UCSF Startups and Innovation in

Medical Devices

BACH ex vivo

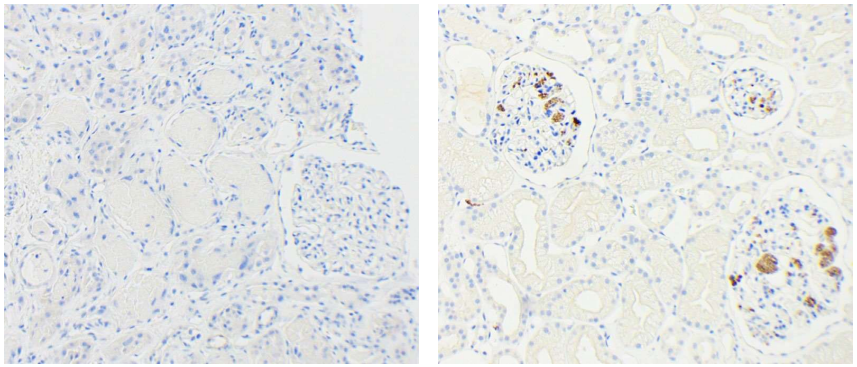
Organ perfusion and gene therapy platform to cure genetic diseases of the kidney

Marshall Stoller, MD
Co-founder
UCSF Professor, Urology

Heiko Yang, MD, PhD
Co-founder
UCSF Fellow, Urology

Control

Ex vivo transduction with protein expression



Immunohistochemistry for GFP, adult human kidney

DISEASE/INDICATION: Genetic diseases of the kidney (e.g. polycystic kidney disease, cystinuria, Dent's disease)

UNMET NEED: Gene therapy has the potential to cure genetic kidney diseases, but delivering gene therapy to the kidney *in vivo* has many technical and clinical limitations. An *ex vivo* approach (combined with kidney autotransplantation) could improve the efficiency of transduction and minimize systemic toxicities.

PRODUCT: Normothermic ex vivo organ perfusion and therapeutic delivery platform to facilitate gene therapy in the kidney.

COMPETITIVE ADVANTAGE/DIFFERENTIATION:

- Normothermic ex vivo perfusion device optimized for human kidney
- Multiple gene therapy delivery routes in ex vivo setting (intravascular, endoscopic, direct injection)
- Allows for vector washout prior to autotransplantation to minimize systemic toxicities.

DATA: Normothermic ex vivo perfusion of human and porcine kidneys up to 36 hours with successful delivery of genetic material.

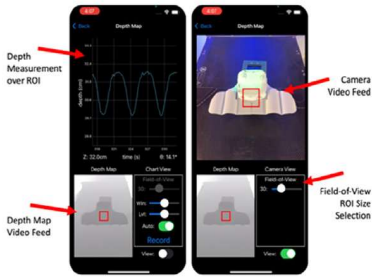
BRAYVE™: *The Smartphone Technology Platform for Radiation Oncology*

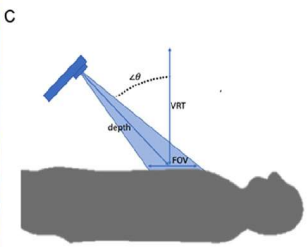
Tomi F. Nano, PhD, DABR
Co-founder, Bravye™
UCSF Assistant Professor of Radiation Oncology, Medical Physicist

Dante Pl. Capaldi, PhD, DABR
Co-founder, Bravye™
UCSF Assistant Professor of Radiation Oncology, Medical Physicist

PROBLEM:

- Only 30% of clinics have access to surface breath-hold systems and patients have no effective way of practicing their breath-holds.
- This more than doubles the chances of cardiac toxicity during radiation treatment.





SOLUTION:

- BRAYVE is a smartphone technology platform for radiation oncology and radiology that empowers clinics to more effectively treat cancer patients undergoing breath-hold, while also giving patients access to the worlds-first at-home device that will improve their breath-hold consistency.

TRACTION:

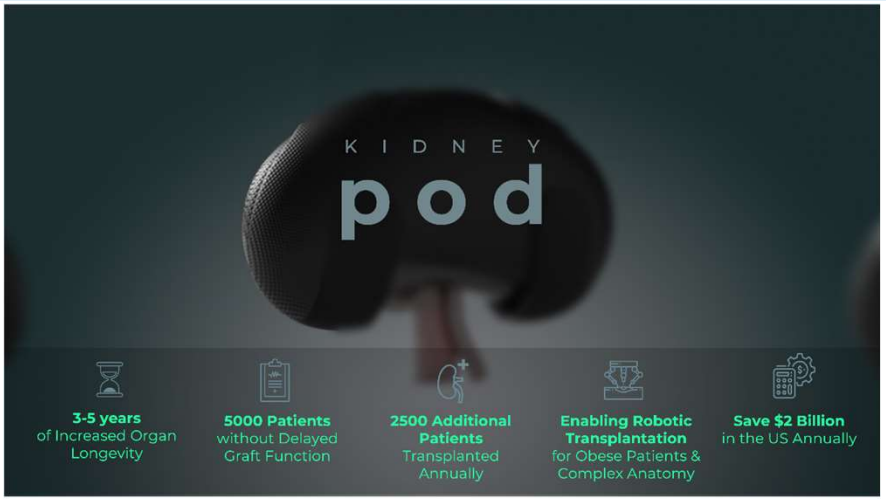
- Provisional patent approved, full patent pending
- MVP 80% complete and technology validated against current systems

LEARN MORE:

An organ preservation device to address the organ shortage, improve transplant outcomes, and accelerate the next wave of innovation in transplant surgery

Keith Hansen, MD
Co-founder and CEO, Diatiro
UCSF General Surgery Resident and Innovator

Tom Sorrentino, MD
Head of Clinical Development
UCSF General Surgery Resident



PROBLEM:

- **1 out of 3 patients return to dialysis** after a kidney transplant, and thousands of kidneys are discarded annually. This is due to **warming injury**.

SOLUTION:

- The Diatiro **KidneyPod** is an **FDA Breakthrough-Designated Device** that creates a microclimate around kidneys during sew-in, thereby preventing warming injuries.

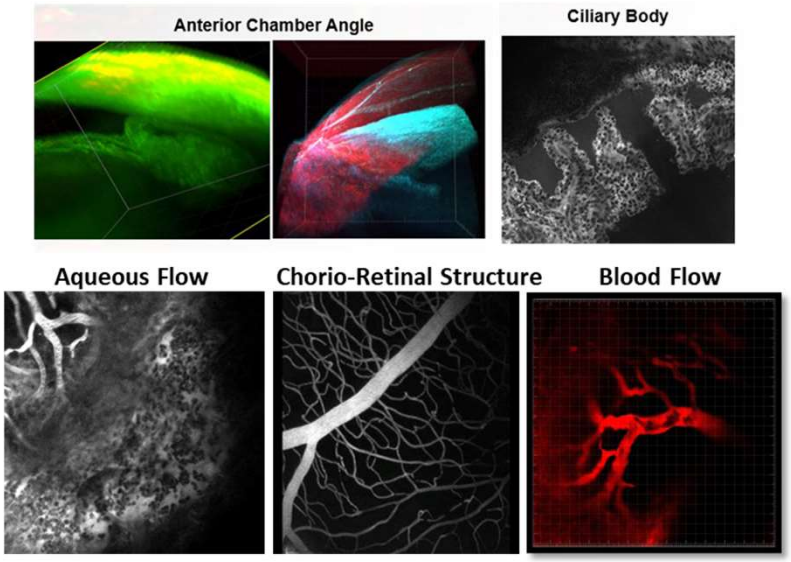
TRACTION:

- Backed by Fogarty Innovation & National Kidney Foundation with $2.6M in Funding
- **Currently completing a $4M Seed**

LEARN MORE:

Next-Gen Ultrafast Imaging & Laser Therapy

Tyson Kim MD, PhD
Founder
Associate Professor, Ophthalmology UCSF
Innovator



DISEASE INDICATION: Primary Open Angle Glaucoma (POAG); Additional indications for Myopia Control, and retinal diseases in dev.

UNMET NEED: Current methods to diagnose glaucoma do not provide a mechanistic understanding to tailor interventions for glaucoma. Patients require multiple interventions, typically combined with life-long medication therapies, that are met with low-adherence rates.

PRODUCT: Clinic-based imaging system and titratable laser-based therapeutic system that can be used to treat patients with mild, moderate, and severe disease, non-invasively; can be repeated as needed to ensure lifelong solution for patients.

COMPETITIVE ADVANTAGE / DIFFERENTIATION: First of its kind non-invasive imaging and therapeutic system which can treat the full range of glaucoma conditions, and offers several workflow advantages to hospitals, clinics and surgery centers.

DEVELOPMENT STAGE: Raising ~$2M in seed funding to run FIH clinical trials for Glaucoma (w/in 12-mo), and to conduct feasibility studies for myopia control and peripheral retina diseases.

Hydronovo™

Regenerate Tissue Through Stem Cell Activation by Restoring Tissue-Nerve Crosstalk

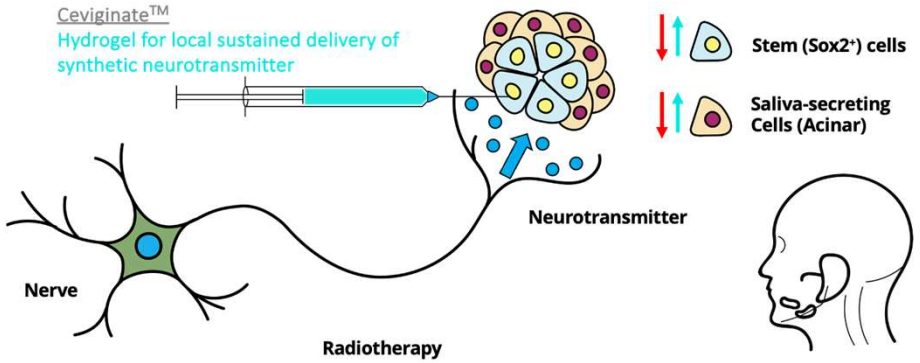
UCSF

Sarah Knox, PhD
Co-founder and CSO, Hydronovo
UCSF Professor of Cell and Developmental Therapy

Chelsea Bahney, PhD
Co-founder and CEO/COO, Hydronovo
UCSF Associate Professor of Orthopedic Surgery

PROBLEM:

- No regenerative therapies are available to treat xerostomia, damage incurred to salivary glands in the course of radiation treatment for head and neck cancers.
- Preventative treatments show little benefit.



SOLUTION:

- An injectable neuromimetic hydrogel to regenerate salivary gland function through stimulation of resident stem cells to overcome xerostomia, or dry mouth.

TRACTION:

- $2.4M SBIR Phase 2 – received a fundable score for 2025
- ~$6.3M in NON-DILUTIVE funding (NIH and CIRM)
- 505(b)2 Accelerated FDA Pathway
- Pre-IND Submission Completed
- U.S.& International Patent Application Filed
- New IP for platform extension to anti-greying therapy

LEARN MORE:

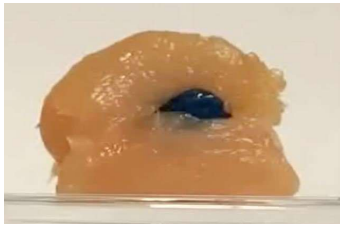
Hydroshield: Self-Associating Polymer Hydrogel for Hydrodissection- Aided Percutaneous Tumor Ablation

Miles Conrad, MD, MPH
Clinical Professor
Department of Radiology,
UCSF Expert in
interventional radiology

Phil Messersmith, PhD
Professor Bioengineering
and Materials Sciences,
UC Berkeley Expert in
biomaterials

Saline

Hydroshield



DISEASE/INDICATION: Renal cell carcinoma will be first indication of focus. Hepatocellular carcinoma and/or breast cancer will be the next indications of focus.

UNMET NEED: Existing hydrogels do resist migration in the peritoneum and other large potential spaces. Furthermore, they are not thermostable and are thus not suitable for thermoablation.

PRODUCT: A hydrogel with a novel formation to resist migration and exhibits thermostability during cryoablation procedures. It coalesces in for six hours and subsequently breaks down over time.

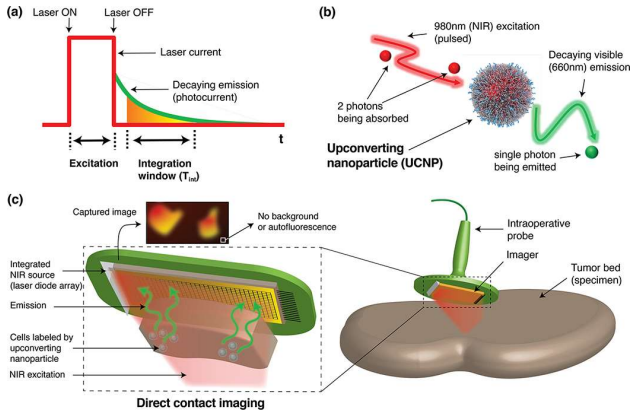
COMPETITIVE ADVANTAGE/DIFFERENTIATION: Saline and current spacer materials (SpaceOAR, Orise) are not designed for use in the peritoneum and easily migrate. Hydrioshield's ability to resist migration prevents injury of adjacent tissue and reduces the need to re-scan patients during a procedure.

DATA: Small animal studies using MRI show that this formulation is stable during thermoablation procedures, resists of migration, and does not cause inflammation

Insyte Bio — *Guiding cancer care at the cellular level*

Mekhail Anwar, MD/PhD
UCSF Associate Professor,
Radiation Oncology &
UC Berkley Electrical
Engineering and Computer Sciences

Matthew Cooperberg, MD/MPH
UCSF Professor, Urology;
Epidemiology & Biostatistics



Overview of time-gated imaging using upconverting nanoparticles. (a) time-gated imaging scheme waveforms. (b) upconverting nanoparticle absorption and emission. (c) proposed intraoperative imaging platform and surgical integration of the micro-imager.

DISEASE/INDICATION: Oncology, initial application prostate cancer

UNMET NEED: Current cancer therapies result in treatment failures due to therapy-tumor biology mismatches and missing cancer cells (during surgery or underdosing).

PRODUCT: VISION is a molecular-microelectronic platform to continuously visualize cancer at the cellular scale, in an ultra-compact chip-scale form-factor

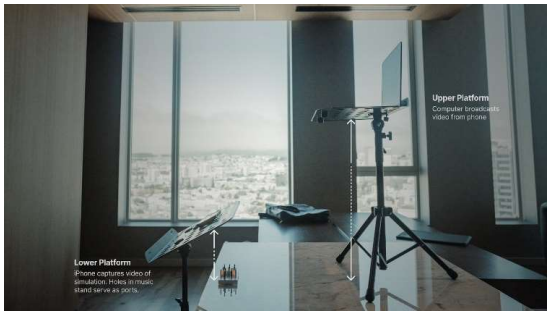
COMPETITIVE ADVANTAGE/DIFFERENTIATION:

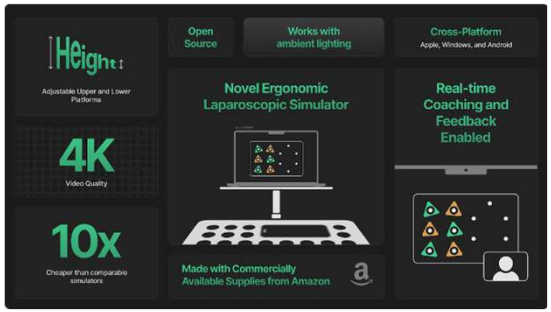
- Molecularly guided surgery
  - Cell deposit visualization enables more complete removal of disease
- Molecularly directed radiation
  - Visualization of the dose delivered to tumors
- Real-time monitoring of targeted therapies and immunotherapy

DATA: Published data. Tumor and nerves in patient tissue samples identified using VISION, approaching near single cell detection.

A Novel Ergonomic Simulator for Laparoscopic Surgery

Tom Sorrentino, MD
Co-inventor
UCSF General Surgery Resident





PROBLEM:

- 80% of surgeons report musculoskeletal pain due to surgeries.
- Current laparoscopic surgery simulators are either too expensive, non-portable, or non-ergonomic.
- Ergonomic simulation training remains inaccessible to most residents.

SOLUTION:

- An affordable, high-fidelity and ergonomic simulator for laparoscopic surgery.
- Simulator utilizes wireless video transmission through Apple's Continuity Camera technology that allows for real-time broadcasting as the camera captures the working surface and displays real-time video on the laptop screen.
- Cost of materials <$35 (not including laptop and iPhone).

TRACTION:

- Currently used by UCSF Surgery residents in their at-home skills curriculum

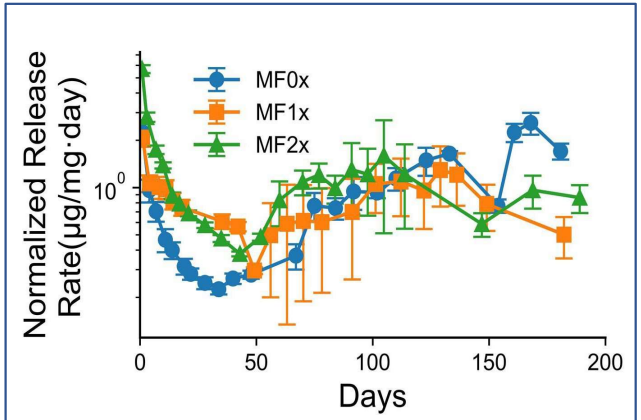
LEARN MORE

Prospira – A New Dissolvable Implant for Allergies

Andrew Goldberg, MD
UCSF Professor, Vice Chairman, Department of Otolaryngology

David Conrad, MD
Otolaryngology, Palo Alto Medical Foundation (PAMF)

Dan Bernards, PhD
The Desai Lab at UCSF Drug Deliver Scientist



Mometasone release over 190 days showing sustained slow delivery into surrounding tissue

Prospira is needle inserted in the office. The implant is the size of a long grain of rice andfully dissolves over 6 months

DISEASE/INDICATION: Environmental Allergies, Nasal Turbinate Hypertrophy and Rhinitis Medicamentosa (Nasal Decongestant Dependency)

UNMET NEED: Nasal steroid sprays (Flonase, Rhinocort, Astelin) have low compliance rates and must be used daily for months. The OTC nasal spray market is complicated, leaving patients uncertain about how to medicate.

PRODUCT: A 2 cm thin dissolvable Mometasone-eluting implant placed into the nasal turbinates by an ENT physician to replace daily allergy medications. The 10 minute in-office procedure provides 6 months of therapy and reducing nasal congestion, discharge and itching.

COMPETITIVE ADVANTAGE/DIFFERENTIATION:

- Sustained drug delivery for allergy season to replace daily medications
- Pre-existing CPT code (30200)
- Lower cost than OTC options for one year and allergy shots

DATA: Ex-vivo testing shows sustained release of Mometasone and long duration of therapy. We have planned a sheep animal model and first-in-human study

SALVISTA

24-Hour Intraocular Pressure (IOP) Monitoring Preventing Glaucomatous Vision Loss

UCSF

O'Rese J. Knight, MD
Co-Founder, SalVista
UCSF Associate Professor Ophthalmology and Innovator

PROBLEM:

- Current methods to diagnose and manage glaucoma are inadequate and represent a significant healthcare burden.
- 24-hr IOP monitoring expands access to care, improves diagnostic accuracy, and enhances clinical decision making.
- Clinical tools for 24-hr IOP monitoring remain elusive.

SOLUTION:

- Deployment of self-sensing cantilevers into a contact lens platform delivers automated 24-hr IOP monitoring
- Normative database and ML provide enhanced decision-making tools for treatment selection
- EMR Integration unlocks Glaucoma Telehealth

TRACTION:

- 3 patents filed or in process
- ~$5.5M raised in non-dilutive funding
- Currently in discussions on FDA De Novo

LEARN MORE:

SIRA MEDICAL

We Bridge The Gap Between Imaging And Reality

UCSF

Jesse Courtier, MD
Co-founder, Sira Medical
UCSF Chief of Pediatric Radiology and Innovator

PROBLEM:

- Surgeons have difficulty translating radiology information into real world patients for preoperative planning.

SOLUTION:

- Augmented reality software to help with preoperative planning by providing patient-specific high fidelity 3D holograms.

TRACTION:

- Received FDA 510k clearance for preoperative planning software
- Nearly $1M from grants, accelerators, and VC funding
- Deployed in 150 surgeries at UCSF
- Completed 5 pilots, 3 ongoing project with UC Davis, and 2 publications in 2024
- IP: developed proprietary software and model creation methods
- Finalist UCSF Digital Health Award

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