



ACLARION

Better Data | Better Care

OCTOBER 2023
NASDAQ: ACON

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Problem



Patient is in pain but which disc is the cause?

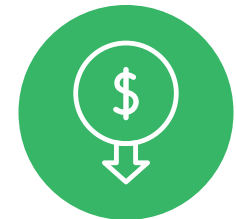
High surgical decision variability



Expensive



Poor Outcomes



Low value



Solution



Technology labels each disc as painful or pain free

Personalized treatment path is optimized



Lower cost



Better outcomes



Higher value care

Better Surgical Outcomes

Gornet et al



2019

Gornet study published in European Spine Journal¹



139

139 cLBP patients with 73 undergoing surgery



85%

85% of patients improved if all Nociscan positive discs treated²



63%

63% of patients improved if a Nociscan positive disc was not treated²



2 year

Durable at 2 year follow up²

Published in the European Spine Journal in 2019 & 2023

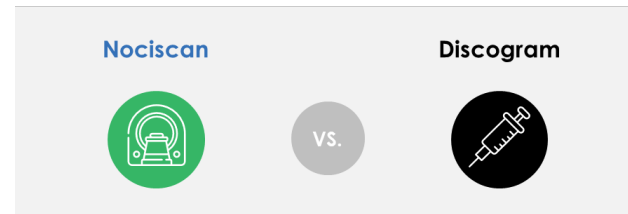
¹ Gornet et al. Magnetic resonance spectroscopy (MRS) can identify painful lumbar discs and may facilitate improved clinical outcomes of lumbar surgeries for discogenic pain. European Spine Journal. 2019; 28 674-687

² Gornet et al. Magnetic resonance spectroscopy (MRS) identification of chemically painful lumbar discs leads to improved 6-12-24 month outcomes for discogenic low back pain surgeries. European Spine Journal. 2023; 32(6) 1973-1984



Objective: Determine if non-invasive diagnostic (Nociscan®) is cost-effective compared to provocative discography

- Economic modeling based on the Gornet trial and spine industry economic cost factors
- Statistical modeling and analysis performed by independent PhD healthcare economist
- Statistically dominant clinical and economic results¹
- Presented at SPINWEEK, International Society for the Advancement of Spine Surgery (ISASS), American Society of Pain and Neuroscience (ASPN)



Per Patient per Surgery

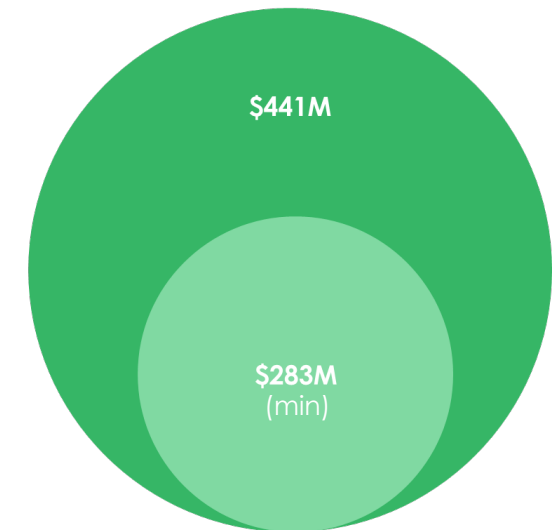
Cost savings

(\$1,712)

Sx Success ²

+10%

Annualized US Savings ³



¹ Wilson et al, Cost-effectiveness of a Novel, Non-Invasive Diagnostic Test for Chronic Low Back Pain Patients, 2023

² 15-point ODI Change; Sx Success = Surgical Success

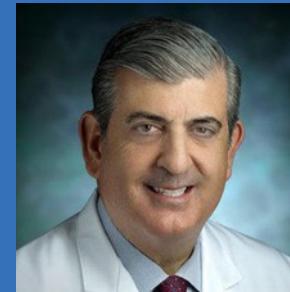
³ Min and Max Estimate



Prospective, randomized, controlled trial evaluating the outcomes of surgical patients when the surgeon has access to Nociscan data compared to when the surgeon does not have access to Nociscan data

- 300 patients estimated
- Begins Q4 2023
- 42 months to complete
- Anticipated outcome: Demonstrate improved clinical results when using Nociscan

Principal Investigator & Anchor Site



JOHNS HOPKINS
MEDICINE

Nicholas Theodore, MD, MS
Director of Neurosurgical Spine Center,
John Hopkins Medicine

NIH - BACPAC

Back Pain Consortium (BACPAC)



Two NIH studies aimed at finding the best diagnostic tools for chronic low back pain and evaluating their effectiveness via clinical outcomes in four different patient sub-groups.

- Sponsored by the National Institutes of Health (NIH)
- comeBACK - Up to 300 patients to undergo Nociscan to provide unique, objective, intradiscal biomarker data for enhanced phenotyping - <https://comeback.ucsf.edu/research>
- BEST – Up to 200 patients to undergo Nociscan to evaluate effectiveness in determining optimal treatments including going directly to surgery <https://besttrial.org/>
- Began Q4 2021
- Complete Q2 2024



ACTIVE

Autologous mesenchymal stem/stromal Cells for Treatment of workers affected by chronic low back pain due to multilevel InterVertebral disc degeneration



ACTIVE will evaluate the efficacy of intradiscal injection of autologous BM-MSCs in workers affected by chronic low back pain (cLBP) unresponsive to conventional therapy

- Sponsored by Campus Bio-medico University
- Up to 204 scans: T0, T3, T6, and T12 months
- Began Q4 2020
- Complete Q1 2024
- Anticipated outcomes: Demonstrate that Nociscan results correlate to improved treatment outcomes
- <https://clinicaltrials.gov/ct2/show/NCT04759105>



FONDAZIONE
POLICLINICO UNIVERSITARIO
CAMPUS BIO-MEDICO

Nociscan Product

Spectroscopy analyzes the chemical composition of tissue



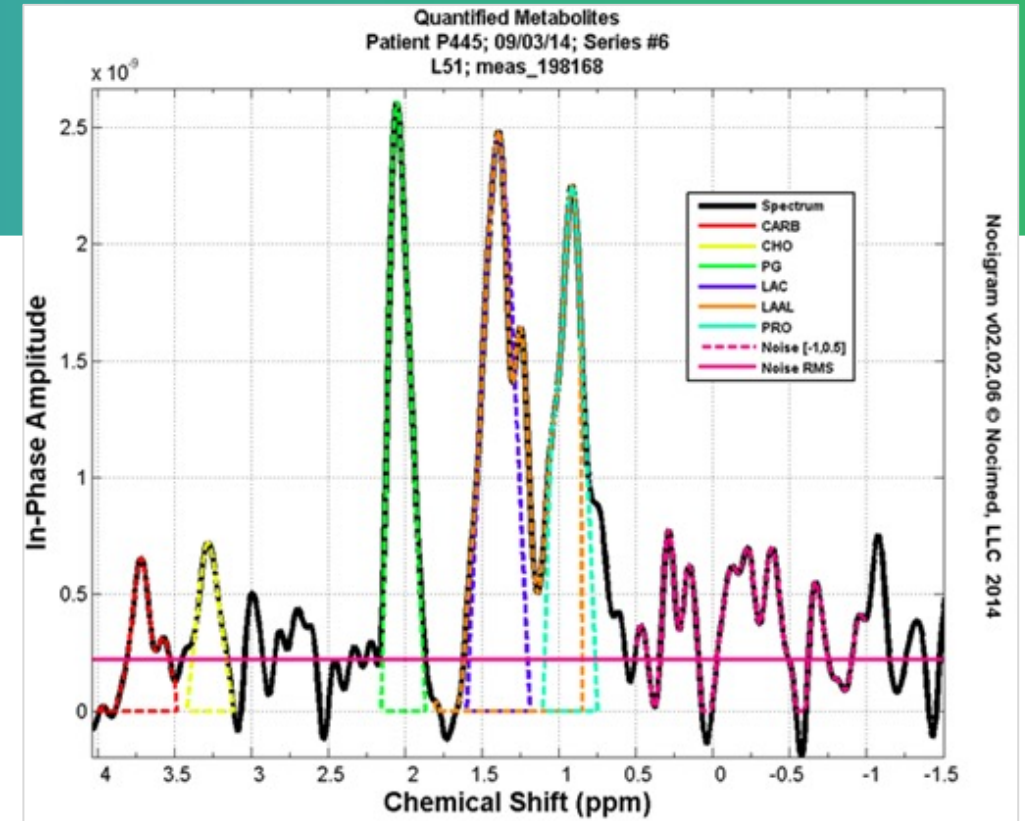
Proprietary signal processing software transforms raw spectral data into clear biomarkers

✓ Acidic pain markers¹

- Alanine (LAAL = lactic acid + alanine)
- Lactic Acid (LAC)
- Propionate (PRO)

✓ Structural integrity markers¹

- Carbohydrate/collagen (CARB)
- Proteoglycan (PG)



¹ Keshari KR, Spine (2008) 33(3):312–317

Clear Delineation Between Pain & No Pain

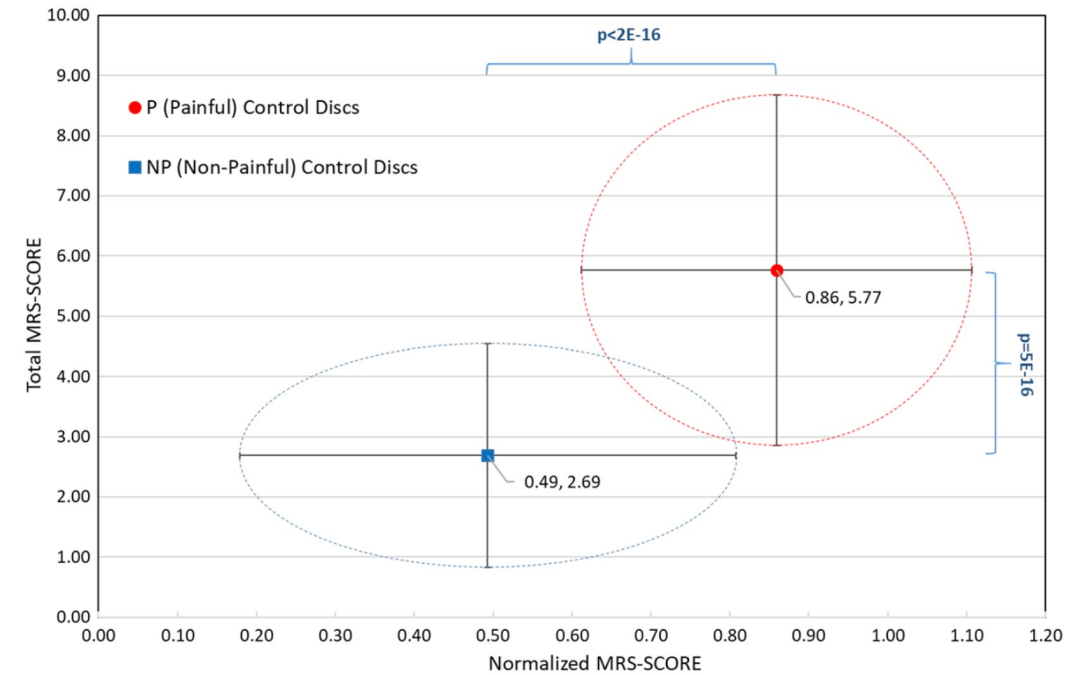


✓ Six ratios for each disc

- Pain markers in the numerator (3)
- Structural integrity markers in the denominator (2)
- Differentially weighted & correlated to clinically painful discs
- Leverage AI for major advancements

✓ Painful Disc

- Structural degradation with acid & neoinnervation¹
- Acid + Nerves = PAIN²
- Elevated pain markers relative to normal internal controls



¹ Freemont AJ, Rheumatology (2009) 48:5-10

² Immke and McCleskey, Nat Neurosci. (2001) Sep;4(9):869-70

Competition



Nociscan

Similar to a standard MRI



Discogram – Current Standard of Care

An invasive procedure in an awake patient that damages healthy discs¹

Nociscan Virtual Discogram	VS.	Provocative Discogram
Non-invasive		Invasive
Objective		Subjective
No pain		Severely painful by design
No radiation		Lumbar CT = ~10x radiation of chest x-ray
Can be added to a standard lumbar MRI		Additional exam after MRI
25-45 min		Half-day procedure with days out of work
Half the cost of discogram - \$1,450 list price		Twice the cost of Nociscan - \$2,000 to \$5,000 ²

¹ Cuellar JM, Spine J (2016),16(3):273–280
² Definitive Healthcare; Does not include Physician Fees

Intellectual Property



22 issued U.S. Patents



17 issued International Patents



13 Pending Patent Applications



**Exclusive worldwide license from UCSF
for intervertebral disc biomarkers & ratios**



IP broadly covers:

Use of proprietary biomarkers & ratios to identify clinically painful and non-painful discs

Post processing technologies to more reliably & accurately measure biomarkers from MRS spectra

AI to correlate raw spectra to clinical outcomes

Use of internal tissue controls when using MRS

Product Status



Current product

Spine surgery decisioning tool to replace discography & improve surgical outcomes

- Early commercialization in progress
- AI process improvements for reproducibility & scalability in progress
- MRI integrations to support scalability



Next Generation

Population management platform for chronic low back pain

- Selected for NIH BEST Study
- Predictive analytics capability based on clinical outcomes ¹
 - Surgical interventions
 - Regenerative therapies
 - Conservative care
 - Preventive care



¹ 510(k) pathway required

Regulatory Approvals Secured



Current product approvals

- **NOCICALC** – marketed through FDA registration as a Class 1 exempt device & CE Mark
- **NOCIGRAM** – marketing indication established through the 21st Century Cures Act as clinical decision support software & CE Mark

Next generation AI product

- AI based predicates from HeartFlow & Cleerly via 510(k)



Market Opportunity

\$10B¹

U.S. lumbar fusion & disc replacement
market – **actionable now**

\$40B²

U.S. lumbar spine market
(fusion & non-fusion surgery plus
presurgical care) – **expansion**

\$135B³

U.S. low back & neck pain
market – **ultimate market⁵**

266 million patients worldwide with degenerative spine disease & LBP each year – 16 million in US⁴

¹ Martin BI, Spine (2019) Mar 1;44(5):369-376.

² Kim LH, JAMA Network Open (2019) 2(5)

³ Dieleman JL, JAMA (2020) 323(9)

⁴ Ravindra VM, Global Spine Journal (2018) 8(8): 784-794

⁵ May Pursue a 510K Pathway to enter this market

Augmented Intelligence Landscape



- Founded 2007 – heart disease
- Cloud-based model
- Avoid invasive angiogram
- \$240M Series E in 2018
- Series E Valuation - \$1.5B post



- Founded 2016 - stroke
- Cloud-based model
- Earlier stroke detection
- \$100M Series D in 2022
- Series D Valuation - \$1.3B post



- Founded 2016 – heart disease
- Cloud-based model
- Avoid invasive angiogram
- \$223M Series C in 2022
- Series C Valuation - undisclosed



- Founded 2009 – heart disease
- Cloud-based model
- Avoid invasive angiogram
- \$27M Series B in 2022
- Series B Valuation - undisclosed

Reimbursement Landscape



CPT Category III Codes secured January 1, 2021

CPT Code	Description
0609T	MRS, determination & localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, in ≥3 discs – PAID TO IMAGING CENTER
0611T	MRS, determination & localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs – PAID TO ACLARION



Transition to Category I codes



Increase volume of Category III code billing



Partner with surgeon KOL's & societies to engage payers

International Society for the Advancement of Spine Surgery indicates MRS as a SOC alternative to discogram

Process to Standard of Care



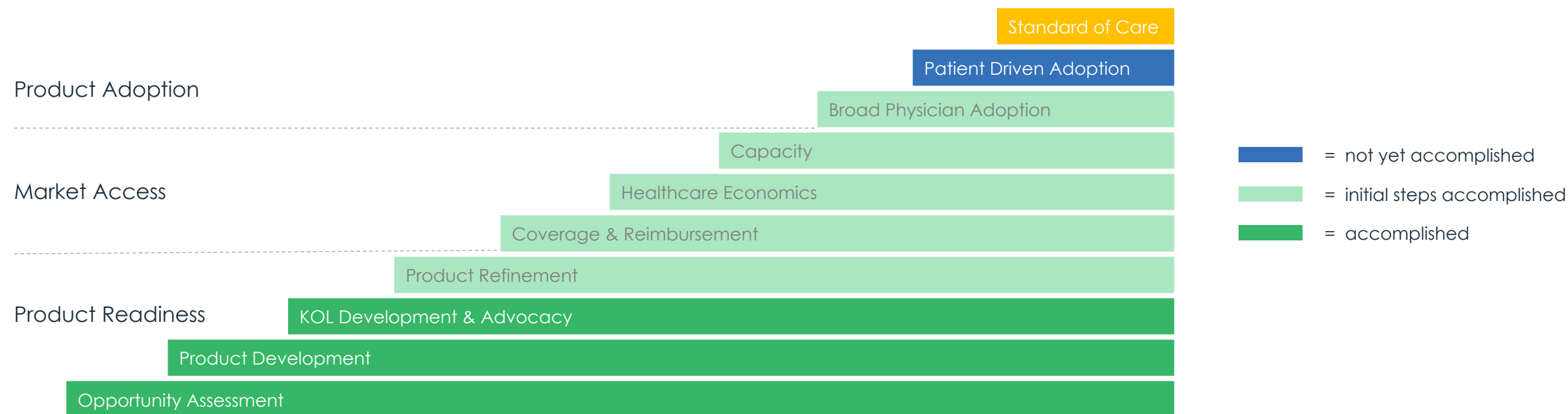
Broad Commercial Adoption

- Secure Local Payer Coverage

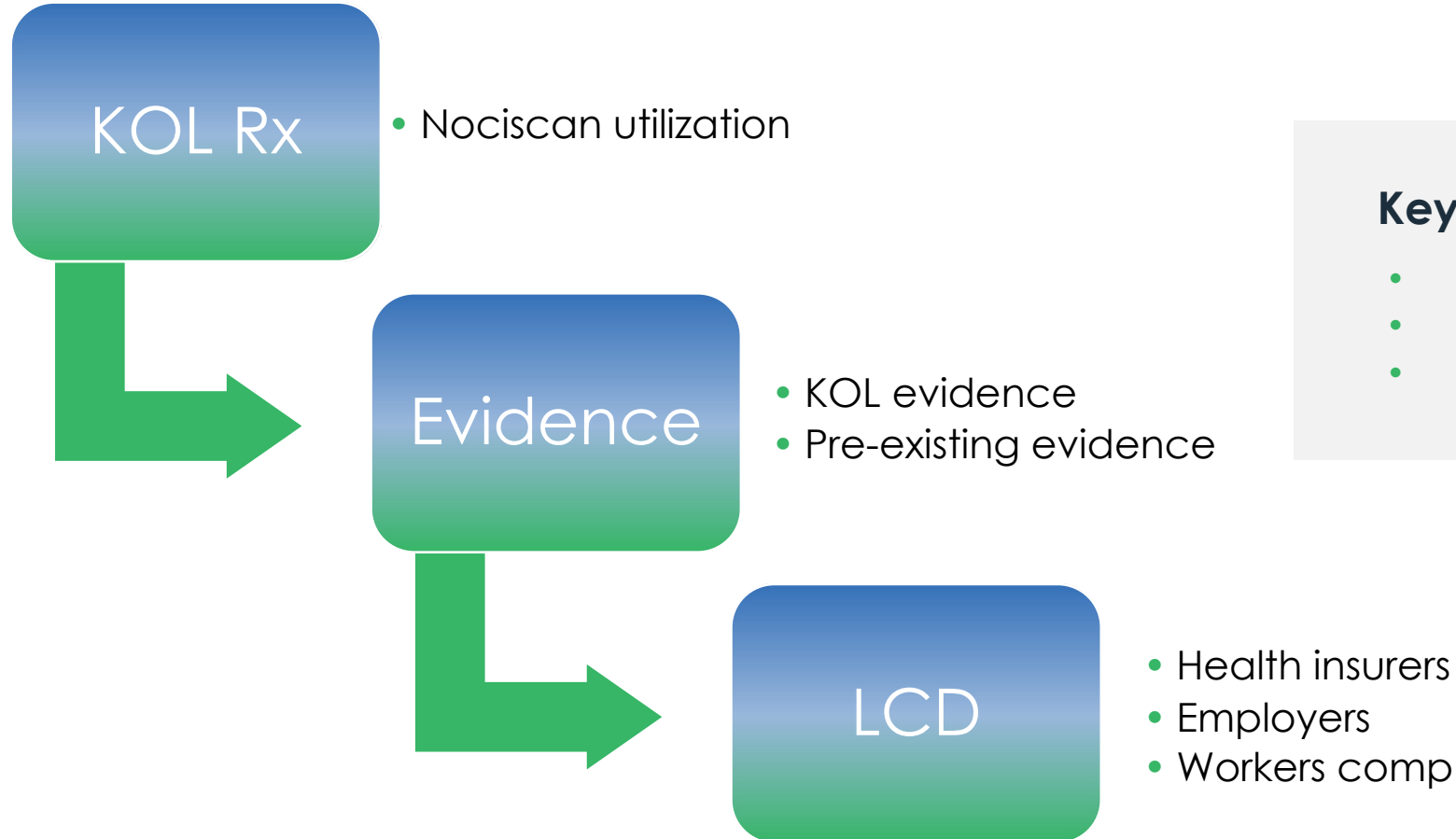
 - Bill Category III CPT codes
 - Appeal denials
 - Track payment by customer
- Increase Local Scan Volume

 - Add local sales coverage
 - Increase physician customers
 - Broaden imaging center access
- Leverage Local Marketing Support

 - Build customer facing material
 - Support trade shows
 - Publish clinical studies



Local Payer Coverage Decisions – Key Catalyst



Key Near Term Catalysts

- MRI activations for KOLs
- Increased scan volumes
- Coverage decision from local payers

Key Opinion Leader Development & Advocacy



	George Frey MD	Christopher Ames MD	Sig Berven MD	Juan Uribe MD	John Keller MD
Region	Denver, CO	San Francisco, CA	San Francisco, CA	Phoenix, AZ	Grand Rapids, MI



	Eric Potts MD	Roger Hartl MD	Greg Basil MD	Apesh Patel MD	Dean Karahalios MD
Region	Indianapolis, IN	New York City, NY	Miami, FL	Evanston, IL	Chicago, IL



Management Team



Jeff Thramann, MD
Executive Chairman

- Serial entrepreneur with multiple exits
- Over 100 US & International patents
- Public company board experience
- Neurosurgeon & spine fellow
- U.S. Military Academy @ West Point
- Cornell University Medical College
- Barrow Neurological Institute



Brent Ness
CEO & Director

- Experienced healthcare leader with highly relevant background
- AI experience at HeartFlow & Cleerly
- Spine experience at Medtronic, Mighty Oak & ProNerve
- Imaging experience at GE
- University of North Dakota
- University of Colorado MBA



John Lorbiecki
CFO

- Seasoned financial executive
- Divisional CFO at Kyphon & SNT within Medtronic
- Crossover operational experience
- Early & late stage company exposure
- University of St. Thomas magna cum laude
- University of Chicago MBA



Ryan Bond
Chief Strategy Officer

- Leading strategy since 2018
- Instrumental in securing Cat III CPT codes
- Coordinated key clinical trials
- Spine experience at Nuvasive
- Ohio University

Independent Board



Non-independent

- ✓ **Jeff Thramann, MD**
Executive chairman
- ✓ **Brent Ness**
CEO
- ✓ **David Neal**

Independent

- ✓ **Bill Wesemann**
Lead independent director
Compensation committee chair
- ✓ **Steve Deitsch**
Audit committee chair
- ✓ **Amanda Williams**
Nominating committee chair
- ✓ **Scott Breidbart, MD**

Advisory Board



Scientific



Jeff Lotz, PhD **Chairman**

Aclaron co-founder
UCSF endowed chair in Orthopaedic Surgery
Vice chair for research
Deputy editor for Spine
Principal investigator, BACPAC
UC Berkeley, BS, Mechanical Engineering
Stanford, MS, Mechanical Engineering
MIT/Harvard, PhD, Medical Engineering

Medical



Bob Eastlack, MD **Surgical Section Chair**

Head of Spine Surgery, Scripps Clinic
Director of clinical research
Co-director spine fellowship program
President San Diego Ortho Society
Stanford, BS, Human Biology
Baylor, MD
UCSD residency & Mayo spine fellowship



Larry Tanenbaum, MD **Radiology Section Chair**

VP, CTO, Director at RadNet
Mount Sinai Associate Professor
University of Pennsylvania, BA, Biochemistry
UCSD, MD
USC, residency

Key Takeaways



- ✓ Address a leading cause of healthcare expenditures in the U.S. – up to \$134.5B market ¹
- ✓ Industry 1st noninvasive diagnostic with strong clinical evidence of value
- ✓ 39 issued US & International patents with another 13 pending – supports a platform technology
- ✓ CPT codes issued & regulatory path secured in US, EU & UK – gateway to commercialization
- ✓ Strong value proposition for patients, doctors, imaging centers and payers
- ✓ Established path to success for AI algorithms in heart disease and stroke
- ✓ Successful management team with relevant industry knowledge

¹ Dieleman JL, JAMA (2020) 323(9)



ACLARION

www.aclarion.com

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