RealNose.ai

UNLOCKING THE SUPERPOWER OF SCENT

AI-Bionano Machine Olfaction for Cancer Detection

What is **RealNose** ?

Inspired by the remarkable canine ability to detect cancer via olfaction, RealNose develops bioprogrammable olfactory sensors, blending AI and bionanotechnology. RealNose revolutionizes early cancer detection, providing unparalleled precision, speed, and affordability. With RealNose, we're turning scent into a powerful diagnostic tool, starting with prostate cancer.

Why RealNose?

Dogs demonstrate remarkable success in detection through scent

- Diseases like prostate cancer by sniffing urine
- Other cancer diseases, Parkinson's, Alzheimer, Epilepsy
- Signature of explosives, drugs, bodies etc.

The mechanism of olfaction

- Doesn't depend on molecular biomarkers
- It maps scent profiles and recognizes patterns
- Analogous to vision

AI - Right timing

- AI has revolutionized computer vision
- The time is now to harness AI for advanced olfactory detection solutions

Current Detection Methods

- PSA: Non-invasive blood test with low accuracy
- DRE: Invasive physical examination with limited accuracy
- Biopsy: Highly invasive, can lead to severe side effects
- Imaging tests (MRI, Ultrasound): high cost, limited accuracy

Transforming Cancer Detection

Our Solution

We're creating a unique AI-powered bioprogrammable olfactory sensing solution designed specifically to detect prostate cancer from urine samples

Technology

Our solution involves a fusion of AI and bionanotechnology, encapsulating organic receptors that mimic a dog's olfactory system

AI/ML

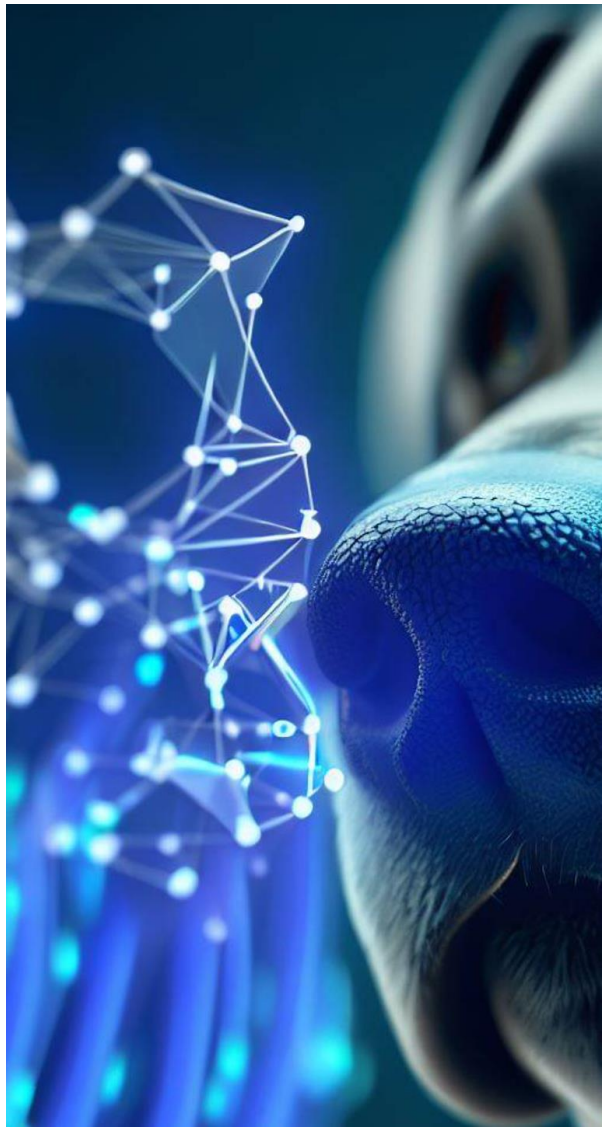
We use Machine Learning to train these receptors to recognize prostate cancer scent patterns, offering a non-invasive and highly accurate detection method

Expandability

This technology is not limited to prostate cancer only; it can be adapted to detect other types of cancer and diseases, offering vast possibilities for future applications

User friendliness

Our device is compact, user-friendly, and can seamlessly integrate into existing diagnostic procedures in healthcare facilities



Management Team

Nikolas Stefanou, CEO – Full Time

Extensive entrepreneurial experience

Co-founder, CEO at Clickdelivery.gr - Series A, 3M EUR - Exited in 2015 to Delivery Hero, for 14 times forward revenue

BS Electrical and Computer Engineering from National Technical University of Athens

MS in Electrical Engineering from Texas A&M University

MBA with honors from Chicago Booth School of Business

Dr. Andreas Mershin, CSO – Full Time

He is an expert in nanotechnology and biophysics and has led groundbreaking research on replicating olfactory systems. He is the lead inventor listed on the MIT-TLO held patent resulting from his leading the DARPA MITRealNose effort

Director of MIT Label Free Research Group (2004-2023) and Instructor at MIT Sloan Executive Education "Lab to Market the MIT Way" (2014-2023)

MSci in Physics from Imperial College, London

MS and PhD in Physics and Biophysics from Texas A&M University

TBA

TBA, AI & ML Specialist – Full Time

Actively looking for an experienced professional AI & ML engineer

Dr. Shuguang Zhang , Advisor – Part Time

MIT PI and Director of the Molecular Architecture Laboratory, co-founded and led own invention to USD$1.2B IPO exit (3DMatrix)

MS, PhD (Genetics)

TBA

TBA, AI & ML Specialist –Advisor – Part Time

In talks with an AI & ML professor in MIT's Electrical Engineering department

TBA

TBA, Healthcare professional – Clinical Advisor – Part Time

Actively looking for an experienced professional with clinical trials expertise

The history of **RealNose**

- Conceived at MIT, research funded by DARPA and GSK, and supported by Medical Detection Dogs
- Featured in Wall St Journal, Wired, PBS(s), Financial Times, MIT Tech Review, MIT News, Plos One Journal
- Presented at the Global Machine Olfaction Technologies Conference, published in Plos One Journal, patented with USPTO

DARPA

2010 –2013

- MIT: 4M USD DARPA funding
- DARPA VOCs Testing: 200x better limits of detection against dogs
- 1st patent filed

Massachusetts Institute of Technology

2015

- MIT: Patent granted: Methods and apparatus for artificial olfaction - US9140677B2

gsk

2018

- MIT: 2M USD GlaxoSmith Funding
- Nth (miniaturized Prototype)

Scentient

2021

- Scentient.ai co-founded by Andreas Mershin
- Prostate Cancer detection from urine samples using GC-MS
- Similar sensitivity and selectivity as trained canines
- Published in Plos One Journal


PLOS ONE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Feasibility of integrating canine olfaction with chemical and microbial profiling of urine to detect lethal prostate cancer

Claire Guest, Rob Harris, Karen S. Sfanos, Eva Shrestha, Alan W. Partin, Bruce Trock, Leslie Mangold, Rebecca Bader, Adam Kozak, Scott Mclean, Jonathan Simons, Howard Soule, Thomas Johnson, [...], Andreas Mershin [view all]

Published: February 17, 2021 • https://doi.org/10.1371/journal.pone.0245530

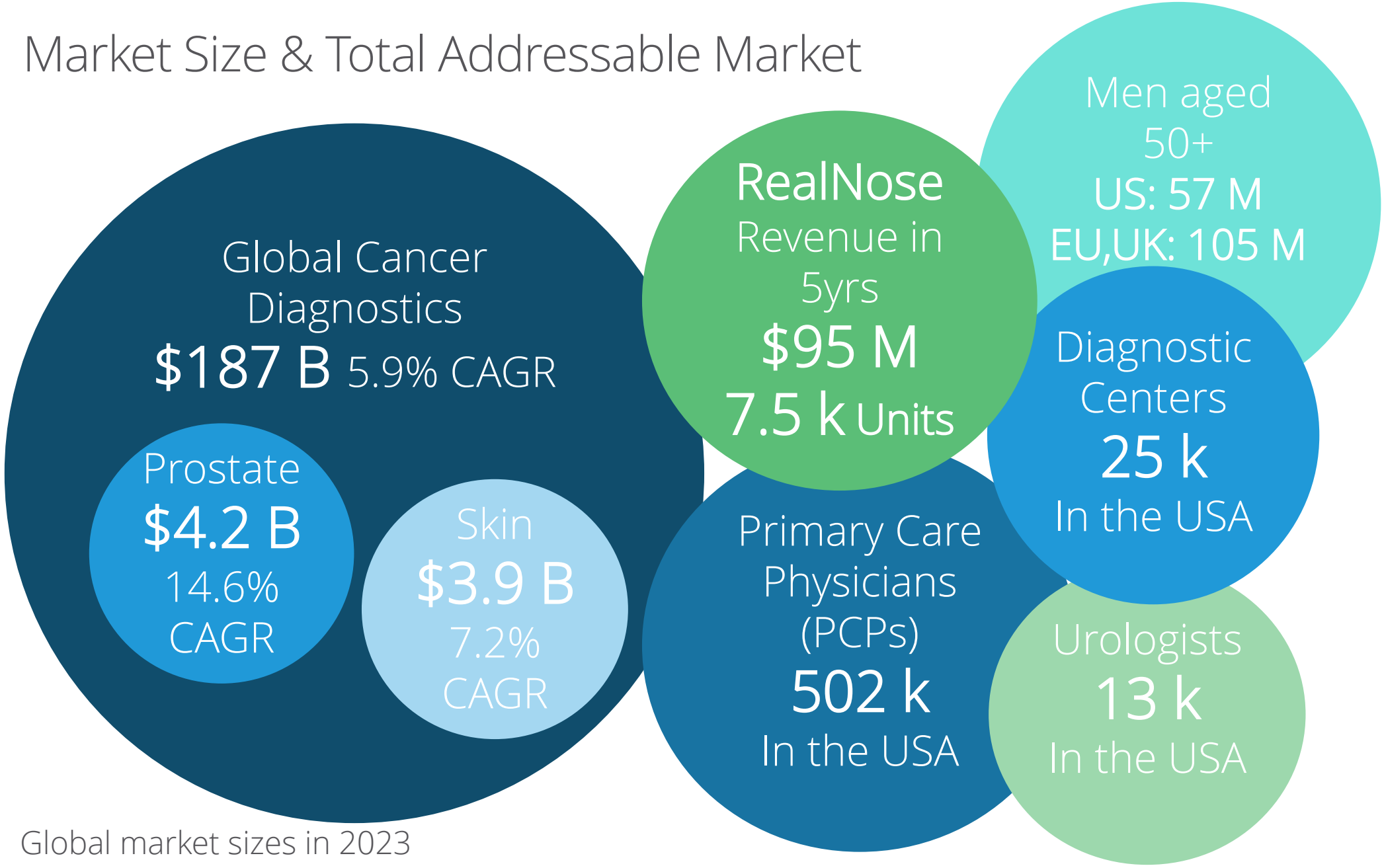
See the preprint

RealNose.ai

2023

- Scentient.ai dissolved
- Incorporation of RealNose Inc.

Market Size & Total Addressable Market



Global market sizes in 2023

Source: IMARC Group, Marketwatch, The Insight Partners, GlobeNewswire, IbisWorld, Statista, World Bank

The landscape in prostate cancer early detection

Metrics	PSA (4 ng/mL)	DRE	Biopsy	MRI Scan	SelectMDx	ExoDx	Scentient.ai (Founded by Andreas)	RealNose
Tech	Blood Analysis	Physical	Invasive	MRI	Urine, mRNA	Urine, exosomes	Urine GC-MS	Urine scent sensing
Cost	$ 50	Included in doctor's visit	$ 2,200	$ 1,800	$ 250	$ 760	$ 200	**$ 30**
Sensitivity (Low Score=Many False Negatives)	~30%	~55%	~83%	~80%	~77%	~86%	91%	**~95%**
Specificity (Low Score=Many False Positives)	~85%	~65%	~95%	~65%	~50%	~35%	99%	**~99.5%**
AUC (High Score=Better Trade-Off between sensitivity and specificity)	~0.60	~0.65	n/a	~0.80	~0.63	~0.81	0.93	**~0.96**
Regulatory Approval	FDA Approved	n/a	n/a	FDA Approved	CLIA, CE	FDA breakthrough device designation	none	**Aim for CLIA, CE & later FDA**

Prototype & MVP Development

Development

- Prototype:
  - Select 8 different receptors from a large pool of human and other mammalian receptors
  - Collect 100 Urine samples and optimize sensors and AI/ML algorithm
- 1st medical application (prostate cancer detection) - MVP:
  - Collect 700 Urine samples and validate device and AI/ML model

Time and Cost

- Prototype:
  - 8 months to develop and min cost of $1M (limited urine samples)
- 1st medical application (prostate cancer detection) - MVP:
  - 12 months to develop and estimated cost of $1.6M (incl. prototype)
- Subsequent applications will be developed faster and will cost much less

Receptor Lifespan and Cost

- Receptors have a lifespan of about two weeks
- Replacement required every two weeks, which constitutes the major cost
- Cost to produce the receptors needed per month per device is approximately $700

Go-to-market Strategy

Target Customers

- Diagnostic Centers
- Primary Care Physicians (PCPs) and Specialists
- Insurance companies
- Geographic Expansion: US, EU, UK

Sales and Distribution

- Direct Sales: Key Account Managers focusing on large accounts and insurance networks, aiming to secure high-value contracts
- Indirect Sales: Partner with healthcare equipment distributors to sell to smaller accounts such as PCPs and diagnostic centers

Revenue Model

- Medical Device-as-a-service (MDaaS)
- Monthly subscription fee: $2,000 /month /unit (Retail Price) including receptor cartridge replacement
- Partner with insurance companies to subsidize cost in their networks

Regulatory Approvals

- Anticipate CLIA (US) & CE (EU) certification initially and/or FDA clearance

Partnerships and Current Status

IP Licensing

- Methods and apparatus for artificial olfaction – Patents: US9140677B2
- MIT Technology Officer assigned: Jim Roberts negotiations started May 2023

Device Prototyping

- Partnered with French Company Aryballe to use their e-Nose with MZI sensors
- Tested with urine samples and concluded that it does not have the required resolution for cancer detection
- Negotiated a deal to integrate our receptors into their e-Nose

Data Collection

- Negotiation in progress with The Johns Hopkins Hospital and Iatriko Athinon (Athens Medical Group, Greece) to gather urine samples

Traction and Investment Commitments

Partnerships

- In positive talks with GE Health Care to explore synergies
- Initiated talks with United Healthcare (the largest health insurance company in the US) to tap into their network
- They have been very receptive & excited

Grants

- Applied to NSF Convergence Accelerator Track L: Real-World Chemical Sensing Applications
- The track builds on olfaction and chemical sensing, sensor technologies, digital olfaction, AI
- LOI accepted, full proposal in review. Results: Nov 2023, Grants given in Jan 2024
- Phase 1 funding: $750k for 12 months, Phase 2 funding: $5M for 24 months

Investment Commitments

- Term sheet of $500k from a Technology & AI focused VC fund with the requirement to raise another $500k
- Soft commitments of $250k from two angel investors
- Collaboration with Wells Fargo Advisors to fundraise

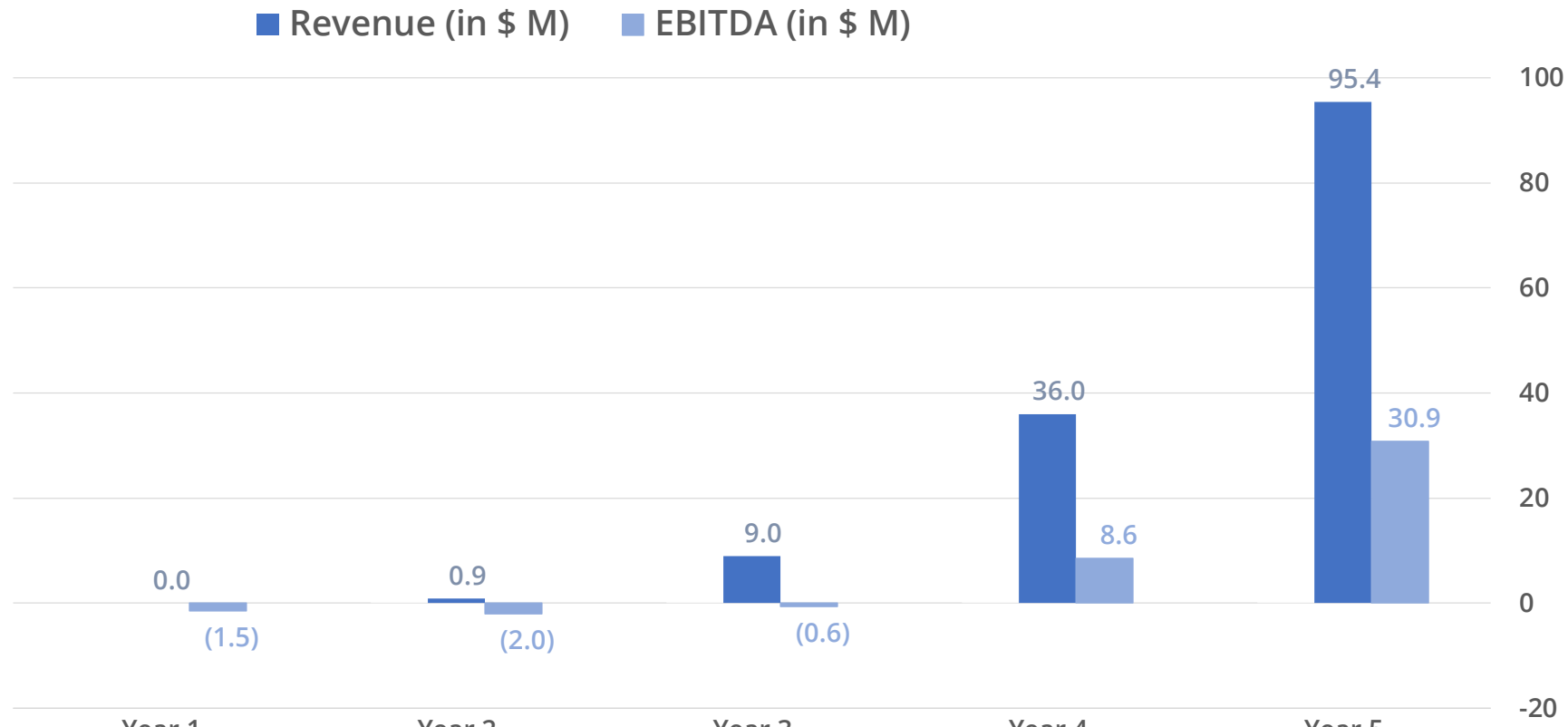
The Ask – Seed $ 1.6 M – Series A $ 5 M

	YEAR 1	YEAR 2	YEAR 3

Milestones	• Develop Prototype Device
	  • Receptor production
	  • Partner with Aryballe
	• Develop 1st Medical Application (MVP)
	  • Prostate Cancer Detection
	• Partner with hospitals to gather samples
	• Develop the AI/ML algorithms
	• Publish Results
		• Apply for CLIA certification and/or FDA approval process
		• Partner with Insurance companies to deploy and subsidize RealNose in their networks
		• Acquire 2 major Distributors
		• Deploy 200 Units
		• Develop 2nd Medical Application
		  • Skin Cancer Detection
			• Develop 3rd & 4th Medical Applications
			  • Skin Cancer Detection
			  • Parkinson's Disease
			• Partner with hospitals to take samples
			• Continue FDA process with Clinical Trials
			• Acquire 6 major Distributors
			• Deploy 800 Units

Use of funds	• Cost of 1st Application (MVP) $ 573 k • Product $ 889 k *COGS, Salaries, Marketing, Patents* • Equipment, G&A $ 134 k • **Total** **$ 1,596 k** • **Cash Flow Buffer** **$ 4 k**	• Cost of Application (2nd) $ 413 k • Product $ 2,410 k *COGS, Salaries, Marketing, Patents* • G&A $ 84 k • Total $ 2,907 k • Cash Flow Buffer $ 493 k	• Cost of Applications (2) $ 826 k • Product $ 8,672 k *COGS, Salaries, Marketing, Patents* • G&A $ 84 k • Total $ 9,582 k • Cash Flow Buffer $ 1,918 k
Source of funds	• Revenues $ 0 k • **Seed** **$ 1,600 k**	• Revenues $ 900 k • Series A $ 2,500 k	• Revenues $ 9,000 k • Series A $ 2,500 k

Financial projections



	Year 1	Year 2	Year 3	Year 4	Year 5
Total Applications Developed	1	2	4	6	8
Total Units Deployed	0	100	900	3100	7500
Revenue (in $ M)	0.0	0.9	9.0	36.0	95.4
EBITDA (in $ M)	(1.5)	(2.0)	(0.6)	8.6	30.9

What is our vision ?

Innovate

- Be the best in digitizing olfaction

Disrupt detection industry

- Create a new trend with a potential to grow in a billions-market segment

Expand product

- Several Cancer Diagnostics
- Several Biopharma production lines
- Wineries, Breweries
- Food Production

Further expand

- You' re constantly leaking biologically relevant information
- Dogs can mine this information
- … and so can machines

Back up slides & Some more details

Financial model - Projections

Cost of Application Development	
Cost of 1st Application (MVP) - Prostate Cancer	
Cost of receptor genes	$7,200
Cost of receptors	$36,000
Cost of integrating receptor sensors into Aryballe's e-Nose	$200,000
Cost of devices	$10,000
Cost of access to data	$320,000
Total Cost of 1st Application (MVP)	**$573,200**
Cost of subsequent Applications (Medical)	
Cost of receptor genes	$7,200
Cost of receptors	$36,000
Cost of integrating receptor sensors into Aryballe's e-Nose	$40,000
Cost of devices	$10,000
Cost of access to data	$320,000
Total Cost of Subsequent Applications (Medical)	**$413,200**

Unit Economics	
Cost of Receptors for a Commercial Unit per month	
Cost of materials for 8 receptors per unit per month	$480
Cost of labour for inhouse receptor cartridges production per month (won't apply)	$270
Cost of outsourced receptor cartridges production per month (without materials)	$150
Cost of Commercial Unit	
Cost of device	$2,000
Cost of receptors per unit per month (outsourced)	$630
Cost of cloud computing per month (Incremental per unit)	$50
Cost of logistics per month (per unit)	$50
Total Cost of Commercial Unit per Month	**$730**
Commercial Unit Retail Price - MDaaS	
Device (without receptors) sale	$0
Subsciption fee per unit per month	$2,000
RealNose & Distribution Gross Margin (Outsourced Receptor Production)	**64%**
Commercial Unit Distribution Price - MDaaS	
Device (without receptors) sale	$0
Subsciption fee per unit per month	$1,500
Distribution Gross Margin	**25%**
RealNose Gross Margin (Outsourced Receptor Production)	**51%**

Financial Plan	Year 1	2	3	4	5
Development & Customers					
New Applications Development	1	1	2	2	2
Total Applications Developed	1	2	4	6	8
New Distributors Onboarded	0	1	3	6	10
Total Distributors Onboarded	0	1	4	10	20
New Champions (Insurance Co. & Lab chains)	0	0	2	4	6
Total Champions (Insurance Co. & Lab chains)	0	0	2	6	12
New Units Deployed	0	100	800	2200	4400
Total Units Deployed	0	100	900	3100	7500
CAPEX					
Equipment	$(50) k	$0 k	$0 k	$0 k	$0 k
OPEX					
Product Development					
Cost of Applications Development	$(573) k	$(413) k	$(826) k	$(826) k	$(826) k
Legal & Regulatory Fees	$(55) k	$(273) k	$(435) k	$(975) k	$(2.16) M
COGS					
Cost of Commerical Units (Devices only)	$0 k	$(200) k	$(1.60) M	$(4.40) M	$(8.80) M
Cost of Commerical Units (Receptors)	$0 k	$(378) k	$(3.78) M	$(15.12) M	$(40.07) M
Cloud Computing	$(60) k	$(63) k	$(85) k	$(160) k	$(325) k
Logistics	$(0) k	$(3) k	$(25) k	$(100) k	$(265) k
Overheads					
Salaries (inc. labor & fringe overhead)	$(774) k	$(1.40) M	$(1.85) M	$(2.16) M	$(2.47) M
Marketing	$0 k	$(90) k	$(0.90) M	$(3.60) M	$(9.54) M
G & A	$(84) k	$(84) k	$(84) k	$(84) k	$(84) k
Total OPEX	**$(1.55) M**	**$(2.91) M**	**$(9.58) M**	**$(27.42) M**	**$(64.54) M**
Revenues					
Devices Sale	$0	$0 k	$0.00 M	$0.00 M	$0.00 M
Subscription Fees	$0	$0.90 M	$9.00 M	$36.00 M	$95.40 M
Total Revenue	**$0**	**$0.90 M**	**$9.00 M**	**$36.00 M**	**$95.40 M**
EBITDA	**$(1.55) M**	**$(2.01) M**	**$(0.58) M**	**$8.58 M**	**$30.86 M**
EBITDA margin		*-223.05%*	*-6.47%*	*23.82%*	*32.35%*
Net Income	$(1.22) M	$(1.59) M	$(0.46) M	$6.78 M	$24.38 M
Taxes Payable	$256 k	$590 k	$0.69 M	$(0.74) M	$(5.12) M
Free Cash Flow	$(1.60) M	$(2.01) M	$(0.58) M	$7.84 M	$25.74 M
Cumulative Cash	**$(1.60) M**	**$(3.60) M**	**$(4.19) M**	**$3.65 M**	**$29.39 M**

Financial model - Assumptions

Assumptions	
Receptors	
#Receptors needed per development cartridge	24
#Receptors needed per commercial cartridge	8
Cost per receptor gene	$300
Cost per receptor cell free expression kit (or cell based)	$1,500
Receptor instances per kit	50
Receptor life (2xHalf-life) #Months	0.5
Mandays needed to manufacture receptor instances (pkg of 50)	2
Outsourced receptor production (From Y2 onwards) per unit (8 receptors) per month	$150
Devices (Aryballe's e-Nose with RealNose Receptors)	
Mandays to integrate receptor sensors into Aryballe's e-Nose - 1st Application (Prototype)	250
Mandays to integrate receptor sensors into Aryballe's e-Nose - Subsequent Applications	50
Aryballe's manday Cost	$800
Device (without receptors) cost	$2,000
Units needed per application development	5
Incremental cost of cloud computing per unit per month	$50
Data Collection for Medical Applications	
Cost of urine sample (or other medical sample)	$400
# of samples needed for high accuracy	800
Commercial Unit Retail Price: Medical Device-as-a-Service (MDaaS)	
Device (without receptors) price	$0
Subsciption fee per unit per month (includes 2 cartriges of 8 receptors per month)	$2,000
Commercial Unit Distribution Price: Medical Device-as-a-Service (MDaaS)	
Device (without receptors) price	$0
Subsciption fee per unit per month (includes 2 cartriges of 8 receptors per month)	$1,500
Distribution & Key Account Management	
New units per distributor per year (distributor's effort)	100
New units per champion (insurance companies, diagnostic lab chains) per year	200
Logistics cost per unit per month	$50

Assumptions - Continued	
Overheads	
Salaries	
CEO	$185,000
CSO	$185,000
AI Scientist (1 in Y1H2)	$150,000
Bio Scientist (1 in Y1)	$100,000
Data Scientist (1 in Y1H2, 2 from Y3 onwards)	$100,000
Channel Distribution Manager (0-Y1, 1-Y2, 2-Y3, 3-Y4, 4-Y5)	$120,000
Key Account Manager (0-Y1, 1-Y2, 2-Y3, 3-Y4, 4-Y5)	$120,000
Marketing Manager (1 from Y2 onwards)	$120,000
Labor Overhead & Fringe Benefits	30%
Cloud Computing	
Cloud Computing Base System cost per month	$5,000
Legal & Regulatory Fees	
MIT patent licensing fees per year (flat fee)	$10,000
MIT patent licensing fees % of revenue	2%
Legal fees and IP expenses (new patents) per year	$45,000
Regulatory approvals and clinical trials (from Y2 onwards) per year	$200,000
Marketing	
Marketing (% on revenue)	10%
G & A	
Rent per month	$4,000
Utilities per month	$1,000
Equipment (in Y1)	$50,000
Other Expenses (Accounting, Travel, HR) per month	$2,000
Other	
Tax rate	21%

Timeline of Applications Development	Months
1st Application (MVP) - Prostate Cancer	
Receptor Gene and Expression Development	5
Sensor Integration with Aryballe's e-Nose Development	3
Data Collection - Urine Samples	2
AI Algorithm development - Optimization	2
Total Time to develop 1st Application (MVP)	**12**
Subsequent Applications (Medical)	
Receptor Gene and Expression Development	2
Sensor Integration with Aryballe's e-Nose Development	1
Data Collection - Medical Samples	2
AI Algorithm development - Optimization	1
Total Time to develop Subsequent Applications (Medical)	**6**

Cost-Effectiveness of RealNose

Current Screening Costs

- Prostate-Specific Antigen (PSA) Test: $50 - $100 (uninsured cost)
- Prostate Biopsy: $1,000 - $2,500

RealNose Subscription Cost

- $2,000 per month, per device, per PCP or Diagnostic Center
- Assuming one PCP screens approximately 20 patients per week (a conservative estimate), the cost per screening is approximately $25

Potential Patient Charges

- A price of $30-$50 per screening to the patient could cover costs and provide some margin
- This would be generally comparable to the out-of-pocket cost of a PSA test, and most insurances would cover it

Benefits for PCPs & Diagnostic Centers

- Increased visits due to offering a novel, non-invasive screening method
- Potential income from the screening fee, assuming some margin over the cost

Benefits for Insurance Companies

- Early detection of prostate cancer can significantly reduce treatment costs
- The average cost of prostate cancer treatment ranges from $15,000 to $30,000 for early-stage cases, to over $100,000 for advanced cases
- Savings from avoided biopsies & less expensive treatments with early detection

Exit Opportunity

MedTech - HealthTech Multiples	Multiple	Real Nose Exit Valuation in 5 Yrs
Revenue	6.43x	$613 M
EBITDA	21.4x	$661 M

Mercer Capital's Value Focus: Medtech & Device Industry Second Quarter 2022

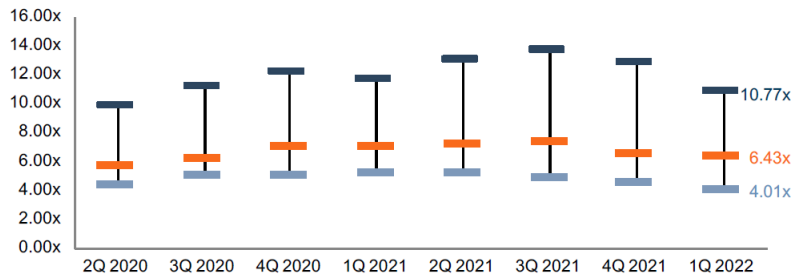
Revenue Multiples

75% Quartile Median 25% Quartile

Median Revenue multiples from each MCM group. Data source: Bloomberg

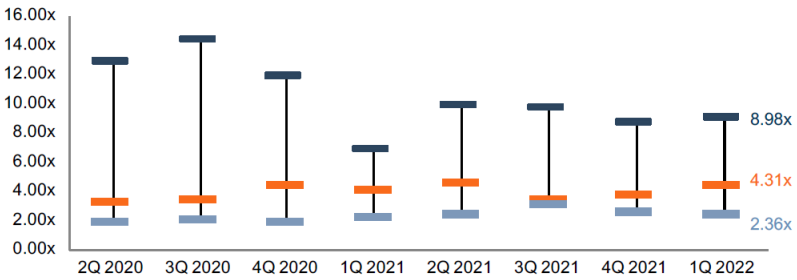
Medical Devices

EV / Trailing LTM Revenue



Healthcare Technology

EV / Trailing LTM Revenue



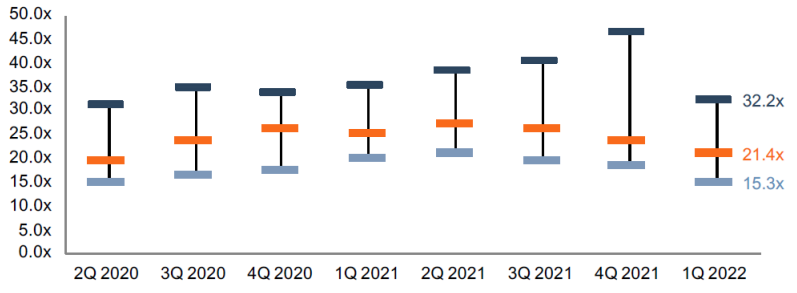
EBITDA Multiples

75% Quartile Median 25% Quartile

Median EBITDA multiples from each MCM group. Data source: Bloomberg

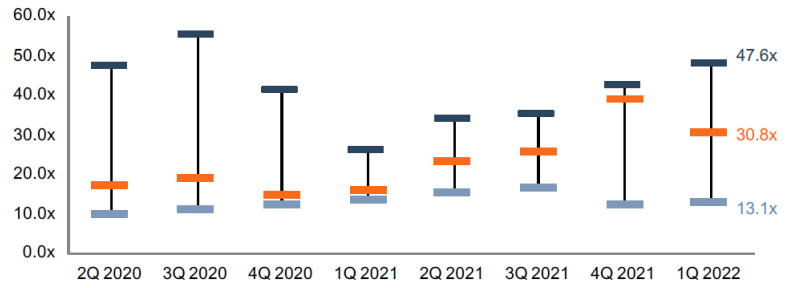
Medical Devices

EV / Trailing LTM EBITDA



Healthcare Technology

EV / Trailing LTM EBITDA



- Exosome Diagnostics
  - Maker of ExoDx test
  - Without any other products
  - Was acquired for $577 M
  - 2 years after 1st validation study
  - With much lower accuracy and higher cost than RealNose

Competition in the scent sensing arena

Metrics	GC-MS	Noze	Aryballe	Volatile.ai	Tuneable	Aromyx	Kuniku	Aromabit	RealNose
Sensor Tech	Chemical	MOx	MZI on peptides	PID	NIR Spectro-scopy	Olfactory Cells	Olfactory Cells	QCM	Olfactory Receptors
Trainability	✗	✓	✓	✓	✓	✓	✓	✓	✓
Portability	Low	Unknown	Med	Med	Med	Low	Med	High	**High**
Sensitivity	High	Low	Med	Med	Low	Med	Med	Med	**High**
Selectivity	Med	Low	Low	Low	Low	Unknown	Unknown	Low	**High**
Bio programmable	✗	✗	Maybe	✗	✗	✓	✓	Maybe	✓
Prototype	n/a	✓	✓	✓	✓	✓	✓	✓	✓
Patents	n/a	✓	✓	✓	✓	✓	✓	✓	✓

RealNose.ai

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Thank you!