

March, 2023

# EVAXION

AI-Powered  
Immunotherapies

[evaxion-biotech.com](https://evaxion-biotech.com)

# Forward-looking statements

This announcement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "target," "believe," "expect," "hope," "aim," "intend," "may," "might," "anticipate," "contemplate," "continue," "estimate," "plan," "potential," "predict," "project," "will," "can have," "likely," "should," "would," "could," and other words and terms of similar meaning identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including, but not limited to, risks related to: our financial condition and need for additional capital; our development work; cost and success of our product development activities and pre-clinical and clinical trials; commercializing any approved pharmaceutical product developed using our AI platform technology, including the rate and degree of market acceptance of our product candidates; our dependence on third parties including for conduct of clinical testing and product manufacture; our inability to enter into partnerships; government regulation; protection of our intellectual property rights; employee matters and managing growth; our ADSs and ordinary shares, the impact of international economic, political, legal, compliance, social and business factors, including inflation, and the effects on our business from the worldwide COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia; and other uncertainties affecting our business operations and financial condition. For a further discussion of these risks, please refer to the risk factors included in our most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at [www.sec.gov](http://www.sec.gov). We do not assume any obligation to update any forward-looking statements except as required by law.

We aspire to lead the exploration of AI to develop superior immunotherapies for patients in need



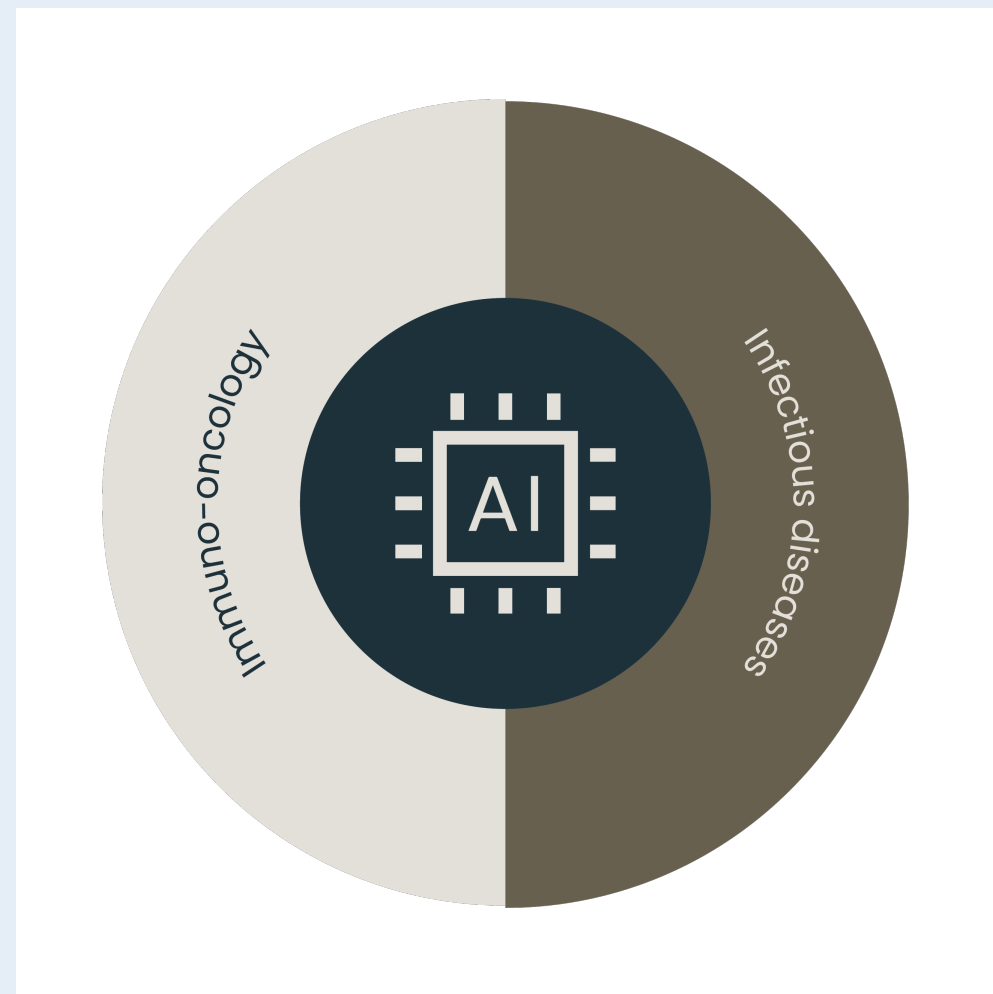
Driving the development of AI platforms for target discovery in cancer and infectious diseases



Advancing a clinical pipeline of personalized cancer immunotherapies

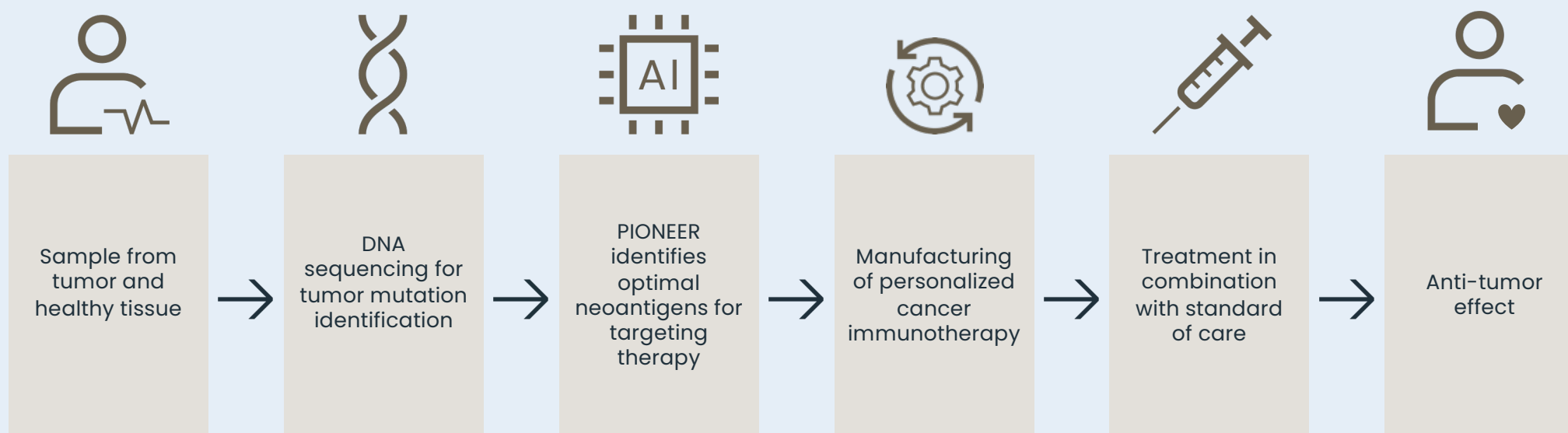


Accelerating the development of novel vaccines for infectious diseases in pre-clinical partnerships



# Personalized cancer immunotherapy

– a new drug optimized for each patient



# PIONEER – Clinically validated AI platform for personalized cancer immunotherapy

PIONEER identifies optimal neoantigens for T-cell activation and anti-tumor effect in each patient

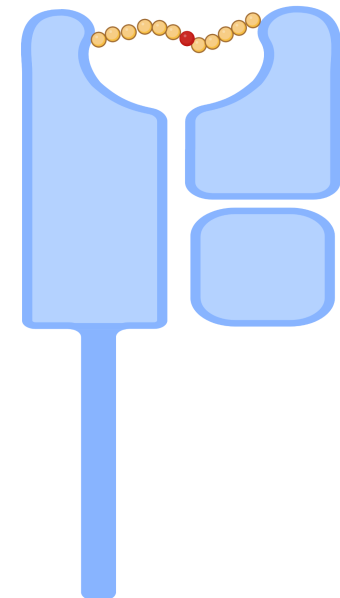
Key biological steps simulated by PIONEER:

1. Mutation
2. Expression
3. Translation
4. Presentation on **MCH** class I and II
5. T-cell response
6. Clonal neoantigens

Step 1: Identifying tumor specific mutations (neoantigens)



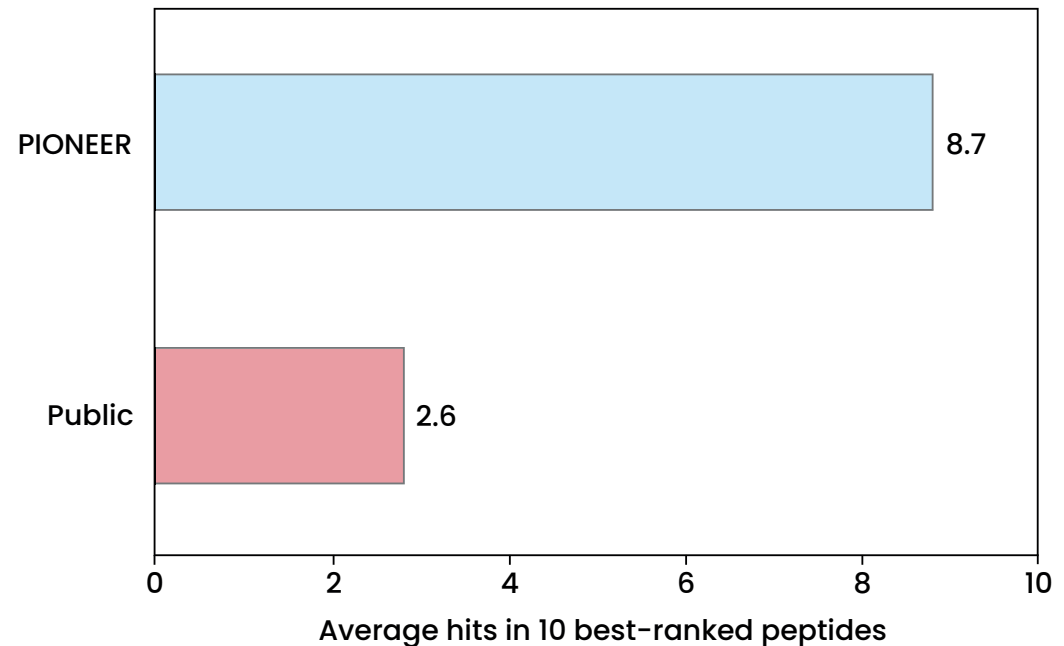
Step 4: Neoantigen processing and presentation in MHC



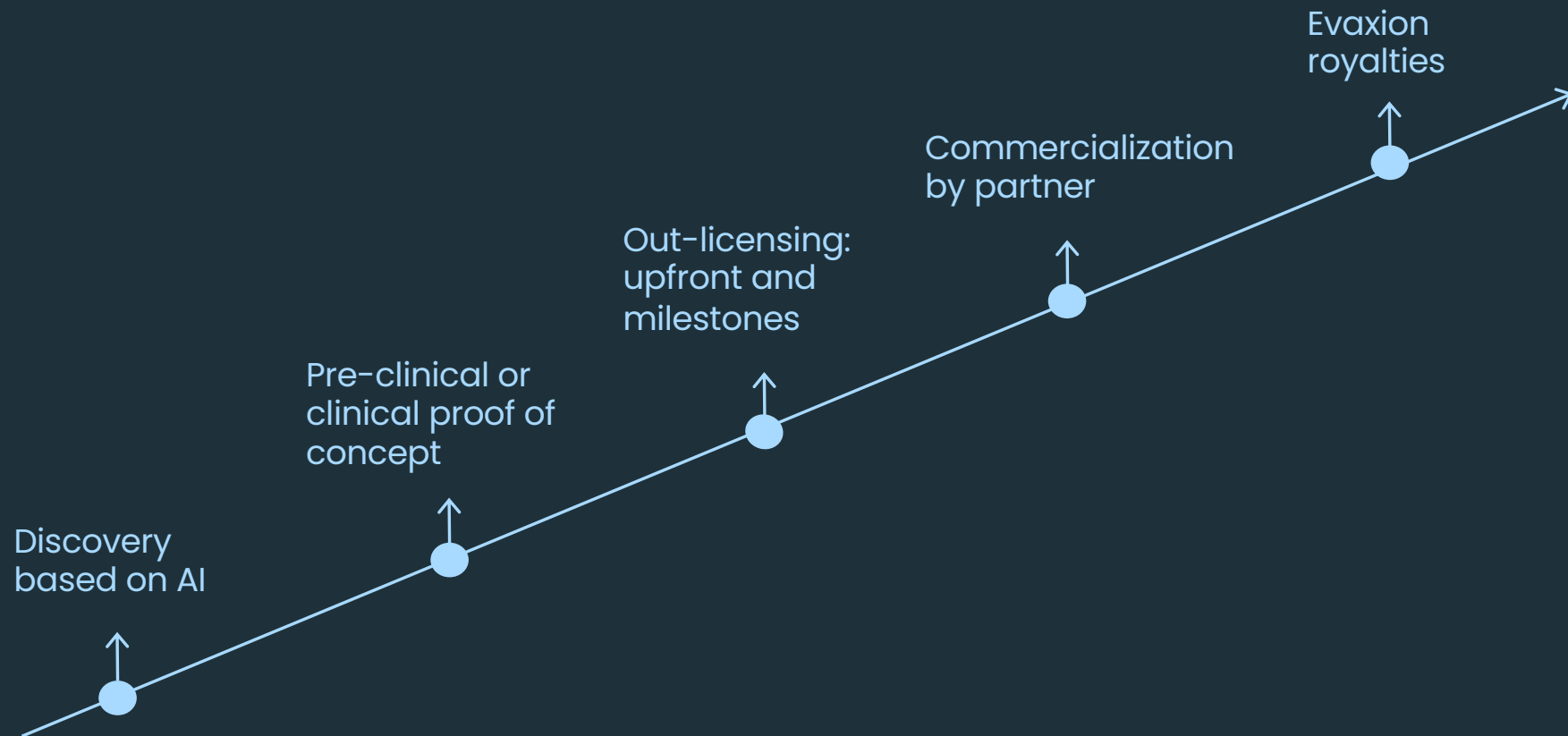
# PIONEER outperforms public tools

## PIONEER vs. best public tools

- The best publicly available tools are only capable of identifying 2.6 correct neoantigens in the top 10
- In comparison, PIONEER identified 8.7 correct neoantigens in the top 10
- A superior prediction is anticipated to result in an enhanced antitumor immune response




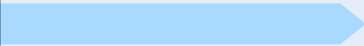
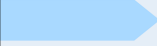
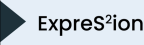


# Business model



# Immunotherapy Pipeline

Internal development of oncology programs while advancing infectious disease programs in partnerships

	AI platform	Product Candidate	Stage of development		
			Pre-clinical	Phase 1	Phase 2
Oncology therapeutic vaccines	PIONEER  Personalized cancer immunotherapies	EVX-01 (Liposomal/peptide) <b>Metastatic melanoma</b>			
		EVX-02 (DNA) <b>Adjuvant melanoma</b>			
		EVX-03 (Targeted DNA) <b>NSCLC</b>			
Infectious diseases prophylactic vaccines	EDEN  Vaccines against bacterial diseases	EVX-B1 (Proteins) <b><i>S. aureus</i>, SSTI</b>			
		EVX-B2 <b><i>N. gonorrhoeae</i></b>			
	RAVEN  Vaccines against viral diseases	EVX-V1 <b>Cytomegalovirus (CMV)</b>			



# EVX-01

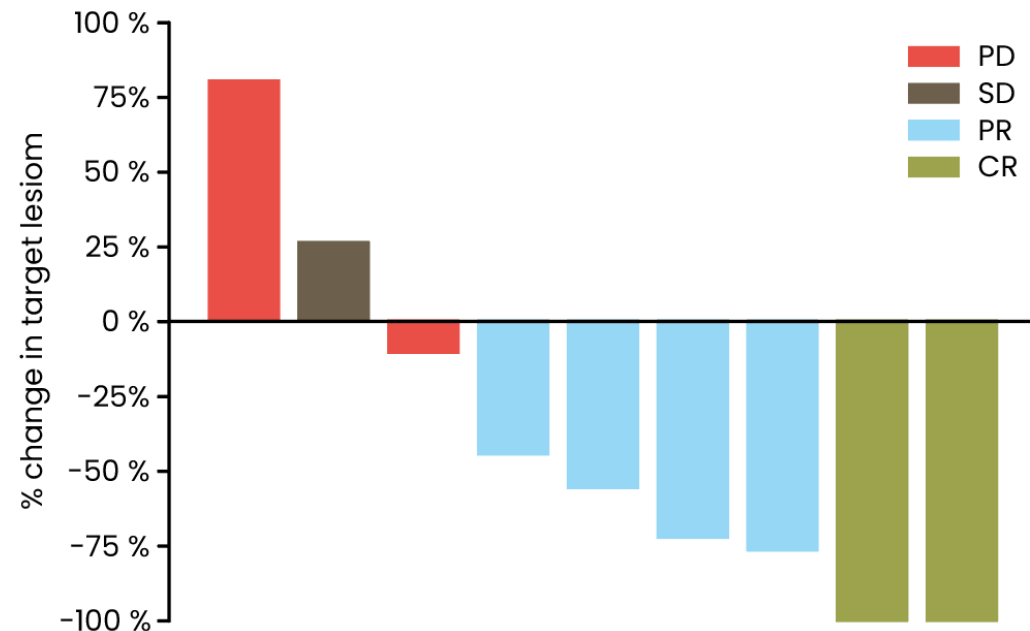
## Strong interim data in clinical phase 1/2a

### Study in brief

- Metastatic melanoma
- EVX-01 biweekly x 6 + anti-PD-1
- Interim data from 9 patients
- Neoantigen-specific immune response in all patients
- Tumor reduction in 6 out of 9 patients
- Good safety and tolerability

Individual patient

EVX-01 target lesions



Patient interim data

# EVX-01

## Promising efficacy data in Phase 1/2a

76% of the administered neoantigens induced reactive T cells of which 83% were *de novo* responses

Correlation between EVX-01 activated T cells and clinical response

Overall response rate (ORR), complete response (CR) and partial response (PR) achieved by EVX-01 in combination

	EVX-01 phase 1/2a	KEYTRUDA® LABEL <sup>a</sup>	KEYNOTE-006 <sup>b</sup>
ORR	<b>67%</b>	33%	40%
CR	<b>22%</b>	6%	7%
PR	<b>44%</b>	27%	33%

**Preliminary data from EVX-01 Phase 1/2a clinical trial (n=9; NCT03715985)**

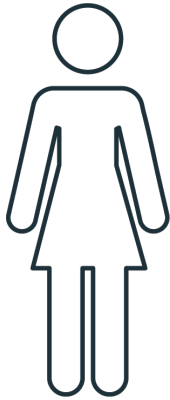
a) KEYTRUDA® label study Keynote-006

b) Robert et al. 2015. Pembrolizumab versus Ipilimumab in Advanced Melanoma. N. Engl. J. Med. 372: 2521–32, Keynote 006 responses after 2 months corresponding to time from biopsy to first dose of EVX-01

# EVX-01

## A patient case

**Patient**  
64 years



**Diagnosis**  
Stage IV metastatic melanoma

**Status**  
Stable disease after 10  
months with anti-PD1

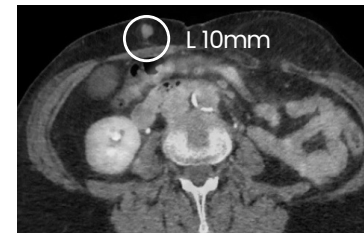


**Effect**  
Strong immune activation  
by EVX-01

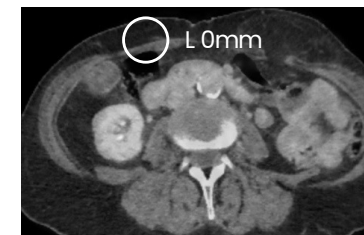


**Result**  
Complete response (CR)

Scan at enrollment



Scan 1 year after  
starting EVX-01



# EVX-01

## Global clinical Phase 2b trial started

Locations: Clinical sites in  
Australia, Europe, USA

Trial Population: 80 patients with  
metastatic melanoma

Status: Enrollment started in  
Australia in September 2022

In partnership with Merck & Co.,  
Inc (MSD)

Interim readout H2 2023



# EVX-01

## Phase 2b trial design & projected timelines



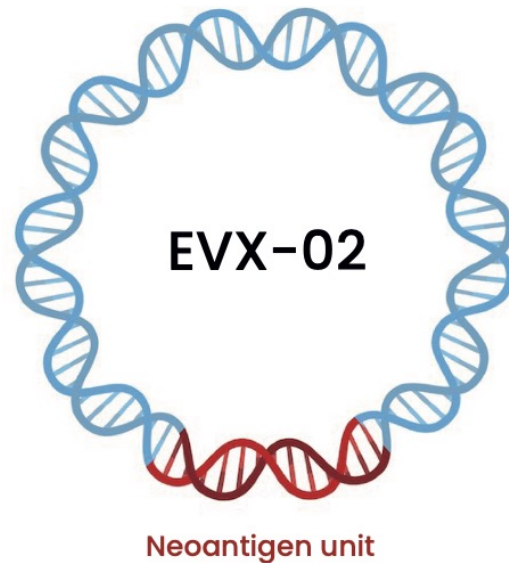
**Pembrolizumab** ————— Dosing every 6 weeks from week 1 to week 102 —————>

<b>Sept 2022</b> <b>Dec 2022</b> <b>Jan 2023</b>	FPFV FDA IND approval FDA fast track designation	<b>Q4 2023</b> <b>2024</b> <b>2025</b>	Interim readout 1-year readout 2-year readout
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## EVX-02

A personalized DNA-based cancer immunotherapy in Phase 1/2a

EVX-02 + nivolumab  
as adjuvant therapy  
after melanoma  
resection



## Interim readout

Well tolerated in all patients

Neoantigen-specific T-cell  
responses in all patients

T-cell responses robust  
and long lasting

Proof of mechanism for new  
DNA-delivery technology

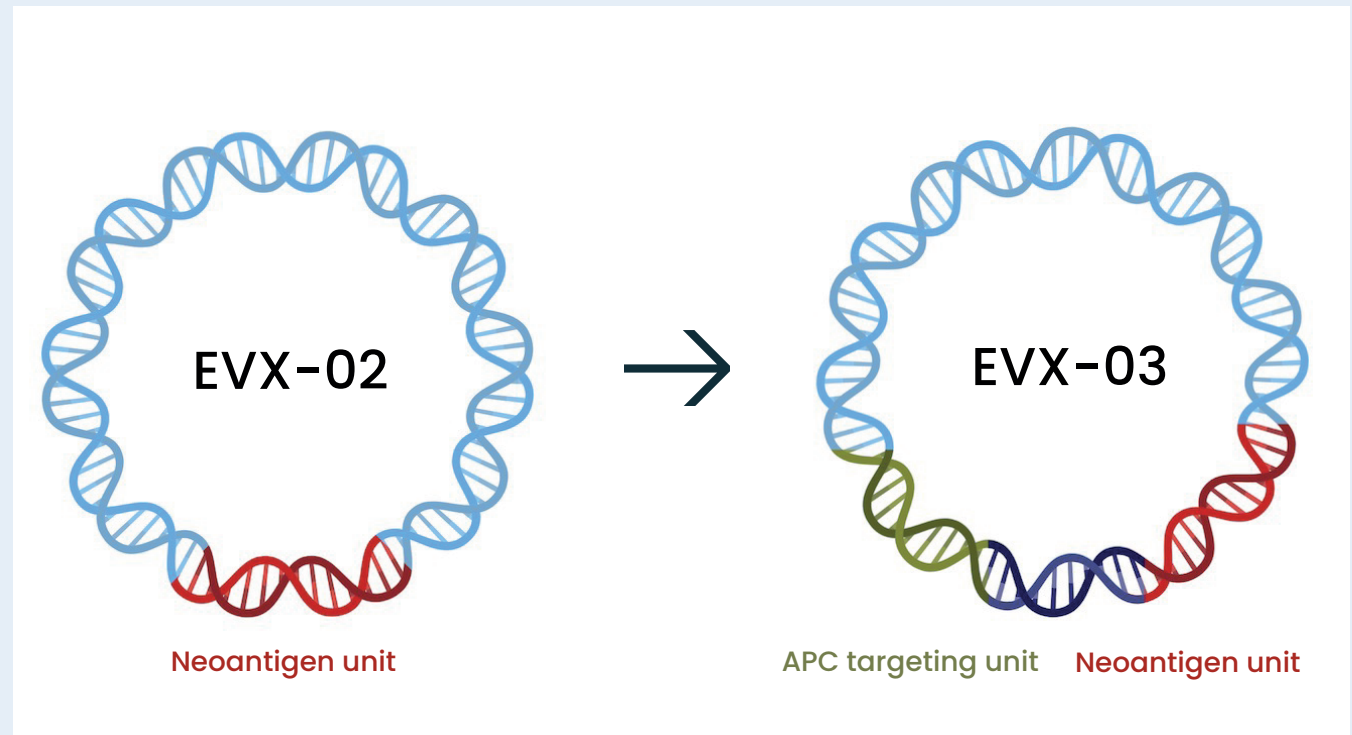
## EVX-03

# Our next-gen DNA-based neoantigen immunotherapy with APC-targeting unit

Directing APCs to neoantigens augments antigen presentation

APC-targeting accomplished through immune activating units in the DNA

The technology is fully owned, patent protected, and with broad utility for vaccines



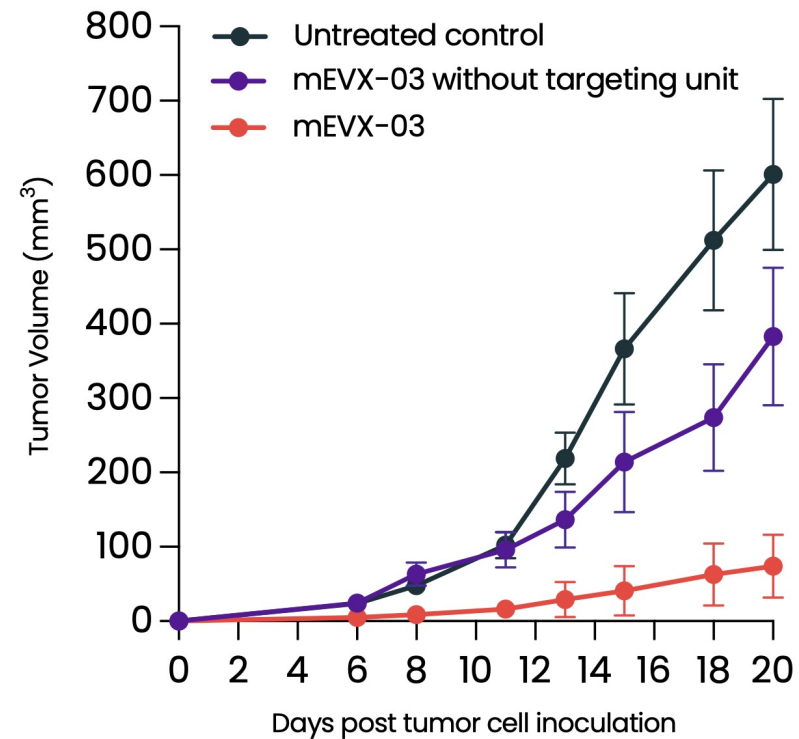
# EVX-03

## Highly effective in pre-clinical models

- Strong antitumor effect\*
- Superior potency to 1st generation DNA vaccine
- Durable neoantigen-specific T-cell responses
- GLP toxicology completed without concerns
- Start of clinical Phase 1a planned for H2 2023

\*Data from pre-clinical studies of EVX-03 in a colorectal cancer model (CT26)

Highly effective and safe in pre-clinical models





# Oncology pipeline in brief

## Three personalized cancer immunotherapies, generated with the PIONEER AI platform

- EVX-01 Phase 2b for metastatic melanoma – 67 % ORR in Phase 1/2a
- EVX-02 Phase 1/2a ongoing in resectable melanoma. Final readout expected Q2 2023
- EVX-03 APC-targeting DNA, IND-enabling studies ongoing

## Partnership opportunities

- Co-development of clinical assets
- Out-licensing of APC-targeting DNA technology
- Collaboration on PIONEER platform

# Competitor landscape

Evaxion strongly positioned in personalized neoantigen vaccine field

Company	Format	Phase
Gritstone Bio	ChAd <sup>1</sup> prime/samRNA <sup>2</sup> boost	2/3
Moderna/Merck	mRNA	2b
Evaxion	Peptide	2b
BioNtech/Roche	mRNA	2
Evaxion	DNA	1/2
Nykode/Roche	DNA	1/2
Geneos Therapeutics	DNA	1/2
NEC ONCOLmmunity	Bacterial Vector	1
Nouscom	Viral vector	1
Stemirna	mRNA	1

1. ChAd – chimpanzee adenovirus
2. samRNA – self-amplifying mRNA

+4 companies at preclinical stage, including CureVac

## Addressing a large and growing market

Cancer immunotherapy market est. to USD 277 billion in 2030\*

NSCLC market est. to USD 33 billion by 2029\*\*

Melanoma market est. to USD 7.4 billion by 2029\*\*

\*Precedence Research

\*\*GlobalData

## Increased deal-making for therapeutic cancer vaccines

**Gritstone-BMS** clinical trial collaboration (2018) No financials disclosed

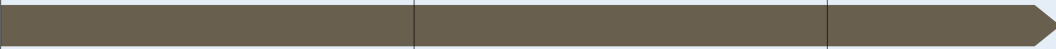
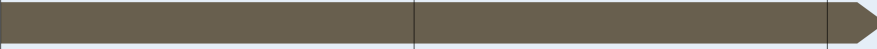
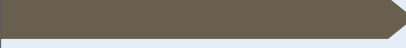
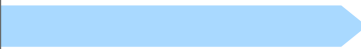
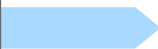

**Nykode-Roche** out-licensing deal (2020). Upfront + early MS of USD 200M and royalty ≈ 10%

**BioNTech-Neon Therapeutics** M&A. USD 67M (2020)

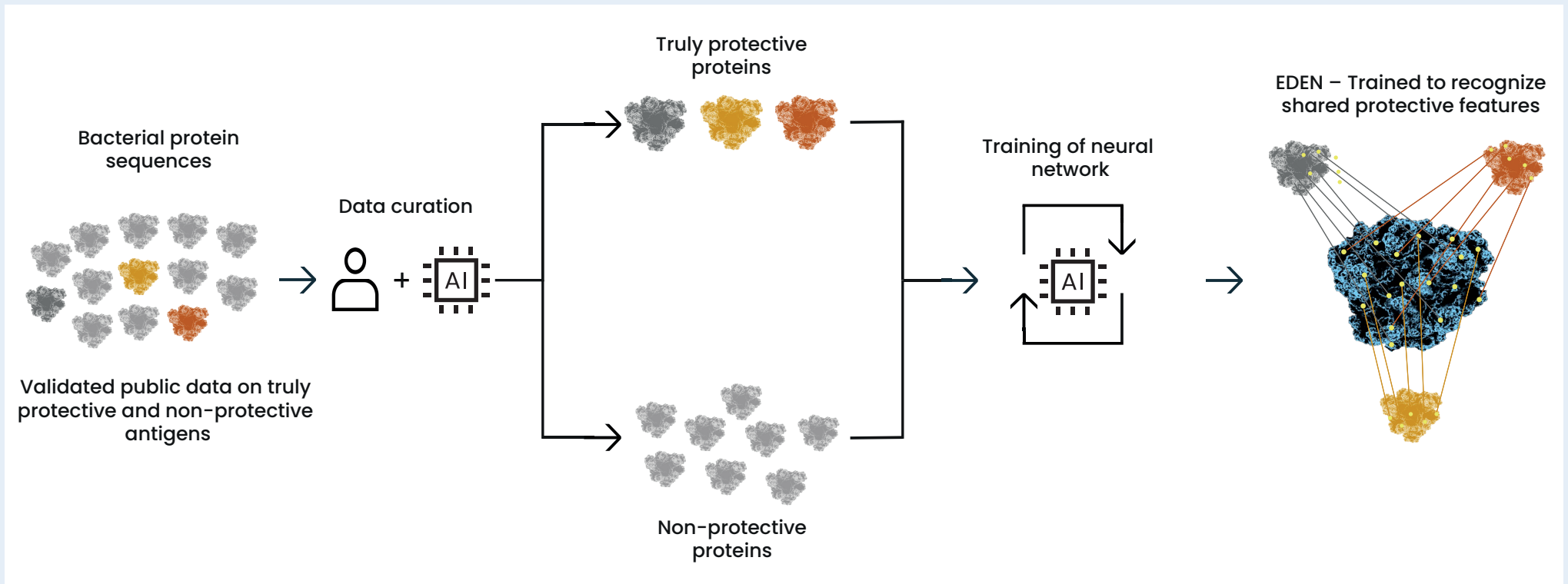
**Moderna-Merck** partnership. Upfront USD 200M (2016) + option exercise USD 250M (Oct 2022)

# Immunotherapy Pipeline

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	RAVEN Vaccines against viral diseases	EVX-V1 Cytomegalovirus (CMV)	 ExpresSion		

# EDEN – trained to recognize shared protective features



# EDEN – from platform to product

Pre-clinically validated in:

- *Staphylococcus aureus* (EVX-B1)
- *Neisseria gonorrhoeae* (EVX-B2)
- *Pseudomonas aeruginosa*
- *Klebsiella pneumoniae*
- *Acinetobacter baumannii*
- *Moraxella catarrhalis*
- Non-typeable *Haemophilus influenzae*

Discovery

Pre-clinical dev.



- 1. Input:** Any bacterial proteome
- 2. EDEN:** Probability assesment of immunogenicity
- 3. Output:** Ranking list of novel protective proteins
- 4. Selection:** 20–30 highest ranked proteins, vaccine antigen design and structural modelling
- 5. Verification:** Protection and immunogenicity in animal models, functional assays
- 6. Optimization:** Antigen opt., fusion proteins, adjuvant/modality testing and CMC readiness
- 7. Vaccine defined:** Best product candidate for devopment defined

# EVX-B1

Four-component *S. aureus* vaccine for prevention of skin and soft tissue infections (SSTI)

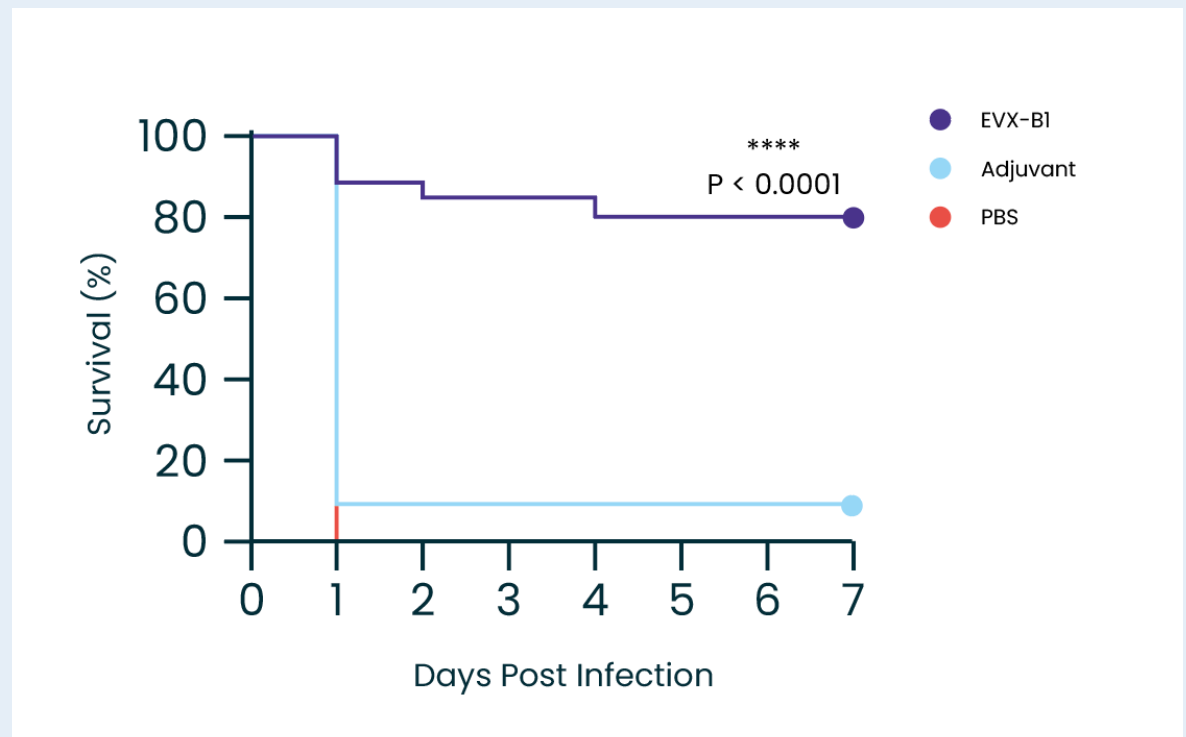
Highly significant protection in lethal USA300 sepsis model

High IgG titers and potent T-cell response after two doses

Functional immune response to all 4 target proteins

Ready for IND-enabling toxicology studies

*S. aureus* vaccine candidate demonstrating protection in challenge models



# EVX-B2

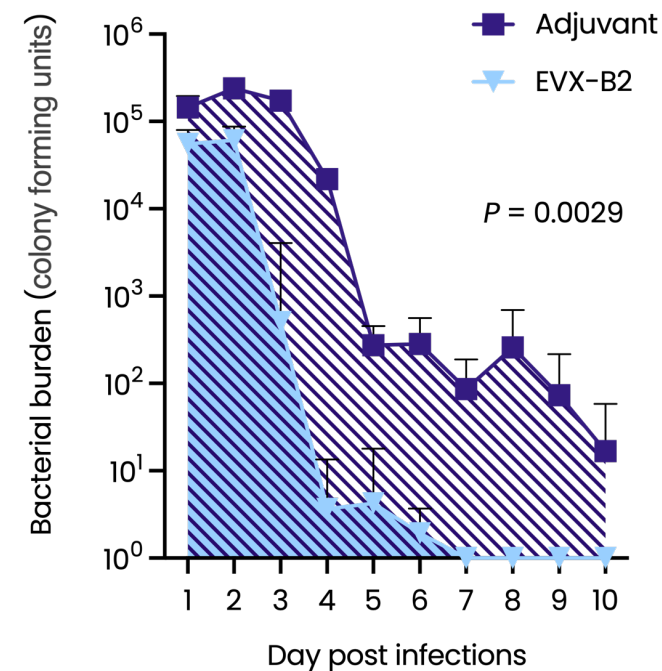
Multi-component *N. gonorrhoeae* vaccine candidate

Protection against different *N. gonorrhoeae* strains (MS11 shown) in vaginal colonization model

High level of immunogenicity

Broad neutralization capacity demonstrated in panel with 50 *N. gonorrhoeae* strains

*N. gonorrhoeae* vaccine candidate demonstrating broad protection

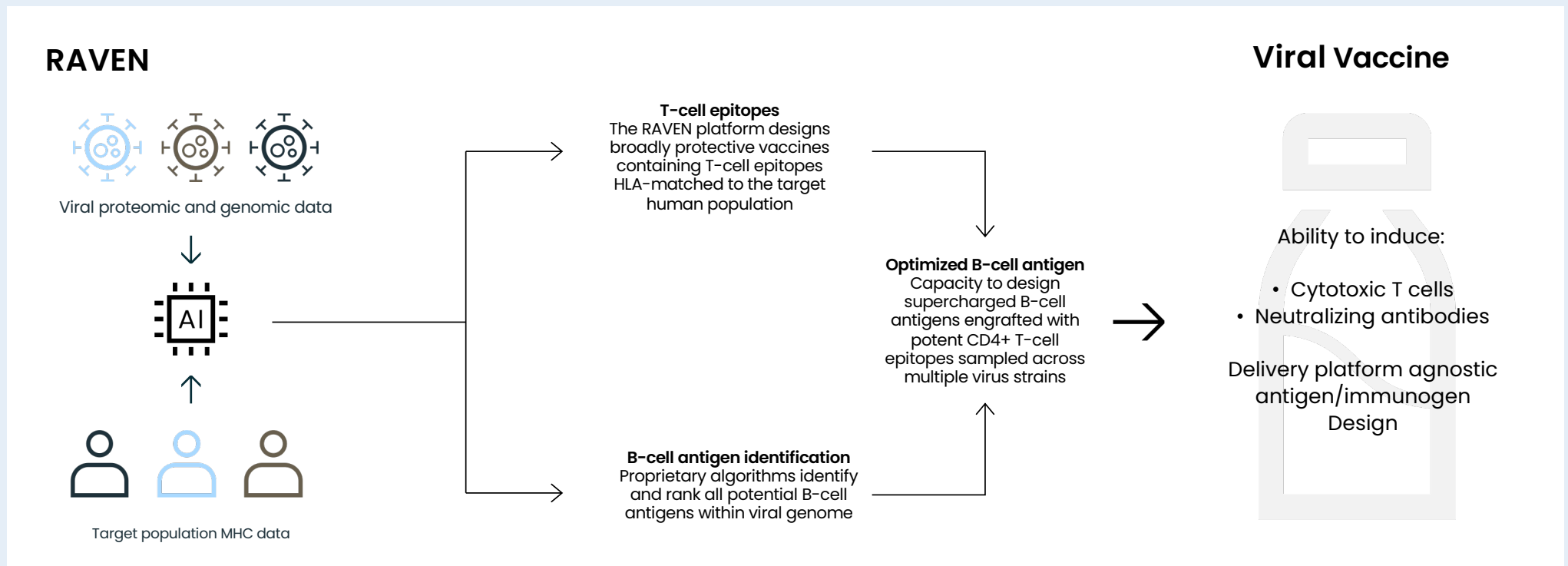


UMass Chan  
MEDICAL SCHOOL

NIH  
National Institutes  
of Health



# RAVEN – Proprietary AI platform for the design of superior viral vaccines



# Vaccines against infectious diseases

**Two proprietary AI platforms** (EDEN and RAVEN) identifies superior vaccine candidates

- Novel vaccine antigens with high and broad protection to any bacteria or virus
- Fully AI-driven unbiased approach

**1 near-clinical stage bacterial vaccine program, EVX-B1** (*S. aureus*)

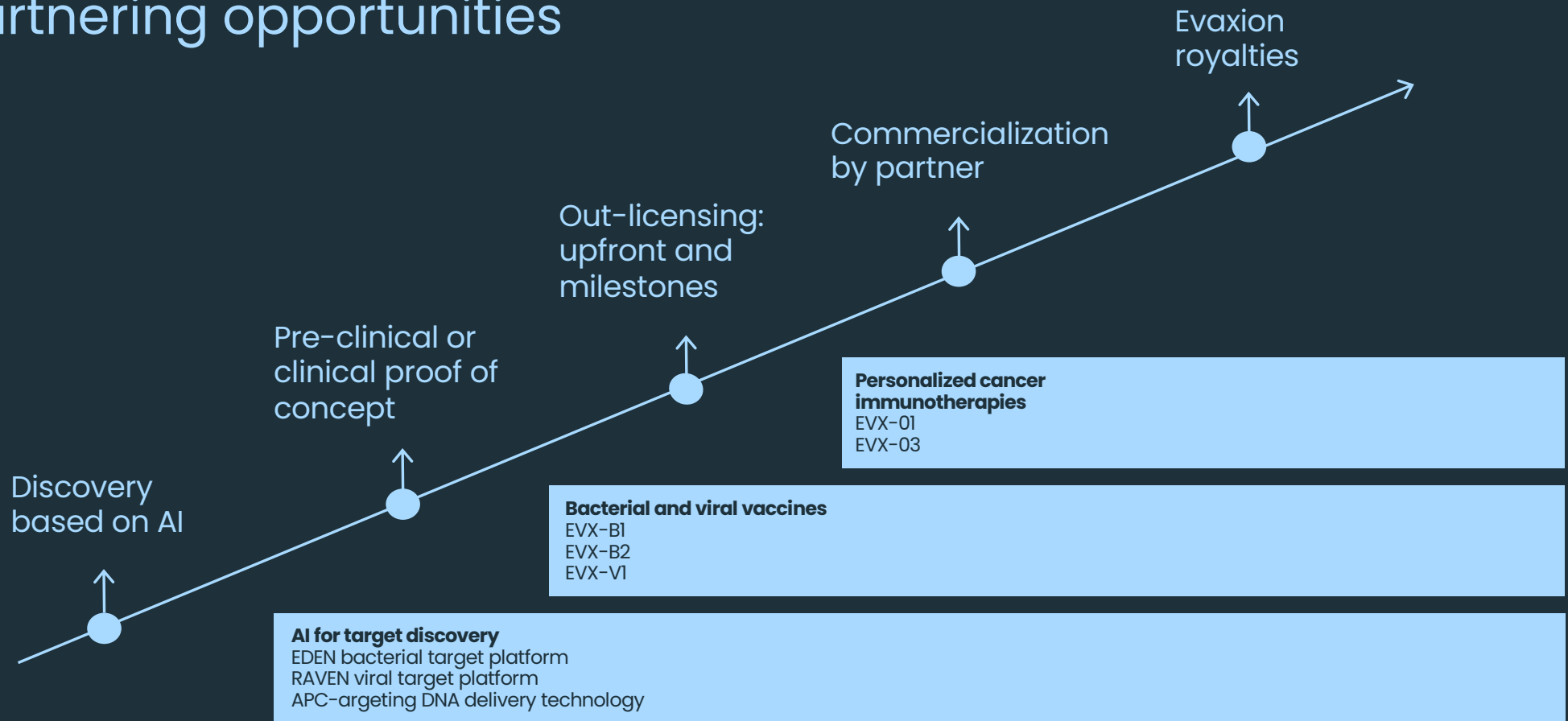
**Additional bacterial and viral vaccine targets maturing in discovery pipeline:**

- EVX-B2 (*N. gonorrhoeae*) and portfolio of many other bacterial pathogens
- EVX-V1 (cytomegalovirus) – collaborative vaccine discovery project with ExpreS<sup>2</sup>ion

**Partnership opportunities**

- EVX-B1, EVX-B2 co-development or out-licensing, new multi-target collaborations

# Business model with multiple partnering opportunities



# Milestones

## **Q2 2023**

Full readout EVX-01 Phase 1/2a

## **Q2 2023**

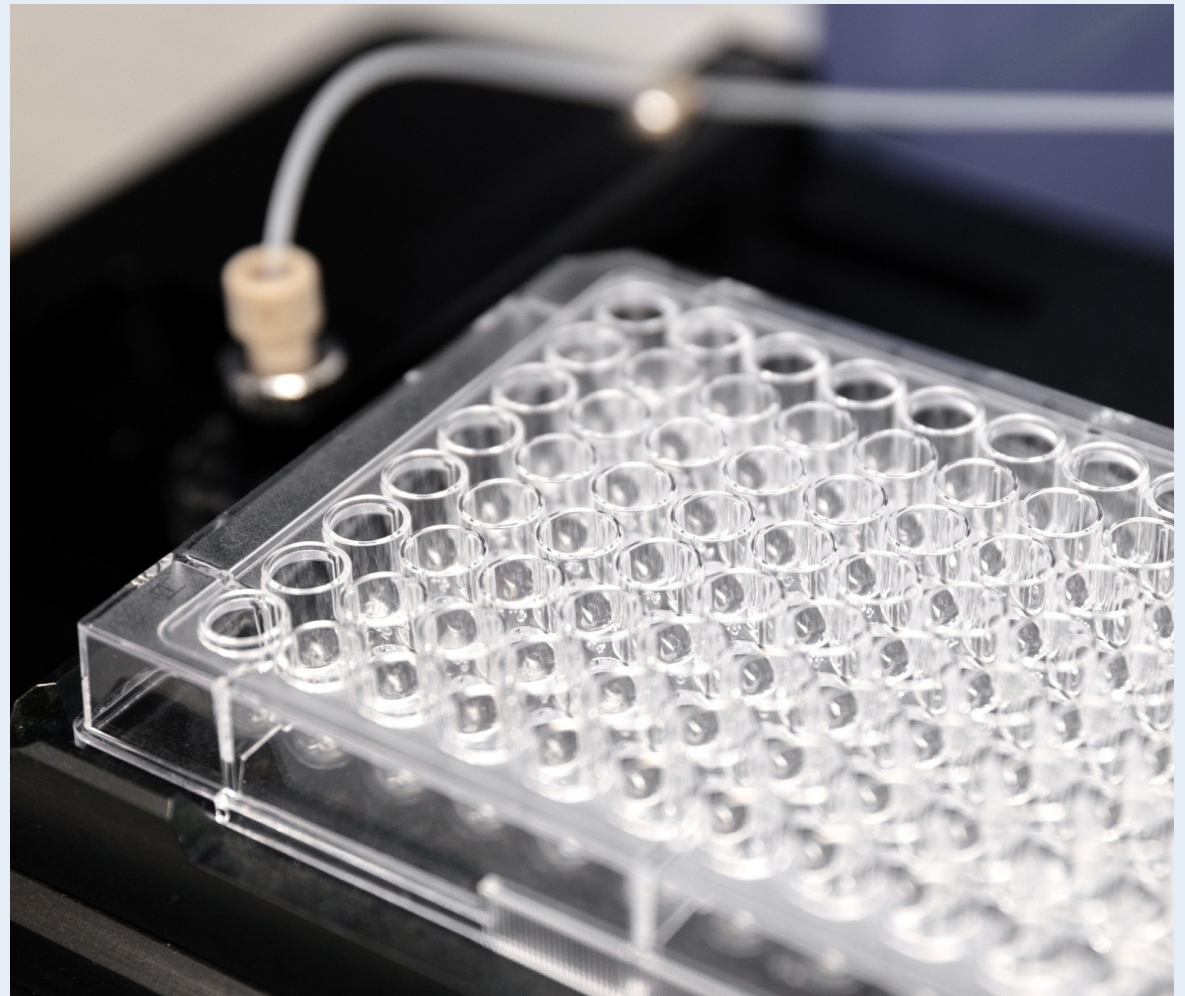
Readout EVX-02 Phase 1/2a

## **Q4 2023**

Interim clinical readout EVX-01 Phase 2b

## **Q4 2023**

Start of clinical Phase 1 of EVX-03



# Management team with extensive immunology, AI and leadership experience



Chief Executive Officer  
**Per Norlén, MD, PhD**

targintx

xintelx

ALLIGATOR  
bioscience

AstraZeneca



Chief Financial Officer  
**Bo Karmark, MSc BA.**



AQUAPORIN



Chief Innovation Officer  
**Andreas Mattsson, MSc**



DTU  
Technical University  
of Denmark



Chief Scientific Officer  
**Birgitte Rønø, PhD**



NIH  
National Institutes of Health  
Turning Discovery Into Health



Chief Medical Officer  
**Erik Heegaard, DMSc, PhD**



NOVARTIS



Chief Operating Officer  
**Jesper Nyegaard,  
MSc Cand Oecon**





# Key facts

- Strong clinical pipeline in oncology
- Broad preclinical pipeline in infectious diseases
- 15 years of pioneering AI development
- Strong IP portfolio securing lead candidates and AI
- Proprietary APC-targeting
- Multiple partnering opportunities
- DNA technology



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