

## Cellula BioPharma, Inc.

CONTACT INFORMATION

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**COMPANY INFORMATION** 

**CEO/President Name:** Magnus Hook

**Industry/Technical area of Interest:** Healthcare - Rx/Therapeutics

Subcategory (if any):

**Incorporation or Formation Date: 10.12.2022** 

State: Delaware

List Management Team Names: Dr. Magnus Hook, CEO

Dr. Xiaotong Song, CSO

### **BUSINESS SUMMARY**

Cellula BioPharma is an IND-stage biotechnology start-up that was founded in 2022 by entrepreneurs and scientists from Texas A&M in Houston, TX. The company has pioneered the development of a novel proprietary platform of chimeric antigen receptor (CAR) T cell therapy for solid tumors. Cellula's nucleotide metabolic reprogrammed CAR-T platform, known as MR-CAR, is designed by engineering CAR-T cells to express CD26 and a T-cell anchoring ADA1. The MR-CAR platform can be used in combination with different targeting CAR-T cells. Proof-of-concept and toxicity studies have been validated in three different mouse models. Small-scale production of lead product has been completed. Within three years, Cellula plans to complete the clinical-grade material manufacturing and submit an IND application for a phase 1 study to be initiated in Q1 2026. The company is currently raising \$5M in seed funding followed by \$10M in series A funding for IND enabling studies for liver cancer and lung cancer.

### **CUSTOMER PROBLEM AND SOLUTION**

The specific problem that our innovation addresses is that while CAR T cell therapy has represented a breakthrough in the treatment of blood cancers and has led to the FDA approval of six CAR-T products, CAR-T clinical trials targeting solid tumor have had very disappointing outcomes. CAR-T for solid tumors is limited by poor T cell trafficking and persistence, and an immunosuppressive microenvironment.

Cellula has developed a nucleotide metabolic reprogrammed CAR-T (MR-CAR) platform by engineering CAR-T cells to express (i) CD26 on the T cell surface and (ii) a T-cell anchoring ADA1 (Adenosine deaminase 1) fused with scFv(CD3). MR-CAR exerts its activities through different mechanisms.

- a) CD26 is critical for T cell mobility and improves T cell access to solid tumors.
- b) ADA1 irreversibly converts adenosine to inosine, releasing the adenosine-mediated immunosuppression.
- c) Inosine serves a carbon source for T cells in the absence of glucose, improving CAR-T persistence.

### TARGET MARKET

First, there is a sizeable market for GPC3-MR-CAR T cell therapy. GPC3 overexpression is found in HCC, sarcoma tumors, gastric cancer, colorectal cancer, non-small cell lung cancer, and thyroid cancer. Given that an estimated 48.8% of patients with GPC3 positive HCC, the market for GPC3 positive HCC therapy is estimated to be \$3.6 billion by 2027. Our proposed commercial product GPC3-MR-CAR T cells would target mainly these GPC3-positive HCC.



### **2023 Executive Summary**

Second, there is also a sizeable market for our commercial product HER2-MR-CAR T cell therapy. HER2 is a validated therapeutic target for a range of tumor types including breast, non-small cell lung cancer, and prostate cancer, which belong to the leading cause of cancer related death in the US. Based on Fortune Business Insights, the global lung cancer therapeutics market size is projected to reach \$48,725.9 million by 2026. HER2-MR-CAR T cells would target mainly HER2-positive NSCLC and the market is estimated to be \$12,000 million.

#### COMPETITORS

Cellula is developing two types of MR-CAR T cell therapies - Glypican-3 (GPC3)-MR-CAR T cell therapy for GPC3-positive hepatocellular carcinoma (HCC) and HER2-MR-CAR T cell therapy for HER2-positive non-small cell lung cancer (NSCLC). Standard-of-care agents still represent the major competitor. In developed countries, standard of care for cancer treatment includes surgery, radiation therapy, targeted therapy, and immunotherapy. In 2022, the FDA approved a HER2-targeted ADC (antibody drug conjugates), DS-8201, for the treatment of HER2-positive NSCLC. Other novel CAR-T approaches are also potential competitors, including the recently developed ADA1-armed CAR-T by USC/Stanford and the CD26+ CAR-T therapy developed by the biotech company Ares.

### **COMPETITIVE ADVANTAGE**

Recently, there has been a substantial shift towards low-toxicity, targeted, quality of life-favorable agents. This represents a major advantage for MR-CAR over standard-of-care and HER2-ADC since CAR-T specifically targets tumor without destroying normal tissues.

Moreover, MR-CAR has significant advantages over ADA1-modified CAR-T (USC/Stanford) and CD26+ CAR-T (Ares).

1)USC/Stanford CAR-T express secreted ADA1 or membrane-bound ADA1. However, secreted ADA1 may provide inosine to tumor cells, which could support tumor progression. Meanwhile, membrane-bound ADA1 can non-specifically activate T cells (clinical side effects) by engaging its receptor CD26 on T cells. Instead, MR-CAR express cytoplasmic ADA1, which only secrets in stress condition, providing a trans-signal to activate CAR-T in a tumor-specific manner.

2)Ares isolates natural CD26-high T cells to produce CAR-T, but the CD26 expression level in T cells is low. Cellula uses genetic approach to increase CD26 level in CAR-T.

### INTELLECTUAL PROPERTY POSITION

Three patent applications as described below, including two provisional patent application and one PCT application, have been filed to protect the technology. The patent applications cover the utilization of ADA and CD26 in T cell therapy for the treatment of tumors. The patents are owned by Texas A&M, and Cellula has been negotiating with the university since November 2022. The company will soon be able to obtain a license for the rights.

- 1) 63/238,927, Delivery of adenosine deaminase to cancer cells, immune cells and the tumor microenvironment, 08/31/2021
- 2) 63/355,396, ADA-CD3-scFv/CD26-overexpressed MRCAR-T cell therapy platform, 06/24/2022
- 3) PCT/US22/42193, Chimeric antigen receptor (CAR) T cell therapy platform, 08/31/2022

### SALES/MARKETING STRATEGY

N/A

### **EXIT STRATEGY**

Cellula's commercial strategy involves raising funds for an IND-enabling study followed by a Phase 1 study. The company's exit plan is to pursue IPO or M&A opportunities upon the completion of the Phase 1 study within the next five years.

## IP Summary: Cellula BioPharma, Inc.



Cellula BioPharma, Inc. – 0 relevant US patents found CEO Magnus Hook – 0 relevant US patents found CSO Xiaotong Song – 3 relevant US patents found (1 granted, 2 provisional, 1 PCT)

General Notes – TNVC application states that Cellula BioPharma, Inc. is negotiating with Texas A&M for the license to the rights to three patents, two provisional and one PCT (63/238,927 -- 63/355,396 -- PCT/US22/42193).

## Texas A&M University has verified Cellula BioPharmas's licensing agreement for their listed patents.

Notes on IP position and strategy from application:

Three patent applications as described below, including two provisional patent application and one PCT application, have been filed to protect the technology. The patent applications cover the utilization of ADA and CD26 in T cell therapy for the treatment of tumors. The patents are owned by Texas A&M, and Cellula has been negotiating with the university since November 2022. The company will soon be able to obtain a license for the rights.

- 1) 63/238,927, Delivery of adenosine deaminase to cancer cells, immune cells and the tumor microenvironment, 08/31/2021
- 2) 63/355,396, ADA-CD3-scFv/CD26-overexpressed MRCAR-T cell therapy platform, 06/24/2022
- 3) PCT/US22/42193, Chimeric antigen receptor (CAR) T cell therapy platform, 08/31/2022

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Chimeric antigen receptor (car) t cell therapy platform	WIPO PCT	Xiaotong Song Ruoning Wang Children's Hospital Abhijit Sarkar Yue Hu	Texas A&M, The Nationwide Children's Hospital	WO2023034408A1	Filed 08/31/2022 PCT Application

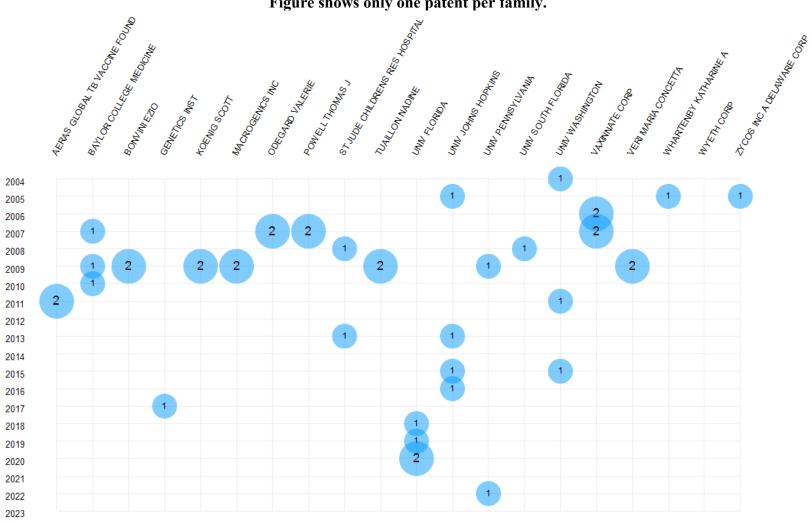
# Similar technologies: Patent Applications by Year



Search terms: ("vaccine immune regulator") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows only one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Modulating regulatory T cell activity via Interleukin 35	US Grant	St. Jude Children's Research Hopsital	US9518113B2	("vaccine immune regulator")	Similar application	Design and scope
2	Immune modulation by regulating expression of the "minor" gene in immune dendritic cells	PCT	Univ Johns Hopkins, Drew Pardoll, Katharine A Whartenby, Kevin S Gorski, Camie Chan	WO2005077048A3	("vaccine immune regulator'')	Similar application	Design and scope
3	Construction of chimeric antigen receptor targeting cd20 antigen and activity identification of engineered t cells thereof	US Grant	Cellular Biomedicine Group Inc	US11608369B2	Listed similarity to WO2023034408A1	Similar application	Design and scope

# Cellula BioPharma, Inc. IP: Independent Claims of WO2023034408A1



- 1. An engineered cell comprising a nucleotide sequence encoding an Adenosine deaminase (ADA).
- 2. The cell of any one of the preceding claims, wherein the cell comprises chimeric Antigen Receptor (CAR).
- 3. The cell of any one of the preceding claims, wherein the CAR comprises (which may or may not be in the following order, N to C terminus) an antigen binding domain, ADA, an extracellular linking domain, a transmembrane domain, a costimulatory signaling region, and a signaling domain.
- 4. The cell of any one of the preceding claims, wherein the ADA is a protein having Adenosine deaminase activity.
- 5. The cell of any one of the preceding claims, wherein the ADA is a human ADA or a derivative thereof.
- 6. The cell of any one of the preceding claims, wherein the ADA is a human ADA 1.
- 7. The cell of any one of the preceding claims, wherein the ADA is a human ADA 2.
- 8. A pharmaceutical composition comprising the engineered cell of any one of the preceding claims and a pharmaceutically acceptable carrier.
- 9. A method of treatment, wherein the method comprises administering the engineered cells of any one of the preceding claims to a patient in an amount effective for treatment of a cancer.
- 10. A recombinant oncolytic virus comprising a nucleotide sequence encoding an ADA, wherein the nucleotide sequence encoding the ADA is operably linked to a promoter.
- 11. A recombinant protein comprising an amino acid sequence encoding an ADA.

WO 2023/034408 PCT/US2022/042193

### **CLAIMS**

### What is claimed is:

1. An engineered cell comprising a nucleotide sequence encoding an Adenosine deaminase (ADA).

- 2. The cell of claim 1, wherein the cell is T cell, natural killer cell, natural killer T cell, dendritic cell, macrophage, mesenchymal stem cell, and derivatives thereof.
- 3. The cell of any one of the preceding claims, wherein the cell comprises chimeric Antigen Receptor (CAR).
- 4. The cell of any one of the preceding claims, wherein the CAR comprises (which may or may not be in the following order, N to C terminus) an antigen binding domain, ADA, an extracellular linking domain, a transmembrane domain, a costimulatory signaling region, and a signaling domain.
- 5. The cell of any one of the preceding claims, wherein the ADA is a protein having Adenosine deaminase activity.
- 6. The cell of any one of the preceding claims, wherein the ADA is a human ADA or a derivative thereof.
- 7. The cell of any one of the preceding claims, wherein the ADA is a human ADA 1.
- 8. The cell of claim 7, wherein ADA 1 is a secreted protein.
- 9. The cell of claim 8, wherein the ADA 1 comprises an optimized human IL2 signal peptide operably linked to the ADA, and a linker sequence and a human CD3 specific ligand, antibody, scFv, or its derivates.
- 10. The cell of claim 9, wherein the CAR comprises an amino acid sequence having at least 70%, or at least 75%, or at least 80%, or at least 85%, or at least 90%, or at least 95%, or 100% sequence identity to an amino acid sequence selected from the group consisting of SEQ ID NOS: 1, 3, 5, 7, 9, 18, 20, 22, and 24.



## Circle Concrete Tech, Inc.

CONTACT INFORMATION
Contact Name: Jeff Shi

Contact Phone Number: 352-222-3130 Contact Email Address: xijun.shi@txstate.edu

**COMPANY INFORMATION** 

**CEO/President Name:** Dave Kruse

Industry/Technical area of Interest: Transportation

Subcategory (if any):

**Incorporation or Formation Date:** 04.04.2022

State: Delaware

List Management Team Names: Dave Kruse, CEO

Dr. Zachary Grasley, CIO Dr. Xijun Shi, CTO

### **BUSINESS SUMMARY**

Plient concrete produces 20% less greenhouse gases, 20% less conventional air pollution, and consumes 64% less energy compared to conventional reinforced concrete based on our analysis. This is because 1) Conventional concrete uses non-renewable natural resources, while Plient concrete uses recycled materials. These "waste" materials are better disposed of when used in concrete than landfilled. 2) The production of steel rebar is the largest single source of greenhouse gases produced in concrete construction. The use of Plient concrete to replace conventional steel rebar reinforced concrete will lead to significant savings in carbon footprint and energy consumption. The annual production of recycled steel fiber from scrap tire is 0.63 million metric tons. Utilization of this steel fiber in Plient to replace conventional steel reinforcement will lead to a reduction in CO2 emissions of 222 million metric tons, which can offset 4% of the total annual CO2 emissions in the US.

### **CUSTOMER PROBLEM AND SOLUTION**

The concrete industry is emission intensive. The presence of rebar in concrete structures significantly slows down the manufacturing process. The use of recycled steel fiber from scrap tire in Plient to replace steel rebar will lead to significant savings in cost and carbon footprint. Furthermore, the use of Plient makes it possible to cast concrete structures with irregular shapes because rebar can be reduced or eliminated. This is particularly advantageous for 3D printed concrete structures, which are now being commercially produced in the US. The other impacts of commercializing Plient come from the disposal of the "waste" materials used in the final product. Reclaimed asphalt pavement is conventionally used in hot mix asphalt pavement, but the application has limitations such as pavement cracking issues. The recycled steel fiber is conventionally treated as ready-to-melt steel, which is a less economical and environmentally friendly application in comparison to direct reuse.

### TARGET MARKET

The precast pipe market is our target market. The US precast concrete pipe market is around \$7.8B. Pipe is the low hanging fruit for entry because of the already existence of an ASTM standard that accepts steel fiber reinforced concrete pipe. Currently, the pipe industry uses two steel cages for large diameter pipes. At a pipe company we interviewed, the automated fabrication of each cage and the time to cast a pipe are almost perfectly matched (about 4 minutes each). However, with two cages in the large pipes, the throughput is cut in half, meaning the pipe machine has to wait 4 minutes



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for the second cage to be produced. By using Plient Concrete, the outer cage can be eliminated, and pipe companies can roughly double the throughput in a given day. Second, many pipe companies want to become the pioneers in producing

more sustainable concrete pipes. Plient concrete contains a high content of recycled materials, which is very environmentally friendly.

#### COMPETITORS

The competitors of Plient are traditional steel reinforced concrete products, which include concrete reinforced by either steel rebar or steel fiber. These traditional reinforced concrete materials have been successfully used in daily construction for decades, so the transition from the existing technology to new technology can be challenging and may take a very long time. The construction industry is a "conservative" industry with high liabilities associated with the practice of designing and constructing concrete structures. Therefore, to introduce a new technology, de-risking is needed via targeted, full-scale prototyping and prove-out to generate data that demonstrate the viability of the innovation and inform the decision-making and specification development process. In the past few years, we have conducted both lab and field tests to confirm that Plient pipes without rebar can perform equivalently or better than conventional concrete pipes containing rebar reinforcement.

#### COMPETITIVE ADVANTAGE

"Plient contains reclaimed asphalt pavement (RAP) and scrap tire recycled steel fiber (RSF). RSF is used as a fiber reinforcement and RAP is added as intermediate sized coarse aggregate to achieve optimized aggregate gradation for improved workability and cracking resistance. The current state of the art is to use steel cages to reinforce concrete pipes. Production of certain cages requires laborious hand assembly, significantly lowering the productivity of the concrete pipe plants. The value proposition of Plient pipes is "cheaper

### INTELLECTUAL PROPERTY POSITION

The innovation originated from a research project focused on using RAP in concrete, for which Dr. Xijun Shi served as one of the primary investigators while earning his PhD from Texas A&M University. Dr. Shi later extended the research topic by introducing scrap tire RSF in the concrete mix design and invented Plient with his Postdoc advisor Dr. Zachary Grasley. Dr. Shi became an Assistant Professor at Texas State University in 2020 and began investigating commercialization of Plient with Dr. Grasley. In December 2020, Texas A&M University filed a PCT (PCT/US2020/063295) application for Plient. The Plient team won the 2021 Texas State University New Ventures Competition and received \$20,000 in non-dilutive start-up funding. Furthermore, the team participated in the Texas State I-Corps regional program and NSF I-Corps National Program and completed more than 140 customer interviews. A Go decision was made after the customer discovery and market validation activities.

### SALES/MARKETING STRATEGY

Our commercialization approach involves two parallel paths: commercializing in private projects and commercializing in public projects. For private projects, the pathway to commercialization involves our precast partners submitting 'alternate designs to land developers. Afterwards, the appropriate ASTM committees will be engaged to update standards so that alternate designs are ultimately unnecessary. For public projects in Texas, we will work with District Engineers to identify low-risk projects for prove-out. After prove-out, TxDOT Districts will modify their specifications to allow the new technology. Our business model would entail buying steel fiber from tire recyclers and then reselling this steel fiber at a higher price to concrete companies. We are working with tire recyclers to become their official steel supplier to the concrete industry. We project our gross margins to be around 51%.

### **EXIT STRATEGY**

Our goal is to become cash flow positive in the next 3 years and sell ourselves to a large international concrete company in the next 7 years.

# IP Summary: Circle Concrete Tech Inc.



Circle Concrete Tech Inc. – 0 relevant US patents found CEO Dave Kruse – 0 relevant US patents found CIO Zachary Grasley – 1 relevant US patents found CTO Xijun Shi – 1 relevant US patents found

General Notes – TNVC application states that Circle Concrete Tech Inc. relies on a patent application (PCT/US2020/063295) where the company managers are coinventors, applied for by TAMU. It is unclear what the licensing agreement is between Circle Concrete Tech and TAMU for this patent based on their application.

## Licensing agreement between Circle Concrete tech and Texas A&M University has been verified.

Notes on IP position and strategy from application

The innovation originated from a research project focused on using RAP in concrete, for which Dr. Xijun Shi served as one of the primary investigators while earning his PhD from Texas A&M University. Dr. Shi later extended the research topic by introducing scrap tire RSF in the concrete mix design and invented Plient with his Postdoc advisor Dr. Zachary Grasley. Dr. Shi became an Assistant Professor at Texas State University in 2020 and began investigating commercialization of Plient with Dr. Grasley. In December 2020, Texas A&M University filed a PCT (PCT/US2020/063295) application for Plient. The Plient team won the 2021 Texas State University New Ventures Competition and received \$20,000 in non-dilutive start-up funding. Furthermore, the team participated in the Texas State I-Corps regional program and NSF I-Corps National Program and completed more than 140 customer interviews. A Go decision was made after the customer discovery and market validation activities.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Eco-friendly, crack-resistant cementitious materials	US Application	Zachary C. Grasley Xijun Shi Anol K. Mukhopadhyay	Texas A&M University	US20230082445A1	Filed 12/04/2020 Alt Nos. PCT/US2020/063295

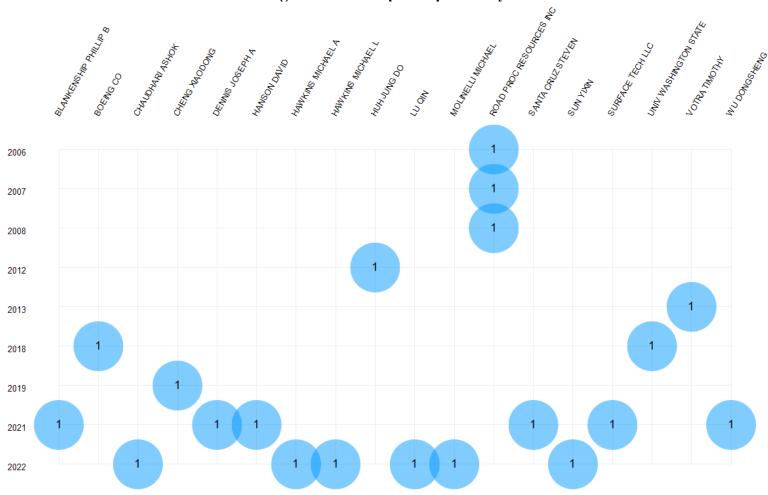
# Similar technologies: Patent Applications by Year



Search terms: ("concrete reinforce recycle") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Methods for manufacturing geopolymer concrete using recycled wind turbine rotor blades	PCT	General Electric	WO2021145857A1	("concrete recycle fiber")	Recycled metal for concrete	Type of concrete and reinforcement recycled metals
2	Stay-in- place concrete floor and ceiling system without steel reinforcing m ade from recycled wind blades	PCT	Chaudhari Ashok Molinelli Michael	WO2022266089A1	("concrete reinforced steel recycle")	Recycled metal for concrete	Type of concrete and reinforcement recycled metals
3	Geopolymer concretes for energy storage applications	US Grant	Catholic University of America	US11525077B2	("geopolymer concrete")	Recycled metal for concrete	Usage of concrete as opposed to its method of creation
4	Geopolymer composite for ultra high performance concrete	US Grant	Catholic University of America	US9090508B2	("geopolymer concrete")	Recycled metal for concrete	Binders in concrete differ from related technology

# Company Name IP: Independent Claims of US20230082445A1



- 1. What is claimed is: 1. A cementitious material, comprising:a cement; a first recycled fiber reinforcement material; a recycled aggregate material; and water.
- 10. A crack-resistant cement concrete, comprising:a cement; at least one recycled fiber reinforcement material; a recycled aggregate material; a coarse aggregate; and water.
- 12. The crack-resistant cement concrete, wherein the at least one recycled fiber reinforcement material is a recycled steel fiber.
- 17. A crack-resistant cementitious mortar, comprising:a mixture in water of a cement and of a recycled steel fiber and an aggregate of a reclaimed asphalt pavement.
- 18. A method for increasing the crack-resistance of a cementitious material, comprising:replacing sand in a cement mortar with a recycled aggregate material; adding a first recycled fiber reinforcement material to the cement mortar; and adding a volume of water.

- [0171] 54. Dawood, E. T. and Ramli, M. Evolution of durable high-strength flowable mortar reinforced with hybrid fibers, ISRN Civil Engineering 2012.
- [0172] 55. Adamson, et al. International Journal of Fracture 77(3):213-222, 1996.
- [0173] 56. Østergaard, et al. Cement and Concrete Composites 26(5):563-572, 2004.
- [0174] 57. EN 14651: 2005+A1: 2007 Test method for metallic fibre concrete, Measuring the flexural tensile strength (limit of proportionality (LOP), residual) European Committee for Standardization, B-1050 Brussels, September 2005.
- [0175] 58. UNI 1039-2, Steel Fibre Reinforced Concrete-Test Method for Determination of First Crack Strength and Ductility Indexes, 2003.
- [0176] 59. Shah, et al, Fracture mechanics of concrete: applications of fracture mechanics to concrete, rock and other quasi-brittle materials, John Wiley & Sons, 1995.
- [0177] 60. Petersson, P. Cement and Concrete research 10(1):91-101, 1980.
- [0178] 61. Wittmann, et al. Materials and Structures 20(2): 103-110, 1987.
- [0179] 62. Tang, et al. Materials Journal 90(5):463-471,
- [0180] 63. Gettu, et al. Cement and Concrete Research 28(3):349-355, 1998.
- [0181] 64. Park, et al. Engineering Fracture Mechanics 75(13):3806-3818, 2008.

What is claimed is:

- 1. A cementitious material, comprising:
- a cement;
- a first recycled fiber reinforcement material;
- a recycled aggregate material; and
- 2. The cementitious material of claim 1, further comprising a second recycled fiber reinforcement material.
- 3. The cementitious material of claim 2, wherein the second recycled fiber reinforcement material is recycled carbon fiber.
- 4. The cementitious material of claim 1, further comprising a virgin aggregate material.
- 5. The cementitious material of claim 4, further comprising a coarse aggregate material.
- 6. The cementitious material of claim 1, wherein the first recycled fiber reinforcement material is recycled steel fiber from scrap tires.
- 7. The cementitious material of claim 1, wherein the recycled aggregate material is reclaimed asphalt pavement.
- 8. The cementitious material of claim 1, wherein the cement comprises about 20% by volume thereof.
- 9. The cementitious material of claim 1, wherein the cementitious material has both an increased ductility and an increased crack resistance without loss to impact toughness, splitting tensile strength and compressive strength.
  - 10. A crack-resistant cement concrete, comprising: a cement;
  - at least one recycled fiber reinforcement material;
  - a recycled aggregate material;
  - a coarse aggregate; and
  - water.
- 11. The crack-resistant cement concrete of claim 10, further comprising a virgin aggregate material.

- 12. The crack-resistant cement concrete, wherein the at least one recycled fiber reinforcement material is a recycled
- 13. The crack-resistant cement concrete of claim 10, wherein the at least one recycled fiber reinforcement material comprises a recycled steel fiber and a carbon steel fiber.
- 14. The crack-resistant cement concrete of claim 10, wherein the recycled aggregate material is reclaimed asphalt
- 15. The crack-resistant cement concrete of claim 10, wherein the cement comprises about 20% by volume
- 16. The crack-resistant cement mortar of claim 12, wherein both crack resistance and ductility are increased without loss to impact toughness, splitting tensile strength, and compressive strength.
  - 17. A crack-resistant cementitious mortar, comprising: a mixture in water of a cement and of a recycled steel fiber and an aggregate of a reclaimed asphalt pavement.
- 13. The crack-resistant cementitious mortar of claim 17, further comprising recycled carbon fiber in the mixture.
- 14. The crack-resistant cementitious material of claim 17, further comprising a virgin aggregate material in the mix-
- 15. The crack-resistant cementitious mortar of claim 17, wherein the reclaimed asphalt pavement is fine reclaimed asphalt pavement.
- 16. The crack-resistant cementitious mortar of claim 17, wherein the cement comprises about 20% by volume thereof.
- 17. The crack-resistant cementitious material of claim 17, wherein both crack resistance and ductility are increased without loss to impact toughness, splitting tensile strength, and compressive strength.
- 18. A method for increasing the crack-resistance of a cementitious material, comprising:
  - replacing sand in a cement mortar with a recycled aggregate material;
  - adding a first recycled fiber reinforcement material to the cement mortar; and
  - adding a volume of water.
- 19. The method of claim 18, further comprising adding a second recycled fiber reinforcement material to the cement mortar; and
  - adjusting the volume of water.
- 20. The method of claim 18, wherein the second recycled fiber reinforcement material is recycled carbon fiber.
- 21. The method of claim 18, further comprising adding a virgin aggregate material to the cement mortar; and adjusting the volume of water.
- 22. The method of claim 18, wherein the first recycled fiber reinforcement material is recycled steel fiber.
- 23. The method of claim 18, wherein the cement comprises about 20% by volume thereof.
- 24. The method of claim 18, wherein the cementitious material is a cement concrete, the method further compris-

adding a coarse aggregate; and adjusting the volume of water.



### **Corveus Medical**

### CONTACT INFORMATION

Contact Name: Tyler Melton

Contact Phone Number: 713-591-3705

Contact Email Address: tyler@corveusmedical.com

#### COMPANY INFORMATION

**CEO/President Name:** Tyler Melton

Industry/Technical area of Interest: Healthcare - Device

Subcategory (if any):

**Incorporation or Formation Date: 04.15.2021** 

State: Delaware

List Management Team Names: Tyler Melton, CEO

Ishan Kamat, CMO Byron Smith, Engineer

### **BUSINESS SUMMARY**

At Corveus Medical, we are developing a one-time, catheter solution that provides instant relief from the symptoms of heart failure by performing a single, targeted, denervation. Heart failure affects over 6M Americans, and hospitalizations contribute to a mounting cost burden of \$35B on the healthcare system. We solve this by inactivating a nerve branch that been shown in several publications to provide significant benefit for class III heart failure patients. We have tested our device over 5 iterative acute porcine studies which demonstrated functionality, feasibility and collected direct user feedback and one chronic study where we showed safety. To date, we have completed a pre-seed raise of \$902k and are currently raising \$1.5M to drive the company to a critical value-inflection point: first-in-human heart failure studies to present at heart failure conferences, recruit further clinical trial sites, and to start to earn the requirements for Medicare reimbursement.

### CUSTOMER PROBLEM AND SOLUTION

We are developing a catheter-based device that performs a targeted sympathetic nerve ablation to treat heart failure. Chronic heart failure is characterized by cardiac muscle weakening, which reduces the heart's ability to pump blood to the rest of the body. To compensate, the nervous system diverts blood volume from the abdominal vasculature to help restore blood flow. While this mechanism is safely activated during normal periods of exercise, in patients with heart failure, this mechanism over-stresses both the heart and lungs, causing fluid accumulation in the lungs. Current medications afford some clinical benefit but in many cases are ineffective at relieving symptoms or reducing hospital admissions, which represents a major cost burden on hospitals in the United States. Our catheter-based technology equips the cardiologist with a novel tool to perform a splanchnic nerve ablation to treat heart failure, proven by several human studies.

### TARGET MARKET

Over 6 million patients suffer from heart failure, leading to a tremendous cost burden of over \$30 billion on healthcare in the United States. Most expenditures are caused by repeated hospitalizations, resulting in poor quality of life for patients, rising costs for administration, and strain on physician availability and resources. Community barriers like homelessness, access to primary care, and availability of medical resources contribute to the healthcare disparity in vulnerable populations. By targeting the heart failure patients that are most frequently subject to repeated hospital readmissions,



Corveus Medical can directly address societal needs of patients with heart failure. We will start with the 60k of these patients who are non-responsive to therapy but do not have other comorbidities. We will then grow into the patients with comorbidities (240k) and eventually to all patients who are non-responsive to medication (1.4M). We would then go into other heart failure segments.

#### COMPETITORS

There are currently no commercially available direct competitors. Neuromodulation as a treatment modality for heart failure is currently used in the form of pacemaker-like devices, where cardiac leads powered by an implantable generator re-synchronizes cardiac function. Cardiac Resynchronization Therapy (CRT) is the only neuromodulation device category that is widely used in the US. CRT is implanted by an electrophysiology (EP) cardiologist.

One other early-stage experimental company, Axon Therapies, has developed a splanchnic nerve denervation device that relies heavily on concepts from renal denervation. Unfortunately, their solution concept relies on high energy output over a non-specific ablation zone, risking damage to surrounding tissues. Initial studies performed by Axon Therapies have proven clinical benefit in heart failure patients. These results have attracted attention from major strategics and leaders in heart failure treatment.

#### **COMPETITIVE ADVANTAGE**

Our device contains all unique features that are required for cardiologist adoption after working along-side interventionalists when designing the solution. We have the ability to stimulate a nerve prior to any ablation, giving users confidence they are in the right location, and we utilize an ablation needle probe that leaves the vein and moves directly to the nerve to destroy as much as possible that increases the durability of the procedure. We also do not affect the heart directly therefore do not impact other cardiovascular treatment and options. In comparison to our direct competitor, we can reduce potential collateral damage while removing more of the nerve, we can confirm the procedure was complete prior to leaving the cath-lab and with our mechanism and we can go after other nerves long-term that are too far away for their technique.

### INTELLECTUAL PROPERTY POSITION

We currently have a PCT applicated filed, owned by the Texas Medical Center and is already licensed back in perpetuity to Corveus, that covers the ablation method and confirmation technique. We also have a patent filed covering the puncture method and needle ablation mechanism that we recently received a 'Noticed of Allowance' and now expect to be granted the patent soon. We will build on our unique needle, ablation and method to further add to our patent portfolio. To date, we have been working with WSGR and are now also engaged with Cooley.

### SALES/MARKETING STRATEGY

We are a class III device and cannot sell until approval. After approval for our device indication to treat heart failure, we will launch in Q3 2026 to academic and urban centers in the US. We will pursue a European launch thereafter. We will also utilize our early trial sites as early adopters and we already have clinical champions in both major medical centers in Houston and San Francisco.

### **EXIT STRATEGY**

As a class III device, we plan a two-pronged approach as we near clearance. We will create the infrastructure to for a commercialization launch but also will keep in mind that other class III companies do exit to major strategics, something we would be open to as well. We have already had early discussions with a few strategics who are very interested and are monitoring our data/progress. Our competitor already has a strategic partner, and we envision once they are acquired, it will trigger additional exit interest by other strategics in the space.

# IP Summary: Corveus Medical



Corveus Medical – 0 relevant US patents found CEO Tyler Melton – 1 relevant US patents found CMO Ishan Kamat– 1 relevant US patents found Engineer Byron Smith – 0 relevant US patents found

General Notes – TNVC application states Corveus Medical has one PCT application filed (US2022/033802) for perpetual licensing of technology from Texas Medical Center, and a non-provisional patent (17/841,424) with status "Notice of Allowance" which they expect to be granted soon.

## Licensing agreement between Corveus Medical and Texas Medical Center has been verified.

Notes on IP position and strategy from application

We currently have a PCT applicated filed, owned by the Texas Medical Center and is already licensed back in perpetuity to Corveus, that covers the ablation method and confirmation technique. We also have a patent filed covering the puncture method and needle ablation mechanism that we recently received a 'Noticed of Allowance' and now expect to be granted the patent soon. We will build on our unique needle, ablation and method to further add to our patent portfolio. To date, we have been working with WSGR and are now also engaged with Cooley.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Systems and methods for interrupting nerve activity to treat a medical condition	US PCT	Tyler Melton Ishan Kamat	Texas Medical Center	WO2022266327A1	Filed 06/16/2022 Alt Nos. WO2022266327A1 Licensing from Texas Medical Center in perpetuity, inventors are company managers.
2	Unknown	Notice of Allowance	Unknown	Unknown, likely Texas Medical Center	17/841,424	Private non-provisional patent, Corveus claims it's near granted.

# Similar technologies: Patent Applications by Year



Search terms: ("interrupting nerve")
Bars indicate number of related patents per year, blue line indicates trend (Database: PatentInspiration)
Figure shows only one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Devices and methods for treatment of heart failure by splanchnic nerve ablation	US Granted	Axon Therapies Inc. Levin Howard; Gelfand Mark	US2022338924A1	("stimulate nerve heart ablation")	Uses ablation of nerves to treat heart failure	Method of nerve stimulation
2	Devices, systems, and methods for treatment of heart failure by splanchnic nerve ablation	US Application	Axon Therapies Inc.  Levin Howard; Gelfand Mark; Engelman Zoar Jacob; Panescu Dorin; Leung Mark S.	US2022257315A1	("stimulate nerve heart ablation")	Uses ablation of nerves to treat heart failure  Identical technology to [1], but filed distinctly (ie. Not same family).	Method of nerve stimulation

# Corveus Medical IP: Independent Claims of W02022266327A1

- 1. A method of treating or preventing heart failure or a symptom of heart failure in a subject in need thereof comprising: a. inserting a catheter into a vascular lumen defined by a vascular tissue of the subject; b. guiding the catheter towards a location proximal to a target nerve, wherein the target nerve comprises the greater splanchnic nerve: c. piercing the vascular tissue of the subject with a needle assembly extending outwards from the catheter towards the target nerve, wherein the needle assembly comprises an electrode assembly; and d. delivering a stimulation energy to the target nerve with the electrode assembly, thereby fully or partially ablating the target nerve and treating or preventing heart failure or a symptom of heart failure in the subject.
- 2. A vascular catheter comprising: a. a longitudinal axis; b. a distal end; c. a proximal end; d. a catheter shaft comprising an exit port, e. a needle assembly lumen comprising a needle assembly comprising a first needle configured to extend through the exit port and puncture vascular tissue in contact with the catheter, wherein the needle assembly comprises one or more electrodes configured to deliver electrical energy to a tissue in contact with the one or more electrodes; f. a gui dewire lumen; and g. a catheter tip.
- 3. A device comprising a device for treating a medical condition, the device comprising: a catheter having a longitudinal axis and comprising a needle lumen therein that is substantially parallel to or substantially coincident with the catheter longitudinal axis, wherein the needle lumen terminates in a lateral opening at a distal portion of the catheter; and a needle assembly configured to extend within and/or from the needle lumen, the needle assembly comprising: a first needle having a first tip and a second needle having a second tip, wherein the first needle and the second needle are disposed at a needle assembly distal end, the needle assembly having A) a non-bifurcated configuration prior to at least partially extending from the needle lumen and/or the lateral opening, and B) a bifurcated configuration when at least partially extending from the needle lumen and the lateral opening, wherein when the needle assembly is in a bifurcated configuration, the first tip and the second tip are spaced apart by a deployed distance measured from the first tip and the second tip, wherein vdhen the needle assembly is in a non-bifurcated configuration, the first tip and the second tip are spaced apart by a iion-bifurcated distance measured from the first tip and the second tip, wherein the deployed distance is larger than the non-bifurcated distance, and wherein when the needle assembly is in the bifurcated configuration, each of the first needle and the second needle are at a non-zero angle relative to the longitudinal axis of the catheter; a first ablation electrode disposed on the first needle, the first ablation electrode in electrical communication with a first source of energy; and a second ablation electrode disposed on the second needle, the second ablation electrode in electrical communication with the first and/or a second source of energy.

WO 2022/266327 PCT/US2022/033802

### **CLAIMS**

### WHAT IS CLAIMED IS:

1. A method of treating or preventing heart failure or a symptom of heart failure in a subject in need thereof comprising:

- a. inserting a catheter into a vascular lumen defined by a vascular tissue of the subject;
- b. guiding the catheter towards a location proximal to a target nerve, wherein the target nerve comprises the greater splanchnic nerve;
- c. piercing the vascular tissue of the subject with a needle assembly extending outwards from the catheter towards the target nerve, wherein the needle assembly comprises an electrode assembly; and
- d. delivering a stimulation energy to the target nerve with the electrode assembly, thereby fully or partially ablating the target nerve and treating or preventing heart failure or a symptom of heart failure in the subject.
- 2. The method of claim 1, wherein treating or preventing heart failure or a symptom of heart failure in the subject comprises reducing intracardiac blood pressure, or reducing an accumulation of blood within a cardiopulmonary circuit of the subject.
- 3. The method of claim 1, further comprising:
  - a. delivering a preliminary stimulation energy to the target nerve prior to piercing the vascular tissue of the subject, or delivering a preliminary stimulation energy to the target nerve after piercing the vascular tissue of the subject, or combinations thereof;
  - b. measuring a physiological response corresponding to the preliminary stimulation energy, thereby indicating whether the location proximal to the target nerve is in sufficient proximity to the target nerve.
- 4. The method of claim 1, wherein the physiological response comprises nerve activity, muscle movement, cardiac activity, adverse changes in pulmonary capillary wedge pressures (PCWP), gastrointestinal changes including increased motility, increase or decrease in less palmer sweating, increase or decrease in temperature for rectal and/or skin measurement, increase or decrease in renal output in relation to changes in vascular dilation, decrease in metabolism, decreased glucose release, decreased glucagon release, or increases in brain natriuretic peptide.
- 5. The method of claim 1, wherein the physiological response comprises measurement of action potential through the target nerve.



## CryoDesalination LLC

CONTACT INFORMATION

**Contact Name:** William Buchsbaum **Contact Phone Number:** 713-703-0597

Contact Email Address: billy@cryodesalination.com

**COMPANY INFORMATION** 

**CEO/President Name:** William Buchsbaum **Industry/Technical area of Interest:** Cleantech

Subcategory (if any):

**Incorporation or Formation Date:** 10.14.2012

State: Texas

List Management Team Names: W Buchsbaum, CEO

K Dawson, CTO M Bloom, Sec

### **BUSINESS SUMMARY**

CryoDesalination develops and commercializes innovative technology that lowers the cost of operation and carbon footprint of removing salts and heavy metals from seawater, brine, and industrial wastewater. Our proprietary process is applicable when there is a need to handle high salinity feeds; reduce the cost of desalination (both capital costs and operating costs); or recover water, salts, or minerals. There are many potential market applications. CryoDesalination provides practical and economical solutions to most problems involving water recovery, recovery of valuable minerals & chemicals, and clean-up of contaminated aqueous streams. Our process can treat feed streams originating from practically any source: oceans; brackish aquifers; mining; oil & gas exploration; chemical processes; manufacturing; or agriculture. It can be used to clean up waste streams and lagoons from fertilizer and metals refining industries. It can recover valuable chemicals and minerals, such as lithium.

### **CUSTOMER PROBLEM AND SOLUTION**

Water is necessary for both life and for economies to thrive. Yet water scarcity is becoming more acute due to climate change and population increases. The solution includes desalination of seawater and the treatment & reuse of wastewater. Unfortunately, the cost of water produced by currently available desalination technologies is much too high. CryoDesalinations freeze desalination process produces lower-cost water, making fresh water affordable for both industrialized & developing countries.

CryoDesalination is based on a natural phenomenon: Freezing saltwater produces salt-free ice. Melting that ice yields fresh water. Freeze desalination is a proven process. However, previous commercialization efforts encountered a major problem: the inability to effectively separate ice from the surrounding brine at commercial scale. Our patented Ice-Brine Separation System solves this problem. This enables us to provide a greener, more economical alternative to legacy desalination technologies.



### TARGET MARKET

We are focused on marketing to four verticals:

- 1. LNG regasification terminals Gasification of LNG to NG releases large amounts of cooling energy that is wasted to the environment. Combining CryoDesalination with LNG regasification results in the lowest cost desalinated water possible (40-50% CAPEX savings and 80% OPEX savings).
- 2. Industrial desalination (Mining, fertilizer, coal, chemical plants) This is a wide vertical focused on industrial processes that produce wastewater. Currently, these industries use reverse osmosis (expensive and small operating envelope) and thermal desalination (extremely expensive). CryoDesalination can give these facilities a much better operating cost position as well as a new source of marketable freshwater.
- 3. Lithium and Rare earth metal mining. In pump-based mining operations, metals are flushed from the earth with fresh water and evaporated over time. CryoDesalination accelerates metals extraction and recover the flush water for reuse.

### **COMPETITORS**

Reverse osmosis is the state-of-the-art technology for the desalination of water with TDS < 70 g/L. For wastewater with TDS > 70 g/L as well as insoluble containments like heavy metals or oils, thermal desalination, or brine concentration/crystallization is the state-of-the-art technology.

With lower CAPEX & OPEX as well as a smaller carbon footprint, CryoDesalination competes favorably with both RO & thermal desalination. Further advantages over RO include a higher tolerance for contaminants and the ability to handle higher salinity.

### COMPETITIVE ADVANTAGE

CryoDesalination advantages over other desalination technologies:

- -Lower Capex
- -Lower OPEX
- -No limit on salinity
- -Smaller environmental footprint
- -Low corrosion due to low operating temperature (no need for expensive materials)
- -Low maintenance & labor
- -No feed pretreatment required
- -No chemicals required
- -Economies of Scale: RO and thermal desalination plants require multiple duplication of equipment. For instance, RO membrane tubes have size limitations. To increase throughput RO plants must increase the number of membranes tubes. Because of the multiple duplication of equipment, the cost of larger capacity plants remains almost proportional to their capacity. In contast, CryoDesalination capacity increases are not limited by the size of special equipment. The unit cost of CryoDesalination, therefore, decreases with larger capacities. CryoDesalination is a high-volume process benefitting from Economy of Scale.

### INTELLECTUAL PROPERTY POSITION

CryoDesalination LLC fully owns all its intellectual property (through both patents and trade secrets), patents have been granted in 21 countries. We plan to apply for additional patents in the future. Our IP confers a strong competitive advantage because it solves the ice brine separation problem that has prevented previous freeze desalination processes from succeeding.

### SALES/MARKETING STRATEGY

Both desalination and industrial water treatment are small communities with well-defined trade groups and influencers. We are spreading our message through defined case studies directly with interested customers.



### **EXIT STRATEGY**

The most likely exit will be selling our company to one of the large desalination and water treatment companies such as Veolia or IDE. Depending on our performance as well as market conditions, we may elect to take the company public or sell to a private equity group.

# IP Summary: CryoDesalination LLC



CryoDesalination LLC–1 relevant US patents found CEO William Buchsbaum – 0 relevant US patents found CTO Kent Dawson – 0 relevant US patents found

General Notes – TNVC application states that CryoDesalination LLC has one currently issued patent (US8696916) and does not list any currently pending patents or any licensing deals with outside entities.

Notes on IP position and strategy from application

CryoDesalination LLC fully owns all its intellectual property (through both patents and trade secrets). Patents have been granted in 21 countries. We plan to apply for additional patents in the future. Our IP confers a strong competitive advantage because it solves the ice brine separation problem that has prevented previous freeze desalination processes from succeeding.

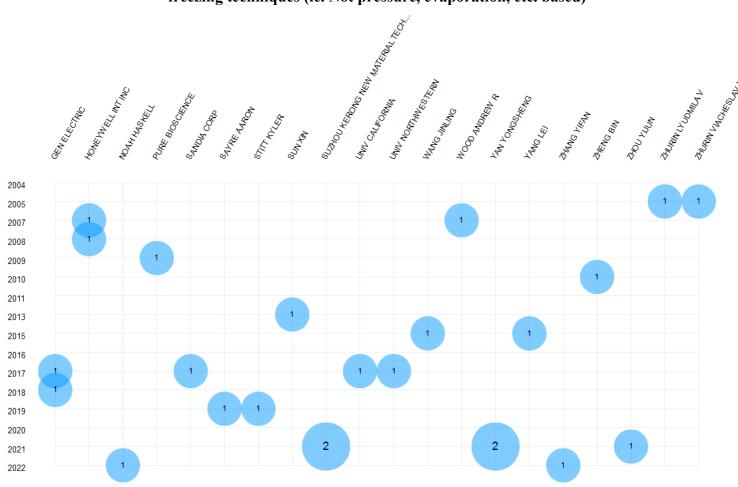
	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Process and apparatus for water purification	US Grant	Norbert Nathan Buchsbaum	Cryodesalination LLC		Granted: US, ES, AU, CA, EP, SG Application pending: WO IP Right Grant: MX

# 



Search terms: ("water pure freeze") & US or WO in Applicants Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration) Figure shows one patent per family.

The search terms "water pure freeze" were used to discern technologies broadly relating to water purification based on freezing techniques (ie. Not pressure, evaporation, etc. based)



# Short list of similar technologies



Ref	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Water desalination system and method for fast cooling saline water using fast freeze process	US Application	General Electric	US2018141826A1	("water pure freeze")	Similar technology goal	Method of separation of pure water from saline
2	Water desalination system and method for fast cooling saline water using turbines	US Grant	General Electric	US10246345B2	("water pure freeze")	Similar end goal	Different applications
3	Vacuum freezing nucleated liquid water for purifying brackish water	US Application	Advanced Cooling Tech Inc	US11365133B1	("water pure freeze")	Similar application	Highly different methodology for purification

# CryoDesalination LLC IP: Independent Claims of US8696916



- 1. What is claimed: 1. A process for purifying water, comprising: contacting an aqueous mixture with a flotation medium, wherein the flotation medium has a density greater than or equal to the density of ice or hydrate and less than the density of the aqueous mixture or a concentrated brine thereof at its freezing point; reducing the temperature of the aqueous mixture to a temperature below the freezing point of the aqueous mixture to form ice or hydrate and a concentrate comprising brine and precipitated solids; and phase separating the concentrate and the flotation medium; recovering the concentrate; and recovering the ice or hydrate and flotation medium as a slurry.
- 2. A process for purifying water, comprising: contacting an aqueous mixture with a flotation medium, wherein the flotation medium has a density greater than or equal to the density of ice or hydrate and less than the density of the aqueous mixture or a concentrated brine thereof at its freezing point; reducing the temperature of the aqueous mixture to a temperature in the range from about  $-15^{\circ}$  C. to about  $-65^{\circ}$  C. to form ice or hydrate and a concentrate; phase separating the concentrate and the flotation medium; recovering the concentrate; and recovering the ice or hydrate and flotation medium as a slurry.

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(i.e., purified water) as a slurry with flotation medium. Separation of the ice and brine in this manner overcomes the significant hurdle of ice recovery, greatly improving the viability of the freezing process for purification of water or formation of concentrates.

Embodiments disclosed herein may provide for one or more of the following advantages as compared to distillation and vapor compression: no or minimal heat transfer metal surfaces, low temperature differentials, less thermodynamic inefficiencies, no corrosion problems or scaling problems 10 (due in part to the low temperature operations), no or little feed pretreatment.

Embodiments disclosed herein may also have one or more of the following advantages as compared to distillation and/or osmosis: low capital investment, low energy consumption, 15 low operating costs, low maintenance, no chemicals, low environmental footprint, no salinity limitations in the feed stream, continuous operations, and scalability. Processes according to embodiments disclosed herein may be built in a permanent location, or may be modular skid-mounted units, 20 applicable to industrial, agricultural, military, and marine use, as well as disaster relief. Smaller units may also be provided for residential use.

While the disclosure includes a limited number of embodiments, those skilled in the art, having benefit of this disclosure, will appreciate that other embodiments may be devised which do not depart from the scope of the present disclosure. Accordingly, the scope should be limited only by the attached claims.

What is claimed:

1. A process for purifying water, comprising:

contacting an aqueous mixture with a flotation medium, wherein the flotation medium has a density greater than or equal to the density of ice or hydrate and less than the density of the aqueous mixture or a concentrated brine thereof at its freezing point;

reducing the temperature of the aqueous mixture to a temperature below the freezing point of the aqueous mixture to form ice or hydrate and a concentrate comprising 40 brine and precipitated solids; and

phase separating the concentrate and the flotation medium; recovering the concentrate; and

recovering the ice or hydrate and flotation medium as a slurry.

- 2. The process of claim 1, wherein the flotation medium has a density in the range from about 0.8 to about 1.0 g/cc.
- 3. The process of claim 1, further comprising melting the ice in the recovered slurry of ice or hydrate and flotation medium to form an aqueous fraction comprising water.
- 4. The process of claim 3, further comprising separating the aqueous fraction from the flotation medium.
- 5. The process of claim 1, further comprising washing the slurry with a wash liquid comprising at least one of fresh water, the aqueous fraction, and flotation medium, which may 55 be the same or different than the flotation medium used in the contacting step.
- **6**. The process of claim **5**, further comprising adding to the wash liquid one or more additives improving the displacement of concentrate adhering to the ice surfaces.

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- 7. The process of claim 5, in which the temperature of the wash liquid is varied to enhance the displacement of concentrate adhering to the ice.
- 8. The process of claim 1, wherein the temperature of the aqueous mixture is reduced by direct heat exchange, indirect heat exchange, or a mixture thereof, or by vacuum evaporation of some water contained in the mixture.

9. The process of claim 1, wherein the temperature of the aqueous mixture is reduced by direct heat exchange, indirect heat exchange, or a mixture thereof, with at least one of liquid natural gas (LNG), expanded LNG, ethane, propane, ethylene, propylene, and other cryogenic liquids.

10. The process of claim 1, wherein the contacting and temperature reducing steps are performed at the same time.

- 11. The process of claim 1, wherein the contacting step is performed prior to the temperature reducing step.
- 12. The process of claim 1, wherein the aqueous mixture comprises at least one of seawater, brackish water, brine, saline water, produced water, salts of any kind, alcoholic beverages, coffee, tea, orange juice, and urine.
- 13. The process of claim 1, wherein the flotation medium comprises at least one of an organic oil, a saturated or unsaturated paraffinic, cycloparaffinic, and aromatic hydrocarbon, a synthetic oil or lubricant, and a low temperature synthetic base fluids.
  - 14. The process of claim 1, further comprising:

contacting the flotation medium-ice slurry with a fluid having a higher density than the flotation medium;

displacing adhering or occluded concentrate into the concentrate; and

phase separating the flotation medium/ice, the fluid, and the concentrate.

15. The process of claim 1, further comprising:

contacting the recovered concentrate with a second flotation medium, which may be the flotation medium, wherein the second flotation medium has a density greater than or equal to 0.8 and less than the density of the concentrate at its freezing point;

reducing the temperature of the concentrate to a temperature equal to or below the freezing point of the concentrate to form ice or hydrate and a second concentrate;

phase separating the second concentrate and the second flotation medium;

recovering the second concentrate; and

recovering the ice or hydrate and second flotation medium as a slurry.

**16**. The process of claim **15**, further comprising forming a precipitate while removing heat from the aqueous mixture.

17. The process of claim 16, further comprising:

forming a second precipitate during further heat removal from the concentrate.

- 18. The process of claim 17, wherein the precipitate comprises a different salt or a different metal or mixtures of salt and/or metals than the second precipitate.
- 19. The process of claim 1, wherein purified water recovered is greater than 85% of the water contained in the original aqueous mixture.
- 20. The process of claim 1, further comprising one or more of:
  - i. determining a ratio of brine adherence to ice for a given aqueous mixture as a function of one or more of aqueous mixture composition, freezing rates, flotation medium feed rate, flotation medium feed temperature, flotation medium, aqueous mixture feed temperature, aqueous medium feed rate, water wash temperature, and water wash rate;
- ii. calculating the number of theoretical transfer units to result in a desired water purity or water recovery percentage for the aqueous mixture;
- iii. determining a height of a theoretical transfer unit for the aqueous mixture:
- iv. determining a feed location for the aqueous mixture and/or the flotation medium, based on one or more of the



## Developmate, Inc.

CONTACT INFORMATION

Contact Name: Christian Garcia Contact Phone Number: 6827581396

Contact Email Address: cgarcia@developmate.io

**COMPANY INFORMATION** 

**CEO/President Name:** Christian Garcia

Industry/Technical area of Interest: Information Technology - Software

Subcategory (if any):

**Incorporation or Formation Date:** 08.12.2022

State: Texas

List Management Team Names: Christian Garcia, CEO

Maxwell Kennady, COO Ben Kennady, CTO

### **BUSINESS SUMMARY**

Developmate, Inc. was founded in San Antonio, Texas, in August of 2022. Developmate builds mapping software that aggregates and analyzes data needed by real estate developers to underwrite multi-million-dollar deals. By using Developmate's software, real estate developers save hundreds of hours per year in reduced research time and make better, more informed decisions about where their next development project should be. The real estate development due diligence software market is estimated to be \$1.2 billion opportunity. To date, Developmate's first product, built for affordable housing developers on top of the ArcGIS platform, has generated \$129,500 in annual recurring revenue. The team is working on a proprietary SaaS web mapping application for market-rate real estate developers. That product is slated for launch in April 2023. The team consists of a former real estate developer, a data analyst, and a geographic information systems (GIS) software engineer.

### **CUSTOMER PROBLEM AND SOLUTION**

Real estate developers spend hundreds of hours per year analyzing and validating potential developments. This search and due diligence process is a continuous part of any their job. Yet, to analyze a single site, a developer must access 30 to 50 different data sources on government, nonprofit, and commercial websites. Even when you can find the data, it may be outdated or unavailable for download. This fragmentation causes delays in the development process. Our product is an all-in-one, authoritative mapping software that aggregates and analyzes the data real estate developers need to make investment decisions and weigh trade-offs about buying land, buildings, and pursuing new construction.

### TARGET MARKET

Our target customers are real estate developers looking for a solution that significantly reduces the time used to aggregate and analyze real estate location data. Their responsibilities include sourcing deals, completing research, and verifying information about prospective sites. They are looking for tools to help them understand and simplify the process and data needed to make good investment decisions. These professionals review up to 200 deals per year and spend up to 400 hours a year on research and validation. Our tool significantly reduces the amount of time they must spend aggregating and analyzing data manually by 90% and increase the number of reviewable deals to 1,000.



### **COMPETITORS**

DataStory
ApartmentMarketData
Deepblocks
TestFit
Reonomy
CREXi
4M Analytics
LightBox

#### **COMPETITIVE ADVANTAGE**

Our product utilizes advanced analytics to create custom data layers that end up saving real estate developers hundreds of hours. These data layers are only provided by Developmate and are difficult to replicate. In addition, while many companies offer location intelligence software, Developmate is one of the few whose focus is entirely on the needs of the real estate development sector. As such, our customers enjoy solutions, tools, analysis, and data that are uniquely tailored to their needs. Finally, our team is solving challenges they themselves have faced in the real estate field. Our unique and complementary combination of skill sets, including real estate domain expertise, data analysis, and software engineering experience, means we are poised to build the next generation of due diligence software for real estate development.

#### INTELLECTUAL PROPERTY POSITION

Developmate neither holds nor has filed for any patents or copyrights as of February 2023. The team will file a provisional patent application for our proprietary web mapping application with the US Patent and Trademark Office (USPTO) by May 2023. By May 2024, Developmate will file a patent application with USPTO. As a software company, Developmate intends to utilize all rights and avenues to protect and monetize our growing portfolio of IP assets to strengthen our market position and prepare the company for future growth.

### SALES/MARKETING STRATEGY

Direct outreach has been key to ensuring awareness of our product and generated sales. We have gathered emails from public sources to market directly to real estate developers who would be interested in our products. We also plan to offer "Lunch and Learn" workshops/product demonstrations with local real estate developers once our product is launched in San Antonio. As active members of the communities in which are product is offered, we plan to connect with local trade associations to present ourselves and our product and continuously gather feedback about pain points real estate developers experience in conducting due diligence and location analysis. We also plan to offer local real estate intelligence about the markets we serve on a blog and on LinkedIn and Twitter. We have received and worked to generate positive press, including being featured as one of San Antonio's "Startups to Watch in 2023" by Startups San Antonio, which has led to inquiries and requests to demo our product.

### **EXIT STRATEGY**

We hope to take Developmate, Inc. public. The real estate development industry is leaving the age of information and is entering the age of digitalization. The space is ripe for innovation and is expected to surpass \$80 billion a year. Developmate's goal is develop software solutions that optimize the development process. However, not every company is meant to succeed in the public markets. Developmate could also exist as a privately held corporation that provides dividends to its shareholders. Other acceptable conclusions would be an acquisition by a competing organization or a buyout by a private equity group.

# IP Summary: Developmate Inc.



Developmate Inc. -0 relevant US patents found CEO Christian Garcia -0 relevant US patents found COO Maxwell Kennady -0 relevant US patents found CTO Ben Kennady -0 relevant US patents found

General Notes – TNVC application states that Developmate Inc. has not filed or been granted any patents, nor do they specify any licensing agreement for patents from other companies. The company plans to file a patent in May 0f 2023 but as of drafting this document, they have not done so yet.

Notes on IP position and strategy from application

Developmate neither holds nor has filed for any patents or copyrights as of February 2023. The team will file a provisional patent application for our proprietary web mapping application with the US Patent and Trademark Office (USPTO) by May 2023. By May of 2024, Developmate will file a patent application with USPTO. As a software company, Developmate intends to utilize all rights and avenues to protect and monetize our growing portfolio of IP assets to strengthen our market position and prepare the company for future growth.

# Similar technologies: Patent Applications by Year



Search terms: ("real estate investment data") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	System and method for analyzing real- estate investment opportu nities	US Grant	Rajendran Nikith	US11587174B2	("real estate investment data")	Similar application	Design and scope
2	Systems and methods for performing automated feedback on potential real estate transa ctions	US Application	Real Estate Equity Exchange Inc.	US20200387990A1	("real estate investment data")	Similar application	Means of use
3	Method and formulating an investment strategy for real estate investment	US Grant	General Electric Capital Corp.	US6564190B1	("real estate investment data")	Similar application	Design and scope



### **DrillDocs**

CONTACT INFORMATION

Contact Name: Calvin Holt

Contact Phone Number: 713-876-1349
Contact Email Address: calvin@drilldocs.com

**COMPANY INFORMATION** 

**CEO/President Name:** Calvin Holt

Industry/Technical area of Interest: Energy

Subcategory (if any):

**Incorporation or Formation Date: 07.29.2030** 

State: Delaware

List Management Team Names: Francois Ruel, CTO

Advisors:

Martin Oehlbeck, IP Portfolio

Michael Szafron, Commercial Director

David Iga-Musisi, CFO

### **BUSINESS SUMMARY**

DrillDocs is an oilfield SaaS startup developing rig-based AI and computer vision technologies to improve drilling efficiency. The team has moved from an idea to paid field pilots with major oil and gas companies in under three years. We see incredible potential for the technologies DrillDocs offers, which enhance drilling performance and reduce emissions.

We have a one-pager available and would be happy to email it.

### **CUSTOMER PROBLEM AND SOLUTION**

Problem: Wellbore instability and its non-productive time cost the industry over \$3bn annually globally. Expansion into difficult drilling environments with poor or no shale shaker surveillance tools is causing stuck-pipe and lost wells. Insurance companies estimate that 75% of drilled formations are shales and that 90% of all wellbore stability problems occur in shale basins. One out of every 30 horizontal shale wells in the US loses tools downhole, and 90% of the time, this loss is permanent. Current drilling practices and technology cannot reliably detect wellbore instability.

Solution: CleanSight® computer vision system monitors, measures, and analyzes the rocks exiting the rig's shale shakers in real time. It is the industry's first autonomous cuttings characterization service and operates 24/7, providing alerts and analysis to the drilling team. Data generated includes shaker load, cavings detection, washout zones aka Facial Recognition for rocks to Drill Faster Without Disaster

### TARGET MARKET

Customers: Global operators' drilling, engineering, and operations teams are primary clients. The target segments are Shale, ERD, HTHP, Conventional, Deepwater, and Geothermal. Ancillary clients are mud logging, managed pressure drilling, drilling contractors, and solids control companies interested in developing their automation solutions. DrillDocs has two paid PoC pilots booked in 2023 with three pending (\$35k MRR). We are targeting new bookings for 2024 to achieve (\$187k MRR). Customer Segments

- Oil and Gas Operators
- Onshore and Offshore



All well types, globally

Users - Drilling Engineer, Geomechanics, Company Man

- Solid Control, Mud Logging, MPD contractors
- Drilling Contractor

Early Adopters - Those with the pain Experience

- Innovators
- VC mentality
- Risk-taker
- ExxonMobil, ConocoPhillips, ENI, Hess, Repsol

### **COMPETITORS**

Competitors: The #1 competitor is the status quo. The industry relies on hydraulic and weight (drag) modeling, best practices, rules of thumb, and measurement-while-drilling to detect wellbore instability or hole-cleaning issues. None of them measure directly the amount of rocks being removed. Schlumberger(SLB), Halliburton, and Geolog offer cuttings flow meters, which are costly (\$3k/day), resource-intensive (require manning), and only address hole cleaning and not wellbore instability. They are either slow, expensive or inaccurate, hence the reoccurring multi-billion dollar problem.

Today, no commercial computer vision surveillance solution is available in the drilling market except for DrillDocs's CleanSight®. SLB, Halliburton, NOV, OMV, and H&P have research and development efforts ongoing with a few patents.

### **COMPETITIVE ADVANTAGE**

What makes DrillDocs a Compelling Investment Opportunity?

We're 1st to market, with two patents pending and three in the pipeline that will protect our growing market share. Our team is 2nd to none with domain expertise and direct experience in the problem and solution.

The Camera as a sensor has a small form factor and is low maintenance. We have a technical partnership with world-class organizations in hardware and drilling engineering. We know how to sell a new technology to the drilling industry, and the solution is sticky because its three unique monitoring capabilities appeal to many stakeholders and buyers.

- 1st to Market
- Competitive price point
- 3 services in 1 camera 'Sticky'
- Strong IP portfolio
- Industrial, edge device with simple installation
- Oilfield people building oilfield tech
- Extensive industry relationships
- Axis Communications Technology Partnership
- University of Tulsa R&D Collaboration
- #1 in market awareness (+1000 LinkedIn Followers)

### INTELLECTUAL PROPERTY POSITION

IP Portfolio

We have a deliberate IP strategy. Our first advisor was Kodak's Director of IP and leads strategy

Patents - Our patent application is so successful that went straight to the approval 'highway'. See link. Tying that to the favorable ISR in a story, the application was approved for the patent prosecution highway (attached copy), so a 2023 patent is expected. Our other two patent applications are around controlling the drilling operation using the data arrived from the first patent. A design patent application is also in process. Two additional patents are pending funding – NOverflow and Flare.

The company's computer vision platform is 3rd party and operated internally. Outside AI\_CV consulting is performed under NDA with 100% ownership.

Trademarks - CleanSight®is approved, Drill Faster Without Disaster, and OK2Trip are in the process.



### **NDAs**

DrillDocs has several NDAs in place with clients and partners.

The co-founders have granted all IP belongs to DrillDocs.

### SALES/MARKETING STRATEGY

Sales/Marketing Strategy: We are gearing to deploy CleanSight® on seven US rigs within 12 months after completing paid pilots. Marketing investment is necessary to generate leads and increase brand awareness. CleanSight®'s value messaging has been created with and validated by multiple potential customers and industry leaders. Once the system is proven and generates revenue, the company will market to international operators. Modern marketing and sales methods will be used to accelerate go-to-market adoption.

### Channels

- Direct Sales and Service
- Offshore MPD or Mud L
- Onshore MPD or Mud L
- International Agents

### **Customer Segments**

- Oil and Gas Operators
- Onshore and Offshore
- All well types, globally

Users - Drilling Engineer, Geomechanics, Company Man

- Solid Control, Mud Logging, MPD contractors
- Drilling Contractor

### **EXIT STRATEGY**

We expect a major service contractor like Schlumberger, Halliburton, or Baker Hughes to acquire us to complement their digitization and automation strategies. The potential acquisition or strategic partnership with NOV or a drilling contractor like Nabors exists as we have ongoing dialogs. 2026 is the target date. With our hybrid SaaS model and +70% EBITDA margins, we forecast an x6 multiple on revenue.

## IP Summary: DrillDocs



DrillDocs – 3 relevant US patents found CEO François Ruel – 2 relevant US patents found CFO David Iga-Musisi – 0 relevant US patents found Commercial Director Michael Szafron – 0 relevant US patents found IP Portfolio Martin Oehlbeck – 2 relevant US patents found

General Notes – TNVC application states that DrillDocs has two PCT applications (PCT/US2022/029230, PCT/US22/34092) and a provisional patent which they expect to be granted in 2023 (63/433,421). All IP centers around detection and determination of optimal drill sites.

Notes on IP position and strategy from application

We have a deliberate IP strategy. Our first advisor was Kodak's Director of IP and has led us to a position where we have; Patents - Our first and core patent application was so successful that we can bypass and get straight to the approval's highway. This link shows the national stage US application from the PCT. Tying that to the favorable ISR in a story, with the explanation that the application was approved for the patent prosecution highway (attached copy), so a 2023 patent is expected. Our other two patent applications are around controlling the drilling operation using the data arrived from the first patent. We have a design patent application in progress. Additionally, two of our patents are pending funding: Flare and SmartCube. Our trademarks include CleanSight (which is approved), in addition to Drill Faster Without Disaster and OK2Trip that are in progress. DrillDocs has several NDAs in place with clients and partners. The co-founders have granted all IP belongs to DrillDocs.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Object imaging and detection systems and methods	WO PCT	Francois Ruel Martin E. Oehlbeck Deep Rajendrakumar Joshi Calvin Stuart Holt  Applicant is DrillDocs Company	N/A	WO2022241238A1	Priority claimed from US202163188107P

# IP Summary: DrillDocs



2	Systems and methods to determine and control wellbore stability	WO PCT	Calvin Stuart HOLT Francois Ruel Martin E. Oehlbeck Applicant is DrillDocs Company	N/A	WO2022266504A1	Priority claimed from US202163212146P
3	Improved wellbore control and models using image data systems and methods	US Provisional	Applicant is DrillDocs Company	N/A	63/433,421	Applicants claim will be granted in 2023 since patent is approved for the "patent prosecution highway."



Search terms: ("wellbore control imaging") & US or WO in Applicants
Bars indicate number of related patents per year, blue line indicates trend (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Borehole image blending through machine learning	WO Application	Halliburton Energy Services Inc.	WO2021167634A1	("wellbore control imaging")	Similar methodology of drilling with imaging and detection	Use cases of ML output
2	Imaging subsurface formations while wellbore drilling using beam steering for improved image resolution	US Grant	Pace Nicholas G; Guigne Jacques Y	US8627715B2	("wellbore control imaging")	Improvements to wellbore drilling through imaging	Patent is intended to improve steering rather than detect objects
3	Seismic image data interpretation system	US Pending	Zhun LI Haibin Di Hiren Maniar Aria Abubakar	US20220099855A 1	Similarity to WO2022241238A1	Similar methodology of drilling with imaging and detection	Machine learning input dataset may differ from related patent.

### DrillDocs IP: Independent Claims of WO2022241238A1



- 1. A computer-implemented method comprising: receiving image data from at least one imaging device imaging at least one mechanical mud separation machine ("MMSM"); selecting, from the image data, at least one Region of Interest ("ROI"); analyzing, using a Deep Neural Network ("DNN"), the at least one ROI to identify at least one image aspect in the ROI, wherein the image aspect is at least one of an object in an object flow, signal noise, or another physical object; based on results from the analyzing operation, selecting at least one additional ROIs from the image data; and analyzing the at least one additional ROIs using the DNN.
- 2. A computer implemented method comprising: receiving a field of view comprising image data from an imaging device capturing images of an MMSM; selecting, from the image data, a first ROI, wherein selecting the ROI includes: identifying a ledge of an MMSM within the image data, the ledge being a location where objects in an object flow begin to free fall; setting a top edge of the ROI at the ledge; identifying a frames per second of an imaging device capturing the image data; calculating a vertical length of the first ROI based on the frames per second of the imaging device and the ledge; associating the image data with a timestamp that corresponds to a time at which the image was captured by the imaging device.
- 3. A computer-readable storage device storing instructions that, when executed, perform the method of receiving a field of view comprising image data from an imaging device capturing images of an MMSM; selecting, from the image data, a first ROI, wherein selecting the ROI includes: identifying a ledge of an MMSM within the image data, the ledge being a location where objects in an object flow begin to free fall; setting a top edge of the ROI at the ledge; identifying a frames per second of an imaging device providing the image data; calculating a vertical length of the ROI based on the frames per second of the imaging device and the ledge; associating the image data with a timestamp that corresponds to a time at which the image was captured by the imaging device.

## DrillDocs IP: Independent Claims of WO2022266504A1



- 1. A computer-implemented method of optimizing wellbore parameters, the computer- implemented method comprising: receiving image data from a mechanical mud separation machine (MMSM), the image data including image data of an object flow; identifying, using the image data, at least one wellbore-state indicator; determining, based on in part the identifying at least one wellbore-state indicator, to send information to control at least one wellbore parameter; and sending the information.
- 2. A computer- implemented method comprising: receiving imaging information related to an object flow of a mechanical mud separation machine (MMSM); determining operational information from said imaging information from a mechanical mud separation machine (MMSM), the image data including image data of an object flow; determining actual drilling operational parameters; comparing the actual parameters to the predicted parameters; taking remediation action when data varies from a preset.
- 3. The computer-implemented method 10, wherein comparing the actual rate to the predicted rate comprises: comparing a rate of a predicted shape of cuttings to a rate of an actual shape of cuttings.
- 4. A computer storage device storing instructions that, when executed, perform the method, the method comprising: receiving image data from a mechanical mud separation machine (MMSM), the image data including image data of an object flow; identifying, using the image data, at least one wellbore-state indicator; determining, based on in part the identifying at least one wellbore -state indicator, to send information to control at least one wellbore parameter; and sending the information.

WO 2022/241238 PCT/US2022/029230

### **CLAIMS**

What is claimed:

1. A computer-implemented method comprising:

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receiving image data from at least one imaging device imaging at least one mechanical mud separation machine ("MMSM");

selecting, from the image data, at least one Region of Interest ("ROI");

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analyzing, using a Deep Neural Network ("DNN"), the at least one ROI to identify at least one image aspect in the ROI, wherein the image aspect is at least one of an object in an object flow, signal noise, or another physical object;

based on results from the analyzing operation, selecting at least one additional ROIs from the image data; and

analyzing the at least one additional ROIs using the DNN.

- 20 2. The computer implemented method of claim 1, wherein the at least one image aspect in the at least one ROI is an object in an object flow and the at least one additional ROIs comprises additional image data of the object in the object flow at a falling zone of a first MMSM of the at least one MMSMs.
- 25 3. The computer implemented method of claim 2, wherein the selecting operation comprises:

associating the at least one ROI with a first-time frame;

identifying the falling zone of the first MMSM;

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determining a second time frame and location within a field of view of the at least one imaging device at which the object will likely be present at a falling zone of an MMSM;

selecting additional image data corresponding to the second time frame and location to form one additional ROI.

- 4. The computer implemented method of claim 3, wherein identifying a falling zone of the first MMSM comprises using a DNN.
- 5. The computer implemented method of claim 3, wherein selecting additional image data further comprises:

determining a size of the additional ROI to capture the entire object.

- 45 6. The computer implemented method of claim 5, wherein the size of the additional ROI is 224 x 224 pixels.
  - 7. The method of claim 3, wherein the second time frame occurs earlier in time than the first time frame.

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8. A computer implemented method comprising:

receiving a field of view comprising image data from an imaging device capturing images of

WO 2022/266504 PCT/US2022/034092

### What is claimed:

1. A computer-implemented method of optimizing wellbore parameters, the computer-implemented method comprising:

receiving image data from a mechanical mud separation machine (MMSM), the image 5 data including image data of an object flow;

identifying, using the image data, at least one wellbore-state indicator;

determining, based on in part the identifying at least one wellbore-state indicator, to send information to control at least one wellbore parameter; and

sending the information.

- 10 2. The computer-implemented method of claim 1, wherein the at least one wellbore indicator includes a plurality of cavings.
  - 3. The computer-implemented of claim 1, wherein the at least one wellbore parameter includes at least one selected from the group consisting of: mud weight, wellbore-fluid hydrostatic pressure, and wellbore-fluid flowrate.
- 15 4. The computer-implemented method of claim 1, further comprising:

receiving, by a control application of a wellbore, the information; and

based on the received information, adjusting the hydrostatic pressure of a wellbore.

- 5. The computer-implemented method of claim 1, wherein identifying at least one wellbore indicator comprises analyzing the image data using a Deep Neural Network.
- 20 6. The computer-implemented method of claim 1, wherein the determining is also based on in part at least one operational information of the wellbore.
  - 7. The computer-implemented method of claim 6, wherein the operational information of the wellbore is a standpipe pressure, a vertical depth of a drill head, a well inclination, or a predicted rock strength.
- 25 8. The computer implemented of claim 1, further comprising: determining to change at least one ROI based on the received image data;

Changing at least one ROI by selecting an ROI in a falling zone of the MMSM;

Receiving additional image data at the falling zone;

identifying one or more additional objects by analyzing the additional image data using 30 the DNN;



### Ember Sleep

CONTACT INFORMATION

Contact Name: Aaron Glick

Contact Phone Number: 781-572-8851

Contact Email Address: AGlick@embersleep.com

**COMPANY INFORMATION** 

**CEO/President Name:** Aaron Glick

Industry/Technical area of Interest: Healthcare - Device

Subcategory (if any):

**Incorporation or Formation Date:** 02.13.2023

State: Delaware

List Management Team Names: Aaron Glick, CEO

Carlos Bernal, CTO

### **BUSINESS SUMMARY**

Our vision is that our novel medical device will be the first-line therapy to treat sleep apnea for 9 out of 10 patients. Ember Sleep formed out of the Texas Medical Center Innovation's Biodesign program. Co-founder Aaron Glick is a KOL in the dental sleep medicine field and treated sleep apnea patients for nearly a decade. Co-founder Carlos Bernal is a software engineer that has been specializing in building smart hardware. We are offering a novel medical device to treat sleep apnea and a unique method of fabrication at the point-of-care. We are developing a comfortable device that targets the muscles that cause sleep apnea and have developed the software to fabricate these custom devices. Product offerings provide recurring SaaS based revenue with a per patient revenue through non-custom hardware integration in a market ready for disruptive changes. Sleep physicians and other sleep providers have been increasingly willing to seek alternative options from CPAP and surgery.

### **CUSTOMER PROBLEM AND SOLUTION**

One out of every five people in America have sleep apnea. Sleep apnea is a medical condition where the patient's airway is blocked at night, they struggle to breathe, and this lack of air leads to health complications and untimely death. Patients with sleep apnea are typically tired during the day and have worse health outcomes. The risks of not treating sleep apnea are vast and some include heart failure, heart attack, obesity, car accidents, job impairment, headaches, and stroke. Although current treatment options make patients feel more well-rested and healthier, many stop their life-saving treatment of sleep apnea since they are not comfortable and a burden. Other surgical options are restricted to certain populations and not all people are candidates for this type of treatment. Our solution is a comfortable device that rests on the teeth like a retainer. It opens the muscles of the airway during sleep similar to the surgical option, yet is completely non-invasive.

### TARGET MARKET

Our target market is the dental industry. We are hyper-focused on dentists that own a intraoral scanner (able to digitize the teeth), high technology office (commonly purchase capital equipment less than \$5,000), multi-practitioner office (increased use of our technology and word of mouth), dentists already treating sleep apnea with mandibular advancement devices (>5 cases per month). We are in a unique position to access customers. Aaron Glick is a leader in the dental sleep apnea field and has been invited to present at multiple dental conferences to speak on the topic of technology and sleep apnea. Additionally, all dental providers that are nationally certified through the dental sleep apnea organization have contact information publicly available. We will start in the dental field to further prove effectiveness of the technology through



### 2023 Executive Summary

customized solution delivered by dentists. We then seek to explore non-custom options through sleep physicians and sleep DME providers.

### **COMPETITORS**

Our main competitors are CPAP companies and Inspire. CPAPs, while effective are uncomfortable and force air making it difficult for patients to breathe and requires a mask that can leak and disrupt sleep. After one year, half of patients stop using their CPAP despite it being a life-saving device. Additionally, one of the major CPAP incumbent firms, Philips Respironics, had a large recall recently and many patients are afraid to use CPAPs for fears of developing cancer. Inspire is a \$78 market cap company that offers a surgical procedure for only qualified patients where they cut in three places: just below the jaw, below the clavicle, and near the ribs. As a dentist, I've been frustrated with the options available to treat sleep apnea. I was frustrated enough to quit a wonderful private practice treating sleep apnea patients and faculty position at UTHealth School of Dentistry. We believe there should be a non-invasive, effective, and comfortable option.

### **COMPETITIVE ADVANTAGE**

Our competitive advantage is the non-contact technology that we are using to target muscles of the airway for patients to breathe at night. This technology allows the 1) directionality and 2) continued contraction of a muscle. Both important features to allow for a comfortable and effective treatment for sleep apnea.

Additionally, Carlos Bernal is a seasoned engineer that has previously commercialized a medical device with integrated electronics. Aaron Glick lectures nationally, has written multiple articles / textbook chapter, and highly involved in the sleep apnea field. With the environment at the Texas Medical Center Innovation, our team is able to interface daily with business strategy, engineers, and healthcare providers.

### INTELLECTUAL PROPERTY POSITION

We have filed provisional patent and received a positive unofficial FTO from a major corporate law firm. We continue to innovate and have other potential opportunities for additional patents.

### SALES/MARKETING STRATEGY

Our sales will be a high touch strategy. One of our mentors has access to a large scale network of dental sales representatives that could potentially help scale nationally, however our initial focus will be in well-defined geographical areas to start. Therefore, we have identified a list of 50 potential customers in the greater Houston area. The initial sales strategy will be to drive dentists to adopt and increase usage of our products.

Our marketing strategy will focus on generating peer-reviewed studies and clinical data to show effectiveness of the technology while sales continue in the dental field. Based on our novel fabrication method we have been advised that FDA requirements will be less stringent in the dental market, yet while selling in the dental market can work towards FDA approvals for the greater sleep market. We seek to show effectiveness and compliance data to drive adoption with sleep physicians.

### **EXIT STRATEGY**

Our exit strategy is acquisition from Inspire or CPAP manufacturer. Since the market potential is large with incumbent technology leaving a clinical unmet need, other treatment options do exist. However, we believe that given recent market forces Inspire or a CPAP manufacturer will be seeking to acquire the next generation of sleep apnea care soon. CPAP manufactures have the sales infrastructure that could rapidly grow the business with sleep physicians nationally. Therefore, it is our goal to dominate the dental market to drive clinical data that will be crucial for larger scale adoption with sleep physicians nationally. ResMed, a CPAP manufacturer, most recently acquired a \$1B SaaS company showing their interest in new strategic technologies with recurring revenue. Inspire would benefit greatly from expanded clinical indications, which our product would provide. Inspire recently has acquired companies that screen patients for sleep apnea, thus increasing potential patients.

## IP Summary: Ember Sleep

Ember Sleep – 0 relevant US patents found CEO Aaron Glick – 1 relevant US patents found CTO Carlos Bernal – 1 relevant US patents found

General Notes – TNVC application states that Ember Sleep has a provisional patent filed (no number included).

### Licensing agreement between Ember Sleep and Texas Medical Center has been verified.

Notes on IP position and strategy from application

We have filed provisional patent and received a positive unofficial FTO from a major corporate law firm. We continue to innovate and have other potential opportunities for additional patents.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Unknown	US Provisional	Aaron Glick Carlos Bernal	Texas Medical Center	Unknown	

Search terms: ("sleep apnea muscle stimulation") & US or WO in Applicants

Bars indicate number of related patents per year, blue line indicates trend (Database: PatentInspiration)



# Short list of similar technologies

# **EMBER SLEEP**

Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Medical lead for treating obstructive sleep apnea (osa) with electrical stimulation	WO Application	Medtronic Xomed Inc	WO2021150444A1	("sleep apnea muscle stimulation")	Similar application	Method of stimulation, obtrusiveness of method
2	Systems and methods for treating sleep apnea using neuromodulation	US Application	Synapse Biomedical Inc	US2023001201A1	("sleep apnea muscle stimulation")	Similar application	Method of stimulation, obtrusiveness of method
3	Treatment of obstructive sleep apnea	US Application	Medtronic Xomed Inc	US2021228234A1	("sleep apnea muscle stimulation")	Similar application	Method of stimulation, obtrusiveness of method



### HPTechAi LLC

CONTACT INFORMATION

Contact Phone Number: 9795755

Contact Phone Number: 9795755863 Contact Email Address: mike@hptech.ai

**COMPANY INFORMATION** 

**CEO/President Name:** Mike Ashley

Industry/Technical area of Interest: Transportation

Subcategory (if any):

**Incorporation or Formation Date:** 02.14.2023

State: Texas

List Management Team Names: Mike Ashley, CEO

Advisors: Prof. Swami Gopalswamy

Ginger Goodin; TTI; Blue Door Strategy & Research

### **BUSINESS SUMMARY**

HPTech, officially HPTechAi LLC, is a company centered around the development of technologies in cyber-physical system modeling, design and control. HPTech models and studies systems and systems of systems that embody software and mechanical components. Applications are in partially and fully automated vehicles and industrial, military and space robotics. The core technology, Hard Platooning - originally developed through Texas A&M University, enables a single operator to drive multiple vehicles by physically tethering automated followers to a manually driven lead vehicle. HPTech applies the skillset to develop and deploy this technology to other industries requiring automation and robotics. The mission of HPTech is rapid deployment through the development of safe, simple and reliable systems.

### **CUSTOMER PROBLEM AND SOLUTION**

Trucking is highly competitive with thin margins - carriers look for any competitive advantage. They sign contracts that hold them responsible for shipping a predetermined number of loads which requires that assets stay moving. Carriers translate this need for productivity into a shortage of drivers. HPTech is developing Hard Platooning where an AV truck is physically connected to a human driven lead truck. The 2nd driver either sleeps or is nonexistent. The physical link generates and transmits V2V information over a secure high-bandwidth wired connection. In normal operation, it carries no load and has the appropriate freedom so (1) the followers track the exact path as the leader (no needed changes to infrastructure) and (2) drivers feel they are only driving one truck. The connection also has high strength to allow for towing or to prevent vehicles from veering away during malfunctions. The connection and sensors are robust in all weather conditions and work with existing trucks.

### TARGET MARKET

Line haul in the TL and LTL segments are a primary target. Private carriers, entities with their own trucks to haul their own goods, such as PepsiCo, Walmart, Sysco, etc. (includes parcel carriers such as FedEx, UPS, USPS, etc.) make up 1/3 of FMCSA regulated carriers and all have some form of line haul. They've designed their warehouse spacing based on driver hours of service rules and here more than one load has the same origin and destination at the same time (Hard Platooning directly applies without changes to the industry). For-hire carriers make up the remaining 2/3 and primarily serve the long haul segment. The majority of this group, owner operators and small trucking companies, use load boards while larger carriers typically secure contracts. Long haul drivers live in their truck and run out of hours routinely but with Hard Platooning



### 2023 Executive Summary

they'll plan their trips with off-duty time on interstates while moving and where trucks share a long stretch before separating - the 1st focus.

### **COMPETITORS**

Wireless platooning companies, Peloton (bankrupt) and Locomation attempted to capitalize on the majority of the industry by allowing truck manufacturer and company interoperability - any two operators sharing a stretch of road can join a platoon and save fuel (up to 8%). Questions of safety, reliability, lack of interoperability and how to share the fuel savings are preventing the adoption. The top L4 trucking companies (TuSimple, Torc, Aurora, Waymo Via, Kodiak, etc.) are initially focused on limited exit-to-exit automation. Freight is moved by a human up to a terminal yard on the interstate then an L4 truck carries it to another terminal yard on the interstate where it is again picked up by a human. For exit to exit, Hard Platooning also makes sense. Solving the fully autonomous problem is difficult, some say impossible, and in Q1 of 2023 Embark went bankrupt and significant layoffs were performed at TuSimple and Waymo. It's not clear yet if Waymo Via will continue soon or at all.

### **COMPETITIVE ADVANTAGE**

Competitors are working on technologies that they cannot explain and are unsafe - typically AI and machine learning based systems. HPTech's solution is transparent and has provable operation by relying on traditional closed-form control techniques. Simple sensors, algorithms and hardware translate to a low cost to enable two trucks for Hard Platooning which is a fraction of the cost of a truck and much less than a fully autonomous truck. The operating domain of a Hard Platoon is equal to or better than that of trucks today (snow, rain, ice, dust, ect.) - AV trucks cannot and may never be able to operate here. Operators have much more responsibilities than just driving the truck, they also deal with the shipper and receiver. Keeping the human in the loop allows for rapid adoption because the rest of the supporting industry does not have to change. Lastly, Mike, the founder and CEO is a former truck driver and truck mechanic - he understands trucking.

### INTELLECTUAL PROPERTY POSITION

We expect to license the intellectual property that we developed as researchers at Texas A&M University which encapsulates the core idea of Hard Platooning. The patent is of an apparatus and method entitled: "Automated Vehicle Platooning System and Associated Methods" Application # 18/123,200. Additional IP will be protected when we develop additional solutions during the wide scale integration with carriers, OEMs and through the emergence of the transfer-hub model. Defensive publishing will also be leveraged.

### SALES/MARKETING STRATEGY

De-risking strategies involve options in military logistics, public transit or proving grounds with appropriate operating domains – headway has been made in each sector. After de-risking, three possibilities exist: HPTech (A) owns trucks and pays owner-operators/carriers to have a 2nd truck follow them from one transfer-hub to the next. The majority of the market, small fleets, don't have to purchase a 2nd truck and the revenue generated by the truck (+ the portion that normally goes to a driver) is split between the carrier and HPTech. (B) partners with mid/large carriers, such as Knight Swift, which primarily serve long haul routes. These drivers typically run out of hours and have to park before their load is delivered. (C) partners with parcel carriers (ex: FedEx or UPS) which exclusively have line haul routes (outside of their P&D services). These lanes need increased capacity per driver today. OEM's may also be involved but are not required to be.

### **EXIT STRATEGY**

The exit strategy is acquisition. Truck OEMs, L4 trucking startups/companies and large robotics companies (ex: RRAI) are in the race to full self-driving trucks, most often citing a shortage of drivers. The deployment of Hard Platooning along with the realization that this shortage is being directly addressed will draw attention from these larger companies. Each of these three segments have interest and are possible candidates for acquisition/merger but the OEMs are better suited to scale and directly integrate the technology. OEMs also have established sales channels that end users are comfortable with.

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## IP Summary: HPTechAi LLC

HPTechAi LLC – 0 relevant US patents found CEO Michiel Ashley – 0 relevant US patents found Advisor Prof. Swami Gopalswamy – 0 relevant US patents found Advisor Ginger Goodin – 0 relevant US patents found

General Notes – TNVC application states that HPTechAi LLC has no currently pending patents but is in the process of writing a provisional patent for the work performed by the founder/s as researchers surrounding Hard Platooning.

Notes on IP position and strategy from application

We expect to obtain the intellectual property that we developed as researchers at Texas A&M which encapsulates the core idea of Hard Platooning. Additional IP will be protected when we develop additional solutions during the wide scale integration with carriers, OEMs and through the emergence of the transfer-hub model. Defensive publishing will also be leveraged.

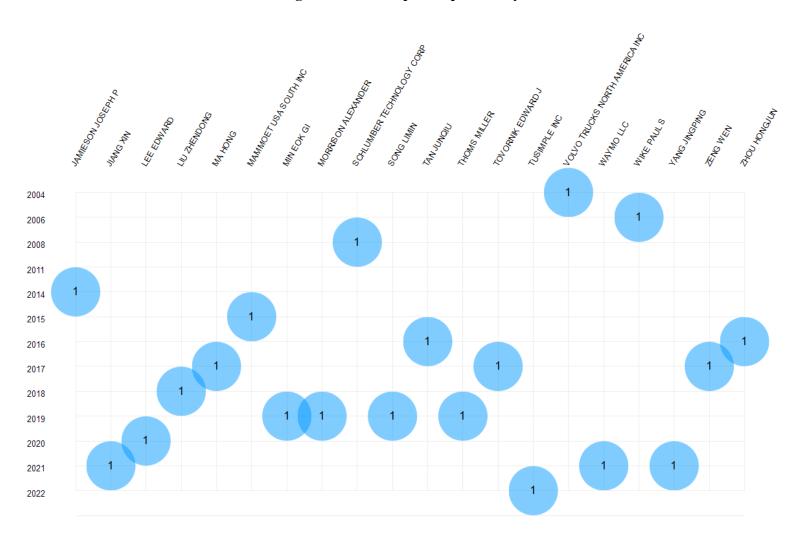
# Similar technologies: Patent Applications by Year



Search terms: ("truck connect follower") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	System and method providing truck- mounted sensors to detect trailer following vehicles and trailer conditions	US Application	Tusimple Inc.	US2021405185A1	("truck connect follower")	Improvement of leader-follower for vehicles	Design and scope
2	Braking controller and method using verification of reported trailer capabilities	US Grant	Bendix Commercial Vehicle Systems LLC	US10814844B2	("hard platooning")	Improvement of leader-follower for vehicles	Intended for braking specifically
3	Platoon vehicle management	US Grant	GM Global Technology Operations LLC	US8352111B2	("hard platooning")	Improvement of leader-follower for vehicles	Platoon management versus actual connection mechanisms



### Luci

CONTACT INFORMATION

Contact Name: Richard Yoon

Contact Phone Number: 9176869372

Contact Email Address: richard@joinluci.com

**COMPANY INFORMATION** 

**CEO/President Name:** Richard Yoon

Industry/Technical area of Interest: Information Technology - Software

Subcategory (if any):

**Incorporation or Formation Date:** 02.04.2020

State: Delaware

List Management Team Names: Richard Yoon - CEO

### **BUSINESS SUMMARY**

Luci is a finance app for Gen-Z and Millennials, combining social and gamified elements. It aims to simplify and make personal finance enjoyable by assisting users in setting, tracking, and achieving financial goals.

Luci generates affiliate revenue through financial products, capitalizing on a \$40B+ market. This monetization strategy has created success stories such as CreditKarma's \$7 billion acquisition and RedVentures' \$11 billion valuation.

Luci recommends financial products to users and earns affiliate revenue when they sign up. Initially, Luci will focus on the credit card market, which makes ~\$275 in affiliate revenue per user signup.

80% of Americans get a credit card b/w 18 to 24. This age group is Luci's main user target, and using our patent-pending technology, Luci helps users find the right card. Using gamified credit missions, Luci helps users build credit, presenting further monetization opportunities when users upgrade to different cards or obtain additional ones.

### **CUSTOMER PROBLEM AND SOLUTION**

### Problem:

Personal finance is boring and daunting, and the way personal finance is taught is broken and not getting through to the current generation (Gen-Z and younger Millennials). It's memorization (not application and habit building), and apps like Mint spit a 10K at you (making it even drier and daunting).

### Solution:

We are building a gamified personal finance app for Gen-Z and Millennials. Our goal is to coach personal finance (not teach), make a strong community, and help prevent adverse outcomes via positive financial habit-building.

### TARGET MARKET

The initial target market is college students, gen-Z, and younger millennials who want to learn and achieve personal financial goals but find existing methods dull and dry. We have found that Luci resonates very well with working college students (40% of full-time college students work, and 70% of part-time college students work). They felt that they currently try to check their finances, but the existing solutions are boring and not engaging, making them forget.

We have also seen good traction with younger working millennials who have tried using other budgeting apps but have found them dry and dull, causing them to give up. We have also seen significant interest from personal finance microinfluencers, who we plan to utilize as part of our growth plan with younger Millennials.



### **COMPETITORS**

Cleo https://web.meetcleo.com/ YNAB https://www.youneedabudget.com/ Mint https://mint.intuit.com/

### **COMPETITIVE ADVANTAGE**

### Product Adv.:

Luci is social and gamified. Being social allows users to grow organically via network effects (such as squad missions where users can accomplish personal finance missions with friends) and encourages community-building. The gamification encourages users to invest emotionally in Luci and discourages users from switching from Luci to other apps to keep their game progressing.

### Monetization Adv.:

Our patent-pending technology turns financial product ads into personalized simulations & projection tools that empower users. We tested this via a prototype that takes users spending data and backtests it against all the credit cards to recommend the best credit card. It has performed very well with 1K users from one Reddit post with a high credit card application conversion of ~8%.

### Team Adv.:

We have the dream team to make Luci possible and are experts in creating games (50+ games & 100M+ downloads), fintech (Honey \$4B acquisition by PYPL), and finance (Goldman Sachs).

### INTELLECTUAL PROPERTY POSITION

We currently have a US patent application: Systems and Methods for Predicting Consumer Spending and for Recommending Financial Products.

You Chang Yoon is my legal name (the first author of the patent application), and I am the founder of Luci. Luci does business under Soon Science Inc. Our patent lawyer has done a prior art search for the application and is confident the patent will be granted.

This technology will be used for our monetization. We can help users find the best financial product that fits their finances by utilizing our patent. We have built a prototype using this patent already here: https://www.joinluci.com/. It received 1K users from one Reddit post, was the most upvoted post of the week, and was also featured on a product hunt: <a href="https://www.producthunt.com/products/luci-2#luci-2">https://www.producthunt.com/products/luci-2#luci-2</a>. In this prototype, we take users spending data and backtest it against all the credit cards to find which card would be the best for how they spend.

### SALES/MARKETING STRATEGY

We plan to utilize campus reps and cash-prized personal finance trivia competitions to grow within a campus. We then want to use college rivalry to expand to other schools by having personal finance trivia competitions between schools. As Luci's presence grows on campus, the social features of the product will also fuel organic growth.

We also plan to target younger millennials via personal finance micro-influencers. Influencers with less than 5K subscribers want to grow subscribers and exciting topics to make content about. Because Luci is such a unique product that can go viral, many influencers want to work with Luci, and just from cold outreach, we have eight micro-influencers to want to work with Luci for free. Luci will provide exclusive access to these influencers and give their subscribers early access. Although we currently don't plan on paying influencers, we may look into influencer and referral programs in the future.



### 2023 Executive Summary

### **EXIT STRATEGY**

Banks and many finance companies want to reach younger customers and would love to gain access to the user group that Luci has access to. Utilizing this need, we plan to be acquired like other fintech companies like Credit Karma which Intuit acquired for \$7B, or Honey, which Paypal acquired for \$4B. I was an early employee and the second product manager at Honey.

# IP Summary: Luci



Luci – 1 relevant US patents found CEO Richard Yoon – 1 relevant US patents found

General Notes – TNVC application states that Luci has a single patent application published (WO2021207719A1).

Notes on IP position and strategy from application

We currently have a pending patent application, and this patent will be used for our monetization. We can help users find the best financial product that fits their finances by utilizing our patent.

	Title	Status	Inventors/Applican	Assignee	Patent/Application No	Notes
1	Systems and methods for predicting consumer spending and for recommending financial products	US Application	Yoon You Chang Teodorescu Mike Horia Mihail Schwee Stephen Callaway Rice Matthew Ha Edward	Soon Science Inc.	WO2021207719A1	Filed 04/11/2021 Alt Nos. US2023116407A1

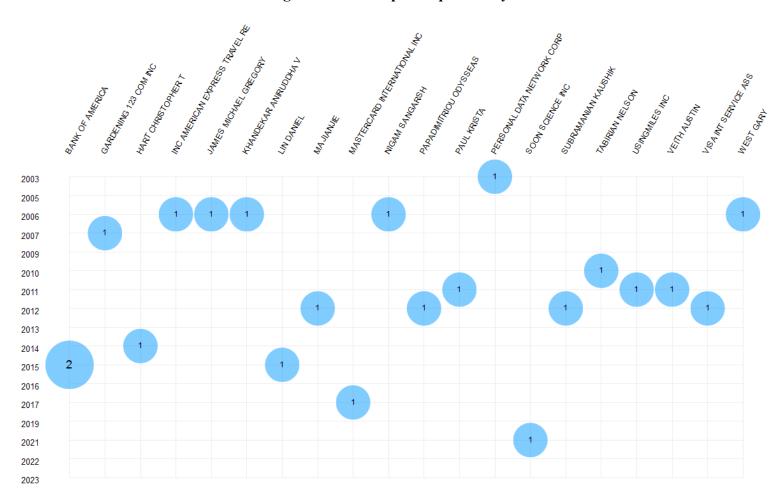
## Similar technologies: Patent Applications by Year



Search terms: ("credit card recommend") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Methods and apparatuses for customized credit card re commendations	US Grant	ConsumerInfo Com Inc ConsumerInfo Com Inc	US11580598B1	("credit card recommend")	Similar application	Design, factors behind recommendation
2	Systems and methods for credit card selection based on a consumer's personal spending	WO Application	Bonfigli Michael Cash Kevin	WO2019195263A1	("credit card recommend")	Similar application	Design, solely based on transactions

## Luci IP: Independent Claims of US2023116407A1



- 1. a device-1 configured to enable a user to open a user-account;
- 2. a device-2 for accessing the user's financial-statements from one or more of user's financial-institutions, the financial-statements comprising a plurality of transactions;
- 3. a device-4 configured to receive, from a computer on a network, information about a credit-card;
- 4. a device-5 configured to receive, from one or more computers of the computer network, merchant-information; and
- 5. A system for predicting user preference for a credit card, the system comprising: (1). a device-1 configured to enable a user to open a user-account; (2). a device-2 for accessing the user's financial-statements from one or more of user's financial-institutions, the financial-statements comprising a plurality of transactions; (4). a device-3 configured to receive from a computer on a network information about one or several credit-cards; (5). a device-4 configured to receive, from one or more computers of the computer network, merchant-information; (6) a storage system-5 configured to store transactions, unique visit identifiers, and linking user transactions to unique visit identifiers; (7) a storage system-6 configured to record user actions and linking said user actions to a unique visit identifier; (8) a system-7 to compare transactions of the user during the current visit to prior user's transactions and user actions; (6). a device-8 for predicting one or more financial-outcome-parameters corresponding to the user using a credit-card during a future-time-period.

plural or singular number respectively. When the word "or" is used in reference to a list of two or more items, it covers all of the following interpretations of the word: any of the items in the list, all of the items in the list, and any combination of the items in the list.

[0150] When it is written that a component or a feature "may," "can," "could," or "might" be included or have a characteristic, that particular component or feature is not required to be included or have the characteristic.

[0151] The terminology used in the Detailed Description is intended to be interpreted in its broadest reasonable manner. The terms used in this specification generally have their ordinary meanings in the art, within the context of the disclosure, and in the specific context where each term is used. The use of examples in this document, including examples of any terms discussed herein, is illustrative only and is not intended to limit the scope and meaning of the disclosure or of any exemplified term. Likewise, the disclosure is not limited to various embodiments given in this specification.

[0152] Although only a few embodiments have been described in detail above, those skilled in the art can recognize that many variations from the described embodiments are possible without departing from the spirit of the invention. It will be apparent to those skilled in the art that various modifications and variations can be made in the present invention without departing from the spirit or scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalent.

What is claimed is:

- 1. A system for determining financial-outcome-parameters of using a credit card, the system comprising:
  - a device-1 configured to enable a user to open a user-account;
  - (2). a device-2 for accessing the user's financial-statements from one or more of user's financial-institutions, the financial-statements comprising a plurality of transactions:
  - (4). a device-4 configured to receive, from a computer on a network, information about a credit-card;
  - a device-5 configured to receive, from one or more computers of the computer network, merchant-information; and
  - (6). a device-6 for determining one or more financialoutcome-parameters corresponding to the user using a credit-card during a future-time-period.
- 2. The system at claim 1, further comprising a device-7 for forming a user-financial-statement and a corresponding virtual-financial-statement,
  - (1). wherein the user-financial-statement comprises usertransaction-records corresponding to transactions of one or more of the financial-statements;
  - (2). wherein the user-financial-statement comprises a user-statement-start-date;
  - (3). wherein the virtual-financial-statement comprises a set of transaction-records, and each of the transactionrecords in the set corresponds to a user-transactionrecord in the user-financial- statement;
  - (4). wherein the virtual-financial-statement comprises a start-date equal to the first day of the future-timeperiod; and

- (5). wherein each transaction-record comprises a transaction-date obtained by adding to the start-date a number of days equal to the difference between the user-transaction-date of the corresponding transaction and the user-statement-start-date.
- 3. The system at claim 2, wherein a financial-outcomeparameter is a rewards-parameter configured to estimate one or more rewards the user would receive if using the creditcard during the future-time-period and if user would perform the transactions in the virtual-transaction-records.
- **4**. The system at claim **3**, further comprising a device-**8** for extracting card-information from the received credit-card, for using said card-information to form one or more rewards-functions, and for calculating the rewards-parameter by applying the rewards-functions to the virtual-card-statement.
- 5. The system of claim 4, wherein the rewards-parameter is configured to estimate the rewards a user would receive from a certain merchant, and wherein the rewards-functions are configured to select, out of transactions in the virtual statement, the transactions with the merchant.
- **6**. The system of claim **4**, wherein the reward-parameter is configured to estimate the rewards a user would receive from purchases in a certain category of goods and services, and wherein the rewards-functions are configured to select, out of transactions in the virtual-card-statement, the transactions in the certain category of goods and services.
- 7. The system of claim 2, wherein a financial-outcomeparameter is an overall-card-value configured to estimate the total overall value the user would receive if using the credit-card during the future-time-period, wherein the overall-card-value is determined by adding and subtracting monetary values of reward-parameters, monetary values of feeparameters and monetary values other benefits associated with the credit-card.
- **8**. The system of claim **2**, further including a device-**9** configured to receive user-input-information from the user and to determine expected user financial circumstances during the future time-period;
  - wherein transaction values corresponding to transactionrecords of the virtual-transactions-statement are adjusted via one or more adjustment-functions such as to incorporate expected user financial circumstances.
- **9**. The system of claim **8**, wherein the expected user financial circumstances during the future time-period comprise one or more of the following: changes in expected spending on certain category of goods and services, changes in expected user income, expected use of other credit cards and payment methods, expected family circumstances.
- 10. The system at claim 2, further including a device-10 configured to receive, from one or more computers on the network, market-information about expected market conditions during the future time-period;
  - wherein transaction values corresponding to transactionrecords of the virtual-transactions-statement are adjusted via one or more adjustment-functions such as to incorporate the market-information;
  - wherein the market-information comprises one or more of the following: expected inflation, expected changes in the price of goods and services, expected changes in interest rates.
  - 11. The system at claim 10, further including the device-9.
- 12. The system at claim 11, further comprising a device-11 for extracting card-information from the received credit-



### NeuraStasis, Inc

CONTACT INFORMATION
Contact Name: Kirt Gill

Contact Phone Number: 832 925-3302 Contact Email Address: kirt@neurastasis.com

COMPANY INFORMATION

CEO/President Name: Kirt Gill

Industry/Technical area of Interest: Healthcare - Device

Subcategory (if any):

**Incorporation or Formation Date: 06.04.2021** 

State: Delaware

**List Management Team Names:** Dr. Kirt Gill / CEO

Joe Upchurch / COO

### **BUSINESS SUMMARY**

NeuraStasis (Houston, TX) is an NIH-supported, Seed-stage medical device company founded in 2021 out of Biodesign at TMC, where it remains a Center for Device Innovation resident. NeuraStasis is developing BlueStem - a non-invasive electrical neurostimulator to improve patient outcomes after an ischemic stroke. The company has licensed and filed intellectual property protecting its technology, including stimulation algorithms, which activate brainstem reflexes that can impact ischemic progression and neuroplasticity.

The company's 1st prototype is approved for clinical testing. A 2nd-gen portable looks-like, works-like device is undergoing developmental testing. A 1st clinical pilot trial in elderly volunteers with cardiovascular risk factors for ischemic stroke is underway, testing tolerability and measuring cerebral blood flow patterns. Upcoming work will lead to an investigational device exemption submission to FDA to allow a feasibility and safety study in acute stroke patients.

### **CUSTOMER PROBLEM AND SOLUTION**

NeuraStasis (Houston, TX) is an NIH-supported, Seed-stage medical device company founded in 2021 out of Biodesign at TMC, where it remains a Center for Device Innovation resident. NeuraStasis is developing BlueStem - a non-invasive electrical neurostimulator to improve patient outcomes after an ischemic stroke. The company has licensed and filed intellectual property protecting its technology, including stimulation algorithms, which activate brainstem reflexes that can impact ischemic progression and neuroplasticity.

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### **TARGET MARKET**

Competitors to BlueStem are still in development. They can be classified into 2 groups: 1) similar neurostimulation technologies and 2) other products (devices, pharmaceuticals, and other interventions) targeting neuroprotection for acute stroke patients.





Neurostimulators: An invasive neurostimulator (BrainsGate) has shown significant results in a subsegment of stroke patients in phase 3 clinical trials but faces implementation challenges. Other noninvasive neurostimulators (Nervive and Electrocore) are conducting their first clinical studies. However, they are limited by targeting a single mechanism of action. NeuraStasis combines the blood flow effects of Nervive with the biochemical modulatory effects of Electrocore in a single device.

Others: These interventions include pharmaceuticals (like NoNO) with significant potential contraindications (such as incompatibility with tPA) or other types of treatment (like hypothermia), which face challenges for implementation.

### COMPETITORS

690,000 acute ischemic strokes (AIS) occur annually in the US. 70% are dead or disabled 5 years after the stroke. Within AIS, an unsalvageable ischemic core of brain tissue forms at the occlusion site in minutes, surrounded by a salvageable area called the ischemic penumbra, which converts to the core over time. Reperfusion treatments aim to save as much penumbra as possible. But irreparable harm is done by the time patients reach treatment. The median US time from diagnosis to reperfusion is 114 to 194 minutes, depending on inter-facility transfer. A way to prevent penumbra from converting would provide significant clinical impact. The BlueStem neurostimulator coordinates the activation of the trigeminal and vagus nerves to slow this conversion. BlueStem increases cerebral blood flow via collateral blood vessels and modulates brainstem networks that influence excitotoxic and inflammatory pathways - complementary mechanisms to mitigate damage.

### **COMPETITIVE ADVANTAGE**

In stroke, "Time is Brain." Everyone talks about the importance of time, but no one is developing an emergency-use device to be deployed in people's homes, nursing homes, or community centers. That's where interventions need to start. Because minutes matter. Though several companies are focused on rapid detection in the home, there is an untapped opportunity to develop an at-home protective device that would be used as early as possible. Think of the peace of mind it would provide if you knew you had a device to protect your family if a stroke occurred at home. Our device BlueStem is better suited to move earlier in the workflow, leading to a significant competitive advantage.

Additional advantages to BlueStem: 1) We are the first to translate electrical neurostimulation to modulate cerebral blood flow non-invasively. 2) By modulating two nerves, we improve on single-nerve neurostimulators by harnessing multiple mechanisms of action.

### INTELLECTUAL PROPERTY POSITION

Our first indication will focus on a subsegment of ischemic stroke patients with large vessel occlusions (LVO). Approximately 2.6M new LVOs occur globally each year, of which 168K are treated in the US annually. The LVO market is serviced by large medical device companies selling neuro-interventional devices for endovascular thrombectomy (EVT). EVT is highly profitable for hospitals; reimbursement for this procedure is significantly higher than medical management alone. We are positioning ourselves to increase EVT utilization and augment existing EVT outcomes. EVT has grown by over 400% since 2015 and is expanding the LVO market at 15% CAGR. We would be creating the neuroprotection segment as no approved device or therapeutic is currently available to slow ischemic damage. Based on an estimated \$4000 for our device (based on comparable interventions and value-based modeling), the US presents an annual \$672MM market opportunity. A global TAM for all LVOs represents a \$10.3B opportunity.

### SALES/MARKETING STRATEGY

We initially focus on the US market for our first indication, for which we anticipate applying market clearance in 2027. Adoption and capture within this market segment will require measured and successful clinical trials. A pivotal trial will be used to demonstrate improvement in stroke outcomes at 90 days and pursue FDA clearance. These trial sites will serve as our first customers and the first step for our go-to-market. From there, initial sales will target hospital networks with stroke center certifications. in the southeastern United States, where there is the greatest incidence and worst outcomes from ischemic stroke. We will partner with the vascular neurologists at these centers to ensure our device is available for use on



patients at the point of diagnosis, whether in their hospital or the site from which they receive transfers. There are approximately 1,660 accredited stroke centers in the US, of which there are 396 comprehensive or EVT-capable stroke centers as of 2021.

### **EXIT STRATEGY**

We initially focus on the US market for our first indication, for which we anticipate applying market clearance in 2027. Adoption and capture within this market segment will require measured and successful clinical trials. A pivotal trial will be used to demonstrate improvement in stroke outcomes at 90 days and pursue FDA clearance. These trial sites will serve as our first customers and the first step for our go-to-market. From there, initial sales will target hospital networks with stroke center certifications. in the southeastern United States, where there is the greatest incidence and worst outcomes from ischemic stroke. We will partner with the vascular neurologists at these centers to ensure our device is available for use on patients at the point of diagnosis, whether in their hospital or the site from which they receive transfers. There are approximately 1,660 accredited stroke centers in the US, of which there are 396 comprehensive or EVT-capable stroke centers as of 2021.

## IP Summary: NeuraStasis Inc.



NeuraStasis Inc. – 0 relevant US patents found CEO Kirt Gill – 0 relevant US patents found COO Joe Upchurch – 0 relevant US patents found

General Notes – TNVC application states that NeuraStasis Inc. has no pending or issued patents and have yet to decide if the company wishes to pursue patents in order to maintain trade secrets.

Notes on IP position and strategy from application

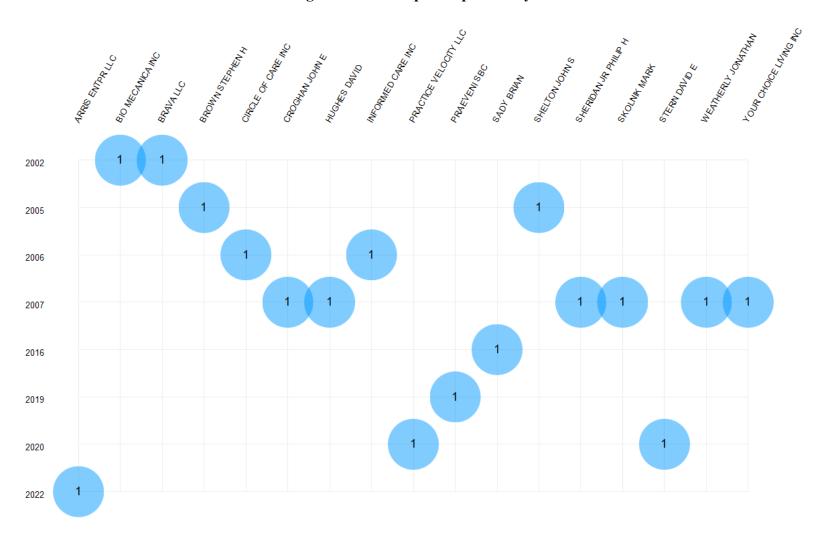
We want to keep it a trade secret. But by further discussions with our lawyers if it strategically better suited for our position, if we go for patents we will process our provisional patent as we currently speak to lawyers.



Search terms: ("virtual medical visit") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Program for virtual medical visits utilizing cellphones	US Application	Sady Brian	US2016034656A1	("virtual medical visit")	Similar platform	Diagnosis abilities
2	Method and system for automated medical records processing with telemedicine	US Grant	Practice Velocity LLC	US11361853B2	("virtual medical visit")	Related tooling that may play a part in company's technology	Scope of solution



## Opsin Biotherapeutics, Inc.

CONTACT INFORMATION

Contact Name: Bob Benkowski Contact Phone Number: 7138280556

Contact Email Address: bob.benkowski@opsinbio.com

**COMPANY INFORMATION** 

CEO/President Name: Robert Benkowski

Industry/Technical area of Interest: Healthcare - Rx/Therapeutics

Subcategory (if any):

**Incorporation or Formation Date: 04.19.2018** 

State: Delaware

List Management Team Names: Robert Benkowski, MBA, CEO

Samar Mohanty, PhD, CTO

### **BUSINESS SUMMARY**

Since the founding of Opsin Biotherapeutics, both DesignPlex Biomedical and Nanoscope Technologies have been funding the research and patent applications. To date, approximately \$500k has been invested including \$115k seed round from family and friends. We have received notice of recommended for funding for a Phase 1 NIH grant which will kick off our Series A funding round once complete. We expect to raise \$15m for our Series A towards the end of 2023. This is expected to carry us to 2025 to completed our IND submission while leveraging the data from our sister company that is already in clinical studies using the same opsin except for the blindness indication. In 2026, we plan to raise a Series B round of \$55M for our clinical studies. We expect to be acquired in the late pre-clinical stage or early clinical stage due to the opportunity that optogenetic neuromodulation offers for chronic pain.

### **CUSTOMER PROBLEM AND SOLUTION**

In 2016, 11,500,000 people misused prescription opioids. In 2017, there were 70,237 national overdose deaths. In addition, or alternative to drugs, many patients are implanted with a spinal cord stimulator however, these exhibit only 50-80% efficacy. Our target patient population are those patients in chronic pain where electrical spinal cord stimulation is not effective therapy.

Our unique optogenetic therapy is a combination product (biologic and device) that is selective, precise, effective, and non-addictive. In the simplest terms, the technology turns pain inhibiting neurons into light sensors, then when exposed to light, the neurons turn off thus stopping the pain. The opsin gene will be introduced into the neurons use laser gene delivery. For spinal cord therapy, an implanted fiber optic light source is used while with peripheral nerve pain, a transdermal light source can be used.

### **TARGET MARKET**

Our initial target market will be for chronic pain conditions where electrical neuromodulation has failed. Our initial indications include:

Chronic cancer pain not treatable by morphine Post traumatic neuralgia Chronic back or leg pain Chronic neuropathic pain disorder



The optogenetic therapy has the potential to offer a durable response for multiple years. As it is a platform technology, it offers the potential for numerous additional indications.

Advantages of optogenetic neuromodulation compared to competing products or services include: (i) it's a non-opioid based gene therapy approach and; (ii) in situ activation of pain modulator can be activated locally and potentially transdermal. Optogenetics approach addresses requirement of cell/circuit specific stimulation and non-viral laser gene delivery – a recipe for scientific & commercial success. The current pain management market is estimated to grow at 3.5% annually and reach \$83B by 2024.

#### COMPETITORS

Chronic pain drugs and devices are used for the management of various indications, such as neuropathic pain, arthritis pain, chronic back pain, cancer pain, migraine, fibromyalgia and others. The chronic pain treatment market for this category is expected to grow at a CAGR of 6.2% during the forecast period, attaining \$28.4 billion revenue by 2024, owing to growing incidence of neuropathic disorders and increasing aging population across the globe. Our competitors include brain and spinal cord stimulators for pain, with a market size \$2.0B (2018, US). The companies in this market are Boston Scientific (Advanced Bionics), Medtronic, Abbot (ANS - Advanced Neuromodulation Systems), Nevro (NBI Development), and Autonomic Technologies. Our competition also includes pharmaceuticals including prescription and over-the-counter medications. The prescriptions of these, including opioids, is expected to reach \$18B in 2020.

### **COMPETITIVE ADVANTAGE**

This is a new model for managing pain where specific neurons that inhibit pain can be activated. We have strong, patented technology, an experienced management team, an advisory board of key opinion leaders, and a goal to be the first optogenetic therapy for pain management.

We have several advantages over existing therapies. Electrical spinal cord stimulators have instances with Infection, lead movement, pain at the implant site, loss of therapy effect over time. We would offer higher spatial resolution and control over specific neural stimulation, parallel stimulation of wide area, millisecond-temporal precision (Precise ON and OFF switch), low light power required for stimulation, cell specificity for activation without incidental stimulation of non-desired neurons.

Advantages of our Optical Pain Modulation include: (i) it's a non-opioid based gene therapy approach; (ii) it uses non-viral gene delivery; (iii) in situ activation of pain modulator can be activated by the patient.

### INTELLECTUAL PROPERTY POSITION

We have licensed two patent applications from Nanoscope Technologies and are in the process of licensing a third patent from Nanoscope Technologies. and submitting our own patent application this quarter. As we progress, we intend to file additional patents as we work our way through in vitro and in vivo studies on our way to clinical use. We have identified 2 additional licensing opportunities for an implanted light source and inhibitory opsin if we need those to increase our indications or accelerate our path to clinical use. Our sister company, Nanoscope Therapeutics, uses the nearly identical opsin and we have rights to all the assays developed for FDA as well as any safety data from their on going clinical studies.

### SALES/MARKETING STRATEGY

Strategy: Our initial go-to-market strategy will be with a strategic partner with access to pain management clinics having large traffic of chronic neuropathic pain patients. We intend to initially sell to Neurosurgery and Neuromodulation specialties currently implanting neurostimulation devices. Our advisory board consists of KOLs and we plan to utilize their network and patient reach to expand our market. We plan to implant in 600 patients in the first year of market penetration, after our clinical study, at an anticipated revenue of \$200K for each patient. We believe this channel alone can provide total revenues of ~\$2B after 5 years of PMA/BLA approval. At a cost-of-goods-and-services (COGS) of ~20-30%, this revenue allows for generating significant profit for further expansion into global market.



### **EXIT STRATEGY**

Our most likely exit path is to be acquired pre-revenue by one of the handful of large pharmaceutical/medical device companies which can leverage our technology to enhance their market leading position on chronic pain management. Early partnerships with such market leaders can be a critical step toward our success and one strategic partner has already expressed interest in participating in our Series A round.

Our strategy is to begin engaging a strategic partner(s) after our initial NIH grant (which is currently recommended for funding), then meet with the FDA through their INTERACT program to vet our initial indication, verification plan, and first-in-human feasibility study plan. We believe if we maintain capital efficiency and stay on the path to demonstrate clinical efficacy with strong health economics, we will have multiple options for a liquidity event for our shareholders.

## IP Summary: Opsin Biotherapeutics Inc.



Opsin Biotherapeutics Inc. – 0 relevant US patents found CEO Robert Benkowski – 0 relevant US patents found CTO Samar Mohanty – 2 relevant US patents found

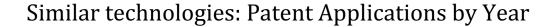
General Notes – TNVC application states that Opsin Biotherapeutics Inc. has applications to license two patents from their sister company, Nanoscope Technologies. They are in the process to license a third patent from the same company. The company is working to submit their own patent applications as well. They state they have full rights to license from their sister company and any data from their associated trials.

CEO Robert Benkowski is an inventor on numerous patents (some active some expired) from work not directly related to Opsin. Exclusive license between Opsin Biotherapeutics and Nanoscope Technologies has been verified.

Notes on IP position and strategy from application

We have licensed two patent applications from Nanoscope Technologies and are in the process of licensing a third patent from Nanoscope Technologies. and submitting our own patent application this quarter. As we progress, we intend to file additional patents as we work our way through in vitro and in vivo studies on our way to clinical use. We have identified 2 additional licensing opportunities for an implanted light source and inhibitory opsin if we need those to increase our indications or accelerate our path to clinical use. Our sister company, Nanoscope Therapeutics, uses the nearly identical opsin and we have rights to all the assays developed for FDA as well as any safety data from their on going clinical studies.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Optogenetic modulation by Multi-Characteristic Opsins for vision restoration and other applications	US Grant	Samarendra Kumar Mohanty Sulagna Bhattacharya	Nanoscope Technologies LLC	US11180537B2	Filed 11/03/2017 Alt Nos. PCT/US2017/059922 Granted in AU, JP, US Pending in CN, EP, WO
2	Method and device for pain modulation by optical activation of neurons and other cells	US Pending	Samarendra Kumar Mohanty	Nanoscope Technologies LLC	US20190359661A1	Filed 11/26/2017 Priority claimed from US201662426402P

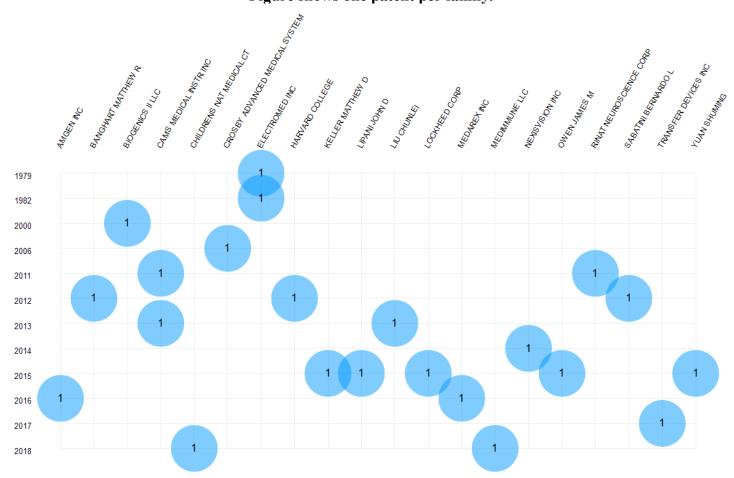




Search terms: ("light nerve pain") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Apparatus and method for managing chronic pain with infrared light sources and heat	US Grant	Owen James M Keller Matthew D Yuan Shuming Lockheed Corp	US8996131B1	("light nerve pain")	Similar application	Design and method for usage
2	Electroceutical device and wrap for using the same	WO Application	360 Approach to Health LLC	WO2017156340A1	("light nerve pain'')	Similar application	Different scope of pain, method of eliminating pain with stimulation

## Opsin Biotherapeutics Inc. IP: Independent Claims of US11180537B2



1. The invention claimed is: 1. A recombinant, ambient-light activatable, enhanced Multi-Characteristic Opsin (eMCO1) chimeric protein having SEQ ID NO: 11, wherein the chimeric protein consists of SEQ ID NO: 1 and a stabilizer-biomarker sequence; wherein the stabilizer-biomarker sequence is the translated sequence of SEQ ID NO: 10; wherein SEQ ID NO: 1 comprises 14 trans-membrane domains; wherein SEQ ID NO:1 comprises S132C, 5304A, 5308A and E610D mutations; wherein the stabilizer-biomarker is connected downstream with the 14 trans-membrane domains.

## Opsin Biotherapeutics Inc. IP: Independent Claims of US20190359661A1



- 1. What is claimed is: 1. A synthetic polypeptide sequence of Bioluminescent Bandwidth engineered Opsin (B2EO-1) protein comprising: An B2EO-1 protein that, when expressed on cell membrane, modulate at least one of ion selectivity, or light sensitivity. The protein of claim 1, wherein the B2EO-1 protein has SEQ ID NO: 1.
- 2. A method for inhibiting pain including migraine, phantom pain, chronic back pain and pain due to rheumatoid arthritis in an animal or human subject comprising:a. delivery of the opsin-gene (SEQ ID NO: 2 or 3) to targeted region(s) of brain or peripheral nervous system carried out by injection of virus carrying promoter-opsin-gene or by other physical/chemical methods; and b. active stimulation of specific cells in the targeted region(s) of brain or peripheral nervous system expressing opsin using an implanted optical neural stimulator; or c. passive stimulation of specific cells in the targeted region(s) of brain or peripheral nervous system using the bioluminescent light emitted by the endogenous cells sensitized with B2EO in presence of injected co-factors (e.g. furimazine, or analogs).
- 3. An implantable optical neural stimulator device for inhibiting pain in the patient comprising:a. an implantable light source and/or waveguide carrying stimulation light designed to be permanently inserted in to targeted region(s) so as to deliver light to the targeted nervous system region(s) that has been genetically modified to express an opsin; b. a power supply, which may be implanted or placed externally so that the implantable light source is driven by the implantable power supply such that the pulses of light is generated when triggered by the patient or health care provider until switched off manually or by a pre-set program; c. a controller coupled to the light source, which can be implanted and configured to result in controlled light intensity sufficient to elicit or inhibit activities in specific neurons or other cell types pre-sensitized with an opsin in targeted region (s) of the nervous system(s).
- 4. A method for inhibiting pain including migraine, phantom pain, chronic back pain and pain due to rheumatoid arthritis in an animal or human subject comprising:a. Optical stimulation of eyes using optical retinal stimulator to enhance the release of endorphins and anti-inflammatory agents such as opioid peptide, and b. Tuning the light intensity, frequency and exposure duration for maximizing pain reduction based on the type of pain.



## (12) United States Patent

Mohanty et al.

#### US 11,180,537 B2 (10) **Patent No.:**

Nov. 23, 2021 (45) **Date of Patent:** 

## (54) OPTOGENETIC MODULATION BY MULTI-CHARACTERISTIC OPSINS FOR VISION RESTORATION AND OTHER APPLICATIONS

(71) Applicant: Nanoscope Technologies LLC,

Bedford, TX (US)

(72) Inventors: Samarendra Kumar Mohanty,

Arlington, TX (US); Sulagna Bhattacharya, Arlington, TX (US)

Assignee: Nancoscope Technologies LLC.

Bedford, TX (US)

(\*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 16/347,375

(22) PCT Filed: Nov. 3, 2017

(86) PCT No.: PCT/US2017/059922

§ 371 (c)(1),

May 3, 2019 (2) Date:

(87) PCT Pub. No.: WO2018/106369

PCT Pub. Date: Jun. 14, 2018

#### (65)**Prior Publication Data**

US 2020/0255484 A1 Aug. 13, 2020

## Related U.S. Application Data

- (60) Provisional application No. 62/418,196, filed on Nov. 6, 2016.
- (51) Int. Cl. C07K 14/47

(2006.01)

A61K 38/00

(2006.01)

(52) U.S. Cl.

CPC ...... C07K 14/47 (2013.01); A61K 38/00

(2013.01)

Field of Classification Search

CPC .... C07K 14/47; A61K 38/00; A61K 48/0058; A61K 48/005; A61P 27/02; A01K 2227/105; A01K 2267/0306; C12N 2750/14143; C12N 2830/008

See application file for complete search history.

#### (56)**References Cited**

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A61P 27/02

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Bamann, Christian, et. al.; "Spectral Characteristics of the Photocycle of Channelrhodopsin-2 and its Implication for Channel Function," J. Mol. Biol. (2008) 375, 686-694, Nov. 1, 2007.

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Wright, Weldon, et. al.; "Restoring vision in mice with retinal degeneration using multicharacteristic opsin," Neurophotonics 4(4), 041505 (Aug. 18, 2017).

## \* cited by examiner

Primary Examiner — Sudhakar Katakam (74) Attorney, Agent, or Firm - Sand IP

#### (57)**ABSTRACT**

This invention, in one aspect, relates generally to compositions and methods for modulating cellular activities by synthetic opsins. Further, the invention provides method for the use of synthetic opsins for vision restoration and other applications, wherein the amino acid sequence of the synthetic opsin is modified to provide enhanced light sensitivity, kinetics and ion-selectivity.

### 6 Claims, 24 Drawing Sheets

Specification includes a Sequence Listing.

#### -continued

ccatggtega ggtgageece aegttetget teacteteec cateteecee eceteceeae	360
ccccaatttt gtatttattt attttttaat tattttgtgc agcgatgggg gcggggggg	420
aaaaaaaaaa aacaccaaac aaaacaaaac aaaacaaaaa acaaaacaaa acaaaacaaa	480
gaggtgegge ggeageeaat eagageggeg egeteegaaa gttteetttt atggegagge	540
ggcggcggcg gcggccctat aaaaagcgaa gcgcgcggcg ggcg	584

What is claimed is:

- 1. A synthetic polypeptide sequence of Bioluminescent Bandwidth engineered Opsin (B2EO-1) protein comprising: An B2EO-1 protein that, when expressed on cell membrane, modulate at least one of ion selectivity, or light sensitivity. The protein of claim 1, wherein the B2EO-1 protein has SEQ ID NO: 1.
- 2. A synthetic nucleotide sequence for Bioluminescent Bandwidth engineered Opsin (B2EO-2) protein comprising: An B2EO-2 protein that, when expressed on cell membrane, modulate at least one of ion selectivity, or light sensitivity. The protein of claim 1, wherein the B2EO-2 protein has SEQ ID NO: 3.
- 3. A method for inhibiting pain including migraine, phantom pain, chronic back pain and pain due to rheumatoid arthritis in an animal or human subject comprising:
  - a. delivery of the opsin-gene (SEQ ID NO: 2 or 3) to targeted region(s) of brain or peripheral nervous system carried out by injection of virus carrying promoteropsin-gene or by other physical/chemical methods; and
  - active stimulation of specific cells in the targeted region(s) of brain or peripheral nervous system expressing opsin using an implanted optical neural stimulator; or
  - c. passive stimulation of specific cells in the targeted region(s) of brain or peripheral nervous system using the bioluminescent light emitted by the endogenous cells sensitized with B2EO in presence of injected co-factors (e.g. furimazine, or analogs).
- **4**. The method of claim **3**, wherein the opsin is activatable by either blue, green, red light band(s) or white light, generated by external sources such as lamp, LED, laser or intrinsic bioluminescence from cells.
- 5. The method of claim 3, wherein the B2EO or other opsins (e.g. ChR2, C1V1, ReaChR, NpHR, ArCh, Chronos, Chrimson, MCO) is(are) delivered to cells of targeted nervous system regions such as thalamic regions including VAL, VPL, VM, VPM, and VPMpc by use of CAG/CMV promoters, or to specific cells such as excitatory pyramidal neurons by use of promoter such as CaMKIIa, Thy1, and human synapsin 1, or inhibitory neurons by use of promoters such as GAD65, SST, and NPY, so as to directly or indirectly down regulate release of ATP, Glutamate, BDNF, IL-6 and CCL2 leading to pain inhibition.
- **6.** The method of claim **3**, wherein the fibroblasts in central/peripheral nervous system is sensitized with the B2EO-1, 2 (SEQ ID NO: 2, or 3) or other opsins by use of promoters including but not limited to human MoMLV, Col1α1; and are controlled by active/passive stimulation to modulate the release of pro/anti-inflammatory cytokine(s) and/or an anti-inflammatory myokine(s) such as IL6, thus reducing pain.

- 7. The method of claim 3, wherein the astrocytes, glia including small satellite glial cells (SGCs) in central/peripheral nervous system is sensitized with the B2EO-2 (SEQ ID NO: 3) or other opsin-encoding genes by use of promoters including but not limited to GFAP, MBP, CMV, U1snRNA; and are controlled by active/passive stimulation to modulate the release of neurotransmitters and ATP, thus reducing hyperexcitability of neurons toward pain.
- **8**. The method of claim **3**, wherein the immune cells, including macrophages and/or mast cells in central/peripheral nervous system is sensitized with the B2EO-2 (SEQ ID NO: 3) or other opsin-encoding genes by use of promoters including but not limited to c-kit, ST2, IL1 RL1; and are controlled by active/passive stimulation to attenuate the release of histamine and pro-inflammatory reagents, thus reducing pain sensation.
- 9. The method of claim 3, wherein the keratinocytes and/or vascular endothelial cells in central/peripheral nervous system is sensitized with the B2EO-1 (SEQ ID NO: 2) or other opsin-encoding genes by use of promoters including but not limited to human VWF, Tie1; and are controlled by active/passive stimulation to enhance the release of endorphins and anti-inflammatory agents such as opioid peptide, thus reducing pain.
- 10. The method of claim 3, wherein selection of coordinates of the targeted regions is carried out by using an imaging modality including magnetic resonance imaging, computed tomography imaging, ultrasound imaging and/or radiography.
- 11. An implantable optical neural stimulator device for inhibiting pain in the patient comprising:
  - a. an implantable light source and/or waveguide carrying stimulation light designed to be permanently inserted in to targeted region(s) so as to deliver light to the targeted nervous system region(s) that has been genetically modified to express an opsin;
  - a power supply, which may be implanted or placed externally so that the implantable light source is driven by the implantable power supply such that the pulses of light is generated when triggered by the patient or health care provider until switched off manually or by a pre-set program;
  - c. a controller coupled to the light source, which can be implanted and configured to result in controlled light intensity sufficient to elicit or inhibit activities in specific neurons or other cell types pre-sensitized with an opsin in targeted region (s) of the nervous system(s).
- 12. The device of claim 11, further comprising an external controller configured to wirelessly communicate with the implantable unit(s).
- 13. The device of claim 11, wherein the implantable power supply is coupled to one or more implantable induc-



## **Pike Robotics**

CONTACT INFORMATION

Contact Name: Connor Crawford Contact Phone Number: 9035711620

Contact Email Address: connor@pikerobotics.com

**COMPANY INFORMATION** 

**CEO/President Name:** Connor Crawford **Industry/Technical area of Interest:** Cleantech

**Subcategory (if any):** Energy and/or IT-Hardware categories as well

**Incorporation or Formation Date: 11.08.2021** 

State: Delaware

List Management Team Names: Connor Crawford, CEO

Dr. Mitch Pryor, Advisor/Secretary

### **BUSINESS SUMMARY**

There are an estimated 213k petrochemical storage tanks across the globe which use floating roofs that sit atop liquid fuel. The roof seals require regular inspections to ensure they are effectively reducing fugitive emissions. There are significant safety concerns associated with the current inspection process using human crews in confined spaces, along with a financial operating loss due to tank down-time, labor, and equipment expenses.

To address these problems, Pike has developed an autonomous wall-climbing robot equipped with a state-of-the-art sensor suite. All of the collected sensor data is fused together to generate a seal inspection report real-time while the tank is in-service. Facility managers will be able to properly schedule repairs based on the condition of the asset and not on an archaic, maintenance schedule. We offer this novel inspection system as a service, lowering the financial barrier for customers who want to modernize their business operations with robotics.

## **CUSTOMER PROBLEM AND SOLUTION**

Floating roof seals are used on petrochemical storage tanks to prevent fugitive emissions. These seals fail over time, accounting for 6% of all anthropogenic methane emissions. A build-up of flammable vapors will also occur, putting the multi-million dollar asset at risk of fire. To proactively prevent failure and plan repairs, a manual inspection is required. The existing methodology consists of human crews inside the tank, a strategy which is dangerous, costly to perform, inaccurate, and requires up to 3 months of downtime.

To address these problems, Pike has developed an autonomous wall-climbing robot equipped with a state-of-the-art sensor suite. This robot replicates and improves upon the traditional inspection and reporting methods without having to put technicians in harm's way. This system will be approved for hazardous locations with an Ex-rating, allowing it to perform in-service inspections. The tank does not have to be taken offline and drained as was previously the case.

### TARGET MARKET

The Robot as a Service industry is expected to reach a valuation of \$142B by 2025. Monitoring of methane emissions will reach a value of \$2.2B by 2032. Trends supporting the growth of these markets include a rise in regulation and a desire to reduce confined space entries with robotics. Robotic inspection of storage tanks to help reduce methane emissions falls under both of these larger markets. By 2027 at the 213k+ storage tanks, located across 8,200 facilities, 28k in-service seal



inspections will be performed annually on open-roof tanks, costing \$11k on average. 18k out-of-service inspections are performed on closed-roof tanks. Customer interviews have informed us that we could charge up to ~\$44k for an in-service inspection of these tanks. This gives a global TAM of \$1.1B for the seal inspection market. Pike will start out by providing our inspection services to the 1200 storage tank facilities in the Gulf Coast region, a SOM valued at \$153M in 2027.

### **COMPETITORS**

The three big players today are Mistras, TEAM, & Acuren, who perform facility inspections with human crews. Their people are permanently located on-site, allowing them to be more responsive. All three have recently acquired tech which complements their LOBs. Mistras and Acuren each bought drone companies to perform partial visual inspection of the seals for open-roof tanks, but they cannot perform the full physical inspection. TEAM has also positioned themselves for internal development given their expanded R&D budget. There are also robotic service companies who provide alternatives for inspection of tank walls and floors, pipelines, boilers, etc. They usually work as sub-contractors to the big three above. O&G operators prefer to use only one service provider per site for simplicity. If these robotic companies wish to be the primary contractor for storage tank sites, a partnership with Pike would allow them to offer the final component for fully autonomous in-service tank inspection.

### **COMPETITIVE ADVANTAGE**

Our competitive advantages start with our IP (see above). The engineering expertise on our team, which comes out of the Nuclear and Applied Robotics Lab, is directly aligned with the required capabilities of our inspection robot. Other robotic developers also have great engineering teams, but their R&D budgets are limited. They do not have the bandwidth to develop a solution for every use case. Pike's smallness gives us the flexibility to focus on this one.

Even if a competitor was able to replicate the mission elements of our solution (motion control, detection software, & tether management), there is still the Ex-rating certification, a costly process, which takes over a year for approval. This provides a buffer to develop a customer base before new competitors arrive. There is a trend across the industry to force the use of robotic systems for confined space inspections. Pike will be primely-suited to expand our market when such initiatives are introduced for roof seal inspections.

### INTELLECTUAL PROPERTY POSITION

Our robot's novel design and inspection methodology has two patents pending in the U.S. The claims in these patents are broad enough that we will be protected against any copycats. Pike Robotics and UT Austin recently concluded negotiations on a 2-year option-to-license agreement that gives Pike the patent rights to this patent portfolio (UT Tech IDs 7399 PRY and 7953 PRY).

U.S. application No. 17/431,988 filed Aug 18, 2021 claims priority to International Application No. PCT/US2020/020420 (WO2020176864A1) filed Feb 28, 2020, and U.S. Provisional Application No. 62/811,795 filed Feb 28, 2019. This patent is directly related to UT Tech ID 7399 PRY, titled "Tank Seal Inspection".

In February 2023, a continuation-in-part (CIP) application was filed based on UT Tech ID 7953 PRY, titled "A Robot for Floating Roof Tank Seal Inspection" to add matter not disclosed in the aforementioned patent application. This was to protect the new features of the inspection robot that have been developed.

### SALES/MARKETING STRATEGY

Our go-to-market strategy consists of 3 phases. In the first phase, we will provide open-roof inspections to smaller, midstream storage tank facilities in Texas and Oklahoma. Smaller facilities will be easiest to convert, as they generally bid out each job instead of working with just one vendor. There are fewer hurdles to becoming a preferred vendor. After an incumbent vendor provides an inspection, we will provide a free inspection on the same tank to compare results and prove our effectiveness. Our services will be offered at 70% of the standard industry fee, which we can do while maintaining an 85% gross profit margin. In phase two, we will expand our service offering to include closed-roof inspections and target larger



customers and refinery site types. Phase three consists of expansion geographically (including international) and introduction of a new type of revenue stream through the offering of a permanent robotic solution that resides within the storage tank at all times.

#### **EXIT STRATEGY**

In 2025, we will expand our offering to include IFR seal inspections, solidifying our competitive advantage, and we will begin to garner a respectable market share, targeting 5% by end of year. Because in-service IFR inspections are so difficult, we will become an increasingly attractive strategic acquisition target to companies like Mistras and TEAM, who are looking for ways to add revenue streams and reduce margins. In 2025 we will be at the peak of our own rapid growth stage; 2025-2027 EBITDA projections are \$1.5m, \$10m, and \$28m, respectively. 2026 will be the first year with excess cash to distribute, which may satisfy antsy investors looking to realize gains. For these reasons, our current plan is to delay M&A activity until 2027, at which point we believe we will command an appropriate valuation and generate satisfying returns to our shareholders. We project a terminal value in 2027 of \$179m, dilution for pre-seed investors of only 9%, and a 54x return on investment at 132% IRR.

## IP Summary: Pike Robotics



Pike Robotics – 0 relevant US patents found CEO Connor Crawford – 1 relevant US patents found, 1 relevant non-US patent found Advisor/Secretary Prof. Mitchell Pryor – 1 relevant US patents found

General Notes – TNVC application states that Pike Robotics has two pending patents directly related to UT Tech IDs which is made possible through he company's licensing agreement with UT Austin, which is a 2 year option to license agreement. The patents are directly related to the Tech IDs "Tank Seal Inspection" and "A Robot for Floating Roof Tank Seal Inspection", with the second being included as a CIP application to an existing application in order to protect new features developed by the company.

Connor Crawford is an inventor on non-US (AU) patent AU2016203906A which is for a water barrier. While the patent is abandoned, it shows relevance to Pike Robotics' work.

License between Pike Robotics and the UT System has been verified.

Notes on IP position and strategy from application

Our robot's novel design and inspection methodology has two patents pending in the U.S. The claims in these patents are broad enough that we will be protected against any copycats. Pike Robotics and UT Austin recently concluded negotiations on a 2-year option-to-license agreement that gives Pike the patent rights to this patent portfolio (UT Tech IDs 7399 PRY and 7953 PRY).

U.S. application No. 17/431,988 filed Aug 18, 2021, claims priority to International Application No. PCT/US2020/020420 (WO2020176864A1) filed Feb 28, 2020, and U.S. Provisional Application No. 62/811,795 filed Feb 28, 2019. This patent is directly related to UT Tech ID 7399 PRY, titled "Tank Seal Inspection".

In February 2023, a continuation-in-part (CIP) application was filed based on UT Tech ID 7953 PRY, titled "A Robot for Floating Roof Tank Seal Inspection" to add matter not disclosed in the patent application. This was to protect the new features of the inspection robot that have been developed.

# IP Summary: Pike Robotics



	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Tank Seal Inspection	US Application	Mitchell Pryor Andrew Zelenak Robert Blake Anderson Connor D. Crawford	UT System	US20210380187A1	Filed 02/28/2020 Alt Nos. PCT/US2020/020420
2	A Robot for Floating Roof Tank Seal Inspection	CIP Application	N/A	UT System	N/A	

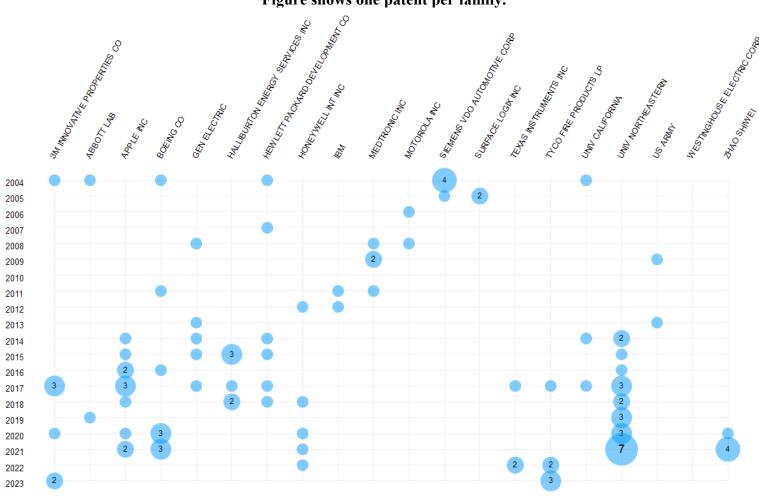
## Similar technologies: Patent Applications by Year



Search terms: ("seal detect device") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Ground based robot with an ogi camera with computer vision to automate the inspection	US Application	MFE ENTRPR INC	US2023008107A1	("inspect robot leak")	Similar overall intention	Use cases
2	Ultrasonic method and apparatus for detecting leaks	US Grant	General Motors	US4719801A	("inspect robot leak")	Similar use case	Methodology of detection
3	System and method for detecting leaks in sealed compartments	PCT	Qst Holdings, L.L.C.	WO2007050586A2	Similarity to US4719801A	Similar use case	Methodology of detection
4	System and method for generating three- dimensional robotic inspection plan	US Grant	General Electric Co	US10777004B2	Similarity to US2023008107A1	Similar use case	More related to robotic planning and mapping than seal inspection

## Pike Robotics IP: Independent Claims of US20210380187A1



- 1. A robotic inspection device comprising:a body; a power supply; a drive system including one or more surface engaging drivers to propel the robotic inspection device along a surface of a tank; one or more sensors housed within the body to capture data related to a seal within the tank; and a navigational system to send commands to the drive system to navigate the robotic inspection device along the surface of the tank allowing the one or more sensors to capture the data related to the seal.
- 15. A method of operating a robotic inspection device, the method comprising:receiving, from an external source, an inspection signal requesting the robotic inspection device inspect a seal of a tank; activating a magnetic coupling between the robotic inspection device and a wall of the tank; navigating the robotic inspection device so that a camera within the robotic inspection device can view the seal between a floating lid and the wall of the tank; and recording, using the camera, images or video of the seal as the robotic inspection device traverses the wall of the tank.
- 22. A robotic inspection device comprising:a power supply; a drive system including one or more surface engaging drivers to propel the robotic inspection device along a surface of a tank; a camera and one or more sensors housed within a housing to capture images, video, and data of a seal within the tank; an artificial intelligence or machine learning engine to review, in real-time, the images or video of the seal within the tank and identify one or more areas of the seal for additional inspection; and a controller to receive indications of the one or more areas and to send commands to the drive system to navigate the robotic inspection device along the surface of the tank to the one or more areas allowing the camera to capture additional images or video of the seal in the one or more areas identified by the artificial intelligence, the machine learning engine, or supervisory controller.

ogy can be practiced in many ways. Details of the system may vary considerably in its specific implementation, while still being encompassed by the technology disclosed herein. As noted above, particular terminology used when describing certain features or aspects of the technology should not be taken to imply that the terminology is being redefined herein to be restricted to any specific characteristics, features, or aspects of the technology with which that terminology is associated. In general, the terms used in the following claims should not be construed to limit the technology to the specific examples disclosed in the specification, unless the above Detailed Description section explicitly defines such terms. Accordingly, the actual scope of the technology encompasses not only the disclosed examples, but also all equivalent ways of practicing or implementing the technology under the claims.

[0089] To reduce the number of claims, certain aspects of the technology are presented below in certain claim forms, but the applicant contemplates the various aspects of the technology in any number of claim forms. For example, while only one aspect of the technology is recited as a computer-readable medium claim, other aspects may likewise be embodied as a computer-readable medium claim, or in other forms, such as being embodied in a means-plus-function claim. Any claims intended to be treated under 35 U.S.C. § 112(f) will begin with the words "means for", but use of the term "for" in any other context is not intended to invoke treatment under 35 U.S.C. § 112(f). Accordingly, the applicant reserves the right to pursue additional claims after filing this application to pursue such additional claim forms, in either this application or in a continuing application.

- 1. A robotic inspection device comprising:
- a body;
- a power supply;
- a drive system including one or more surface engaging drivers to propel the robotic inspection device along a surface of a tank;
- one or more sensors housed within the body to capture data related to a seal within the tank; and
- a navigational system to send commands to the drive system to navigate the robotic inspection device along the surface of the tank allowing the one or more sensors to capture the data related to the seal.
- 2. The robotic inspection device of claim 1, further comprising an artificial intelligence, machine learning engine, or supervisory controller to review the data related to the seal within the tank and identify problems with the seal
- 3. The robotic inspection device of claim 1, further comprising an artificial intelligence, machine learning engine, or supervisory controller to review the data related to the seal and schedule additional passes over areas of the seal with identified issues.
- **4**. The robotic inspection device of claim **1**, wherein the body includes an upper portion and a lower portion having an interchangeable nose section allowing an operator to select the interchangeable nose section with a size and a shape to fit between a weather shield affixed to the tank.
- 5. The robotic inspection device of claim 1, further comprising a light source to illuminate the seal of the tank to allow a camera to take images or video of the seal.
- **6**. The robotic inspection device of claim **5**, wherein the light source includes multiple light emitting diodes (LED) positioned on opposite sides of the camera.

- 7. The robotic inspection device of claim 1, wherein the one or more surface engaging drivers are positioned on an outside portion of the body.
- 8. The robotic inspection device of claim 1, further comprising a manipulator arm having a proximal end coupled to the body and a distal end connected to gripper to engage and retract a weather shield on the tank to allow at least a portion of the robotic inspection device be inserted between the weather shield and a wall of the tank.
- 9. The robotic inspection device of claim 1, further comprising a wireless communication module to wirelessly link the robotic inspection device to an external computing device, and wherein the data includes images or video of the seal of the tank which are wirelessly transmitted from the robotic inspection device to the external computing device using the wireless communication module.
- 10. The robotic inspection device of claim 1, further comprising a tether to link the robotic inspection device to an external computing device, and wherein the data related to the seal of the tank are transmitted from the robotic inspection device to the external computing device.
- 11. The robotic inspection device of claim 1, wherein the one or more surface engaging drivers include magnetic wheels to engage the surface of the tank.
- 12. The robotic inspection device of claim 1, further comprising a failsafe system with an independent power source and one or more direct current electromagnets, wherein upon failure of a primary power source the one or more direct current electromagnets are automatically engaged to anchor the robotic inspection device to the surface of the tank.
- 13. The robotic inspection device of claim 1, wherein the one or more sensors include a camera to capture video or still images, LiDAR to measure distance to the seal, depth sensors, or stereovision.
- 14. The robotic inspection device of claim 1, further comprising means for determining, tracking, and reporting a location and orientation of the robotic inspection device on a wall of the tank, or for reporting freefall of the robotic inspection device.
- **15**. A method of operating a robotic inspection device, the method comprising:
  - receiving, from an external source, an inspection signal requesting the robotic inspection device inspect a seal of a tank;
  - activating a magnetic coupling between the robotic inspection device and a wall of the tank;
  - navigating the robotic inspection device so that a camera within the robotic inspection device can view the seal between a floating lid and the wall of the tank; and
  - recording, using the camera, images or video of the seal as the robotic inspection device traverses the wall of the tank.
- 16. The method of claim 15, further comprising analyzing, using an artificial intelligence, machine learning engine, or supervisory controller, the images or video of the seal recorded by the camera.
- 17. The method of claim 15, wherein the inspection signal includes parameters representing tank dimensions, selected inspection routines, identified areas of interest, areas to avoid, communication channel information, location/tank information, external weather conditions, maximum inspection times, or waypoints.



## **PIRvision Lens**

CONTACT INFORMATION
Contact Name: Ya Wang

Contact Phone Number: 979-458-8123

Contact Email Address: ya.wang@pirvisionlens.com

**COMPANY INFORMATION** 

**CEO/President Name:** Roger Edgar

Industry/Technical area of Interest: Energy

Subcategory (if any):

**Incorporation or Formation Date:** 05.16.2022

State: Texas

List Management Team Names: Roger Edgar, CEO

Ya Wang, CTO

James Hubbard, Advisor, University Distinguished professor TAMU

#### **BUSINESS SUMMARY**

We aim to find the best path forward for market acceptance through 3 stages: (I) Non-recurring Engineering (NRE); (II) Manufacturing; and (III) Licensing. Stage I will be the source of revenue in Year 1 and a large share of revenue in Year 2. We will establish our manufacturing capacity to satisfy clients' needs via NRE. These data-version products will follow a typical embedded product engineering cycle of 9 months, with the first sale occurring in late Q3 / early Q4 of Year 1 and the first customer ship in Q2 of Year 2. With the success of customer products anticipated in Stage II, we will license our IP to larger, established embedded component manufacturers. This will enable PIRvision lens to maintain sales growth, leverage the OEM partners' distribution channels, and concentrate on creating new technology, not capacity. We also view this as risk reduction as it would preclude the significant investment in manufacturing capacity required to meet the demand directly.

## **CUSTOMER PROBLEM AND SOLUTION**

Situation – smart devices are only as smart as the dumbest components – PIR sensors have not changed much over 40 years.

Situation – Manufacturers have used PIRs as a means of detecting motion with the purpose of solving occupancy detection. Traditional PIRs have a high rate of "false/negative" results – meaning the device thinks no one is present when they are. Alternatives – there are multiple other ways of detecting occupancy – LiDAR, visual image processing, and Ultra-wide band (UWB). However, these are expensive components and require massive re-engineering.

ActiveLens can be applied to existing PIR devices, dramatically improving accuracy and functionality.

## TARGET MARKET

We are targeting embedded system manufacturers that are creating next-generation smart devices requiring occupancy detection. These include (but are not limited to) energy, lighting, security, safety, transportation – ANY device that needs to sense the proximity of OR discernment between a person, persons, animal, or environment conditions.

There are two parties in this Target Market:

The device manufacturers – An example of this would be Honeywell Home and Building Controls – a maker of industrial building devices

The component suppliers – This would be a PIR / Lens manufacturer. For instance, KEMET is a manufacturer of PIR sensors that are designed for other devices.



### **COMPETITORS**

There are many alternatives to occupancy detection: (1)Traditional PIR sensors, (2) Lidar (Light Detection and Ranging), (3) UWB, (4)Microwave, (5) Ultrasonic, (6) Video Image Processing. Traditional PIR sensors need to be more accurate, with many false-negative outcomes. They have been used in countless applications in energy management like light switches and thermostats, security systems, and industrial automation, to name a few of the board markets. PIR sensors are really designed for motion detection, not occupancy detection. The other methods are newer, more expensive technologies, and have the capacity to collect sensitive, identifying data. In addition, we compete with Fresnel lens manufacturers. Fresnel lenses are optical covers that concentrate light and infrared onto a sensor. They can increase the accuracy of reducing false negatives, but cannot increase the richness of the data.

#### COMPETITIVE ADVANTAGE

ActiveLens can be incorporated with any existing PIR-enabled device making it more accurate and smarter. For the past 40 years and the foreseeable future, PIR sensors have been used and will be used in thousands of applications. Replacing a PIR sensor with an alternative – Lidar, UWB, would require a large investment and represents a complete redesign and dramatically changes the manufacturing and build of material costs for an embedded device. For many devices that are low-cost and low-power, these factors are showstoppers. ActiveLens can be slipstreamed into an existing design much more easily and many devices use PIR and would benefit from ActiveLens. The physical construction of ActiveLens is a thin smart optical lens chopping the input signal and analyzing the resulting smaller bits of inputs- PIRvision's "secret sauce." Before ActiveLens, choppers were electro-mechanical – real moving parts that could break. ActiveLens is electro-OPTICAL—no moving parts and low power usage.

### INTELLECTUAL PROPERTY POSITION

SYSTEM Disclosure Invention Number Application Number Filing Date Title

TAMUS5168 62/863,808 06/19, 2019 Shuttered PIR Sensor Apparatus with A Low Power LWIR Liquid Crystal Optical Modulator for Stationary and Moving Occupancy Detection

TAMUS5170 62/863,842 06/19, 2019 Shuttered PIR Sensor Apparatus with A Low Power LWIR Liquid Crystal Optical Modulator for Stationary and Moving Occupancy Detection

TAMUS5230 62/880,058 07/29, 2019 Shuttered PIR Sensor Apparatus with A Low Power LWIR Liquid Crystal Optical Modulator for Stationary and Moving Occupancy Detection

All the above are combined in this PCT application PCT/US2020/038751 06/19, 2020 Passive Infrared Sensor Systems and Methods

US 17/620,619 12/17, 2021 Passive Infrared Sensor Systems and Methods

Canada 3,143,345 12/17, 2021 Passive Infrared Sensor Systems and Methods China 202080056704.4 12/17, 2021 Passive Infrared Sensor Systems and Methods

Europe 20827631.1 12/17, 2021

Hong Kong 202080056704.4 09/15, 2022

### SALES/MARKETING STRATEGY

There are three phases to the life of PIRvision.

- (I) SOW / PoC / Development boards
- (II) Limited manufacturing (sub 10k units)
- (III) License IP to scale partners

The first phase is to show the product working. This will include consulting along with the distribution of development boards (price range \$200 - \$500) The second phase will be to prove the technology to limited markets and establish manufacturability. The third phase will require the company to license the technology to large manufacturers of smart glass technology.



We are looking at selling direct in conjunction with technology partner companies. We are also interested in finding a distributor for our development boards.

### **EXIT STRATEGY**

Our goal is to create a sound business based on the IP that we have licensed from Texas A&M. We need to build the company to flip. However, some likely candidates could look at acquiring PIRvision. An EDA / Semiconductor IP company – Synopsys, Cadence, or Mentor – these companies markets to semiconductor and device manufacturers IP blocks for building components and chips. Device manufacturers – Google (Nest / Ring), Apple, Honeywell, Siemens, Philips, Schneider – these companies would acquire to protect IP.

PIR manufacturers – KEMET, Sony, Panasonic – like device manufacturers, this is a way to accelerate development and block their competitors.

Patent settlements – we think it is possible that companies will try to violate the patents that we have in place. All of these scenarios are contingent on building a solid business with multiple customers.

## IP Summary: PIRvision Lens



PIRvision Lens – 0 relevant US patents found CEO Roger Edgar – 0 relevant US patents found CTO Ya Wang – 1 relevant US patents found Advisor James Hubbard – 0 relevant US patents found

General Notes – TNVC application states that PIRvision Lens has a single PCT application which combines a series of TAMU Tech IDs, and the application also has pending applications in its family in the US, Canada, China, Europe, and Hong Kong. The company does not have any granted patents. It is unclear regarding the licensing agreement that the company has with TAMU for this patent.

## Licensing agreement between PIRvision Lens and Texas A&M University has been verified.

Notes on IP position and strategy from application

The following TAMU Tech IDs are used in combination in the application PCT/US2020/038751 06/19, 2020 Passive Infrared Sensor Systems and Methods.

- TAMUS5168 62/863,808 06/19, 2019 Shuttered PIR Sensor Apparatus with A Low Power LWIR Liquid Crystal Optical Modulator for Stationary and Moving Occupancy Detection
- TAMUS5170 62/863,842 06/19, 2019 Shuttered PIR Sensor Apparatus with A Low Power LWIR Liquid Crystal Optical Modulator for Stationary and Moving Occupancy Detection
- TAMUS5230 62/880,058 07/29, 2019 Shuttered PIR Sensor Apparatus with A Low Power LWIR Liquid Crystal Optical Modulator for Stationary and Moving Occupancy Detection

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Passive infrared sensor systems and methods	PCT	Ya Wang Libo Wu Zhangjie CHEN	Texas A&M University	WO2020257661A9	Filed 06/19/2020 Alt Nos. US17/620,619 CA3143345A EP20827631.1A CN202080056704.4A

## Similar technologies: Patent Applications by Year



Search terms: ("occupancy detection pir") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Methods and arrangements for an occupancy sensor	WO Application	Leviton Manufacturing Co.	WO2023288166A1	("occupancy detection PIR")	Similar application	Design and scope
2	Occupant counting device	US Application	Lutron Tech Co. LLC	US2021383556A1	("occupancy detection PIR")	Similar goal	Design and use cases
3	Multi- mode occupancy sensor and lighting system control	US Grant	ABL IP Holding LLC	US10440801B1	("occupancy detection PIR")	Assists company's technology (extension)	Not a standalone product

## PIRvision Lens IP: Independent Claims of WO2020257661A9



- 1. A passive infrared (PIR) sensor system, comprising: a PIR sensor configured to produce an output signal in response to receiving infrared (IR) radiation; an electronic shutter positionable in a field of view (FOV) of the PIR sensor, wherein the electronic shutter comprises a liquid crystal (LC) material, wherein the electronic shutter comprises a first state providing a first transmissivity of IR radiation through the electronic shutter and a second state providing a second transmissivity of IR radiation through the electronic shutter that is less than the first transmissivity; and a shutter actuator configured to apply an actuation signal to the electronic shutter to actuate the electronic shutter between the first state and the second state.
- 2. A passive infrared (PIR) sensor system, comprising: a PIR sensor configured to produce an output signal in response to receiving infrared (IR) radiation; a mechanical shutter positionable in a field of view (FOV) of the PIR sensor; and a shutter actuator configured to displace the mechanical shutter across an IR sensing element of the PIR sensor to at least partially block the IR radiation received by the PIR sensor in response to receiving a single pulse-width modulated (PWM) signal.
- 3. A passive infrared (PIR) sensor system, comprising: a PIR sensor configured to produce an output signal in response to receiving infrared (IR) radiation; and a shutter assembly comprising a mechanical shutter positionable in a field of view (FOV) of the PIR sensor, wherein the shutter assembly comprises a shape memory alloy (SMA) element configured to displace the mechanical shutter across an IR sensing element of the PIR sensor to at least partially block the IR radiation received by the PIR sensor in response to receiving an actuator signal.

WO 2020/257661 PCT/US2020/038751

## **CLAIMS**

### What is claimed is:

1. A passive infrared (PIR) sensor system, comprising:

a PIR sensor configured to produce an output signal in response to receiving infrared (IR) radiation;

an electronic shutter positionable in a field of view (FOV) of the PIR sensor, wherein the electronic shutter comprises a liquid crystal (LC) material, wherein the electronic shutter comprises a first state providing a first transmissivity of IR radiation through the electronic shutter and a second state providing a second transmissivity of IR radiation through the electronic shutter that is less than the first transmissivity; and

a shutter actuator configured to apply an actuation signal to the electronic shutter to actuate the electronic shutter between the first state and the second state.

- 2. The PIR sensor system of claim 1, wherein the actuation signal comprises a single pulse-width modulated (PWM) signal.
- 3. The PIR sensor system of claim 1, wherein the electronic shutter comprises a LC element positioned between a pair of substrates.
- 4. The PIR sensor system of claim 3, wherein the LC element comprises a polymer dispersed liquid crystal (PDLC) material.
- 5. The PIR sensor system of claim 3, wherein each substrate comprises a Germanium window.
- 6. The PIR sensor system of claim 3, wherein the electronic shutter further comprises a pair of electrodes in signal communication with the shutter actuator, and wherein each of the pair of electrodes is positioned between the LC element and one of the pair of substrates.
- 7. The PIR sensor system of claim 1, further comprising a controller configured to detect the presence of a stationary human occupant within the FOV of the PIR sensor



## Predyct, Inc.

CONTACT INFORMATION

Contact Name: Himanshu Maheshwari Contact Phone Number: 281-594-0407 Contact Email Address: himanshu@predyct.io

**COMPANY INFORMATION** 

**CEO/President Name:** Himanshu Maheshwari **Industry/Technical area of Interest:** Energy

Subcategory (if any):

**Incorporation or Formation Date:** 03.01.2022

State: Delaware

List Management Team Names: Himanshu Maheshwari, CEO

Dr. Ali Cetin, Head of Al Chiranjit Saha, Head of IoT

#### **BUSINESS SUMMARY**

Predyct is revolutionizing the way energy industry manages their massive infrastructure. Our Zero-power sensor and wireless network delivers data at an unprecedented scale saving cost and reducing emissions. Al-enabled insights eliminate downtime and improve productivity.

Our sensors are easy to install and provide wireless data without the hassle of battery replacement, thanks to our exclusive license for MIT-developed nano-engineered sensor technology. Proven and effective, our technology has gained strong traction, including ongoing pilots with leading energy operators. We are seeking service partners, clients for demonstrations, as well as raising funds for accelerated growth. We are the go-to choice for energy operators looking to transform their operations. Join us in our mission to enable sustainable operations of energy infrastructure.

## **CUSTOMER PROBLEM AND SOLUTION**

In general, there is lack of quality data on the structural health of energy and industrial infrastructure. Current manual data acquisition methods using visual or Non-destructive Testing (NDT) that are costly and require skilled technicians. Technician turnover and skill gap are leading to poor data quality. Conventional sensors demand constant power, requiring frequent battery replacement. Insufficient condition data results in reactive operations and downtime.

Predyct automates infrastructure condition tracking. The complete solution include:

- 1. Zero-power sensor network for tracking silent killers (fatigue, corrosion, erosion etc.) for industrial operations.
- 2. Wireless power and communication network that is easy to install without requiring specialist personnel.
- 3. Hybrid AI, pre-trained on a large physics model, utilizes field data for high fidelity predictions.
- 4. Operations guidance dashboard for critical asset integrity, performance and sustainability insights.

### **TARGET MARKET**

Predyct's predictive automation technology has significant market opportunities across all industrial sectors, as the IoT and Al technology markets continue to grow.

Being located in Houston, we are starting with the energy infrastructure condition tracking as our starting point. Predyct solution can be applied to the management of all energy verticals including:



- A. Wind Energy infrastructure
- B. Offshore production rigs
- C. Refinery
- D. Pipeline
- E. Drilling equipment
- F. New Energy, Storage and CCUS

The overall market in Energy for Non-destructive testing (NDT) is over \$17Billions. We are experiencing a tailwind for both the technology (AI, IoT) and market sector (wind, clean energy, low-carbon energy infrastructure).

While we have a large TAM, we estimate that our serviceable and addressable market in 2023 is over \$5 Billion, with a projected CAGR of 10%.

### **COMPETITORS**

There are companies such as Everactive and Inductosense that are working on energy harvesting or re-packaging the conventional sensors.

Other competitor or perhaps customers later would be NDT suppliers (Mistras, ApplusRTD) and tradition structural monitoring companies (BMT, Pulse). They provide inspection and monitoring services.

There are a number of companies that focus on Machine Health such as Samsara or Augury. They provide a IoT devices and associated analytics for a specific sector (fleet management, machine health).

### **COMPETITIVE ADVANTAGE**

Zero-power sensor network is hyper-scalable, easy to install and provides wireless data access for remote monitoring. At first, the advantage comes from sensor technology and experienced team.

As we continue to aggregate strong dataset, our trained AI algorithms characterizing critical failure modes such as fatigue, corrosion and erosion will provide another layer of competitive advantage. We also provide complete solutions (measurement, analytics and insights) reducing friction to pilot our technology and demonstrating value.

Given the nature of lifecycle condition monitoring, once-installed, we will have long-term relationship with the customers creating additional opportunities for continued growth.

### INTELLECTUAL PROPERTY POSITION

Predyct has secured an exclusive IP for renewable, energy and broader heavy industrial market globally for Nano-engineered sensor technology. The remaining IP period is 16-years. The IP was developed by MIT and it's partners for defense applications.

Predyct plan to develop utility IP to address sector specific challenges.

### SALES/MARKETING STRATEGY

- Our target market includes fast-growing wind infrastructure, ageing energy facilities and OEM equipment in North America and Europe.
- We employ IoT as a Service business model including set-up and annual subscription delivering long-term ARR growth
- Our Initial sales to early adopters in the energy operators and OEMs (end users) creating success stories and customer buy-in
- Paid pilots to demonstrate savings, ease of installation and insights from analytics establishing a track record in 2023
- Channel partnerships with field automation and digital platform providers for rapid expansion from 2024+
- Content-based marketing shortening the customer acquisition cycle to 3-4 weeks



### **EXIT STRATEGY**

Exit strategy of an IPO, acquisition or merger in 2027+, with a goal of favorable revenue multiple.

IoT + AI is a growing market. A number of established companies are looking to acquire this capabilities. Examples include:

- Industrial automation companies (Haliburton, Honeywell, Emerson, Yokagawa)
- Inspection service companies (Mistras, Applus)
- Enterprise Asset Management Companies (IBM Maximo, SAP IAM, Service now)
- Engineering services companies (Wood, WSP, Atkins)
- Digital platform companies (Cognite, C3, SparkCognition)

## IP Summary: Predyct Inc.



Predyct Inc. – 0 relevant US patents found CEO Himanshu Maheshwari – 0 relevant US patents found Head of AI Ali Cetin – 0 relevant US patents found Head of IoT Chiranjit Saha – 0 relevant US patents found

General Notes – TNVC application states that Predyct Inc. has no active patents or patent applications but has secured licensing from MIT and its defense partners for the exclusive use of IP for nano engineered sensor technology relating to renewable energy.

## Licensing agreement between Predyct and MIT has been verified.

Notes on IP position and strategy from application

Predyct has secured an exclusive IP for renewable, energy and broader heavy industrial market globally for Nano-engineered sensor technology. The remaining IP period is 16-years. The IP was developed by MIT and its partners for defense applications. Predyct plans to develop utility IP to address sector specific challenges.

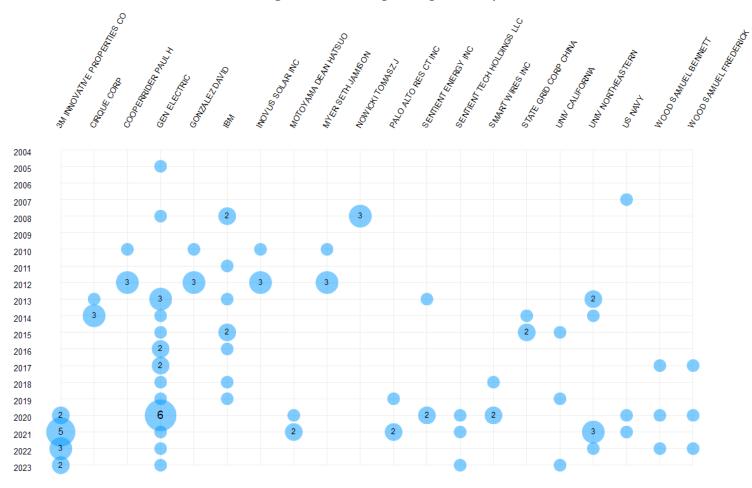
## Similar technologies: Patent Applications by Year



Search terms: ("power grid sensors") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

## Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Energy infrastructure sensor data rectification using regression models	PCT	University of California	WO2015196133A3	("sensors energy infrastructure")	AI for energy infra data	Not sensor related
2	Internet of things (iot) energy device for renewable energy- based micro- grid infrastructure	US Application	Angerame Paul Victor	US2022216695A1	("energy infrastructure iot")	Similar application	No mention of AI
3	Smart sensor for online situation awareness in power grids	US Grant	George Washington University	US11527891B2	(" power grid sensors machine learning")	Similar application	Design and scope
	System and method for distributed, secure, power grid data collection, consensual voting analysis, and situational awareness and anomaly detection	US Grant	Cable Television Laboratories Inc	US11088568B2	(" power grid sensors machine learning")	Similar application	Design and scope



### Prosia Therapeutics, Inc.

CONTACT INFORMATION

Contact Name: Richard Gomer

Contact Phone Number: 713 240 2326

Contact Email Address: rgomer@bio.tamu.edu

**COMPANY INFORMATION** 

**CEO/President Name: Richard Gomer** 

Industry/Technical area of Interest: Healthcare - Rx/Therapeutics

Subcategory (if any):

**Incorporation or Formation Date: 07.31.2020** 

State: Delaware

List Management Team Names: Richard Gomer, CEO

Thomas Meek Darrell Pilling

### **BUSINESS SUMMARY**

Fibrosing diseases are associated with 30-45% of deaths in the US. Despite extraordinary efforts, there are only two drugs approved, both for just one of the many diseases (pulmonary fibrosis), and both only slow the progression of the disease. Prosia is an early-stage drug development company focusing on therapeutics to treat fibrosing diseases. We have highly potent lead compounds that show remarkable efficacy in animal models of lung and cardiac fibrosis. The market for an effective therapeutic for fibrosing diseases would be comparable to multi-billion dollar 'blockbuster' drugs, and Prosia is thus a very high potential reward opportunity. Although there are many competitors, our compounds appear to have higher efficacy. The team is three Texas A&M faculty, all with prior biotech experience. Several venture capital and biotech companies who would buy or fund Prosia have shown interest, but want to see additional data, and we will need ~\$250,000 to do this.

### **CUSTOMER PROBLEM AND SOLUTION**

The customers are the patients dying from fibrosing diseases. There are at least 62 different fibrosing diseases, all without effective cures. Collectively, fibrosing diseases are associated with more deaths in the US than deaths from cancer. Our solution is a remarkably potent set of inhibitors of a key enzyme that drives fibrosis. The enzyme is both necessary and sufficient to drive pulmonary fibrosis in mice. The inhibitors block both the human enzyme and the enzyme in animal models. These potential therapeutics show outstanding efficacy and safety profiles in multiple animal models of fibrosing diseases, and in some cases result in beneficial effects that no other experimental therapeutic has ever shown. We are the only group working on this enzyme as a target to treat fibrosing diseases.

### TARGET MARKET

The target market is patients with fibrosing diseases. For pulmonary fibrosis, there are ~100,000 patients in the US, and the two FDA-approved drugs, even though they only slow the disease and have many side effects, have worldwide annual sales of ~\$3.1 billion. An estimated 10 million people in the US have cardiac fibrosis, and there are no effective drugs for this. Extrapolating from the pulmonary fibrosis data, the cardiac fibrosis market would be well over \$20 billion/ year. Other diseases that these compounds may treat include liver fibrosis (~600,000 patients in the US) and end-stage kidney disease (~786,000 patients in the US). Since all of these diseases are lethal, and there are no therapeutics that stop or reverse fibrosis, there is a desperate need for antifibrotics in the medical community.



### **COMPETITORS**

There is a considerable amount of competition from academic labs, biotech startups, and pharmaceutical companies trying to develop therapeutics for fibrosis. In the pulmonary fibrosis field, there are 886 clinical trials listed, with 224 Phase 2 and 108 phase 3 trials. For cardiac fibrosis, there are 138 trials, with 17 Phase 2 and 12 phase 3 trials. Note however that fibrosing diseases involve misregulation of many processes, and even if one therapeutic from a competitor is useful, a therapeutic like the one Prosia is developing will probably have an additive or synergistic benefit. Since Prosia has dominant IP on inhibitors of a key target, with respect to the specific enzyme we have inhibitors for, we have no competition.

### **COMPETITIVE ADVANTAGE**

Our advantages include an experienced team with complementary expertise in fibrosing diseases and enzyme inhibitor medicinal chemistry, biotech experience, a well-validated drug target, a clear rational understanding of how inhibiting the target inhibits at least four different sub-mechanisms that are clearly linked to fibrosis, remarkably potent and specific inhibitors, outstanding efficacy in animal models, excellent safety profile, a dominant IP position with respect to inhibiting the target, and an overwhelmingly dominant position with respect to the combination of inhibitors and target. We also have a strong team of business advisors. In all published clinical trials, drugs either fail or only slow fibrosis progression, and in preclinical models, these only partially inhibited fibrosis. In the same preclinical models, our potential therapeutics completely inhibited fibrosis. This indicates that our platform has a very strong competitive advantage.

#### INTELLECTUAL PROPERTY POSITION

Our IP comprises inhibitors of a key enzyme (neuraminidase 3, NEU3) potentiating fibrosis. We have a very strong and very comprehensive patent application for our new class of potential drugs for all known fibrosing diseases, as well as other diseases (including some cancers and liver steatosis) where these drugs should show efficacy. We have picket-fence patent applications on other known inhibitors, as well as a patent application for one of our new compounds as a potential therapeutic for COVID-like symptoms including a class of diseases involving overactivation of the immune system. All of this IP is owned by Texas A&M.

### SALES/MARKETING STRATEGY

We approached 10 VC firms, and one VC firm approached us. The 3 VC firms that showed interest were excited by the basic platform, and happy with the team experience (RG and DP previously started a biotech company that had successful Phase 2 trials and was purchased by Roche in a \$1.39B deal, and TM was a vice president at GlaxoSmithKline supervising medicinal chemistry). The VCs all want to see a larger data package before making a decision on whether to fund the company. This level of VC, and this level of funding, would include the VC firm choosing, and paying, an experienced top-level early stage biotech CEO to run the company. We have also approached 6 biotech/ pharmaceutical companies to try to get them to purchase or fund Prosia. As with the VCs, they want to see a larger data package. We go to scientific meetings where there are VC and pharma people, actively seek them out, do informal pitches, and then email them a pitch deck. We are also gearing up to apply for STTR funding.

#### **EXIT STRATEGY**

The ultimate exit strategy is to have Prosia purchased by a major pharmaceutical firm, or to go public. For instance, Promedior, the previous company that Darrell Pilling and I started, was purchased by Roche in a \$1.39 billion deal. An intermediate exit strategy is to have Prosia funded by a large venture capital firm. For instance, one VC firm that approached us, and has thus been interested (but wants to see "more meat on the bone") had a single funding round of more than \$3 billion. The exit strategy of these 'blue chip' VCs is to either do a sale to a large pharma company or do an IPO.

### IP Summary: Prosia Therapeutics Inc.



Prosia Therapeutics Inc. – 0 relevant US patents found CEO Richard Gomer – 3 relevant US patents found Thomas Meek – 1 relevant US patents found Darrel Pilling – 3 relevant US patents found

General Notes – TNVC application states that Prosia Therapeutics Inc. has a number of patent applications (PCT/US2020/017504, US application 20190201485 / 16/293379, US application 202063036915/ PCT/US2021/036152, PCT/US2022/77935) related to inhibitors of a key enzyme potentiating fibrosis. The IP the company uses belongs to TAMU and it is not stated what licensing agreement the company has with TAMU.

Licensing agreement between Prosia Therapeutics and Texas A&M University has been verified. The company has the option to exercise their license to file until July 2023.

Notes on IP position and strategy from application

Our IP comprises inhibitors of a key enzyme potentiating fibrosis. We have a very strong and very comprehensive patent application for our new class of potential drugs for all known fibrosing diseases, as well as other diseases where these drugs should show efficacy. We have picket-fence patent applications on other known inhibitors, as well as a patent application for one of our new compounds as a potential therapeutic for COVID-like symptoms including a class of diseases involving overactivation of the immune system. All this IP is owned by Texas A&M.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Anti-fibrotic neu3 inhibitor compounds and methods of use	US Application	Richard H. Gomer Thomas Meek Tejas Karhadkar Darrell Pilling	Texas A&M University	US20220133671A1	Filed 02/10/2020 Alt Nos. JP2021547082A AU2020221054A WO2020167663A1 EP20755169.8A CA3129891A Pending in all locations where applied

# IP Summary: Prosia Therapeutics Inc.

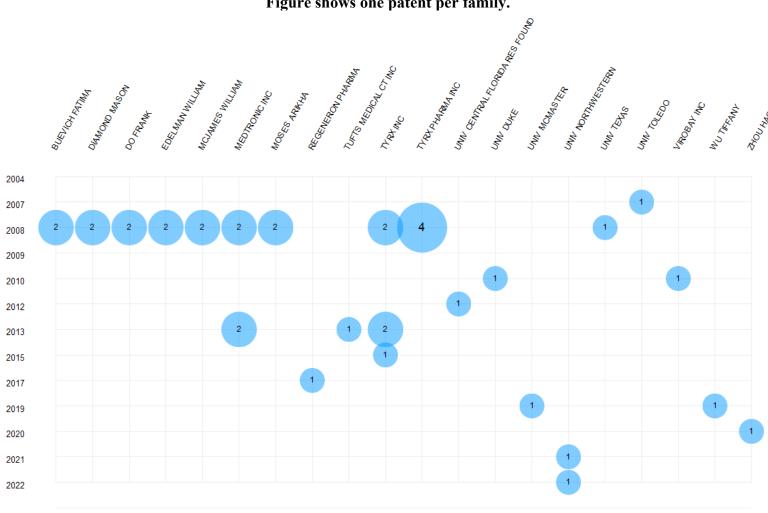


2	Anti-fibrotic sialidase inhibitor compounds and methods of use	US Application	Richard H. Gomer Darrell Pilling Nehemiah Cox Tejas Karhadkar	Texas A&M University	US20190201485A1	Filed 03/05/2019 Alt Nos. EP17783606.1A JP2019512857A AU2017325024A WO2018049003A1
3	Therapeutics for treatment of covid-19 symptoms	PCT	Richard H. GOMER Darrell Pilling Tejas Karhadkar	Texas A&M University	WO2021252347A1	Filed 06/07/2021 Alt Nos. CA3182168A EP21821736.2A

Search terms: ("inhibit fibrosis cardiac") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Methods and compositions for inhibiting fibrosis and scarring	PCT	Univ. North Carolina Chapel Hill	WO2023034898A1	("inhibit fibrosis'')	Similar application	Design and scope
2	Methods and compositions for treating fibrosis	PCT	University of Chicago	WO2022256824A1	("inhibit fibrosis'')	Similar application	Design and scope
3	Inhibition of cardiac fibro sis in myocardial infarction	US Grant	Lander Cynthia Brophy Colleen Patterson Cam	US10336788B2	("inhibit fibrosis cardiac")	Similar application	Design and scope
	Prevention of vascular and cardiac fibrosis via irelalpha inhibition	US Application	University of McMaster	US2019038597A1	("inhibit fibrosis cardiac")	Similar application	Design and scope

- 1. A method of treatment of a fibrotic disorder, the method comprising administering a pharmaceutical formulation comprising a compound of formula (I) R1 is selected from hydrogen, —NO2, —CN, —COOH, —CONH2, —COCH3, C2-5acyl, C1-6alkyl ester, aryl ester, —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO2NH(C1-6aryl), —SO3(C1-6alkyl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2H(C1-6alkyl), —PO2H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —N(C1-6alkyl), —CONH2, —OH, halo, C1-6alkyl, aryl, —COOH, —NHCO(C1-6alkyl), C1-6alkyl ether, —CO(C1-6alkyl), —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO3H(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6alkyl), —PO3H2, —PO2H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2H(C1-6alkyl), —PO2H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —N(C1-6alkyl), —CONH2, —OH, halo, C1-6alkyl, aryl, —COOH, —NHCO(C1-6alkyl), —N(C1-6alkyl), —CO(C1-6alkyl), —CONH2, —OH, halo, C1-6alkyl, aryl, —COOH, —NHCO(C1-6alkyl), —CO(C1-6alkyl), —CO(C1-6alkyl), —CO(C1-6alkyl), —SO3H(C1-6aryl), —SO3H(C1-6aryl), —SO3H(C1-6aryl), —PO3H(C1-6aryl), —PO3H(C1-6aryl),
- 2. A method of treatment of a fibrotic disorder, the method comprising administering a pharmaceutical formulation comprising a compound of formula (I) or its salt, wherein: R1 is selected from hydrogen, a halogen, —NH2, —NO2, —CN, —COOH, —CONH2, —COCH3, COCF3, COCHF2, C2-5acyl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO2NH(C1-6alkyl), —SO3(C1-6alkyl), —PO3H2, —PO2H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), —PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), and tetrazole; R2, R3, and R4 is independently selected from hydrogen, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl, C1-6alkyl), —CONH2, —OH, halogen, C1-6alkyl, aryl, —COOH, —CH(OH)CH3, —CH(OH)(CH2OH), —CH(OH)CH2OH), —NHCO(C1-6alkyl), —SO3(C1-6alkyl), —SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —SO2NH(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6alkyl), —PO3H(C1-6aryl), —PO3H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6alkyl), —NCOH3, C2-5acyl, —CO(aryl), —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl), —COH4, hydroxypropyl, tir-hydroxypropyl, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl), —CONH2, —OH, a halogen, C1-6alkyl, aryl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —COOH, —NHCO(C1-6alkyl), —COCH3, C2-5acyl, —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO3H(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6alkyl), —SO3H(C1-6alkyl), —PO3H(C1-6alkyl), —PO3

3. A method of treatment of liver inflammation, the method comprising administering a pharmaceutical formulation comprising a compound of formula (I) or its salt, wherein: R1 is selected from hydrogen, a halogen, —NH2, NO2, —CN, —COOH, —CONH2, — COCH3, COCF3, COCHF2, C2-5acyl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), — SO2NH(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), — PO2H(C1-6alkyl), —PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), and tetrazole; R2, R3, and R4 is independently selected from hydrogen, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl), —CONH2, —OH, halogen, C1-6alkyl, aryl, —COOH, —CH(OH)CH3, —CH(OH)(CH2OH), —CH(OH)(CH(OH)CH2OH), —NHCO(C1-6alkyl), C1-6alkyl ether, —(CH2)1-3NH2, —COCH3, C2-5acyl, —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO2NH(C1-6aryl), — SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), —PO2H(C1-6alkyl), — PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), tetrazole, and 2-oxazolyl; R5 is selected from hydrogen, —CH2OH, hydroxypropyl, di-hydroxypropyl, tri-hydroxypropyl, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl), C1-6alkyl), —CONH2, —OH, a halogen, C1-6alkyl, aryl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —COOH, —NHCO(C1-6alkyl), — COCH3, C2-5acyl, —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO2NH(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6a 6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), —PO2H(C1-6alkyl), —PO2H(C1-6aryl), —PO3H(C1-6aryl), —PO3H(C1-6ar 6alkyl), —PO3H(C1-6aryl), tetrazole, and 2-oxazolyl; and X is selected from carbon and nitrogen. 130. A method of obesity treatment, the method comprising administering a pharmaceutical formulation comprising a compound of formula (I) or its salt, wherein: R1 is selected from hydrogen, a halogen, —NH2, NO2, —CN, —COOH, —CONH2, —COCH3, COCF3, COCHF2, C2-5acyl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), — SO2NH(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), — PO2H(C1-6alkyl), —PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), and tetrazole; R2, R3, and R4 is independently selected from hydrogen, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl), —CONH2, —OH, halogen, C1-6alkyl, aryl, —COOH, —CH(OH)CH3, —CH(OH)(CH2OH), —CH(OH)(CH(OH)CH2OH), —NHCO(C1-6alkyl), C1-6alkyl ether, —(CH2)1-3NH2, —COCH3, C2-5acyl, —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO2NH(C1-6aryl), — SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), —PO2H(C1-6alkyl), — PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), tetrazole, and 2-oxazolyl; R5 is selected from hydrogen, —CH2OH, hydroxypropyl, di-hydroxypropyl, tri-hydroxypropyl, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl), C1-6alkyl), —CONH2, —OH, a halogen, C1-6alkyl, aryl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —COOH, —NHCO(C1-6alkyl), — COCH3, C2-5acyl, —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO2NH(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6a 6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), —PO2H(C1-6alkyl), —PO2H(C1-6aryl), —PO3H(C1-6aryl), —PO3H(C1-6ar 6alkyl), —PO3H(C1-6aryl), tetrazole, and 2-oxazolyl; and X is selected from carbon and nitrogen.

- 4. A method of treatment of a steatosis, the method comprising administering a pharmaceutical formulation comprising a compound of formula (I) or its salt, wherein: R1 is selected from hydrogen, a halogen, —NH2, NO2, —CN, —COOH, —CONH2, —COCH3, COCF3, COCHF2, C2-5acyl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), — SO2NH(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), — PO2H(C1-6alkyl), —PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), and tetrazole; R2, R3, and R4 is independently selected from hydrogen, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl), —CONH2, —OH, a halogen, C1-6alkyl, aryl, —COOH, —CH(OH)CH3, —CH(OH)(CH2OH), —CH(OH)(CH(OH)CH2OH), —NHCO(C1-6alkyl), C1-6alkyl ether, —(CH2)1-3NH2, —COCH3, C2-5acyl, —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO2NH(C1-6aryl), — SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), —PO2H(C1-6alkyl), — PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), tetrazole, and 2-oxazolyl; R5 is selected from hydrogen, —CH2OH, hydroxypropyl, di-hydroxypropyl, tri-hydroxypropyl, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl), C1-6alkyl), —CONH2, —OH, a halogen, C1-6alkyl, aryl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —COOH, —NHCO(C1-6alkyl), — COCH3, C2-5acyl, —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO2NH(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6a 6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), —PO2H(C1-6alkyl), —PO2H(C1-6aryl), —PO3H(C1-6aryl), —PO3H(C1-6ar 6alkyl), —PO3H(C1-6aryl), tetrazole, and 2-oxazolyl; and X is selected from carbon and nitrogen.
- 5. A method of treating a sialidase-overexpressing cancer, the method comprising administering a pharmaceutical formulation comprising a compound of formula (I) or its salt, wherein: R1 is selected from hydrogen, a halogen, —NH2, NO2, —CN, —COOH, —CONH2, —COCH3, COCF3, COCHF2, C2-5acyl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —SO3H, —SO2NH2, — SO2NH(C1-6alkyl), —SO2NH(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), — PO2NH(C1-6aryl), —PO2H(C1-6alkyl), —PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), and tetrazole; R2, R3, and R4 are independently selected from hydrogen, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), —N(C1-6alkyl), —CONH2, —OH, halogen, C1-6alkyl, aryl, —COOH, —CH(OH)CH3, —CH(OH)(CH2OH), —CH(OH)(CH(OH)CH2OH), —NHCO(C1-6alkyl), C1-6alkyl ether, —(CH2)1-3NH2, —COCH3, C2-5acyl, —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), — SO2NH(C1-6aryl), —SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), — PO2H(C1-6alkyl), —PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), tetrazole, and 2-oxazolyl; R5 is selected from hydrogen, —CH2OH, hydroxypropyl, di-hydroxypropyl, tri-hydroxypropyl, —NO2, —CN, —CF3, —NH2, —NH(C1-6alkyl), — N(C1-6alkyl, C1-6alkyl), —CONH2, —OH, a halogen, C1-6alkyl, aryl, C1-6alkyl ester, aryl ester, —(CH2)1-3NH2, —COOH, — NHCO(C1-6alkyl), —COCH3, C2-5acyl, —CO(aryl), —SO3H, —SO2NH2, —SO2NH(C1-6alkyl), —SO2NH(C1-6aryl), — SO3(C1-6alkyl), —SO3(C1-6aryl), —PO3H2, —PO2H2, —PO2NH(C1-6alkyl), —PO2NH(C1-6aryl), —PO2H(C1-6alkyl), — PO2H(C1-6aryl), —PO3H(C1-6alkyl), —PO3H(C1-6aryl), tetrazole, and 2-oxazolyl; and X is selected from carbon and nitrogen.

### Prosia Therapeutics Inc. IP: Independent Claims of US20190201485A1



- 1. A method of preventing or inhibiting fibrosis in a human comprising administering to a human at least one of Compounds 1-58, or any combination thereof, in an amount and for a time sufficient to inhibit the activity of at least one human sialidase in the human.
- 2. A method of preventing or inhibiting fibrosis in a human comprising administering to a human at least one of Compounds 1-58, or any combination thereof, in an amount and for a time sufficient to inhibit level or activity of TGF- $\beta$ 1 in the human.
- 3. A method of preventing or inhibiting fibrosis in a human comprising administering to a human at least one isolated human or humanized monoclonal antibody that binds to the active site of at least one human sialidase wherein the antibody is administered in an amount and for a time sufficient to inhibit the activity of the at least one human sialidase in the human.

### Prosia Therapeutics Inc. IP: Independent Claims of WO2021252347A1

- 1. A method of treating CALD, the method comprising administering to a patient with COVID-19 an effective amount of a pharmaceutical formulation comprising compound I I
- 2. A method of treating CALD, the method comprising administering to a patient having an oxygen level of less than 90% as measured by pulse oximetry and a pulmonary compliance of greater than 50 ml/cm LLO an effective amount of a pharmaceutical formulation comprising compound I. 5. The method of Claim 4, wherein the patent has a serum concentration of D-dimer greater than 1 pg/ml.
- 3. A method of treating CALD, the method comprising administering to a patient with COVID-19 an effective amount of a pharmaceutical formulation comprising compound II II
- 4. A method of treating CALD, the method comprising administering to a patient having an oxygen level of less than 90% as measured by pulse oximetry and a pulmonary compliance of greater than 50 ml/cm ThO an effective amount of a pharmaceutical formulation comprising compound II.
- 5. A method of treatment of cytokine storm, the method comprising administering to a patient having a serum level of interleukin- 1b greater than 3.2 pg/ml an effective amount of a pharmaceutical formulation comprising compound II.
- 6. A method of treatment of cytokine storm, the method comprising administering to a patient having a serum level of interleukin-6 greater than 7 pg/ml an effective amount of a pharmaceutical formulation comprising compound II.
- 7. A method of treatment of cytokine storm, the method comprising administering to a patient having a serum level of interleukin-12p70 greater than 40 pg/ml an effective amount of a pharmaceutical formulation comprising compound II.
- 8. A method of treatment of cytokine storm, the method comprising administering to a patient having a serum level of interleukin-23 greater than 15 pg/ml an effective amount of a pharmaceutical formulation comprising compound II.
- 9. A method of treatment of cytokine storm, the method comprising administering to a patient having a serum level of interleukin-27 greater than 1 ng/ml an effective amount of a pharmaceutical formulation comprising compound II.
- 10. A method of treatment of cytokine storm, the method comprising administering to a patient having a D-dimer level of greater than 1 pg/ml an effective amount of a pharmaceutical formulation comprising compound II.

Ι

[0419] The above disclosed subject matter is to be considered illustrative, and not restrictive, and the appended claims are intended to cover all such modifications, enhancements, and other embodiments which fall within the true spirit and scope of the present disclosure. For example, although the disclosure focuses on inhibiting human sialidases, the sialidase inhibitors disclosed may be effective against other mammalian sialidases, particularly those with a protein sequence or structure similar to human sialidase. Efficacy of sialidase inhibitors against other mammalian sialidases may be readily determined using the methods set forth in this disclosure. In addition, methods of affecting fibrocytes, fibrosis, inflammation, steatosis, obesity, and cancer using such sialidase inhibitors may be adapted from this disclosure.

1. A method of treatment of a fibrotic disorder, the method comprising administering a pharmaceutical formulation comprising a compound of formula (I)

$$\begin{array}{c|c} R_3 \\ R_4 \\ \hline \\ R_5 \\ \hline \\ R_1 \\ \end{array}$$

 $\begin{array}{lll} R1 \ is \ selected \ from \ hydrogen, \ --NO_2, \ --CN, \ --COOH, \ --CONH_2, \ --COCH_3, \ C_{2-5}acyl, \ C_{1-6}alkyl \ ester, \ aryl \ ester, \ --SO_3H, \ --SO_2NH_2, \ --SO_2NH(C_{1-6}alkyl), \ --SO_3(C_{1-6}alkyl), \ --SO_3(C_{1-6}alkyl), \ --SO_3(C_{1-6}alkyl), \ --SO_3(C_{1-6}alkyl), \ --PO_2NH(C_{1-6}alkyl), \ --PO_2NH(C_{1-6}alkyl), \ --PO_2H(C_{1-6}alkyl), \ --PO_2H(C_{1-6}alkyl), \ --PO_3H(C_{1-6}alkyl), \ --PO_3H(C_{1-6}a$ 

 $\begin{array}{lll} R2,\ R3,\ and\ R4\ are\ independently\ selected\ from\ hydrogen, & -NO_2, & -CN, & -CF_3, & -NH_2, & -NH(C_{1-6}alkyl), \\ & -N(C_{1-6}alkyl),\ C_{1-6}alkyl),\ & -CONH_2,\ & -OH,\ halo, \\ & C_{1-6}alkyl,\ aryl, & -COOH, & -NHCO(C_{1-6}alkyl),\ C_{1-6}alkyl,\ aryl, & -CO(C_{1-6}alkyl),\ & -CO(aryl),\ & -SO_3H, \\ & -SO_2NH_2,\ & -SO_2NH(C_{1-6}alkyl),\ & -SO_2NH(C_{1-6}aryl),\ & -PO_3H(C_{1-6}aryl),\ & -PO_3H_2,\ & -PO_2H_2,\ & -PO_2NH(C_{1-6}alkyl),\ & -PO_2NH(C_{1-6}aryl),\ & -PO_3H(C_{1-6}aryl),\ & -PO_3H(C_{1-6}aryl),\$ 

di-hydroxypropyl, tri-hydroxypropyl, — $NO_2$ , —CN, — $CF_3$ , — $NH_2$ , — $NH(C_{1-6}alkyl)$ , — $N(C_{1-6}alkyl)$ , aryl, —COOH, — $ONH_2$ , —OH, halo,  $C_{1-6}alkyl$ , aryl, —COOH, — $NHCO(C_{1-6}alkyl)$ , — $CO(C_{1-6}alkyl)$ , — $CO(C_{1-6}al$ 

X is selected from carbon and nitrogen.

**2**. The method of claim **1**, wherein the activity of human NEU3 in desialylating LAP is inhibited.

3. The method of claim 1, wherein the activity of human NEU3 in desialylating SAP is inhibited.

**4**. The method of claim **2**, wherein the formation or activation of fibrocytes is inhibited.

5. The method of claim 3, wherein the formation or activation of fibrocytes is inhibited.

**6**. The method of claim **1**, wherein the compound is methyl picolinate.

7. The method of claim 1, wherein the compound is 2-acetyl pyridine.

8. The method of claim 1, further comprising administering the formulation in an amount and for a time sufficient to decrease the level or activity of  $TGF-\beta 1$  in a human.

**9**. The method of claim **1**, further comprising administering the formulation in an amount and for a time sufficient to decrease the level or activity of a sialidase in a human.

10-29. (canceled)

**30**. A method of treatment of a fibrotic disorder, the method comprising administering a pharmaceutical formulation comprising a compound of formula (I)

$$\begin{array}{c}
R3 \\
R4 \\
R5 \\
R6
\end{array}$$

$$\begin{array}{c}
R2 \\
R1 \\
R6
\end{array}$$

or its salt, wherein:

 $\begin{array}{l} R_1 \text{ is selected from hydrogen, a halogen, } --NH_2, --NO_2, \\ --CN, --COOH, --CONH_2, --COCH_3, COCF_3, \\ COCHF_2, C_{2-5} \text{acyl, } C_{1-6} \text{alkyl ester, aryl ester, } --(CH_2) \\ {}_{1\text{-3}} \text{NH}_2, --SO_3 \text{H, } --SO_2 \text{NH}_2, --SO_2 \text{NH}(C_{1-6} \text{alkyl}), \\ --SO_2 \text{NH}(C_{1-6} \text{aryl}), --SO_3(C_{1-6} \text{alkyl}), --SO_3(C_{1-6} \text{alkyl}), --SO_3(C_{1-6} \text{alkyl}), \\ --PO_2 \text{NH}(C_{1-6} \text{aryl}), --PO_2 \text{H}_2, --PO_2 \text{NH}(C_{1-6} \text{alkyl}), \\ --PO_2 \text{NH}(C_{1-6} \text{aryl}), --PO_2 \text{H}(C_{1-6} \text{alkyl}), --PO_2 \text{H}(C_{1-6} \text{aryl}), \\ \text{adays}, --PO_3 \text{H}(C_{1-6} \text{alkyl}), --PO_3 \text{H}(C_{1-6} \text{aryl}), \\ \text{and tetrazole;} \end{array}$ 

R<sub>2</sub>, R<sub>3</sub>, and R<sub>4</sub> is independently selected from hydrogen,  $-NO_2$ , -CN,  $-CF_3$ ,  $-NH_2$ ,  $-NH(C_{1.6}alkyl)$ ,  $-N(C_{1-6}alkyl, C_{1-6}alkyl), -CONH_2, -OH, halogen,$ C<sub>1-6</sub>alkyl, aryl, —COOH, —CH(OH)CH<sub>3</sub>, —CH(OH) (CH<sub>2</sub>OH), —CH(OH)(CH(OH)CH<sub>2</sub>OH), —NHCO  $(C_{1-6}alkyl),$  $\mathrm{C}_{ ext{1-6}}$ alkyl ether,  $-(CH_2)_{1-3}NH_2$ , —COCH<sub>3</sub>, C<sub>2-5</sub>acyl, —CO(aryl),  $-SO_3H$ , -SO<sub>2</sub>NH<sub>2</sub>,  $-SO_2NH(C_{1-6}alkyl), -SO_2NH(C_{1-6}alkyl)$ 6aryl),  $-SO_3(C_{1-6}alkyl)$ ,  $-SO_3(C_{1-6}aryl)$ ,  $-PO_3H_2$ ,  $\begin{array}{lll} & -\text{PO}_2\text{H}_2, & -\text{PO}_2\text{NH}(\text{C}_{1\text{-}6}\text{alkyl}), & -\text{PO}_2\text{NH}(\text{C}_{1\text{-}6}\text{aryl}), \\ -\text{PO}_2\text{H}(\text{C}_{1\text{-}6}\text{alkyl}), & -\text{PO}_2\text{H}(\text{C}_{1\text{-}6}\text{aryl}), & -\text{PO}_3\text{H}(\text{C}_{1\text{-}6}\text{aryl}), \\ \end{array}$ 6alkyl), —PO<sub>3</sub>H(C<sub>1-6</sub>aryl), tetrazole, and 2-oxazolyl; R<sub>5</sub> is selected from hydrogen, —CH<sub>2</sub>OH, hydroxypropyl,

di-hydroxypropyl, tri-hydroxypropyl, — $NO_2$ , —CN, — $CF_3$ , — $NH_2$ , — $NH(C_{1-6}alkyl)$ , — $N(C_{1-6}alkyl)$ , — $CONH_2$ , —OH, a halogen,  $C_{1-6}alkyl$ , aryl,  $C_{1-6}alkyl$  ester, aryl ester, — $(CH_2)_{1-3}NH_2$ , —COOH, — $NHCO(C_{1-6}alkyl)$ , — $COCH_3$ ,  $C_{2-5}acyl$ , —CO(aryl), — $SO_3H$ , — $SO_2NH_2$ , — $SO_2NH(C_{1-6}alkyl)$ , — $SO_3H(C_{1-6}alkyl)$ , —SO

X is selected from carbon and nitrogen.

bleomycin-induced fibrosis than those without fibrosis. Treatment with sialidase inhibitors starting at day 10 reduced the number of cells collected. Since increased numbers of BAL cells indicates increased inflammation in the lung fluid, these results indicate that when administered starting when a fibrosis has already been established, sialidase inhibitors inhibit inflammation.

[0237] FIG. 9I shows the total number of CD11b+ inflammatory neutrophils and macrophages collected from the BAL. Mice with bleomycin-induced fibrosis had increased levels of CD11b+ cells. These levels were decreased by treatment with sialidase inhibitors starting at day 10, indicating that sialidase inhibitors were able to inhibit inflammation when administered starting at a time after a fibrosis has become established.

[0238] FIG. 9J shows the total protein in BAL from the various mice. Bleomycin resulted in an increase in total protein. This increased BAL fluid protein was attenuated by treatment with the sialidase inhibitor oseltamivir beginning at day 10, indicating that a sialidase inhibitor inhibits edema and/or or epithelial barrier destruction during fibrosis when the administration of the sialidase inhibitor begins after a fibrosis has become established.

[0239] Overall, the data in FIGS. 9A-9J indicate that sialidase inhibitors may decrease fibrocyte formation and help prevent or inhibit fibrosis.

[0240] In mice treated as in FIGS. 9F-9J, decreased NEU1, NEU2 and NEU3 staining was also observed at 21 days. Results representative of three independent experiments are presented in FIG. 9K, with ImageJ quantification in FIGS. 9L-9O. The results indicate that sialidase inhibitors also decrease sialidase expression, consistent with inhibition of a positive feedback loop.

#### Example 11

### Fibrotic Mouse Lungs Contain Normal Levels of Total Sialic Acid

[0241] To determine if the reduced levels of sialic acid on glycoconjugates in fibrotic mouse lungs was due to reduced levels of total sialic acid, the sialic acid content of pieces of lung tissue was determined. 0.2 g resorcinol was dissolved in 10 ml water. 1 ml of the 2% resorcinol stock solution was mixed with 8 ml of 12M HCl. 25 µl of 0.1 M CuSO₄ in water was added to this solution, and the volume was adjusted to 10 ml with water. Approximately 1.2×1.2×1.2 mm pieces from lungs frozen in OCT (and used for FIG. 8C) were collected. The OCT was allowed to thaw and the lung pieces were then washed by repeatedly pipetting 500 µl of PBS onto the sample; this was repeated with 3 aliquots of PBS. After removing the PBS, the lung piece was weighed. Lung pieces were placed in 200 ul of PBS in eppendorf tubes. Sialic acid (Vector laboratories) was weighed and dissolved in PBS to make a series of concentration standards. 200 µl of the resorcinol/HCl/CuSO<sub>4</sub> solution was added to the lung tissue pieces in PBS, and to 200 µl of standard solutions. Tubes were then incubated in a heating block at 100° C. for 15 minutes, and the tubes were then cooled to room temperature in a water bath. 0.5 ml of iso-amyl alcohol was added to the tubes and was mixed by vigorous shaking for 1 minute. The tubes were cooled in ice water for 15 minutes and then subjected to centrifugation for 2 minutes at 1000×g. 100 µl of the upper amyl alcohol phase was transferred to the well of a 96-well plate, and the absorbance was read at 450 nm and 580 nm. The absorbance at 580 nm was then subtracted from the absorbance at 450 nm, a standard curve was plotted, and the unknown concentration of sialic acid from the tissue samples were estimated from the curve. Values were then converted to mg sialic acid/g tissue. As shown in FIG. 10, there was no significant difference between the sialic acid content of the control (saline treated) and fibrotic (bleomycin-treated) lungs. This then supports the idea that the reduced levels of sialylation seen in fibrotic lungs is due to an increase level of sialidase activity.

### Example 12

### Sialidase Inhibitors Also Decrease TGF- $\beta$ 1 Levels in Mice

[0242] To determine if sialidase inhibitors could also reduce TGF- $\beta1$  levels in mice, mice were treated with bleomycin or saline, then injected daily with saline, DANA or oseltamivir starting at day 10 after bleomycin treatment, as described in Example 9. The mice were euthanized at day 21 and sections of lung tissue were stained for TGF- $\beta1$ . Results are presented in FIG. 11A and are representative of results for three mice per group. FIG. 11B shows ImageJ quantification of the FIG. 11A staining.

[0243] Both DANA and oseltamivir reduced TGF- $\beta$ 1 levels in bleomycin-treated mice, consistent with the connection between TGF- $\beta$ 1 and sialidases.

[0244] The above disclosed subject matter is to be considered illustrative, and not restrictive, and the appended claims are intended to cover all such modifications, enhancements, and other embodiments which fall within the true spirit and scope of the present disclosure. For example, although the disclosure focuses on inhibiting human sialidases, the sialidase inhibitors disclosed may be effective against other mammalian sialidases, particularly those with a protein sequence or structure similar to human sialidase. Efficacy of sialidase inhibitors against other mammalian sialidases may be readily determined using the methods set forth in this disclosure. In addition, methods of affecting fibrocytes and fibrosis using such sialidase inhibitors may be adapted from this disclosure.

- 1. A method of preventing or inhibiting fibrosis in a human comprising administering to a human at least one of Compounds 1-58, or any combination thereof, in an amount and for a time sufficient to inhibit the activity of at least one human sialidase in the human.
- 2. The method of claim 1, wherein at least one of Compounds 1-58 or any combination thereof is administered
- 3. The method of claim 1, wherein the activity of at least human NEU1 in desialylating SAP is inhibited.
- **4**. The method of claim **1**, wherein the activity of at least human NEU2 in desialylating SAP is inhibited.
- 5. The method of claim 1, wherein the activity of at least human NEU3 in desialylating SAP is inhibited.
- **6**. The method of claim **1**, wherein the activity of at least human NEU4 in desialylating SAP is inhibited.
- 7. The method of claim 1, wherein the activity of at least one human sialidase on terminal sialic acids with an  $\alpha(2, 6)$ -linkage is inhibited.
- **8**. The method of claim **1**, wherein the activity of at least one human sialidase on terminal sialic acids with an  $\alpha(2, 3)$ -linkage is inhibited.

### **Claims**

 A method of treating CALD, the method comprising administering to a patient with COVID-19 an effective amount of a pharmaceutical formulation comprising compound I

5

10

I

- 2. The method of Claim 1, wherein the patent has a serum concentration of D-dimer greater than 1  $\mu$ g/ml.
- 3. The method of Claim 1, wherein the amount of D-dimer in the patient's blood is decreased from greater than 1 μg/ml to less than 1 μg/ml.
  - 4. A method of treating CALD, the method comprising administering to a patient having an oxygen level of less than 90% as measured by pulse oximetry and a pulmonary compliance of greater than 50 ml/cm H<sub>2</sub>O an effective amount of a pharmaceutical formulation comprising compound I.
- 5. The method of Claim 4, wherein the patent has a serum concentration of D-dimer greater than 1 μg/ml.
  - 6. The method of Claim 4, wherein the amount of D-dimer in the patient's blood is decreased from greater than 1  $\mu$ g/ml to less than 1  $\mu$ g/ml.
- 7. A method of treating CALD, the method comprising administering to a patient with
   20 COVID-19 an effective amount of a pharmaceutical formulation comprising compound II



### Resonantia Diagnostics, Inc

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**COMPANY INFORMATION** 

**CEO/President Name:** Matt Jones

Industry/Technical area of Interest: Healthcare - Device

Subcategory (if any):

**Incorporation or Formation Date: 11.12.2020** 

State: Delaware

List Management Team Names: Matt Jones, CEO

Darren Branch, PI

### **BUSINESS SUMMARY**

We founded this company to reduce the time to targeted therapy for bacterial and fungal infections from days to hours. When a doctor suspects that a patient has an infection, they need to know two things: 1. What is causing the infection (identification) & 2. What therapy and at what dosage is going to stop the infection (susceptibility). Today, it typically takes a minimum if 48 hours to get the ID and susceptibility information and testing is done in central laboratories. This means that a patient has to wait a minimum of 48 hours, often longer, to receive targeted therapy - the antibiotic treatment that doctors know is going to be effective against the infection. While waiting for targeted therapy, patients are on broad based antibiotics, which have negative side effects to the patient and make antibiotic resistance worse. Our instrument provides ID & the MIC in approximately 2-3 hours after a patient presents with symptoms, approximately 25 X faster than traditional methods.

### **CUSTOMER PROBLEM AND SOLUTION**

We are addressing the unmet need for a rapid identification and susceptibility testing for bacteria and fungi. Drug resistant infections are a massive public health threat. The UK Government predicts that by 2050 these infections will kill an estimated 10M people per year, 2M more than cancer. Currently, it takes hospitals at least 48 hours to get the minimum inhibitory concentration (MIC), the minimum of amount of antibiotic that will stop an infection. The current turnaround time for testing is making resistance worse. Despite advancements in rapid molecular ID, hospitals continue to conduct the traditional workflow in parallel as it is still the most reliable way to get the MIC. New rapid ID technology has been additive to the overall workflow and it does not provide the information clinicians need - the MIC. Not only does the delay increase resistance to antibiotics, it also increases a patient's mortality risk, which rises ~7% every hour they do not receive appropriate therapy.

### TARGET MARKET

Our initial target customers are large, greater than 500 beds, academic hospitals as they are early adopters and advocates of new medical technology. We plan to acquire these customers following FDA authorization through various techniques that include attending tradeshows, publishing academic papers that detail how our product is an improvement over current products, and through sales and marketing. In the hospitals, we will target their clinical microbiology laboratories. The laboratory director is the economic buyer and the main influencer is the senior microbiologist. Once we have established our product at large hospitals, we will move to sell to the point of care, physician offices, urgent care centers, and medium



and small hospitals. I believe we can capture 10% of hospitals in the US, which is approximately 600 hospitals, in the 5 years following commercial launch. This represents an opportunity of \$500M in annual recurring revenue.

### COMPETITORS

We recognize that the medical diagnostic market is a competitive, mature, and heavily regulated market, with multiple large multinational companies, like Danaher, BD, or BioMerieux, dominating the market. These companies provide legacy solutions that take days to provide the susceptibility profile, which is making the problem of antibiotic resistance worse. Other startups with products under development that are direct competitors are Pattern and SeluxDx. However, our antimicrobial susceptibility testing capabilities are faster than either of these platforms. Additionally, our platform is being designed for use at the point of care, instead of in a hospital or central laboratory.

### **COMPETITIVE ADVANTAGE**

Our competitive advantage is our acoustic sensor and the speed with which we are able to provide the MIC. We will be able to provide the MIC in the same shift that a patient presents with symptoms. Current susceptibility technology is limited as it relies on detecting macro-scale changes based on the slow growth rates of bacteria and fungus, while our approach measures subtle changes at the cellular level during antibiotic/antifungal exposure. Another novel aspect of our solution is that we are capable of offering all three assays, ID, Susceptibility, and host-based response in one instrument. Being able to offer all three tests in one platform will help reduce equipment requirements for laboratories and be able to bring laboratory diagnostics to the point of care. Another advantage is that our sensors are not expensive to produce and as production technology improves, our cost will continue to decrease bringing our technology to additional communities. We save time and money.

### INTELLECTUAL PROPERTY POSITION

We are currently partnering with Sandia National Laboratories via a cooperative research and development agreement (CRADA) to further develop two pieces of acoustic technology into a point of care diagnostic platform. Under the terms of a CRADA, all IP developed during our agreement will either be co-owned or exclusively licensed to Resonantia Diagnostics. Additionally, the PI is prevented from working with other companies on the same IP that we are. We have recently begun the application process for a patent on our acoustic sensor. For our acoustic lysis device, we have significantly redesigned and made significant improvements from our first generation device. These enhancements will likely be new IP. In addition, prior to the CRADA, Resonantia declared the upcoming reader instrument as background IP, which means that Resonantia owns the rights to any future patents that will be submitted as a result of our development work.

### SALES/MARKETING STRATEGY

Following FDA authorization our marketing plan consists of attending tradeshows, publishing articles that demonstrate the superiority of our product over current products, and through standard direct sales. Our target in the hospital will initially be the clinical microbiology lab. Our target customer will be the lab director. The lab director is generally the economic buyer. Two important influencers are the senior clinical microbiologist and the CFO of the hospital. Once we have established our product at large hospitals, we will then sell to physician and urgent care clinics, along with medium and small hospitals. To increase same hospital revenue, we will develop numerous other panels, such as STI, respiratory, and urine. We will utilize key opinion leaders in microbiology to help reach clinical microbiologists throughout the country.

### **EXIT STRATEGY**

Our exit strategy is to go public and build a great company. I believe that we have the opportunity to build a special company, one that will redefine the diagnostics industry by bringing laboratory quality testing to the point of care regardless of the infrastructure, whether that is far forward for the US Military or to the developing world. Because of this, I think we can build a sustainable public company that does a lot of good for the world. With that being said, if the right acquisition offer came, we would have to consider that as a possibility. I believe that we will be in a position to go public in approximately 4-6 years, after we have completed our clinical evaluation and received FDA authorization.

### IP Summary: Resonantia Diagnostics Inc.



Resonantia Diagnostics Inc. – 0 relevant US patents found CEO Matt Jones – 0 relevant US patents found PI Darren Branch – 15 relevant US patents found

General Notes – TNVC application states that Resonantia Diagnostics Inc. is partnered with Sandia National Laboratories though a CRADA agreement to develop their technology. Under the agreement, all IP developed by the company is either co-owned by them or exclusively licensed, with their PI not allowed to work on companies with similar IP. The company has a single issues patent through Sandia (US9512421B) and states they are in the process of developing patents for their acoustic sensor.

All IP is developed under co-ownership or granted exclusive.

Granted patent is background IP, has since been redesigned and redeveloped for commercial use and scale

Notes on IP position and strategy from application

We are currently partnering with Sandia National Laboratories via a cooperative research and development agreement (CRADA) to further develop two pieces of acoustic technology into a point of care diagnostic platform. Under the terms of a CRADA, all IP developed during our agreement will either be co-owned or exclusively licensed to Resonantia Diagnostics. Additionally, the PI is prevented from working with other companies on the same IP that we are. We have recently begun the application process for a patent on our acoustic sensor. For our acoustic lysis device, we have significantly redesigned and made significant improvements from our first-generation device. These enhancements will likely be new IP. In addition, prior to the CRADA, Resonantia declared the upcoming reader instrument as background IP, which means that Resonantia owns the rights to any future patents that will be submitted as a result of our development work.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Miniature acoustic wave lysis system and uses thereof	US Grant	Darren W. Branch Erika Cooley Vreeland Gennifer Tanabe Smith	National Technology and Engineering Solutions of Sandia LLC	US9512421B1	Filed 06/27/2014 Listed as background IP established prior to CRADA agreement.

# IP Summary: Resonantia Diagnostics Inc.



2	Programmable electroacoustic filter apparatus and method for its manufacture	US Grant	Christopher Nordquist Roy H. Olsson Sean Michael Scott Kenneth Wojciechowski Darren W. Branch	National Technology and Engineering Solutions of Sandia LLC	US9276557B1	Filed 07/01/2013
3	Detection of bioagents using a shear horizontal surface acoustic wave biosensor	US Grant	Richard S. Larson Brian Hjelle Pam R. Hall David C. Brown Marco Bisoffi Susan M. Brozik Darren W. Branch Thayne L. Edwards David Wheeler	National Technology and Engineering Solutions of Sandia LLC	US11378576B2	Filed 02/15/2019
4	Shear horizontal surface acoustic wave (SH-SAW) resonators and arrays thereof	US Grant	Darren W. Branch Thayne L. Edwards	National Technology and Engineering Solutions of Sandia LLC	US10261078B2	Filed 08/16/2016
5	Active micromixer using surface acoustic wave streaming	US Grant	Darren W. Branch Grant D. Meyer Harold G. Craighead	National Technology and Engineering Solutions of Sandia LLC	US7942568B1	Filed 06/17/2005
6	Lateral acoustic wave resonator comprising a suspended membrane of low damping resonator material	US Grant	Roy H. Olsson Ihab F. El-Kady Maryam Ziaei-Moayyed Darren W. Branch Mehmet F. Su Charles M. Reinke	National Technology and Engineering Solutions of Sandia LLC	US8525619B1	Filed 05/28/2010
7	High-frequency shear- horizontal surface acoustic wave sensor	US Grant	Darren W. Branch	National Technology and Engineering Solutions of Sandia LLC	US8669688B1	Filed 05/01/2013
8	Microfluidic device for acoustic cell lysis	US Grant	Darren W. Branch Erika Jane Cooley Gennifer Tanabe Smith Conrad D. James Jaime L. McClain	National Technology and Engineering Solutions of Sandia LLC	US9096823B1	Filed 08/31/2010

# IP Summary: Resonantia Diagnostics Inc.

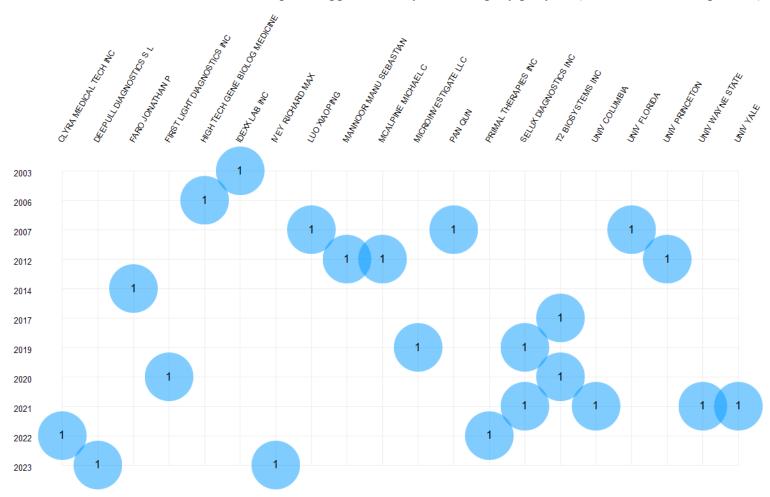


9	Microfabricated particle focusing device	US Grant	Surendra K. Ravula Christian L. Arrington Jennifer K. Sigman Darren W. Branch Igal Brener Paul G. Clem Conrad D. James Martyn Hill Rosemary June Boltryk	National Technology and Engineering Solutions of Sandia LLC	US8425749B1	Filed 06/09/2006
10	Microfluidic package and method of making the same	US Grant	Darren W. Branch Philip R. Miller Thayne L. Edwards David R. Wheeler	National Technology and Engineering Solutions of Sandia LLC	US11554369B2	Filed 05/07/2020
11	Microresonator electrode design	US Grant	Roy H. Olsson, III Kenneth Wojciechowski Darren W. Branch	National Technology and Engineering Solutions of Sandia LLC	US9337800B1	Filed 10/10/2012
12	Methods for suppressing spurious modes in microresonators	US Grant	Roy H. Olsson, III Darren W. Branch	National Technology and Engineering Solutions of Sandia LLC	US10009002B1	Filed 08/17/2016
13	Solid-state tuning behavior in acoustic resonators	US Grant	Darren W. Branch Christopher Nordquist Matt Eichenfield James Kenneth Douglas Aleem Siddiqui Thomas A. Friedmann	National Technology and Engineering Solutions of Sandia LLC	US11405014B1	Filed 06/26/2020
14	Hermetic seal for use in an implantable metronomic drug pump and a mehtod of manufacturing the same	US Application	Winston Wu Darren W. Branch Jay Bischoff	National Technology and Engineering Solutions of Sandia LLC Cognos Therapeutics Inc	US20200368428A1	Filed 04/29/1019
15	Active shunt capacitance cancelling oscillator for resonators	US Grant	Darren W. Branch Kurt Wessendorf Bryan Carson DeAnna Marie Campbell	National Technology and Engineering Solutions of Sandia LLC	US11171604B1	Filed 11/03/2020

### Similar technologies: Patent Applications by Year



Search terms: ("antimicrobial pathogen detect") & US or WO in Applicants
Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Systems and methods for dynamic surveillance of medication and antimicrobial resistance trends	US Application	Becton Dickinson and Co	US20210287809A1	("antimicrobial pathogen")	Similar application	Method of analyzing pathogens
2	Rapid antimicrobial susceptibility testing using high-sensitivity direct detection methods	US Application	T2 Biosystems Inc.	US20190032104A1	("antimicrobial pathogen detect")	Similar application	Design and scope
3	Methods and devices for the detection of pathogenic micro organisms and their antimicrobial susceptibility	US Grant	Idexx Laboratories Inc.	US20040005653A1	("antimicrobial pathogen detect")	Similar application	Design and scope

### Resonantia Diagnostics Inc. IP: Independent Claims of US9512421B1

- 1. The invention claimed is: 1. A miniature acoustic cell lysis system comprising:i) a cartridge comprising a plurality of channels, wherein each channel is configured to receive one or more test samples; ii) a platform comprising a transducer array, which comprises a plurality of acoustic transducers, wherein the transducer array is configured to be coupled reversibly to the cartridge and wherein each acoustic transducer is configured to be disposed beneath each channel and is adapted to propagate an acoustic wave in the channel, thereby generating localized acoustic pressure to lyse a cell by acoustic pressure; and iii) a thermal exchange layer configured to be disposed between the cartridge and the transducer array.
- 2. A miniature acoustic cell lysis system comprising: a cartridge comprising a plurality of channels, wherein each channel is configured to receive one or more test samples; a platform comprising a transducer array, which comprises a plurality of acoustic transducers, wherein the transducer array is configured to be coupled reversibly to the cartridge and wherein each acoustic transducer is configured to be disposed beneath each channel and is adapted to propagate an acoustic wave in the channel; and a thermal exchange layer configured to be disposed between the cartridge and the transducer array.
- 3. A miniature acoustic cell lysis system comprising: a cartridge comprising a plurality of channels, wherein each channel is configured to receive one or more test samples; a platform comprising a transducer array, which comprises a plurality of acoustic transducers, wherein the transducer array is configured to be coupled reversibly to the cartridge and wherein each acoustic transducer is configured to be disposed beneath each channel and is adapted to propagate an acoustic wave in the channel; and a thermal exchange layer configured to be disposed between the cartridge and the transducer array, wherein the operating frequency of at least one acoustic transducer ranges from 60 MHz to 80 MHz.



US009512421B1

US 9,512,421 B1

Dec. 6, 2016

## (12) United States Patent

### Branch et al.

### (54) MINIATURE ACOUSTIC WAVE LYSIS SYSTEM AND USES THEREOF

(71) Applicant: **Sandia Corporation**, Albuquerque, NM

(72) Inventors: Darren W. Branch, Albuquerque, NM

(US); Erika Cooley Vreeland, Albuquerque, NM (US); Gennifer Tanabe Smith, Albuquerque, NM (US)

(73) Assignee: Sandia Corporation, Albuquerque, NM

(US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 149 days.

(21) Appl. No.: 14/318,364

(22) Filed: Jun. 27, 2014

(51) Int. Cl. C12N 13/00 (2006.01) C12M 1/33 (2006.01) G01N 29/036 (2006.01) G01N 29/02 (2006.01)

**G01N 29/02** (2006.01) **H03H 9/145** (2006.01) **H03H 9/02** (2006.01)

(52) U.S. Cl.

(58) Field of Classification Search

See application file for complete search history.

### (56) References Cited

(10) Patent No.:

(45) **Date of Patent:** 

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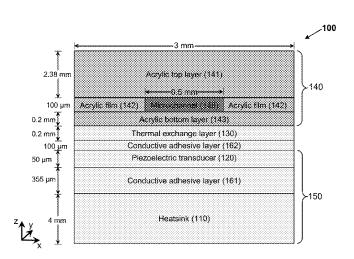
(Continued)

Primary Examiner — Michael Hobbs (74) Attorney, Agent, or Firm — Aman Talwar

### (57) ABSTRACT

The present invention relates to an acoustic lysis system including a disposable cartridge that can be reversibly coupled to a platform having a small, high-frequency piezo-electric transducer array. In particular, the system releases viable DNA, RNA, and proteins from human or bacterial cells, without chemicals or additional processing, to enable high-speed sample preparation for clinical point-of-care medical diagnostics and use with nano/microfluidic cartridges. Also described herein are methods of making and using the system of the invention.

### 25 Claims, 9 Drawing Sheets





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**COMPANY INFORMATION** 

**CEO/President Name:** Madison Heck

Industry/Technical area of Interest: Healthcare - Device

Subcategory (if any):

**Incorporation or Formation Date:** 02.17.2022

State: Delaware

List Management Team Names: Madi Heck, CEO

John Hanks, Dir. Bus. Dev Amir Zavareh, CTO Michel Saint-Cyr, CMO

#### **BUSINESS SUMMARY**

Peripheral arterial disease (PAD), caused by narrowed arteries, affects ~19-21 million Americans and may lead to heart attack, stroke, or amputation. However, >51% of those affected are asymptomatic resulting in a high rate of missed diagnosis amongst providers.

Through early PAD detection, especially in asymptomatic patients, preventative care can avoid severe complications and associated costs. Unlike current screening methods that are inaccurate, tedious, and time-consuming, SageSpectra's handheld device easily and accurately screens for PAD in <3 minutes by measuring a key indicator of tissue health, tissue oxygenation.

Our business model is a recurring revenue subscription model. Providers of Medicare Advantage plans pay a \$50 usage fee each time a patient is screened. Focusing just on Medicare Advantage Enrollees, that is a market size of \$1.4 billion.

SageSpectra's team includes MBAs, medical device industry and engineering experts, a plastic surgeon, and a vascular surgeon.

### **CUSTOMER PROBLEM AND SOLUTION**

Our target customer is insurance providers with Medicare Advantage plans. These providers are paid based on a Capitated Payment System – CMS pays them a prospective amount to cover each beneficiary, and payments are adjusted according to the beneficiary's health status. Therefore, the most profitable beneficiary has a greater number of diagnosed conditions that can be treated with low-cost solutions. Consequently, our customers are both incentivized to diagnose beneficiaries with PAD to reduce long-term costs and receive higher compensation from CMS.

For context, PAD intervention results in annual Medicare costs of \$70,000 per patient; however, that cost increases to ~\$120,000 per patient if diabetes mellitus is present. Our low-cost, portable device is designed to screen at-risk individuals easily and accurately in under 3 minutes. Through early detection of PAD with the SageSpectra device, these high PAD-related intervention costs may be avoided with proper and timely medication.



### **TARGET MARKET**

Our primary target customer is insurance providers with Medicare Advantage plans such as Blue Cross Blue Shield, Anthem, and Cigna. While there is a reimbursement code for PAD screening, it only covers symptomatic patients. However, >50% of PAD patients are asymptomatic; therefore, our strategy is to focus on customers that will have alternative benefits to reimbursement and will be incentivized to screen more patients.

Insurance companies that provide Medicare Advantage plans are incentivized to not only save long-term costs by catching a disease early and treating it with low-cost interventions but also to receive extra payment from CMS per month for PAD-positive beneficiaries.

If we could screen all Americans at risk for PAD, that is a total market size of \$4.2 billion. Focusing just on Medicare Advantage Enrollees, which is growing by 8-10% per year, that is a market size of \$1.4 billion. If we can capture just 10% of that, we are a \$140 million revenue-a-year business.

#### COMPETITORS

Ankle Brachial Index (ABI), the current standard of care for PAD screening, involves multiple blood pressure measurements using doppler ultrasound and inflatable cuffs. However, ABI requires a skilled clinician to perform, is time-intensive, taking 15-20 minutes, and can cost between \$2,500 - \$20,000. Furthermore, because ABI utilizes inflatable cuffs to restrict blood vessels, it is inaccurate for patients with calcified vessels (such as diabetic individuals). Another method of PAD screening, utilized by Semler Scientific's QuantaFlo device, is a portable blood flow test. While the testing time of QuantaFlo is around 5 minutes, the total testing time including preparation and rework can take up to 15 minutes. According to our NSF I-Corps customer discovery interviews, the test can be inefficient and provides many false positives and negatives. Furthermore, unreliable results due to patient movement, edema, or temperature may necessitate the clinician to readminister the test.

### COMPETITIVE ADVANTAGE

Compared to ABI and QuantaFlo, SageSpectra is a faster, more affordable, and more accurate solution for peripheral arterial disease screening.

Our lightweight and portable device improves end-user workflow efficiency by decreasing testing time and employing the use of alternative healthcare providers. With SageSpectra, a nurse or medical assistant can easily screen patients for PAD in <3 minutes, a fraction of the time of current methods.

Unlike ABI which uses vessel-restricting blood pressure cuffs, SageSpectra's non-invasive technology utilizes light to scan the tissue and measure tissue oxygen saturation (StO2), a key indicator of tissue health. This non-restrictive method of screening is not only more comfortable for patients, but it is more accurate amongst patients who have calcified arteries such as diabetic individuals. Furthermore, with SageSpectra's ambient light guard and motion detection design, we are able to improve accuracy caused by external light or patient movement.

### INTELLECTUAL PROPERTY POSITION

SageSpectra, Inc. has an exclusive licensing agreement with Texas A&M University that states further patents developed by SageSpectra may fall under this same agreement. SageSpectra has one patent pending. Our nonprovisional US patent: "Medical devices for measuring tissue properties and methods of use" was filed on November 4, 2022.

### SALES/MARKETING STRATEGY

Based on NSF I-Corps customer discovery interviews, customers are open to a subscription model that covers the cloud-based, HIPAA-compliant code that will run the device and manage the data. Customers want a fee-per-test because their profits from capturing PAD diagnoses outweigh the costs of each test. Each time a patient is screened for PAD with SageSpectra, customers pay a \$50 usage fee. In return, our customers are paid by CMS an extra amount each month for that



beneficiary. Furthermore, they are capturing a significant portion of their asymptomatic beneficiaries who have never been screened considering 1 in 5 people over the age of 60 have PAD, and >50% are asymptomatic.

We are considering partnering with medical device companies that have established sales distribution channels, such as Becton Dickinson. Additionally, we have room to expand in other applications where tissue health is a concern including postoperative monitoring of surgical flaps and monitoring chronic ulcers.

### **EXIT STRATEGY**

Our primary exit strategy is to be acquired by a medical device company since many larger companies continuously aim to diversify or enhance their current technology. One such company is Becton Dickinson. We have a relationship with a Senior VP at Becton Dickinson, and we have plans to meet with one of their business development teams by May. Another potential company is Semler Scientific, a competitor PAD screening tool. Through their financial results and press releases, they have disclosed that they are looking to grow through license deals and acquisitions. If we can show we have a significant competitive advantage based on user needs, SageSpectra believes an acquisition by Semler Scientific could be a possibility in the future.

Our secondary exit strategy would be to engage in an IPO. As mentioned, our company has significant room to expand with many potential applications. If the business owners decide to have more flexibility and increase their stake, an IPO will be considered.

### IP Summary: SageSpectra Inc.



SageSpectra Inc. – 0 relevant US patents found CEO Madi Heck – 0 relevant US patents found Director Business Dev. John Hanks – 5 relevant US patents found CTO Amir Zavareh – 2 relevant US patents found CMO Michael Saint-Syr – 0 relevant US patents found

General Notes – TNVC application states that SageSpectra Inc. has one nonprovisional US patent pending (17/980,737) to be licensed with an agreement from TAMU, and the agreement states that further patents developed by the company may fall under the same agreement.

Notes on IP position and strategy from application

SageSpectra, Inc. has an exclusive licensing agreement with Texas A&M University that states further patents developed by SageSpectra may fall under this same agreement. SageSpectra has one patent pending. Our nonprovisional US patent: "Medical devices for measuring tissue properties and methods of use" was filed on November 4, 2022.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Medical devices for measuring tissue properties and methods of use	US Nonprovisional	John Hanks et al.	Texas A&M University	17/980,737	Filed 11/04/2022

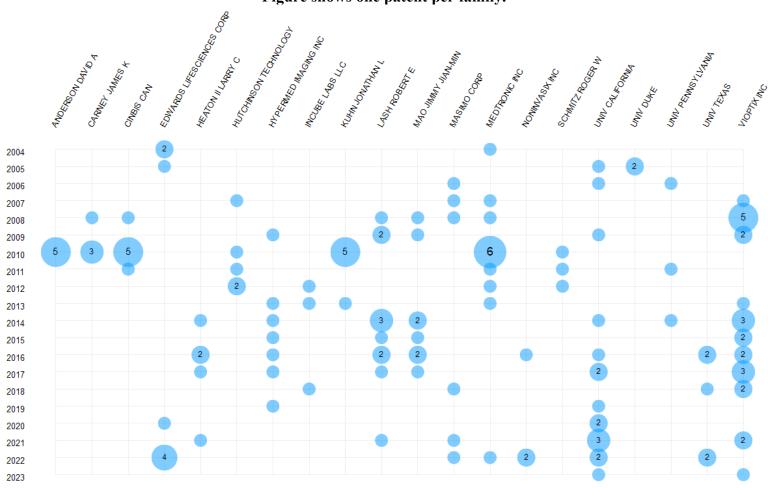
### Similar technologies: Patent Applications by Year



Search terms: ("measure tissue oxygenation") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Remote monitoring of oxygenation status and blood pulsation within skin tissue	PCT	University of Washington	WO2022182956A1	("measure tissue oxygenation")	Similar application	Design and scope
2	Tissue hemoglobin measu ring instrument and tomographic reconstruction method for oxyhemoglobin/deoxyhe moglobin concentrations	US Application	Wellness Allied Inc.	US2021228161A1	("measure tissue oxygenation'')	Similar application	Design and scope
3	Cellphone based tissue oxygenation measuring device	US Grant	Godavarty Anuradha Kaile Kacie The Florida International Univ Board of Trustees	US11464453B2	("measure tissue oxygenation'')	Similar application	Design and measurement tactics



### Taurus Vascular

CONTACT INFORMATION

Contact Name: Melanie Lowther Contact Phone Number: 267 670 0005

Contact Email Address: Melanie@taurusvascular.com

**COMPANY INFORMATION** 

CEO/President Name: Matt Kuhn

Industry/Technical area of Interest: Healthcare - Device

Subcategory (if any):

**Incorporation or Formation Date:** 02.08.2023

State: Delaware

List Management Team Names: Matt Kuhn, CEO

Melanie Lowther, COO

### **BUSINESS SUMMARY**

Endoleak remains the most severe complication of EVAR, impacting up to 50% of patients. Untreated, endoleaks can lead to rupture & death. Health system impact is significant: of 250k annual EVARs, up to 20% require reintervention within 5 yrs due to endoleaks. In the U.S., monitoring and reintervention represent a \$1.5B economic burden.

Using existing price tolerance of current solutions as reference price, \$7.5k, our tech represents a \$1.9B annual ww mkt opportunity as an EVAR adjunct device for endoleak prevention & an additional \$375M ww mkt opportunity as endoleak treatment tool. Coverage under existing EVAR reimbursement codes, expedited Medicare coverage & New Technology Addon Payment following breakthrough designation. Will employ distribution model, sell direct to hospital systems & private surgery clinics. Strategic partnerships with large med device companies will leverage mature distribution channels with hospital General Purchasing Organizations & Value Add Committees.

### **CUSTOMER PROBLEM AND SOLUTION**

There are no dedicated solutions indicated for endoleak treatment or prevention. Current treatments attempt to plug endoleaks with off-label embolic agents. Procedures are challenging, associated with endoleak recurrence rate of 40%, & cost ~\$38k. We're taking a different approach to solving this problem; rather than try to plug leaks, why not drain them?

Our minimally-invasive, catheter based device allows for continuous drainage of endoleaks and depressurization of the aneurysm after EVAR. Our novel tech is a brand-agnostic adjunct to index and reintervention EVAR procedures at the point of care that: 1) Provides a safe & reproducible solution for physicians, 2) Eliminates the risk of all types of endoleaks & reintervention procedures while providing significant potential to improve safety and efficacy of EVAR procedures, 3) Doesn't disrupt clinical workflow, & 4) Is an attractive, revenue-stream-generating, acquisition target because of plug-n-play integration with any endograft.

### **TARGET MARKET**

We plan to bring our device to market, first as a superior solution for endoleak repair, then expanding the indication as an adjunct device that reduces the risk of endoleaks. As a predicted Class III device, we anticipate our technology will obtain FDA approval through the PMA pathway. Future clinical and regulatory activities will focus on approval as a standalone, early-stage intervention for aortic aneurysm repair. We plan to consult with the FDA early and regularly on broader product



development planning and clinical strategy. We anticipate requiring multiple pre-submission meetings leading up to a FIH study, and will request a cadence of interactions with the agency. Related to commercialization strategy, experts in regulatory strategy, reimbursement strategy, and device development will support our efforts. We will pursue Breakthrough Designation and New Technology Add-on Payment (NTAP) to further strengthen market adoption.

### **COMPETITORS**

The only preventative solution for endoleaks is the Aptus Endosystems' Heli-FX EndoAnchor System, acquired by Medtronic for \$110M in 2015. This device only addresses endoleaks caused by poor endograft sealing (<10% of all endoleaks). Our device addresses all types of endoleaks.

There are no dedicated solutions indicated for treatment of patients who develop an endoleak following EVAR. Type II endoleak repair involves off-label embolic agents used to plug leaks. These procedures are challenging, associated with an endoleak recurrence rate of 40%, and tend to cost ~\$38k. Our dedicated solution requires just a quick, simple procedure and will significantly reduce costs at an anticipated ASP of ~\$7.5k, based on current solution price tolerance.

### **COMPETITIVE ADVANTAGE**

Our novel medical device technology is a brand-agnostic adjunct to index and reintervention EVAR procedures at the point of care that

- 1) provides a safe, reproducible, & minimally invasive solution for physicians
- 2) eliminates the risk of all types of endoleaks & reintervention procedures while providing significant potential to improve safety and efficacy of EVAR procedures
- 3) doesn't disrupt clinical workflows
- 4) is an attractive, revenue-stream-generating, acquisition target because of plug-and-play integration with any endograft manufacturer's portfolio
- 5) is a significant improvement over the current standard of care
- 6) improves procedure outcomes and allow patients to live longer, healthier lives after AAA repair

### INTELLECTUAL PROPERTY POSITION

Taurus Vascular filed a provisional patent application in January of 2023 titled "Methods and Systems for Transcaval Treatment of Aneurysms" covering different methods, systems, and devices for treating, repairing, and/or preventing endoleaks after, during, and/or before a patient has undergone an EVAR procedure. This application has been strategically curated to strongly position our IP portfolio with broad landscape coverage. We anticipate filing additional patents to expand coverage of our product's innovative features and superior usability. We are employing a totally novel approach to solving this unmet clinical need using our technology and we have conducted a preliminary IP landscape search and we believe that we have clear freedom to operate within the space.

### SALES/MARKETING STRATEGY

Our product development plan includes continuing to refine our technology design by adding features to further improve usability and ergonomics. We will conduct a series of preclinical studies in cadavers and large animals to demonstrate safety and efficacy of our technology. Successful completion of these milestones support our fundraising efforts with early-stage venture investors to fund V&V studies needed for FDA approval. We anticipate initiating first-in-human studies (FIH) within 2.5 years of closing a \$1.5M seed round. Following FIH, we aim to demonstrate positive safety and efficacy outcomes in a larger IDE Pilot trial. Given the substantiality of the unmet medical need for improving post-procedural outcomes for EVAR, we are well-positioned to secure Breakthrough Device designation and accelerated regulatory approval from the FDA. Following FDA approval, we will likely proceed with commercialization of our technology with the eventual goal of market launch in 2030.



### **EXIT STRATEGY**

Taurus Vascular is an ideal acquisition target for strategic medical technology companies in the EVAR space. After dozens of interviews with our clinical advisors to gain key insights and perspectives; they have validated the need for a solution for mitigating endoleaks. Such a solution would generate significant value for patients, physicians, payers, and providers alike and would be rapidly and widely adopted by stakeholders, representing a lucrative, long-term investment opportunity. Further, our solution would enhance any endograft/EVAR solution portfolio, as opposed to cannibalizing the existing market. The ideal timeline for exit is just following FDA submission and approval, around 2030.

### IP Summary: Taurus Vascular



Taurus Vascular – 1 relevant US patents found CEO Matt Kuhn – 0 relevant US patents found COO Melanie Lowther – 0 relevant US patents found

General Notes – TNVC application states that Taurus Vascular has one provisional patent application filed (Methods and Systems for Transcaval Treatment of Aneurysms) filed 01/2023.

Notes on IP position and strategy from application

Taurus Vascular has filed a provisional patent application in January of 2023 titled "Methods and Systems for Transcaval Treatment of Aneurysms" covering different methods, systems, and devices for treating, repairing, and/or preventing endoleaks after, during, and/or before a patient has undergone an EVAR procedure. This application has been strategically curated to strongly position our IP portfolio with broad landscape coverage. We anticipate filing additional patents to expand coverage of our product's innovative features and superior usability. We are employing a totally novel approach to solving this unmet clinical need using our technology and we have conducted a preliminary initial IP landscape search and we believe that we have clear freedom to operate within the space.

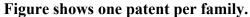
	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Methods and Systems for Transcaval Treatment of Aneurysms	US Provisional	N/A	N/A	N/A	Filed 01/2023

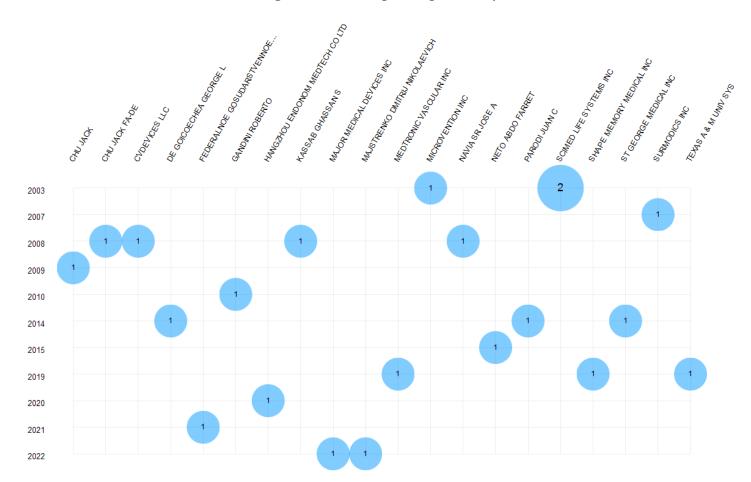




Search terms: ("prevent endoleaks") OR ("catheter endoleaks) & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)





# taurus

# Short list of similar technologies

Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Vascular prosthesis for leak prevention during endovascular aneurysm repair	US Grant	Texas A&M University System Shape Memory Medical Inc	US20200086011A 1	("catheter endoleaks")	Similar application	Design and scope
2	Methods, materials and apparatus for deterring or preventing endoleaks foll owing endovascular graft implantation	PCT	Microvention Inc.	WO2003007785A2	("catheter endoleaks")	Similar application	Case in which endoleaks are prevented differs
3	Method and apparatus for thermal treatment of type II endoleaks in arterial aneurysms	US Grant	Scimed Life Systems Inc.	US6748953B2	("catheter endoleaks")	Similar application	Case in which endoleaks are prevented differs



# Tremedics Medical Devices, INC

CONTACT INFORMATION
Contact Name: Tre Welch

Contact Phone Number: 469-708-6873

Contact Email Address: tre.welch@tremedics.com

**COMPANY INFORMATION** 

**CEO/President Name:** Tre Welch

Industry/Technical area of Interest: Healthcare - Device

Subcategory (if any):

**Incorporation or Formation Date: 11.24.2021** 

State: Merged Texas LLC to Delaware Incorporation in 2021

List Management Team Names: Tre Welch, CEO

Suren Reddy Joseph Forbess Rhett Butler, CPA Hayden Blackburn

### **BUSINESS SUMMARY**

Tremedics Medical Devices is fabricating bioresorbable stents for pediatric patients with congenital heart disease (CHD). We are solving the clinical need for degradable stents for CHD focusing on coarctation of the aorta. Intravascular stents have revolutionized the management of pediatric and adult CHD patients. Except for one stent, many of the metal stents used in pediatric and adult CHD patient population are used "off-label". Metal stents require at least 6 months duration anticoagulant therapy; they can lead to chronic inflammation, restriction of vessel growth, late stent thrombosis, late instent restenosis, and stent fracture. Children also need follow-up surgical procedures to continue to force these stents to grow. If untreated, these heart defects can lead to heart failure, stroke, aneurysms, and death. Tremedics solution is a bioresorbable stent, IlluscorTM, that sustains structural integrity during arterial remodeling and disappears to allow natural arterial growth.

## CUSTOMER PROBLEM AND SOLUTION

Current treatment for coarctation of the aorta is surgical repair within their first year of life and then stenting with a metal stent usually being "off label use" at age 4 or sometimes the native coarctation. This requires multiple revascularization procedures to force the metal stent to grow with the patient. As the patient grows, stents are further redilated and they can fracture increasing the risk of aortic wall rupturing leading to an aneurysm. Tremedics solution is IllusicorTM. It is a balloon mounted bioresorbable stent composed of monofilaments of degradable fibers. Tremedics's bioresorbable stent is a medical device that has received breakthrough device designation from the FDA for treatment of coarctation of the aorta in children from 30 days to 14 years of age. This would help infants growing to adults by being implanted the stent restores blood flow, degrades overtime in the aorta and results in a new tissue formation without restenosis or tearing of the aorta.

# **TARGET MARKET**

Tremedics target market is for infants. We have received Breakthrough Device Designation in 2021 for ages 30 days to 14 years of age. Coarcation of the aorta affects about 2500 new borns every year in the US and approximately 660,000 children and adolescents under the age of 20 globally. This places us in a total available market of \$4 billion growing at a rate of 5% per year. We believe we can capture 20% of the US market leading to a \$200 million market with a prevalence of at least 160,000 infants, children and adults living with coarctation of the aorta and \$900 million globally.



#### **COMPETITORS**

NuMed, Inc Cordis

#### COMPETITIVE ADVANTAGE

Our primary competitive advantage is Illusicor is a stent that degrades overtime in the body leaving native tissue. During this degradation process, the aorta of the infant can grow as they grow into adults. Unlike our competitors, they are permanent implants that are left in the body for the lifetime of the patient. They also require follow-up balloon angioplasty procedures to expand the stent as the infant grows to a child and adult. We are magnetic resonance imaging (MRI) compatible resulting in the infants using no radiation. Most metal stents are not MRI compatible and can only be imaged by fluoroscopy. This requires radiation to make the stent visible inside the body. They also require contrast agents to visualize the stent in the aorta to better understand the positioning and alignment of the stent against the aortic wall. Illusicor has great arterial wall apposition, no restenosis, no vessel occlusion, no thrombus, no deaths, and minimal scar tissue in preclinical studies.

### INTELLECTUAL PROPERTY POSITION

Tremedics has 5 patents granted on the stent technology. We are seeking more intellectual property and will continue to innovate and file more patents.

## SALES/MARKETING STRATEGY

Our sales and marketing strategy is to start marketing the stent upon being in human pivotal studies. We plan to also market by attending different conferences and publishing data on these stents in preclinical studies and bench studies. We have some published data to date on the bench data in Materiala 2021 and feasibility in preclinical studies. Examples of these conferences are the Pediatric and Interventional Symposium and American Heart Association and Transcatheter Therapeutics conference. In order to sell stents, we would need to sell directly to the interventional cardiology catheter labs. This would require meetings with the director of the catheter labs and establishing a presence in the hospital's procurement system for them to purchase these stents. Another means of sales would be establishing and account with a distributor such as Braun and Cardinal Health.

# **EXIT STRATEGY**

We plan to exit through an acquisition. We plan for this to occur during human trials or after FDA clearance of the device. We have relationships with NuMed, Inc who would be a potential acquirer of Tremedics. We have spoken to Cardinal Health VP of Business Development, and they may as well acquire Tremedics after FDA clearance. If no acquisition, then we plan to sell our stent products to pediatric interventional clinics through a supplier such as Braun or Cardinal Health.

# IP Summary: Tremedics Medical Devices Inc.



Tremedics Medical Devices Inc. – 0 relevant US patents found CEO Tre Welch – 1 relevant US patents found Suren Redd – 0 relevant US patents found Joseph Forbess– 0 relevant US patents found Rhett Butler – 0 relevant US patents found Hayden Blackburn – 0 relevant US patents found

General Notes – TNVC application states that Tremedics Medical Devices Inc. has 5 granted patents and one active patent application. 4 of the 5 granted patents are the same patent with adjusted expiration, and the fifth has an active patent application for it's adjusted expiration date.

Notes on IP position and strategy from application

Tremedics has 5 patents granted on the stent technology. We are seeking more intellectual property and will continue to innovate and file more patents.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Stent and method for manufacturing thereof	US Grant	Tre' Raymond Welch	Tre' Raymond Welch	US9155640B2 US9480586B2 US9943423B2 US10786373B2	Filed 11/16/2010 Filed 09/22/2015 Filed 10/04/2016 Filed 03/09/2018
2	Stent and method of manufacture	US Grant	Tre' Raymond Welch	Tre' Raymond Welch	US11464657B2 US20230015598A1 (Pending)	Filed 11/18/2020 Filed 09/28/2022

# Similar technologies: Patent Applications by Year



Search terms: ("stent aorta") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Radially self- expanding stents	PCT	Edwards Lifesciences Corp.	WO2020197778A1	("stents aorta coarctation")	Aorta based stent	Design and scope
2	Stent including a toggle lock strut	US Grant	Medtronic Vascular Inc	US8298279B2	("non-metallic" & "stent)	Structural stent	Design and scope
3	Angioplasty of calcified arteries	US Grant	University of Leicester Ip2ipo Innovations Ltd	US11278300B2	("non-metallic" & "stent	Disruption of artieries	Design and scope
4	Hybrid nanopores and uses thereof for detection of analytes	US Grant	Yissum Research Development Co of Hebrew University of Jerusalem	US10760122B2	("non-metallic" & "stent	Disruption of arteries	Design and scope

# Tremedics Medical Devices Inc. IP: Independent Claims of US10786373B2



1. The invention claimed is: 1. A non-metallic stent having a furled small-diameter state and an expanded large diameter state, the stent comprising, in the furled small-diameter state:a first plurality of central lobes arranged at spaced-apart intervals and extending longitudinally defining a stent axis; a second plurality of central lobes arranged at spaced-apart intervals and extending longitudinally along the stent axis; a first peripheral lobe formed on at least one of the first plurality of central lobes and a second peripheral lobe formed on at least one of the second plurality of central lobes, each central lobe of the first plurality of central lobes, central lobe of the second plurality of central lobes, the first peripheral lobe, and the second peripheral lobe formed by a coiled rotation of an element, wherein the element comprises a Poly-L-Lactic Acid polymer fiber loaded with a material; wherein, as the element is rotated in a rotational winding direction, the first plurality of central lobes are formed in a first longitudinal direction along the stent axis and the second plurality of central lobes are formed in a second longitudinal direction along the stent axis to form respective first and second helices having an opposing winding pattern along the stent axis, and the first peripheral lobe and the second peripheral lobe are opposed from each other; and at least one longitudinal rod along the stent axis, which is attached to one or more sides of the first plurality of central lobes and the second plurality of central lobes and woven between an interior area and an exterior area of the stent.

# Tremedics Medical Devices Inc. IP: Independent Claims of US11464657B2



- 1. The invention claimed is: 1. A stent having a furled, small-diameter state and an expanded, large-diameter state, the stent comprising, in the furled, small-diameter state:a polymer element coiled to form:a first plurality of central lobes arranged longitudinally along a stent axis from a first end to a second end of the stent, a second plurality of central lobes extending from a middle section of the stent to the first end of the stent, a third plurality of central lobes extending from the middle section of the stent to the second end of the stent, and at least one peripheral lobe on each of the first plurality of central lobes, the second plurality of central lobes and the third plurality of central lobes; wherein the polymer element rotates in a first rotational direction to form the first plurality of central lobes, and each of the first plurality of central lobes is spaced along the stent axis as the polymer element moves from the first end to the second end; wherein the polymer element rotates in a second rotational direction to form the second plurality of central lobes, and each of the second plurality of central lobes is spaced along the stent axis as the polymer element moves from the first end to the middle section; wherein the polymer element rotates in the first rotational direction to form the third plurality of central lobes, and each of the third plurality of central lobes is spaced along the stent axis as the polymer element moves from the second end to the middle section; wherein the second plurality of central lobes and the third plurality of central lobes form an opposing winding pattern to the first plurality of central lobes along the stent axis; and wherein the terminal ends of the polymer element are in the middle section.
- 2. A stent having a furled, small-diameter state and an expanded, large-diameter state, the stent comprising, in the furled, small-diameter state: a polymer element coiled to form: a first plurality of central lobes arranged longitudinally along a stent axis from a first end to a second end of the stent, a second plurality of central lobes extending from a middle section of the stent to the first end of the stent, a third plurality of central lobes extending from the middle section of the stent to the second end of the stent, and at least one peripheral lobe on each of the first plurality of central lobes, the second plurality of central lobes and the third plurality of central lobes; wherein the second plurality of central lobes and the third plurality of central lobes form an opposing winding pattern to the first plurality of central lobes along the stent axis; and wherein the terminal ends of the polymer element are in the middle section.



US010786373B2

# (12) United States Patent Welch

# (54) STENT AND METHOD FOR MANUFACTURING THEREOF

(71) Applicant: Tre' Raymond Welch, Dallas, TX (US)

(72) Inventor: Tre' Raymond Welch, Dallas, TX (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 79 days.

(21) Appl. No.: 15/916,523

(22) Filed: Mar. 9, 2018

(65) **Prior Publication Data** 

US 2018/0193176 A1 Jul. 12, 2018

# Related U.S. Application Data

(60) Division of application No. 15/285,267, filed on Oct. 4, 2016, now Pat. No. 9,943,423, which is a division of application No. 14/860,878, filed on Sep. 22, 2015, now Pat. No. 9,480,586, which is a continuation of (Continued)

(51)	Int. Cl.	
	A61F 2/88	(2006.01)
	A61F 2/82	(2013.01)
	A61F 2/844	(2013.01)
	A61F 2/954	(2013.01)
	A61F 2/966	(2013.01)
	A61F 2/856	(2013.01)

(52) U.S. Cl.

# (10) Patent No.: US 10,786,373 B2

(45) **Date of Patent:** Sep. 29, 2020

## (58) Field of Classification Search

### (56) References Cited

### U.S. PATENT DOCUMENTS

### FOREIGN PATENT DOCUMENTS

EP 2644170 A1 10/2013

#### OTHER PUBLICATIONS

Agrawal, C.M. et al., Evaluation of poly(L-lactic acid) as a Material for Intravascular Polymeric Stents; Biomaterials; vol. 13; No. 3; pp. 176-182; 1992.

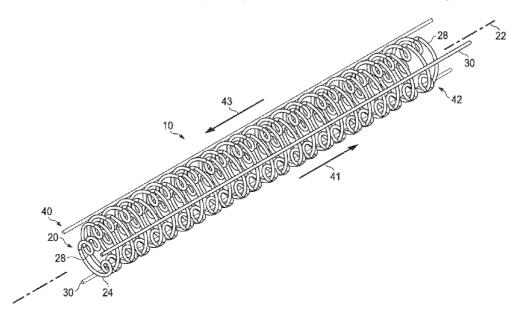
(Continued)

Primary Examiner — Jacqueline Woznicki (74) Attorney, Agent, or Firm — Hitchcock Evert LLP

# (57) ABSTRACT

According to one aspect of the present disclosure, a method and technique for manufacturing a stent are disclosed. The stent is a non-metallic stent having a furled small-diameter state and an expanded large-diameter state where the stent, in the furled small-diameter state, includes a plurality of central lobes arranged at spaced-apart intervals and extending longitudinally defining a stent axis, the plurality of central lobes defining a cylindrical plane of the stent. The stent also includes at least one peripheral lobe formed on at least one of the plurality of central lobes, the peripheral lobe oriented along the cylindrical plane.

# 5 Claims, 5 Drawing Sheets





US011464657B2

# (12) United States Patent Welch

# (10) Patent No.: US 11,464,657 B2

(45) **Date of Patent:** Oct. 11, 2022

#### (54) STENT AND METHOD OF MANUFACTURE

(71) Applicant: Tré Raymond Welch, Dallas, TX (US)

(72) Inventor: Tré Raymond Welch, Dallas, TX (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 0 days.

(21) Appl. No.: 16/951,878

(22) Filed: Nov. 18, 2020

(65) Prior Publication Data

US 2021/0154032 A1 May 27, 2021

# Related U.S. Application Data

(60) Provisional application No. 62/939,064, filed on Nov. 22, 2019.

(51)	Int. Cl.	
	A61F 2/88	(2006.01)
	A61F 2/90	(2013.01)
	A61L 31/04	(2006.01)
	A61L 31/18	(2006.01)
	A61F 2/82	(2013.01)

(52) **U.S. Cl.** 

# (58) Field of Classification Search

CPC .... A61F 2/885; A61F 2/82; A61F 2/90; A61F 2250/001; A61F 2250/0067; A61F 2250/0098; A61L 31/18

See application file for complete search history.

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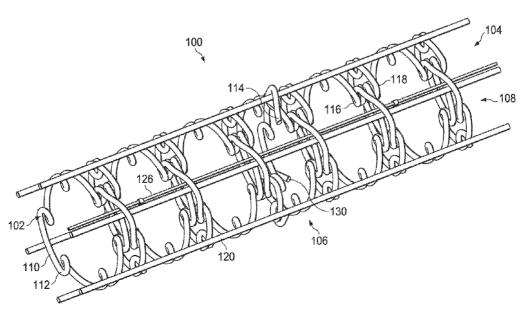
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## (57) ABSTRACT

A dual opposing helical stent having a furled, small-diameter state and an expanded, large-diameter state. In the furled, small-diameter state, the stent includes a plurality of central lobes arranged at spaced-apart intervals and extending longitudinally defining a stent axis. The stent also includes peripheral lobes formed on the plurality of central lobes. The terminal ends of the stent are welded in a middle section of the stent. A method and technique for manufacturing the stent is also disclosed.

# 14 Claims, 6 Drawing Sheets





# Waltech International Inc

CONTACT INFORMATION

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**COMPANY INFORMATION** 

**CEO/President Name: Rockey Rojar** 

Industry/Technical area of Interest: Information Technology - Hardware

Subcategory (if any):

**Incorporation or Formation Date:** 06.11.2021

State: Delaware

List Management Team Names: Dan Walsdorf- Founder & President

Rockey Rojar - Co-Founder

### **BUSINESS SUMMARY**

With 12 million RV owners, America has over 400 million RVing days yearly, contributing to 3.5 trillion grams of CO2 emission. HVAC units cause 50% of it. By bringing 15 to 20% of efficiency WalTech can significantly impact this world.

Currently, we have over 300 users, and 63% of them are monthly subscribers. Our revenue model is through monthly subscriptions and product sales. We now sell through the D2C channel (Facebook ads) and will heavily focus on building the business through proper channel partner strategy by partnering with dealers and installation partners.

We are an industry first to the DC world, and this vast market consists of semis, sailboats, van life, and any off-grid living. We are currently bootstrapping and are ready to raise our first round to improve compatibility and scale production.

# **CUSTOMER PROBLEM AND SOLUTION**

Three major challenges exist in manufacturing smart products in the RV industry.

- 1- Power difference: Unlike homes that run on AC power, RVs run on DC power. So smart home products will work on RVs. WalTech has solved the problem by being the world's first thermostat to work on AC and DC power.
- 2- Compatibility: Unlike standard HVAC systems across all home wiring. The RV industry has more than 10 types of wiring. This makes manufacturing smart devices for RVs very complicated. WalTech has solved this issue with our innovative (patent pending) technology by being universally compatible with 95% of existing thermostats out there.
- 3- Connectivity: Being on the road always means less access to Wi-Fi. Bad connectivity is a real problem for making smart products in the camping industry. Waltech has solved this problem by designing this product with a built-in cellular sim card and Wi-Fi. This ensures connectivity as long as you are in a cellular network anywhere in North America,

# TARGET MARKET

Our target market is 12 million RV owners with single & multi-zone thermostats. Our first product line is compatible with 40% of thermostats out there, and the new product will be compatible with 95% of existing thermostats in the RV market. Once we have more market presence, we want to approach the RV OEMs. Half a million RVs get sold every year, and the market is very strong and growing.



### **COMPETITORS**

Micro Air is the only competitor in the RV industry. They have nine different models built for each HVAC wiring type. Our biggest advantage is that the micro air is only a Wi-Fi thermostat, unlike us, which supports cellular and Wi-Fi.

Other companies like Coleman Mach, Dometic, and GE are focused on cooling and heating equipment manufacturing and not focused on smart thermostats. Even if they do, they are only compatible with their HVAC equipment and not universally compatible like Waltech.

### **COMPETITIVE ADVANTAGE**

Micro-Air is a circuit board company, and that is their main business. Smart devices are not their prime business. Our advantage will be our patent-protected technology

Wide power acceptance, Cellular + Wi-Fi, and Universal compatibility.

### INTELLECTUAL PROPERTY POSITION

We currently have a nonprovisional patent filed for

- Broad power range acceptance (Our thermostat operates from as low as 7.5V to 32V on both AC & DC)
- Cellular connectivity on DC-powered smart device paired with Wi-Fi.

Our provisional patent is for Universal compatibility

- Universal compatibility allows us to upgrade to all the existing thermostats out there with one single design.

## SALES/MARKETING STRATEGY

With 40% compatibility, we currently market through DTC channels, predominantly through Facebook ads. Where get an overwhelming response on these ads, especially regarding compatibility. With our second line of product (95% compatibility), we will be able to increase our revenue on ads spent significantly.

We are seeing higher demands and inquiries from the wholesalers. But our biggest challenge is that we manufacture in small quantities and cannot afford the margin for wholesale distributors. With our first biggest production run(2k), we will be able to start supplying through channel partners.

We also will create a pipeline strategy to onboard around 5000 RV repair and inspection shops in the US as installation partners. This will help us to create a great network of Waltech-certified installation partners. We believe in strategic partnerships and are currently in conversation with many technical training academies for partnerships like NRVTA for better branding and expansion.

# **EXIT STRATEGY**

Smart thermostat manufacturer Ecobee was acquired for \$750M by a generator company last year.

Our exit strategy is also similar. We want to be an industry leader and eventually get acquired by similar industry giants catering to the DC power world. Generators, Cooling & Heating manufacturers, Google, Alexa, etc.

# IP Summary: Waltech International Inc.



Waltech International Inc. -0 relevant US patents found Founder/President Dan Walsdorf -2 relevant US patents found Co-Founder Rockey Roger -0 relevant US patents found

General Notes – TNVC application states that Waltech International has two pending patent application, one provisional and one nonprovisional. Application numbers are provided (7744003 – nonprovisional, 63411653 – provisional).

Both Waltech's provisional and non-provisional patents are assigned to its CEO Dan Waldorf. No licensing agreement currently exists between Walsdorf and Waltech International.

Notes on IP position and strategy from application

We currently have a nonprovisional patent filed for Broad power range acceptance (Our thermostat operates from as low as 7.5V to 32V on both AC & DC) and Cellular connectivity on DC-powered smart device paired with Wi-Fi. Our provisional patent is for Universal Compatibility, which allows us to upgrade to all the existing thermostats out there with one single design.

	Title	Status	Inventors/Applicant	Assignee	Patent/Application No	Notes
1	Wide Input-Range Connected Thermostat	US Application	Daniel B Walsdorf	Daniel B Walsdorf	US20230066603A1	Filed 05/13/2022
2	Unknown	US Provisional	Daniel B Walsdorf	Daniel B Walsdorf	Unknwon	Unknown

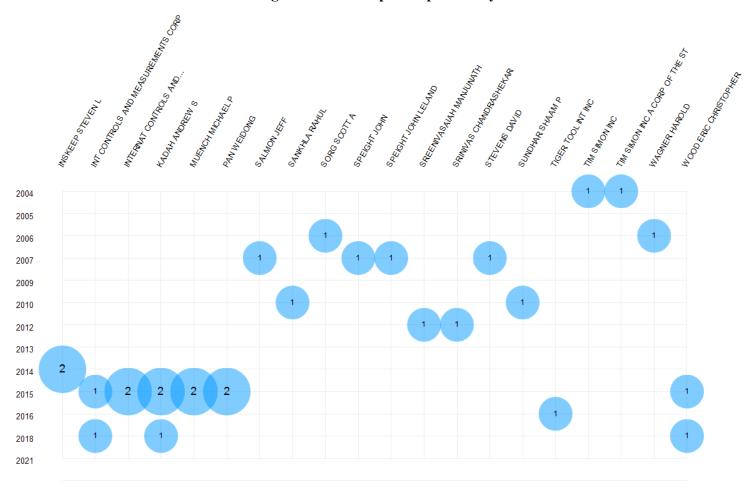
# Similar technologies: Patent Applications by Year



Search terms: ("dc power thermostat") & US or WO in Applicants

Numbers in circles indicate the number of patent applications by each company per year (Database: PatentInspiration)

Figure shows one patent per family.



# Short list of similar technologies



Ref #	Title	Status	Inventors/ Applicant	ID Number	Search Terms	Relevance To Company's Technology	Potential Distinctions
1	Thermostat operable from various power sources	US Grant	Tim Simon Inc.	US6886754B2	("ac dc thermostat")	Variable power thermostat	Not a complete product
2	DC Thermostat with Low Battery Response	US Grant	Pan Weidong Muench Michael P Kadah Andrew S Wood Eric Christopher Internat Controls and Measurements Corp	US9501050B2	("dc power thermostat")	DC power thermostat	Not AC powered as well
3	Solar Powered Air Conditioner	US Grant	Debesa Ramon	US8516840B2	("ac dc thermostat")	A/C for mobile scenarios	Not directly related to the thermostat

voltage equal to or greater than 7 Volts, and less than or equal to 28 Volts. DC/DC Converter **240** may be implemented as a buck converter, a buck-boost converter, a boost converter, or another DC/DC converter architecture known in the art. Capacitor **250** is a filter capacitor for the output of DC/DC Converter **240**, which improves the accuracy of the output of DC/DC Converter **240**. Capacitor **250** may be a ceramic capacitor, an electrolytic capacitor, or any other capacitor structure known in the art.

[0020] The capability to accept both DC and AC voltage levels enables the thermostat system to be used in many diverse applications. The thermostat system may be used to control a DC-powered HVAC system in a van, truck, recreational vehicle, boat, yacht or other marine watercraft, an AC-powered system in a residential or commercial building. or a DC battery-powered system operating an off-grid commercial or residential facility. The thermostat system may include a standard mounting bracket to enable easy removal and installation. In one embodiment, an owner may use the thermostat system in a van, truck or recreational vehicle during travel to control the interior temperature of the vehicle. Upon arrival at a residential facility, including but not limited to a cabin, yurt, home or other shelter, the thermostat system housing may be removed from the mounting bracket in the vehicle and installed in a mounting bracket in the residential facility. In this manner, a single thermostat system may enable control of HVAC systems in different locations. In another embodiment, multiple thermostat systems may be installed in each location, allowing simultaneous monitoring and control of multiple facilities.

We claim:

- 1. A thermostat system for climate control comprising:
- a power conversion module further comprising,
  - a power input of either a direct-current voltage or an alternating-current voltage;
  - a power output coupled to a power bus;
- a battery management system including a battery and a battery management circuit, the battery management circuit configured to select an output from either the battery output voltage or the primary output voltage based on an operating condition;
- a communication module,
- a temperature monitor,
- one or more environmental sensors,
- a graphical user interface display, and
- a processor.
- 2. The system of claim 1, wherein the power conversion module accepts a direct-current voltage of greater than 7.5V and less than 32V.

- 3. The system of claim 2, wherein the battery management circuit selects the battery output voltage when the operating condition is a high-power operating condition of the system.
- **4**. The system of claim **3**, wherein the communication module communicates with a remote server using a cellular radio protocol.
- **5**. The system of claim **3**, wherein the communication module communicates with a remote server using a WiFi protocol.
- **6**. The system of claim **4**, wherein the environmental sensor further comprises a motion sensor.
- 7. The system of claim 6, wherein the processor accepts input from the temperature monitor and the environmental sensor and provides status information to the graphical user interface
- **8**. The system of claim **7**, wherein the processor further communicates status information to the communication module.
- 9. The system of claim 8, wherein the system is contained within a housing which is mountable on a bracket and removable from the bracket.
- 10. The system of claim 1, wherein the power conversion module accepts an alternating-current voltage of greater than 7.5V and less than 32V.
- 11. The system of claim 10, wherein the battery management circuit selects the battery output voltage when the operating condition is a high-power operating condition of the system.
- 12. The system of claim 11, wherein the communication module communicates with a remote server using a cellular radio protocol.
- 13. The system of claim 11, wherein the communication module communicates with a remote server using a WiFi protocol.
- **14**. The system of claim **12**, wherein the environmental sensor further comprises a motion sensor.
- 15. The system of claim 14, wherein the processor accepts input from the temperature monitor and the environmental sensor and provides status information to the graphical user interface.
- **16.** The system of claim **15**, wherein the processor further communicates status information to the communication module.
- 17. The system of claim 16, wherein the system is contained within a housing which is mountable on a bracket and removable from the bracket.

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