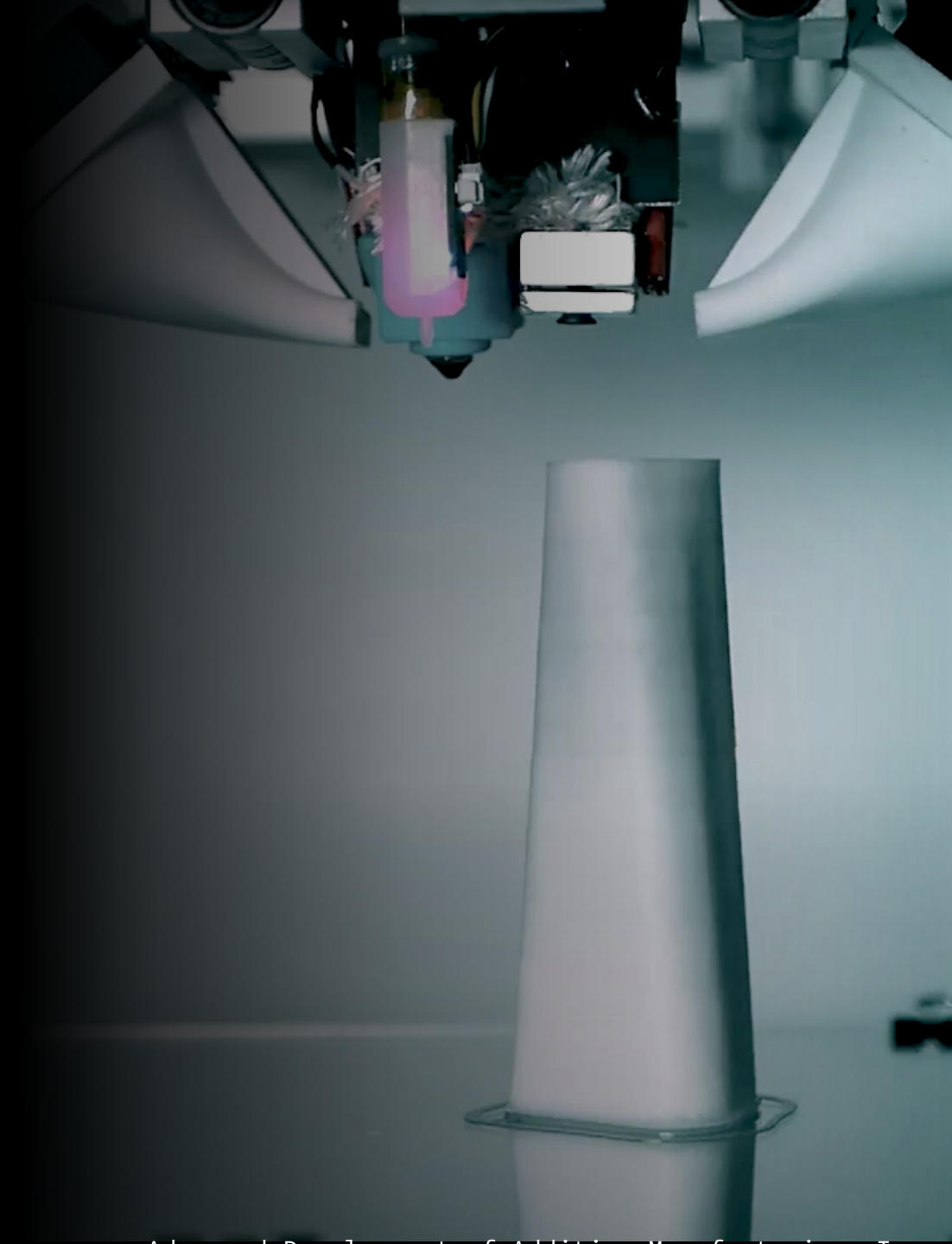




A.D.A.M.

Point-of-Care
Medical Device Production System
for
Bone Implants



Implant 3D-Printing: Background

Why is the adoption of POC implant manufacturing lagging despite the obvious benefits?

1999 First 3D-printed organ successfully implanted

2010 FDA approves first 3D-printed orthopaedic implant

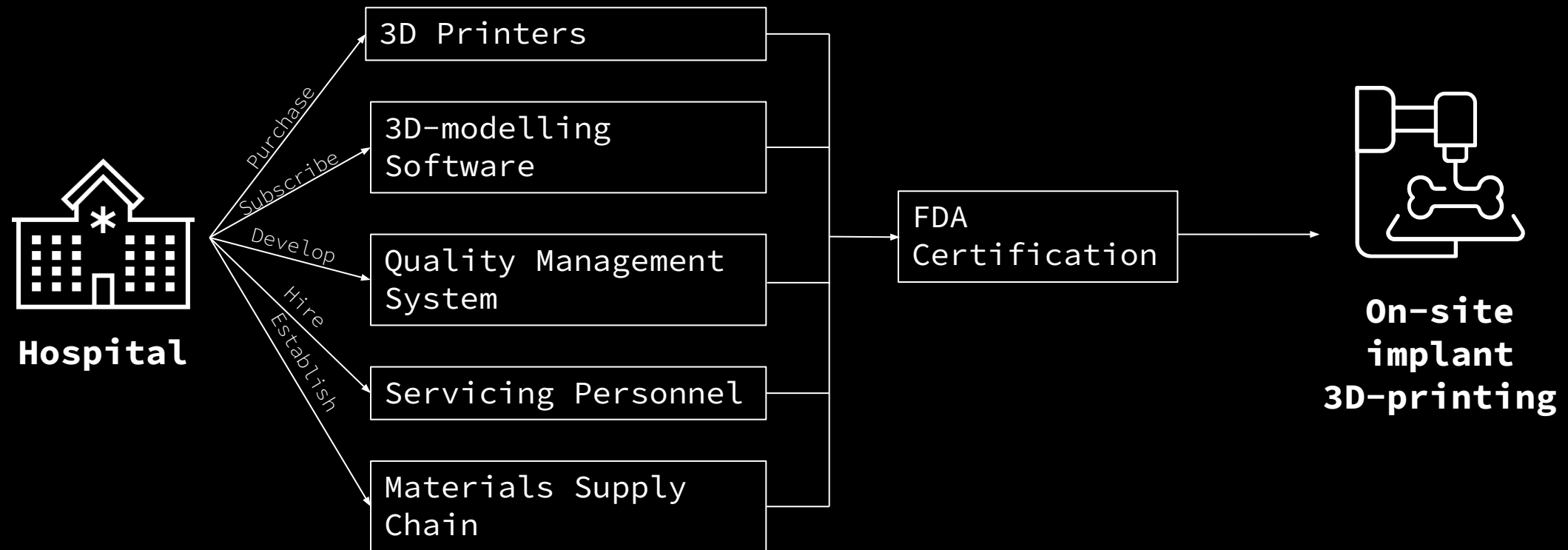
2021 First implant 3D-printed and implanted at same facility

2022 First POC implant manufacturing lab established in the US



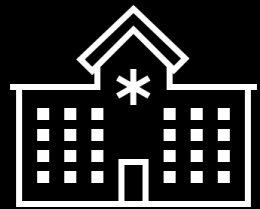
Problem

Setting up the Point-Of-Care custom implant manufacturing process at the hospital is costly (>\$1M), time-consuming (>2 yrs), and burdensome



Solution

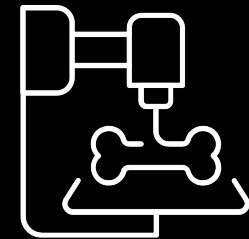
Turnkey system that can be set up within 3 months, cut costs by >50%, increase profit/surgery, and generate additional revenues for hospital



Hospital



A.D.A.M.



**On-site
implant
3D-printing**

- QMS Certification
- Clear Reimbursement
- Revenue Share Model

Why Now

Market is growing, ready to adopt POC printing, yet not competitive



Hospitals have started adopting POC manufacturing after COVID-19



Market is not saturated – only **ONE** hospital in the US has a POC lab for implants



FDA is tailoring the regulatory framework for POC Medical Device Production Systems to the market's needs



Target market is projected to grow

- **Global Orthopaedic Implants Market** – USD **47.8B** in 2021, USD **72.1B** by 2030 at **4.67% CAGR**
- Total Addressable Market initially ~ 10%, (4.7B), with portfolio expansion – 30-50%



Product: A.D.A.M. System

A.D.A.M. will offer hospitals its bone implant 3D-printing service for a monthly fee



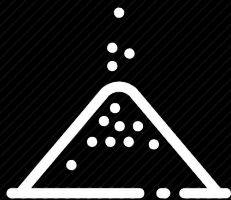
3D Printers

Proprietary BJP and FDM



Digital Platform

Medical data cloud storage, 3D-modelling, ordering



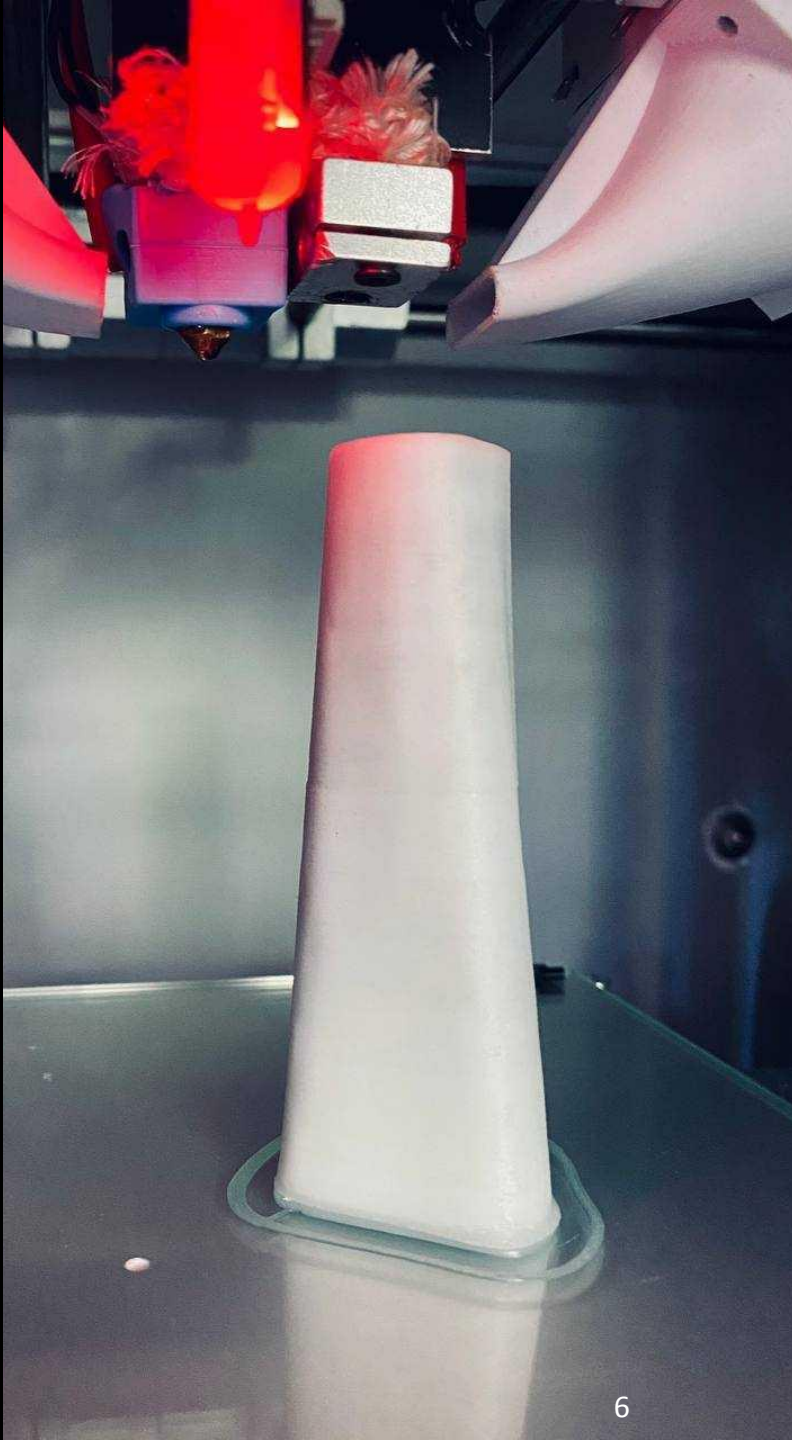
Materials

Bioceramic and biopolymer composites



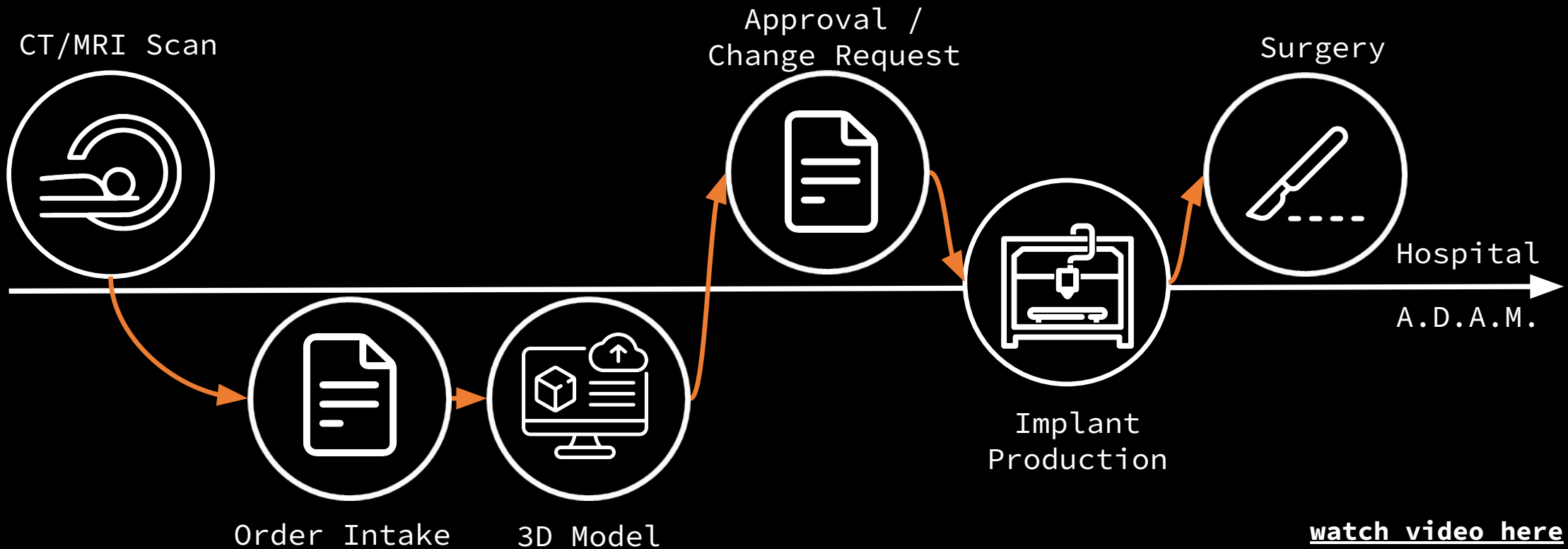
QMS

Seamless end-to-end workflow









How A.D.A.M. Works

Cloud manufacturing of tissues with a possibility for implant portfolio expansion



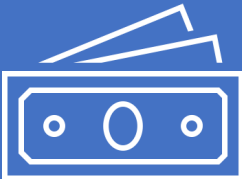




Competitive Landscape

A.D.A.M.'s competitors offer either implants, hardware, or software. The only competitor with a POC facility does not offer bioactive materials.

								
Biodegradable materials	✓						✓	✓
Bioresorbable materials	✓	✓	✓	✓	✓		✓	✓
Proprietary hardware				✓	✓	✓		✓
Proprietary software				✓	✓	✓		✓
POC printing capability						✓		✓
Target Market	Australia	US, EU	EU	EU, US (located in EU)	EU	US, EU, Asia, LatAm	US	US, EU, Ukraine

Competitive Advantages

A.D.A.M. can deliver a more holistic and efficient solution to the hospitals than its competitors to improve patients' outcomes

				
Lower costs	Shorter production time	Superior properties of materials	Scalability of the business model	Turnkey solution
R&D office in Ukraine	proprietary printing technology	compared to the predicates	faster entry into further implant markets	all implant 3D-printing services covered

Traction/Milestones

With less than \$1M and in less than 3 years, A.D.A.M. has reached the following milestones:

Digital Platform MVP

2020

2 Advanced Materials

2021

MVP for 2 printing systems

2021

510(k) eligibility confirmed by FDA

2020

Animal studies protocol (Charles River)

2021

Implants tested (Yale, UConn)

2021

3 PCT patents, 1 provisional in the US, 2 in UA

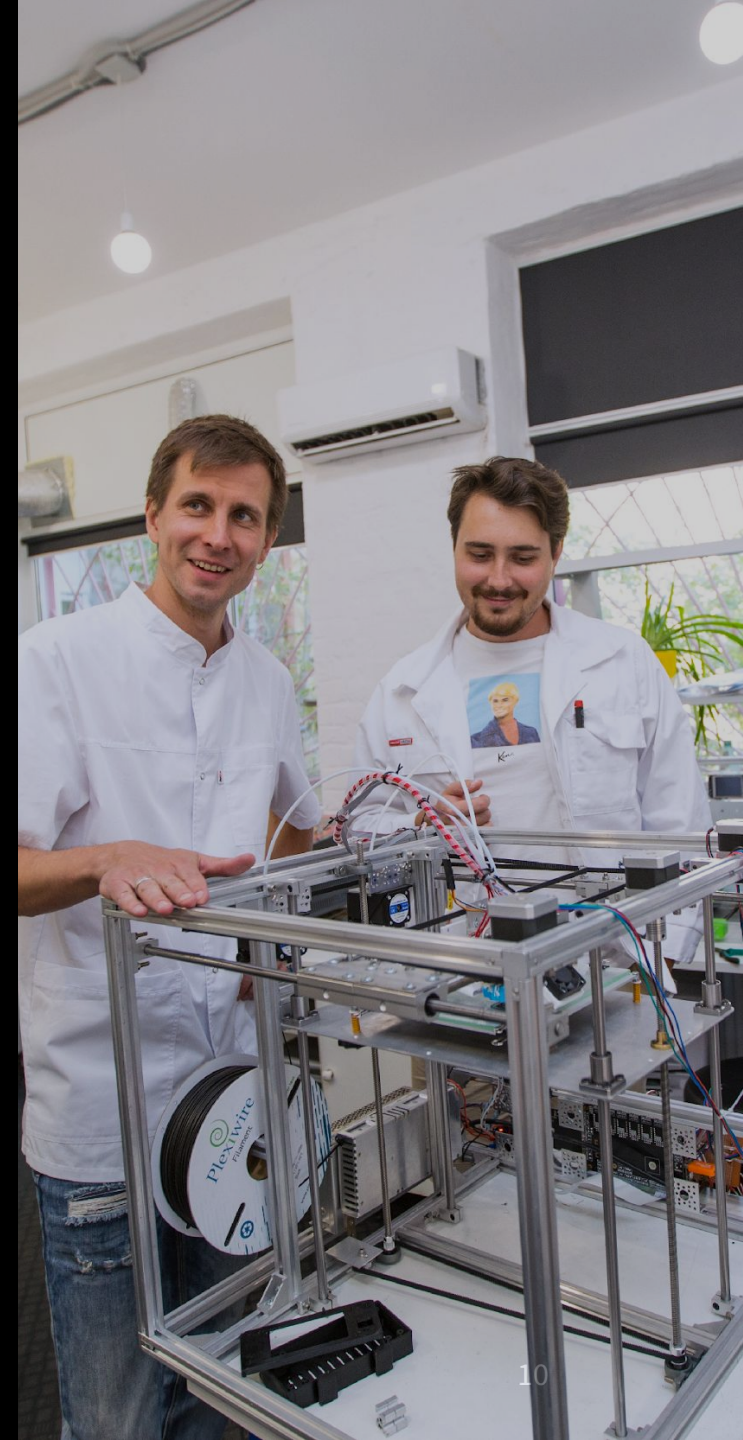
2020

3 hospital partnerships

2022

Strategic partnership with MOH of Ukraine

2022



Partnerships

A.D.A.M. has already secured partnerships with one of the largest hospital groups in the US, an Ivy League university and the MOH in Ukraine

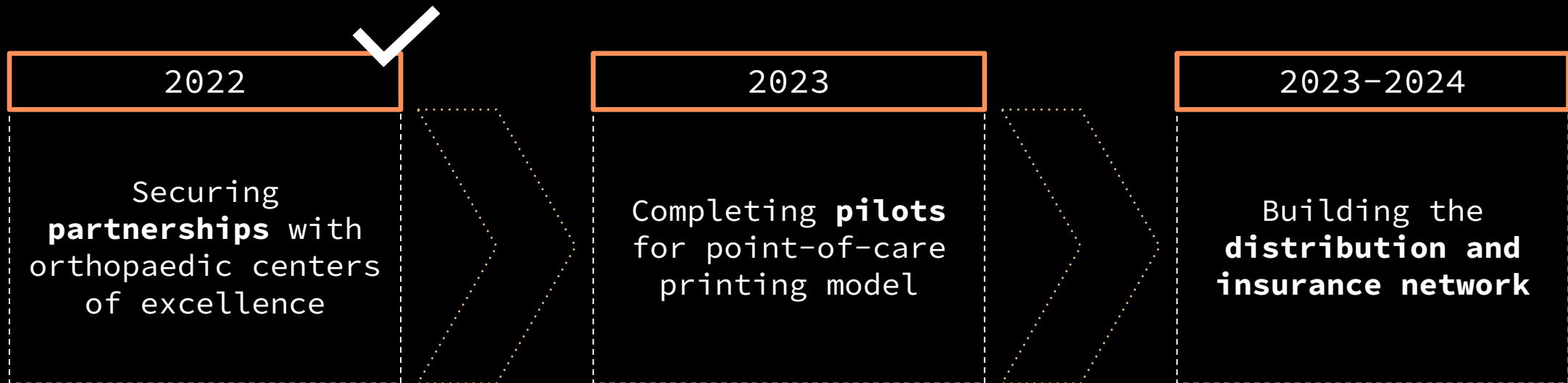


- R&D and Clinical Translation
- Business development with the ultimate goal of POC facility set-up

2-4 POC facilities in Ukraine over 2 years to treat the wounded

Go-To-Market

Existing partnerships will allow to bring the existing service to the market and grow the product offering



Business Model

A.D.A.M. will charge subscribing hospitals a system installation fee and a monthly fee thereafter

Subscription Type	≤ 30 Implants	≤ 50 Implants	≤ 100 Implants
Installation Fee	\$ 280 000	\$ 320 000	\$ 510 000
To replicate, the hospital would need to pay at least \$300k above A.D.A.M.'s costs for Certification alone			
Monthly Fee	\$ 90 000	\$ 140 000	\$ 240 000
	\$ 3 000/implant	\$ 2 800/implant	\$ 2 400/implant

VS market's \$ 3 000 - \$ 20 000 average price for PEEK PSI

Revenue Projections

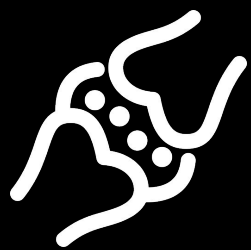
A.D.A.M. projects \$2.7M in revenues in the U.S. in the first year after commercialization and >30% gross profit margin for POC model

	YR 1	YR 2	YR 3	YR 4	YR 5
No. of Clinics	2	5	8	14	20
Revenue	\$ 2,670,000	\$ 7,630,000	\$ 13,740,000	\$ 24,720,000	\$ 36,000,000
COS	\$ 1,810,554	\$ 5,161,891	\$ 9,283,218	\$ 16,708,911	\$ 24,317,407
Gross Profit	\$ 859,446	\$ 2,468,109	\$ 4,456,782	\$ 8,011,089	\$ 11,682,593

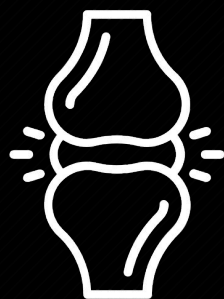
Additional revenues to be generated from:

- implant delivery
- licensing in
- other markets (EU, Ukraine)

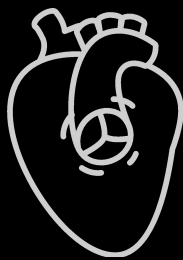
Next Product Lines



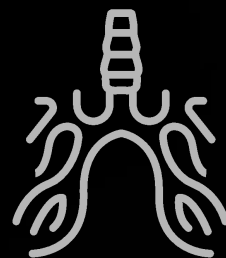
Cartilage



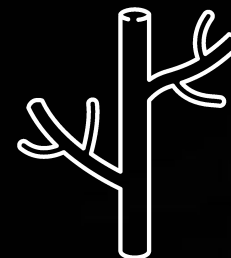
Ligaments



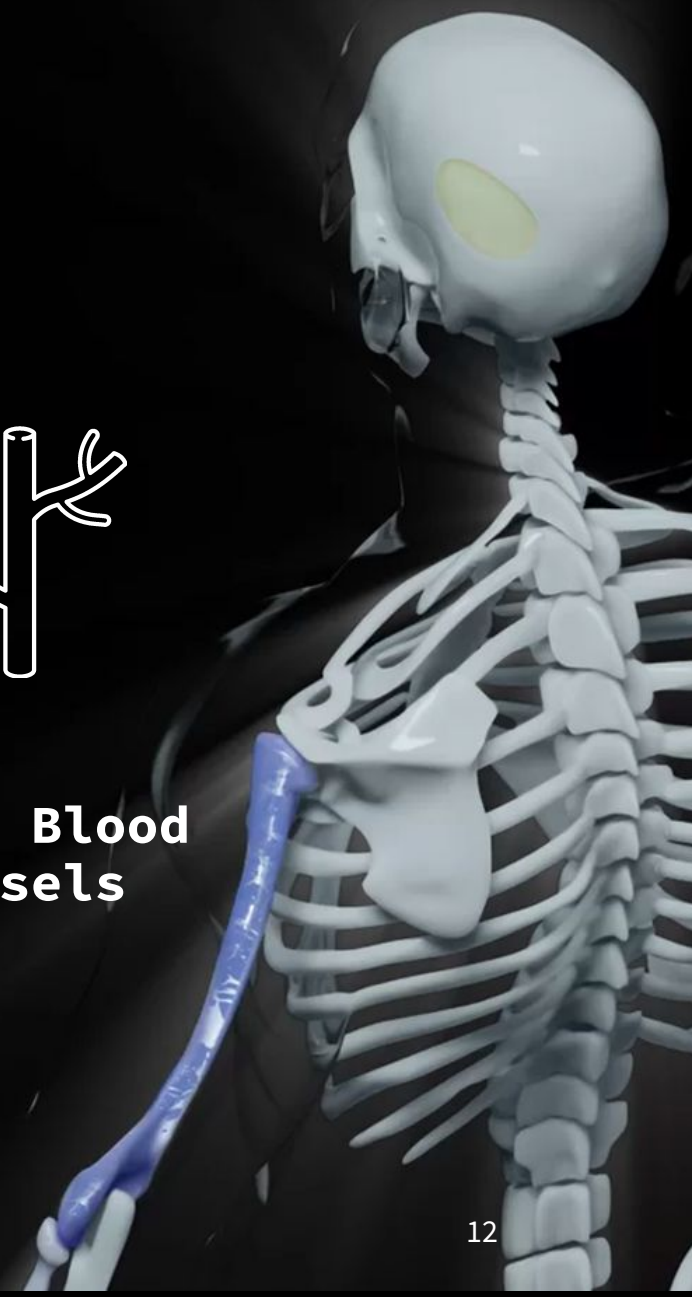
**Heart
Valves**



Bronchial



**Major Blood
Vessels**



Fundraising

A.D.A.M. is raising \$8M at \$25 pre-money valuation to achieve product readiness and regulatory clearance for the market entry

\$1.2M Product Development

Completion of animal studies for bioceramic and biopolymer bone implants

\$1.5M Clinical & Regulatory

2 material composites and 2 printers ready for market launch

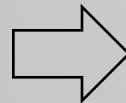
\$0.2M Marketing

FDA 510(k) Clearance

\$2.1M Operational Expenses

Global IP Coverage Secured

Digital Platform Ready for Commercial Use



Team

Our team has a unique blend of skills in medical, technical and regulatory fields, necessary to bring A.D.A.M. to market



Denys Gurak

CEO

Formerly a top executive of industrial conglomerates; expert in global medical trials regulations



Mykhaylo Pluzhnik

CTO

Engineer focusing on thermal processing, materials chemistry, project management



Carlton Savory, MD

Chief Medical Officer

The first Command Surgeon of the Joint Special Operations Command, former Assistant Chief of Orthopaedics at Walter Reed



Svitlana Kost, PhD

Head of Quality Assurance

Experience in developing Quality Assurance Systems for Pharma and Medical Devices



Oleg Rogankov, PhD

R&D - Production Tech Engineer
Materials physics scientist and technological processes expert



Vadym Volkov, MD

R&D - Medical

Assistant Professor of General Surgery in Odesa, Ukraine; practicing surgeon



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served in the U.S. Congress incl. as a
Chairman of House Committee on Intelligence.
Formerly an executive at a Fortune 500 corp



Eugene Fedorchenko

Digital Strategy Advisor
Strategic business advisor with over decade
of track record in management, law and
go-to-market domains



Contact

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Appendix 1. Risks

R&D Office in Odesa: War in Ukraine

Team relocation to Lviv; relocation options to US/Canada/Netherlands

All know-how secured on cloud - proprietary hardware and materials can be recreated within 1-2 months & ~\$100k

Pre-Revenue: Failure to Fundraise

1st commercial project in Ukraine - revenue generation in Ukraine, enough for R&D and operational support

FDA Clearance Required for Market Entry in US

510(k) eligibility confirmed by FDA - only animal studies required

Completed biomechanical testing - results indicate A.D.A.M. better than predicates

Appendix 2. Case: Hospital System in Lviv

Hospital Need:

- 10 bioresorbable implants, 10 PEKK implants, 10 surgical meshes, 20 surgical models

A.D.A.M.'s offer:

- Installation of A.D.A.M. system (with additional capabilities to print PEKK) for \$200k
- Monthly fee of \$60k for up to 30 printed implants

