Whitecloud Technologies, LLC

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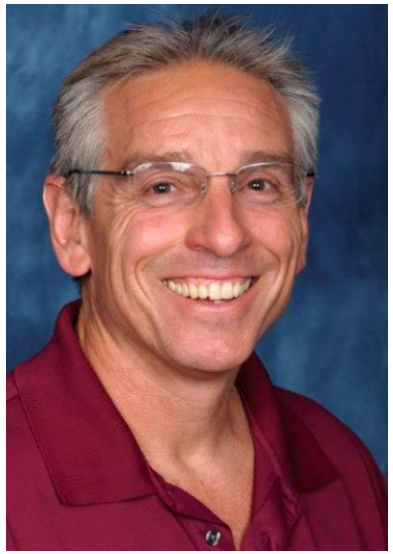


Frank Castro, 502-287-3924

MD, Stanford Medical School

Tulane Orthopedic Residency & Spine Fellowship

25 years of Spine Surgery Experience

30 United States Patents

President, Cardinal Spine & Whitecloud Technologies

Natasha Lonnon, CEO

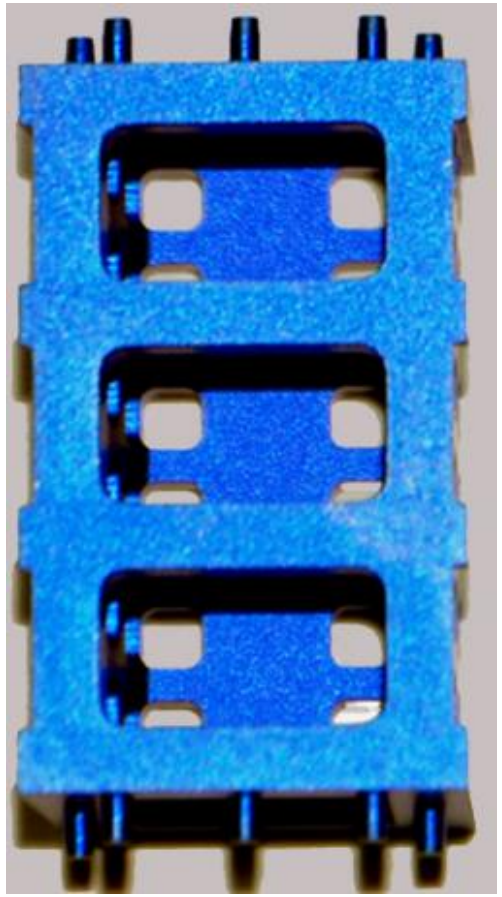
MBA, University of Louisville

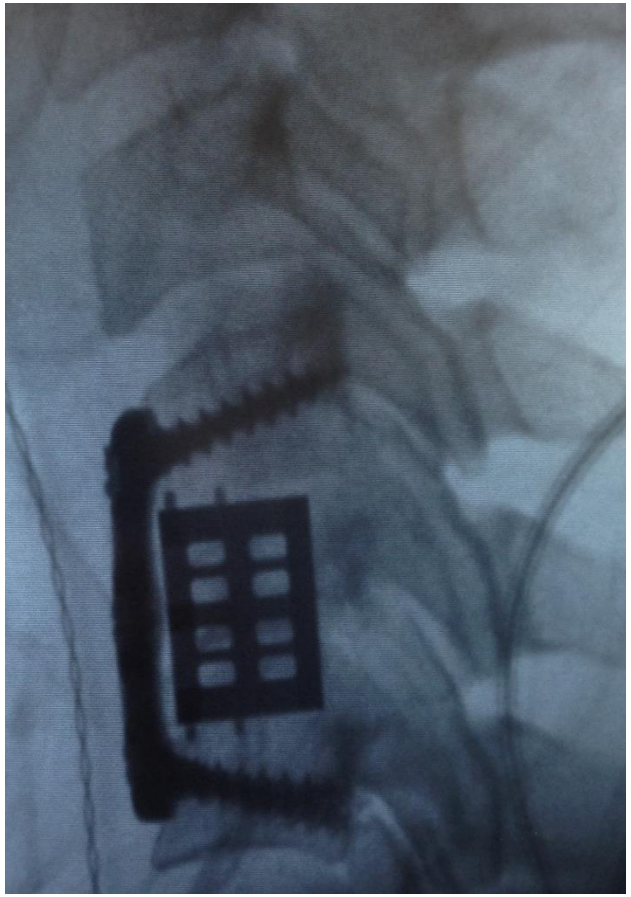
VP Cardinal Spine & Whitecloud Technologies

Team

- Manufacturing: Hammill Maume, Ohio
- Regulatory: PaxMed International San Diego, CA
- Biomechanical Testing: Element Fairfield, Ohio
- Accounting: ScrogginsGreer Cincinnati, Ohio
- Sales: Network of 75 Independent Spine distributors from Cardinal Spine Experience

Previous Experience: Cardinal Spine's Palo Alto C-VBR First FDA Approved Cervical VBR Acquired by K2M/Stryker in 2017





*Castro FP Jr. Five-year follow up on the single level corpectomy. J Neuroscience & Neurological Disorders 2021;5:083-086. https://doi.org/10.29328/journal.jnnd.1001055

*Sets the cervical vertebral body replacement standards for:
longest follow-up
highest fusion rate
lowest complication rate

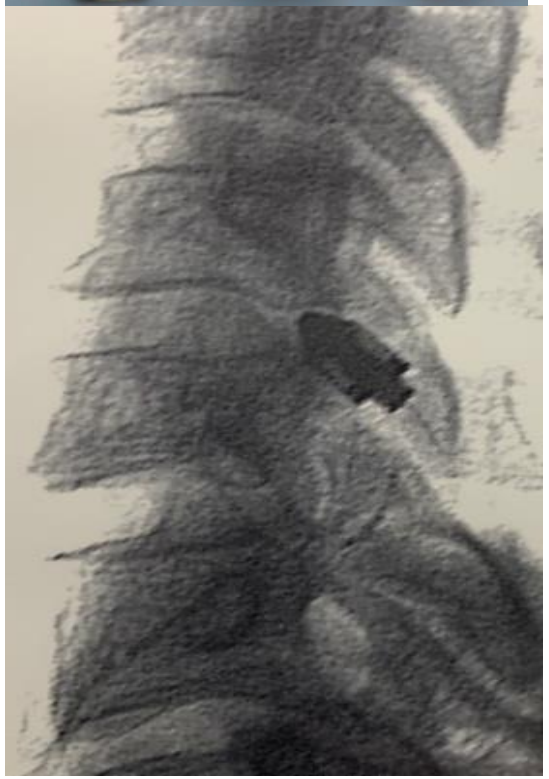
It is the safest cervical corpectomy device available.

Medical Device Milestones

1. Patent applications and prototype creation
2. Biomechanical testing of the “worst case scenario” (the biomechanically weakest device)
3. Cleaning and Sterilization of the “worst case scenario” (trays of the largest implants with insertion tools)
4. 510K Application
5. Additional biomechanical/cadaveric studies as required by the FDA
6. 510K Approval
7. Building inventory and acquiring distributors and surgeon users.
8. All devices will have a 50% profit margin. Commissions typically run 35%, landed costs are 5-10% and administrative costs are 5-10%.

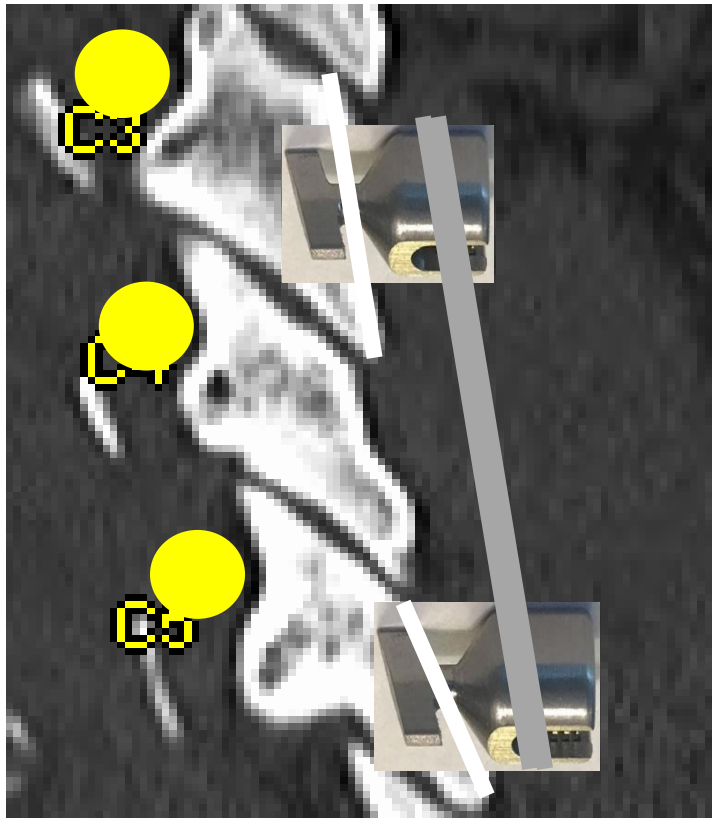
The SIMoeJo for **S**acro**I**liac Joint Fusions

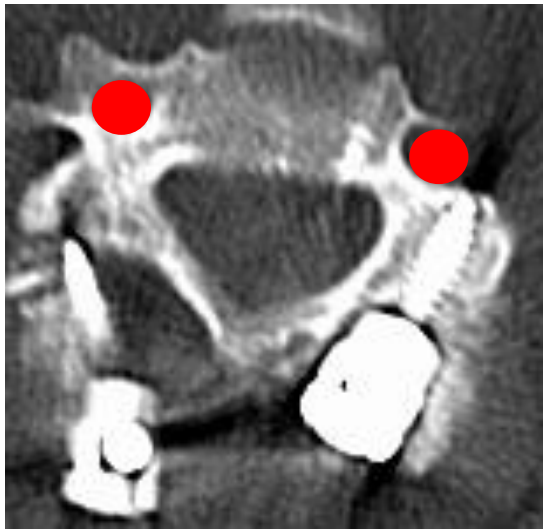
- **Milestones**: 1-3 accomplished. 510K application scheduled for May 2023.
- **Market Size**: $600M/year (Patients with sacroiliac pain and/or instability)
- **Strategy**: sell at $3000/device via independent distributor network to net $1650/device. One or two devices used per case.
- **Competitive Advantage**: Simple surgical technique allows expansion of user market to include Pain Management Physicians
- **US Patents**: 10,772,738; 10,932,919; 10,980,643; 11,419,736



The Frankenhammer

- **Milestones**: 1-5 accomplished. 510K application submitted in May 2021.
- **Market size**: $50M/year. (Patients with 1-3 non-unions after anterior cervical fusion procedures)
- **Mission**: reduce 30% complication rate of open posterior cervical fusion procedures to less than 5%.
- **Strategy**: sell at $2000/device via independent distributor network. Profit $1000/device. Average 4 devices/case
- US Patents: 10,772,738; 10,932,919; 10,980,643; 11,419,736

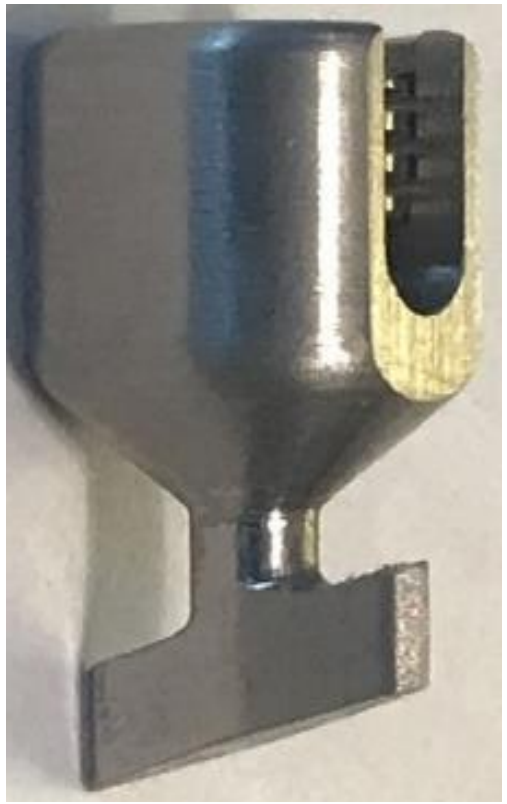




The LM90

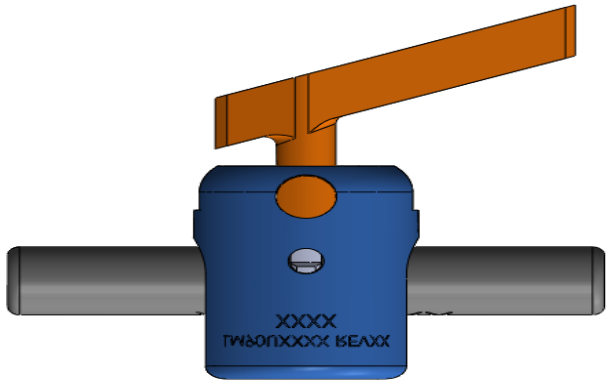
- **Goal:** to reduce construct failure rate by increasing pullout strength as compared to traditional fixation screws. (Molly bolts provide stronger fixation than screws or nails).
- **Mission:** to reduce the 12% screw injury rate to nerves (yellow) and arteries (red) to < 1%.

The LM90 for Lateral Mass Fixation

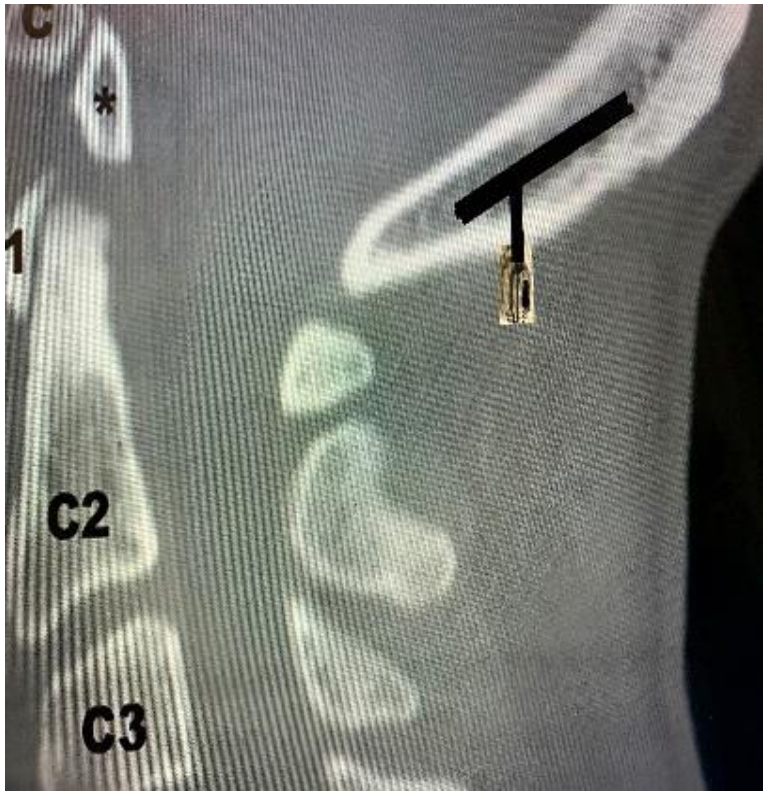


- **Milestones**: 1-4 accomplished. 510K application in June 2023.
- **Market Size**: $500M/year (Open posterior cervical fusion procedures)
- **Strategy**: Sell at $750/device via independent distributors. Profit margin of 50%. Two to ten devices per case.
- **Competitive Advantages**: Stronger fixation, less inventory, first to market, reduces neurovascular complications to < 1%
- **US Patents** 11432829; 11413073

The OC45



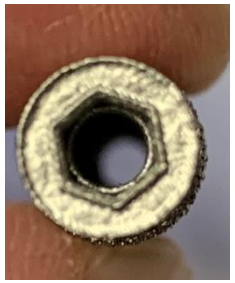
Goal: increase pullout strength (construct rigidity) with fewer devices (2 OC45s vs. 8 screws and 1 plate).
Mission: to reduce the traditional 20% screw fixation complication rate for intracranial hematomas, CSF leaks, venous sinus bleeds, and meningitis (should an infection occur) to less than < 1%

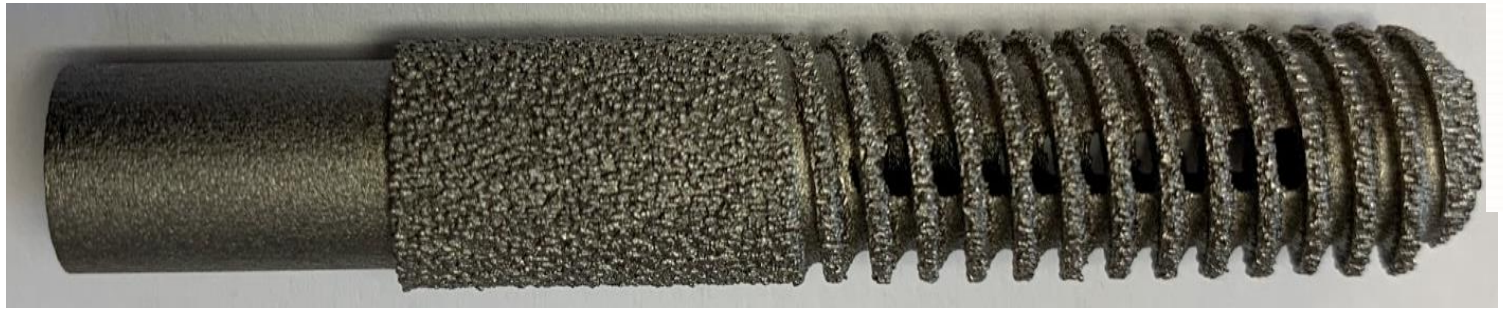


The OC45 for Occipital Fixation

- **Milestones**: 1-4 accomplished. 510K application scheduled for June 2023.
- **Market Size**: $50M/year (Posterior cervical fusions which require extension to the occiput)
- **Strategy**: Sell at $1200/device via independent distributors. Profit margin 55%. Two devices/case.
- **Competitive Advantages**: Stronger fixation, less inventory, first to market, fewer complications
- **US Patents** 11432829; 11413073

MoeBetta Pedicle Fixation System for Patients with Low BMD



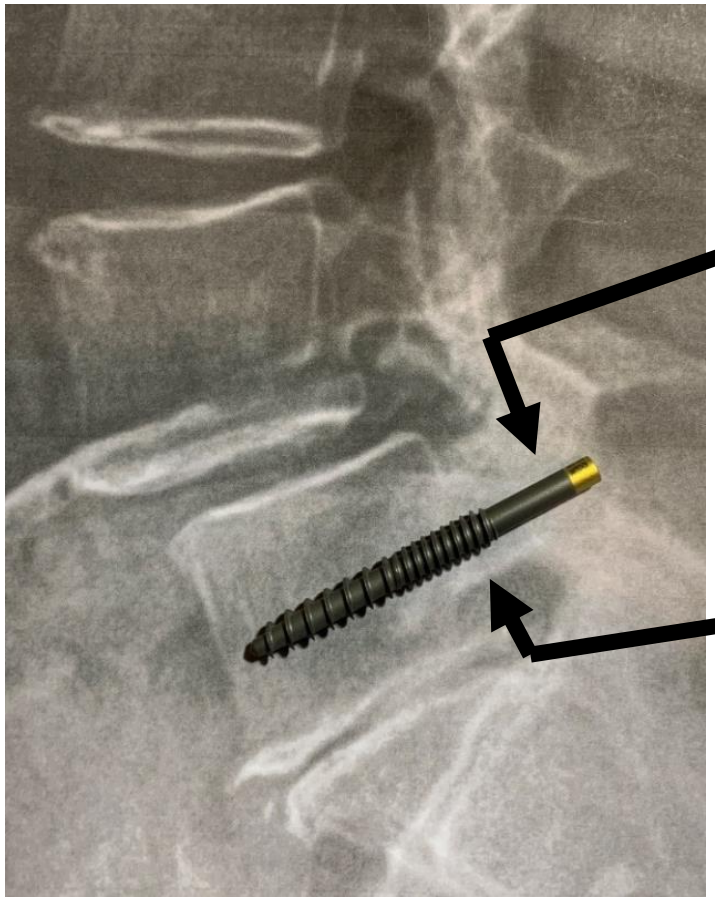


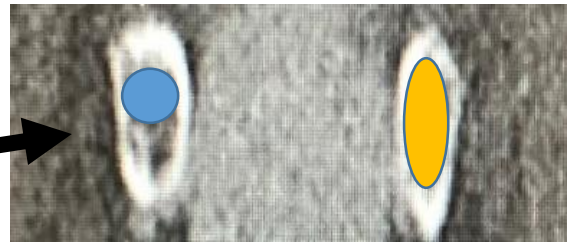
2022 Orthopedics This Week Spine technology Awards

- Because "Not all of your patients have to have a loose screw™"
- **Goal**: to be the **first** FDA approved patient specific, pedicle specific porous ingrowth fixation system using pre-operative CT/MRIs to determine implant dimensions
- **Mission**: to reduce implant loosening and construct failure rates from 75% to less than 10% in patients with a low bone mineral density (BMD).

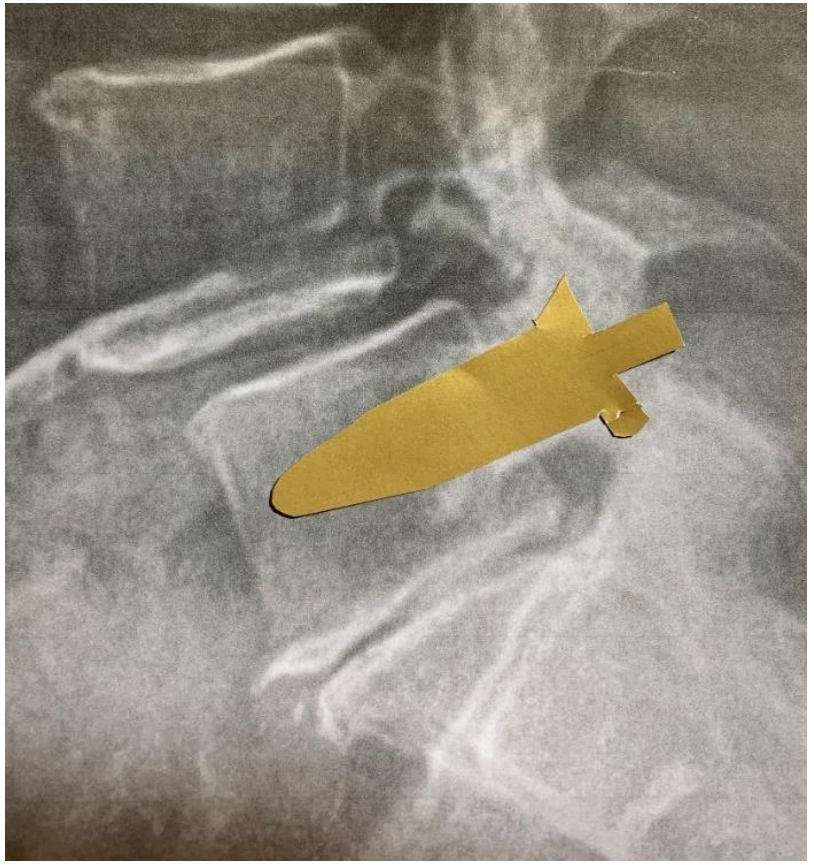
Surface contact area and construct stability of traditional screws with pedicular bone are limited by the **smallest** diameter of the pedicle. MoeBetta implants **maximize** surface contact area. As bone ingrowth increases, so does long-term construct stability.

Traditional fixation





Threadless MoeBettas



Threadless MoeBettas are percutaneously implanted as an outpatient and 3-6 months are allowed for porous ingrowth

The MoeBetta Pedicle Fixation System

- **Milestone** reached: Biomechanical testing
- **Market Size**: $5B/year (Elderly patients with stenosis, neurogenic claudication, and osteopenia or osteoporosis)
- **1-Level Case**: $4000 - Expenses ($2200) = $1800 profit
- **Each additional level**: $2000 - $1100 = $900 profit
- 75% of cases involve 3 - 5 levels
- **Strategy**: Partner with a major spine company after 510K (Market expansion varies with each company's bone growth technology. For example, Medtronic's Bone Morphogenic Protein can expand the market size another $1B/year)
- **US Patents**: 11419653, 11419654

Whitecloud Technologies' Financials

- 15 Accredited investors have provided $1.8M capital. Investment minimum = $50K
- Company has no debt.
- Capital needed for building inventory and marketing of the FHR, LM90, OC45, and SIMoeJo and development of the MoeBetta.
- Q4 2024 is ETA for profitability (shareholder distributions, sooner if a technology is acquired)