – CA-Mode

The fourth asset is our method of visualizing and differentiating microcalcifications in breast cancer (CA-mode). In the domestic (US) market, we foresee more than 10,000 systems sold yearly. Then there is the international market of similar market size. And, then again, there are the low-income countries which is a third market supported mainly by charities and USAID. Today, over six hundred thousand women die annually from breast cancer. The worldwide market for CA-mode scanners is more than \$1 billion in sales annually. The differentiation of Type I (benign) from Type 2 (cancer) is critical here in the US, where 1.2 million women undergo biopsies, and 80% are unnecessary. In the third world, where mammography is a financial impossibility, the UltraVision scanner equipped with these new algorithms will serve as a low-cost, real-time, radiation-free, arguably better diagnostic method than mammography. The timing of this divesture is late set for late 2026 after the clinical trials are concluded at Memorial Sloan Kettering Cancer Center in New York. The probable list of acquirers for the Breast Division is Hologic, Philips, Siemens, GE, and Canon. They all have a history of acquiring technology in the billion-dollar range.

Charles Scott developed (and is patenting) the algorithm for the visualization of breast microcalcifications which will be extended to the differentiation of breast calcifications. As the algorithm does not increase the acoustic power output, the FDA requires only a 510K approval for the trivial "use-case" change. Memorial Slone Kettering Cancer Center (MSKCC) is planned to perform clinical evaluations with the help of various grant sources at the NIH and DOD.

Over the past three decades, the availability of breast cancer screening by mammography in the US has been responsible for a 43% decrease in mortality by diagnosing women with Ductal Carcinoma In Situ (DCIS), otherwise known as Stage 0 cancer. When detected and treated early, DCIS has been reported to have a cause-specific survival rate of 100%, but if not treated, it can progress to invasive breast cancer associated with a mortality rate of 3.36% in the next ten years.

The Breast Imaging Reporting and Data System (BIRADS) has provided a standardized breast imaging lexicon built around mammography. This X-ray technology detects microcalcifications (MCs) and can see structural deformities or lesions. BIRADS is used to interpret the positions of the found MCs, as some patterns that are more indicative of cancer than others. For example, BIRADS 3 carries a management recommendation for short-term follow-up, whereas the more severe finding of BIRADS 4 recommends a biopsy.

The 38 million mammograms performed in the US annually lead to 1.6 million biopsies which find just under 300,000 new cancer cases. Or taken another way, mammography, in the case of DCIS, produces 80% false positives and 1.3 million women undergo biopsies unnecessarily.

To date, it has not been possible to distinguish whether DCIS will progress into invasive cancer or not, so most radiologists choose to biopsy any found DCIS that has a BIRADS 4 score. DCIS is found by visualizing just MCs 60-90% of the time. Many benign conditions also present with MCs, resulting in these 80% false positive findings.

We propose to address the need to reliably differentiate benign and malignant MCs by ultrasound, significantly reducing the issue of overdiagnosis and, consequently, overtreatment.

There are two main chemically different types of MCs: Type I (calcium oxalate) and Type II (calcium hydroxyapatite). Type I MCs are seen most frequently in benign tissue and are rarely associated with breast cancer. Type II MCs are found in benign and malignant lesions but most often in proliferative lesions, including invasive breast cancer. Type II MCs appear to be produced by cancer and have a function in promoting cancer's mitosis.

At UltraVision Corporation, we have developed and are patenting an ultrasonic method to both visualize and discriminate between Type I and Type II MCs in vivo.

Our method, which we call the CA-mode, is unique and currently being patented in the US and Europe.

While creating an image, normal ultrasound transmission pulses create a very small push on the tissues in an amount proportional to the acoustic impedance of the material it passes through. In breast tissue, this acoustic impedance is 1.636 Mrayls; in MCs, this can be as high as 6.6 Mrayls for Type I and 11 Mrayls for Type II. This difference in acoustic impedance causes the MCs to absorb energy from the push and move (just a few microns and only for a few microseconds)

until they return to their original positions from their molecular bindings. We have developed a method to detect and present this movement as a noticeable visual difference fused in a color over a B-mode ultrasound image.

Our preliminary studies in breast phantoms show that Type II MCs can easily be visualized, so far, down to 40 microns in diameter. There is an assumption here that if cancer makes the Type II MCs, the smaller MCs that we can find, the earlier we can find cancer. For reference, mammography only detects MCs of over 100 microns. We are exploring and believe we can detect down to 10-micron MCs.

In our presentation, the MCs appear as short red axial streaks, making them very visible when fused in color over a B-mode image as in Type I MCs, which appear in this breast blood vessel image to the right.



We have tested our methods in PVA phantoms, pork, and humans and have always found every MC either implanted in phantoms or previously found by mammography in women.

We are further optimizing and testing our algorithm to discriminate between Type I and Type II MCs in a prospective feasibility study involving 20 patients at Memorial Sloan Kettering Cancer Center (MSKCC) in New York, NY. Patients with mammography-detected MCs recommended for breast biopsy (BIRADS 4) will be recruited. Subsequently, all these patients will undergo a stereotactic breast biopsy and histopathology, per the MSKCC standard of care. The biopsied specimens' pathology results will serve as the standard of reference for our analysis. Before the biopsy, all patients will be examined at MSKCC using our FDA-approved ultrasound system to detect and analyze suspicious MCs.

In the short term, the results from this study may serve as the foundation for a larger study where Type I and Type II MCs will be shown in different colors in real-time in the clinic. This larger study is to propose a hypothesis that is already popular today that if only Type 1 MCs are found in a lesion, the BIRADS score can be moved from 4 to 3, and biopsy can be deferred. The patient should be monitored until structural changes or Type II MCs are found, and this monitoring can be reduced over time.

In the long-term, our patented CA-mode that has the ability to discriminate between Type I and Type II MCs using a low-cost in vivo ultrasound test, may lead to the avoidance of unnecessary breast biopsies for hundreds of thousands of women annually in the US, and concomitantly, reduce undue patient anxiety, pain, and healthcare costs.

The market for selling an ultrasonic scanner equipped with MC detection and differentiation is at least 10,000 scanners per year in the US and the same in Europe. This is far too large a volume for UltraVision to manufacture and service, so we would prefer to sell the division to larger interested companies, like GE, Philips, Siemens, Canon, or Hologic, whom have already expressed an interest.

Studies have found that a handheld ultrasound used as an independent detection modality for breast cancer in low and middle-income countries maintained a diagnostic sensitivity of 89.2% and a specificity of 99.1%. Here, we aim to make an under \$20,000 scanner with MCs detection and differentiation. We would also equip it with shear elastography to view the stiffness of the tissue. This is another characteristic of cancer. We would make scanners available to lower-income countries funded by the United States Agency for International Development (USAID).

Access to mammography in these lower-income countries is restrictive, if available at all. Mammography costs \$200,000 to \$600,000 for the equipment, and maintenance costs several hundred thousand dollars annually. UltraVision may choose to keep or sell the low-cost product line separately to service these low-income countries.

We believe the availability of this new technology will dramatically reduce the deaths of the 685,000 women who die of breast cancer each year worldwide today.

This breast project will be largely funded by grants for the NIH and the DOD, and then we will seek divestiture. The "big three" (GE, Siemens, and Philips) have 70% of the ultrasound market and have gotten there by acquiring innovative companies. Canon, a Japanese company, acquired Toshiba's Medical Systems Corporation in 2016 for \$6.4 billion. Toshiba has claimed to visualize microcalcifications in the breast, but in multiple worldwide clinical evaluations, their method was found to be ineffective. Canon spent six billion dollars in acquiring Toshiba, and Canon may wish to clarify its claim to visualized microcalcifications, so it may also be a candidate acquirer.

During the NIH grant process, we can team with other researchers to develop other aspects of the CA-mode. Type II microcalcifications are also generated by cancer in different body organs like the prostate and thyroid. Type I microcalcifications grow in the urinary tract, becoming kidney stones.

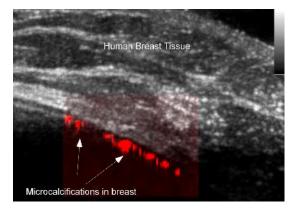
Due to many misdiagnoses from the difficulty in classifying microcalcifications, the Mammography Quality Standards Act (MQSA) was enacted by Congress in 1992 to ensure that all women could have access to quality mammography examinations to detect breast cancer early when it is most treatable. The MQSA Act has many consequences, including a website containing data on every clinic allowed to perform mammography in the US. This website details over 8,675 mammography clinics' conformances. These clinics utilize more than 25,000 ultrasound systems for determining solid vs. cystic. Cystic (liquid-filled) lesions are usually benign, but solid-filled require further investigation. Recently with the awareness of dense breasts, where mammography is compromised, ultrasound is now mandated for breast diagnosis in most states.

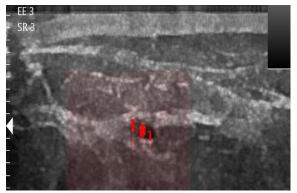
We now fully understand our method of the visualization of microcalcifications and its potential. We are confident that we can discriminate Type I from Type II microcalcifications and will complete the CA-mode discrimination task within six months. This task is new, as it has been only two months since we realized the true value of differentiation from recent discussions with Dr. Katja Pinker of Memorial Sloan Kettering Cancer Center (MSKCC).

The typing of microcalcifications, or as we call it, 'differentiation,' adds a new dimension to the value of this diagnostic biomarker. In research, dual-energy mammography can differentiate microcalcifications, but the method is more expensive and has yet to move into commercial availability.

Histopathology (the process of examining sections of tissue on slides under a microscope) with polarized light can identify Type I microcalcifications in excised tissue but, processing the excised tissue into 7-micron thick slices to view in the microscope can tear or crush the microcalcification, which has been identified by mammography and has at least a 100-micron diameter. This makes it challenging to visualize Type I's bifringence, the optical differentiation of the Type I microcalcification.

Our method of finding and differentiating microcalcifications adds a new avenue of cancer diagnosis, noninvasively, in real-time, and in vivo.





Human breast with three mammography proven microcalcifications in a cyst

Microcalcifications are also generated by cancer in other body organs like the prostate and thyroid, and these are most likely to be Type II. Microcalcifications also grow in the kidney and urinary tract. These can be seen clearly in CA-mode before they become greater than 1mm in diameter and are then known as kidney stones. These are Type I unless cancer is present.

Our method of finding and differentiating microcalcifications adds a new avenue of cancer diagnosis in vivo.

Breast	Project Budget (All numbers are in thousands of dollars.)	
1)	Programming the differentiation of MCs	200
2)	Securing patents and intellectual property	50
3)	FDA, meetings, consultants, legal, and application	100
4)	If FDA compliance is complex	100
5)	Acoustic power compliance	50

Total \$500.

Other Budgetary Costs (All numbers are in thousands of dollars.)

UltraVision Corporation has short-term loans to various banks and shareholder loans, which we would like to retire.

Budget for bank and shareholder loans

\$600.

UltraVision's Projected Use of Funds

UltraVision has taken orders with deposits from OEMs that cover its running costs and is finalizing an agreement with Cadwell Inc for licensing, and that alone will cover running costs and core needs for the foreseeable future.

UltraVision has three projects requiring additional funds, the UltraVision-C retail Project, the Spinal Project, and the Breast Project, that will bring suitably profitable outcomes. Their budgets are detailed herein.

The Breast project will be conducted simultaneously with the Spine project to an acquisition. Identified acquirers for the products of this project are Hologic, GE, Siemens, Philips, and Canon. This product may be sold to all or several of these companies, and our time frame is late 2026. We may also keep or sell the low-cost product line separately for low-income countries through the United States Agency of International Development (USAID). We may also keep the rights to CA-mode to include it in the UltraVision-C products. The value is in the volume of scanners that will be needed in this breast cancer segment of the market. The best estimate is that there are 25,000 scanners in mammography US clinics today.

Our first task is to file a provisional patent on our proposed discrimination methods. Our detection methods are already well covered by patents. Secondarily, we write and test the code, which will take two to six months. In April of this year, we will apply for NIH and DOD funding for clinical testing at MSKCC. NIH funding is instrumental as the NIH has negotiated costs that can be billed to grants, so such prestigious clinics like Memorial Slone Kettering have set workable fees for their services. Typically, the Institute of Cancer will allow up to \$400,000 for a Phase I grant, which, if successful, will be followed by up to a \$2 million grant for a Phase II grant. The only issue with the NIH grant process is the time it takes, so we are thus projecting an acquisition date for this company division to be in late 2026. The grant itself will generate awareness in the breast cancer community, so we will be approached by others seeking to develop their nuances of this new fundamental imaging method.

UltraVision's Financial and Legal Position

UltraVision has 21 investors and 15 employees or consulates who have been granted shares or stock options and one consultant who has been given a warrant under the company's Stock Incentive Plan (2016). There are 12,417,550 shares, 2,562,111 stock options, and 225,000 warrants, creating a total of 15,204,662 fully diluted shares outstanding as of 12/30/2022. \$1.50, making the company's capital \$22,806,993.

The company is seeking investment to fund the development of the PediView, Breast Project, the UltraVision-C launch, and general operations. The company sees the need for a \$5 million investment. Initially, \$3 million will be raised at \$1.50 per share. As the company becomes closer to divestitures, the company is forecast to increase the stock price to \$3 to \$5 to raise an additional approximately \$2 million if needed. The goal is to keep the company's outstanding shares under twenty million.

The divestitures currently planned for 2026 will result in substantial dividends returned to investors as the company is not expected to need these funds for further development. These dividends would be expected to be at least \$5 per share in 2026-2027 per divestiture and could be much higher. We expect these two divestitures will return at least \$100 million each in late 2026.

Guy Scott, combined with the Scott family trusts, owns about 70% of the company before this next investment round. Guy has invested more than \$8 million into the company and currently has loaned the company a further \$0.5 million.

UltraVision Corporation is incorporated in Delaware and registered as doing business in Florida. All employees have signed the company's nondisclosure, not-compete, and patent assignment agreements as held in the Data Vault.

UltraVision Corporation's board comprises nine people: Frank Gerardi as Chairman of the Board, Guy Scott as CEO, Charles Scott as President, James Davis Sr, Dr. Robert Bourke, Paul Papi, James Davis Jr, Eric Kraus, James Walsh, and Dr. Charles Theofilos.

The company has a Data Vault but struggles to maintain it due to research pressures. It is at <u>www.winprobe.net</u>, and the password is lucy and will be updated over the next few weeks as time permits.

The company has several websites, the foremost being <u>www.ultravisionusa.com</u>. All the sites will be updated and maintained in the second half of 2023 when the UltraVision-C becomes available for internet retail sales.

There is a Confidential Private Placement Memorandum, a Subscription Agreement, A Stockholders Agreement, a Stock Restriction Agreement, and a Confidential Investor Questionnaire, all available in the Data Vault and available in printed form to the interested investor that we ask for agreement before accepting an investment.

UltraVision has sales of \$1 million in 2022 and can expect to see royalties and sales of more than \$1.5 million in 2003. The royalties can be expected to double every year for the foreseeable future.

UltraVision Corporation has no pending or threatened legal actions.

The use of the funds is detailed in each of the projects herein.

Signature attesting to the best efforts for the accuracy of these documents.

Walter Guy Scott, CEO UltraVision Corporation Some of the information in this proposal may contain forward-looking statements. Although we believe that our plans, intentions, and expectations reflected in such forward-looking statements are reasonable, you should not rely upon our forward-looking statements because the matters they describe are subject to known and unknown risks, uncertainties, and other unpredictable factors, many of which are beyond our control.