



# Research & Development

Darren Ellis  
February 2023





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**ArcticZymes**

2

**Customers**

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**Product Development**

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**Product Placement**

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**Innovation Cycle**

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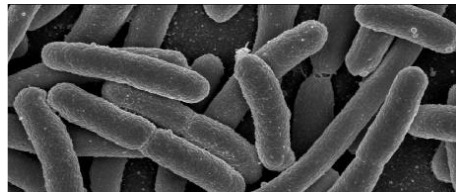
**Summary**

# ArcticZymes is well-named

## Cold-adaptation



The Arctic ecosystem is a vast genetic resource



Enzyme properties



Cold-active



Heat-sensitive



Salt tolerant

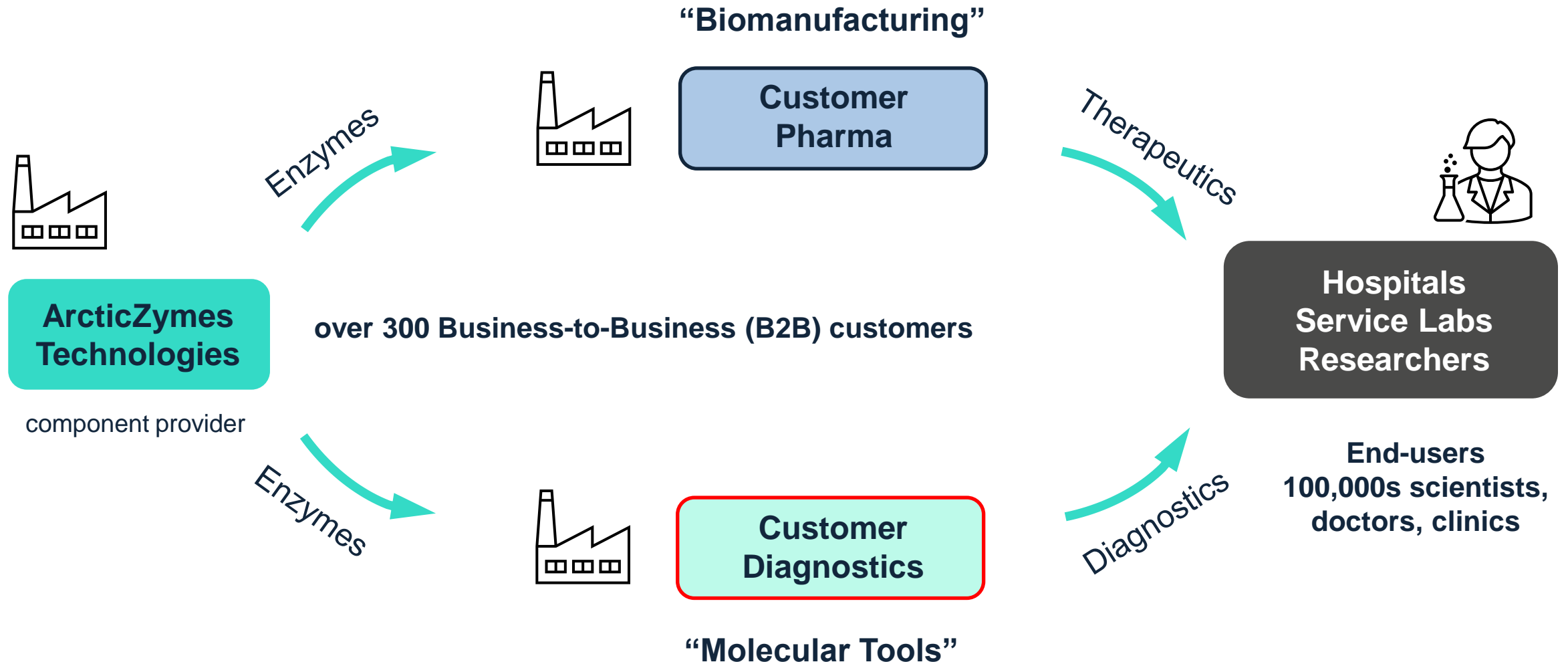


Unique



# ArcticZymes operates B2B

Primary markets – Biomanufacturing and Molecular Tools (Dx)



# Primary B2B markets – customer groups

## Product Family Alignment

Molecular Tools (Molecular Diagnostics & Research)



**Shrimp Alkaline Phosphatase**



**Cod Uracil DNA Glycosylase**



**IsoPol™ Polymerase family**



**Ligase family**



**Proteinase**



**SAN (Salt Active Nuclease) HQ family**



**M-SAN HQ**



**RNA Polymerases**



**Endo/Exo Nuclease family**



**Reverse Transcriptase**



**Taq DNA Polymerases**



**Pyrophosphatases**



**RNase Inhibitor**



**2-O-Methyltransferases**



**RNA Capping Enzymes**

Biomanufacturing (Therapeutics)

Nucleic Acid Extraction; Amplification and Sequencing technologies

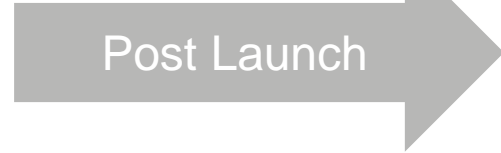
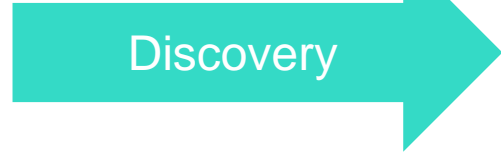
Cell & Gene therapy (viral vectors); RNA therapeutics (mRNA vaccines); Recombinant protein production

# R&D Team

## Organization

24 staff – 13 PhD's, international

Functional Areas



Core Competencies



**Bioinformatics & Sequence Mapping**



**Rec. expression in *E. Coli* & *P. pastoris***



**Technical Support**



**Structure analysis & *in-silico* engineering**



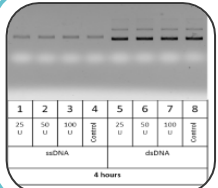
**Process development**



**Functional Assay Dev & Data**



**Functional assays**



	1	2	3	4	5	6	7	8
25 µl				Control	25 µl	50 µl	100 µl	Control
50 µl								
100 µl								

**Formulation & stability testing. Assays & QC**



**Business Dev Customer relations**

Programme Management

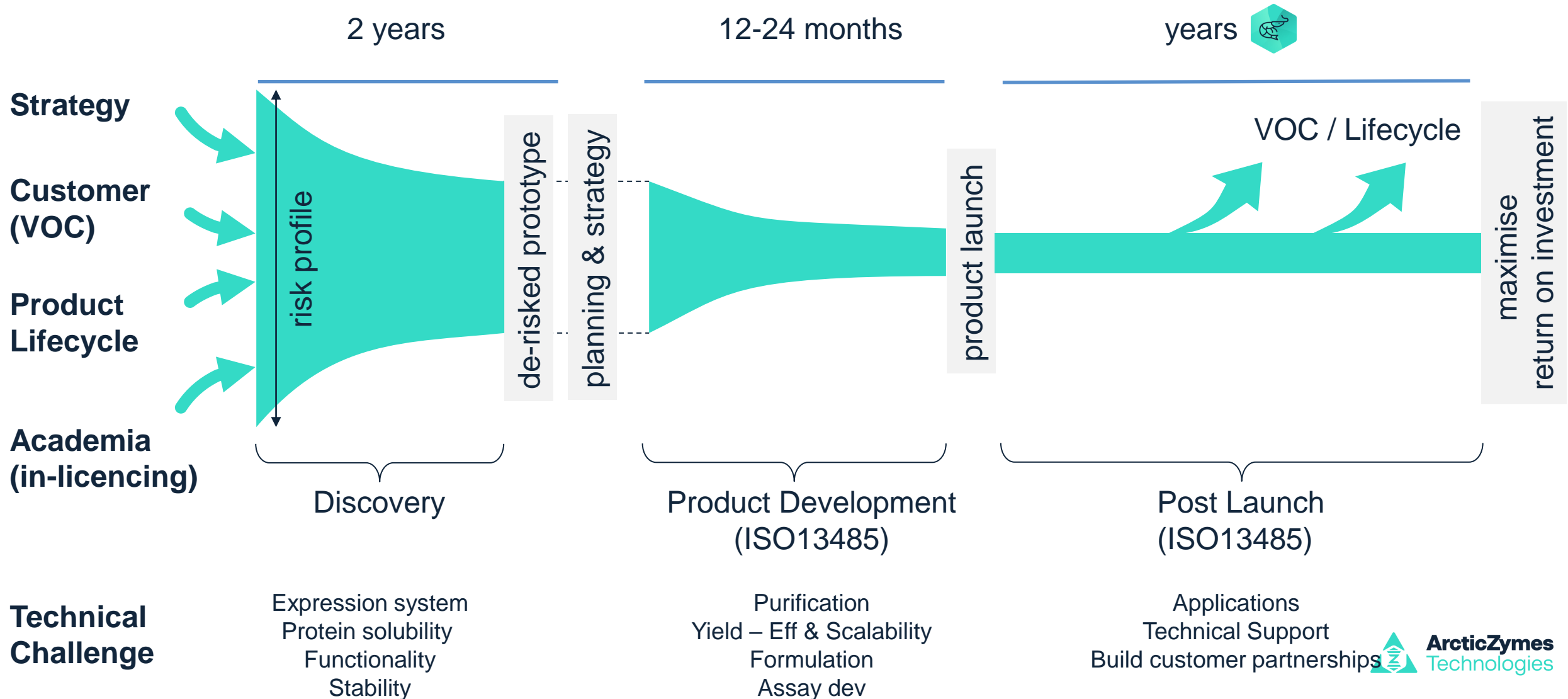
~5 FTE

~13 FTE

~4 FTE

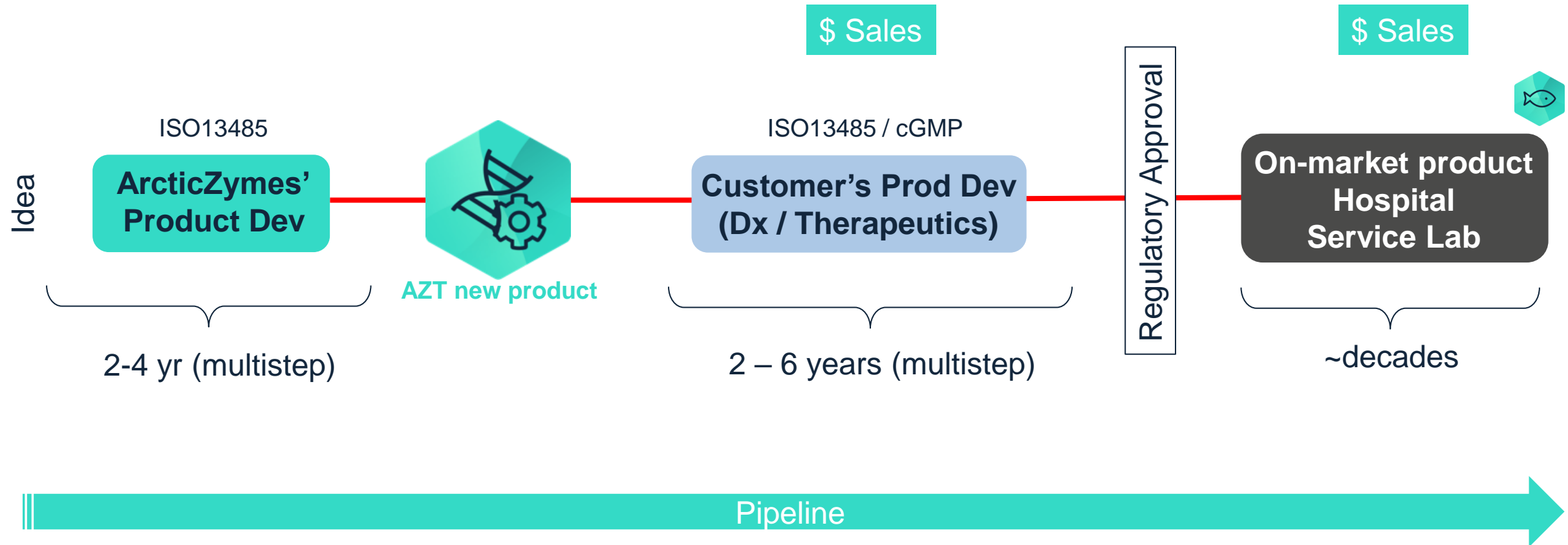
# How we develop products – ISO13485

## Phases, Goals, Risks, Timelines



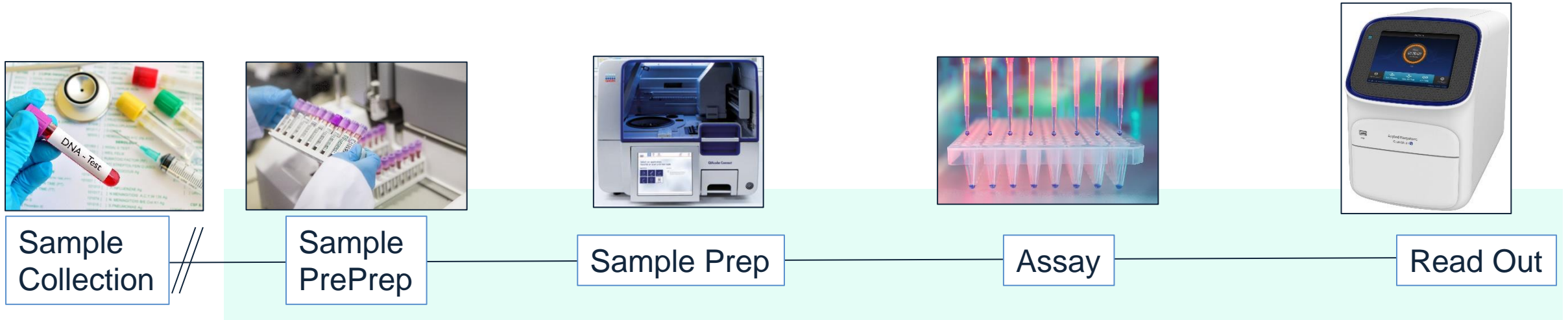
# Combined B2B product development – pipeline

## Time-to-market



# Product Placement – Molecular Dx

## Case Study - Viral Dx qPCR workflow



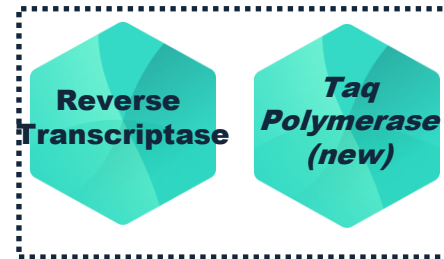
**Nuclease**



**Proteinase**



**Cod UNG**



**RT-PCR**



**IsoPol™  
Polymerases**

Applications

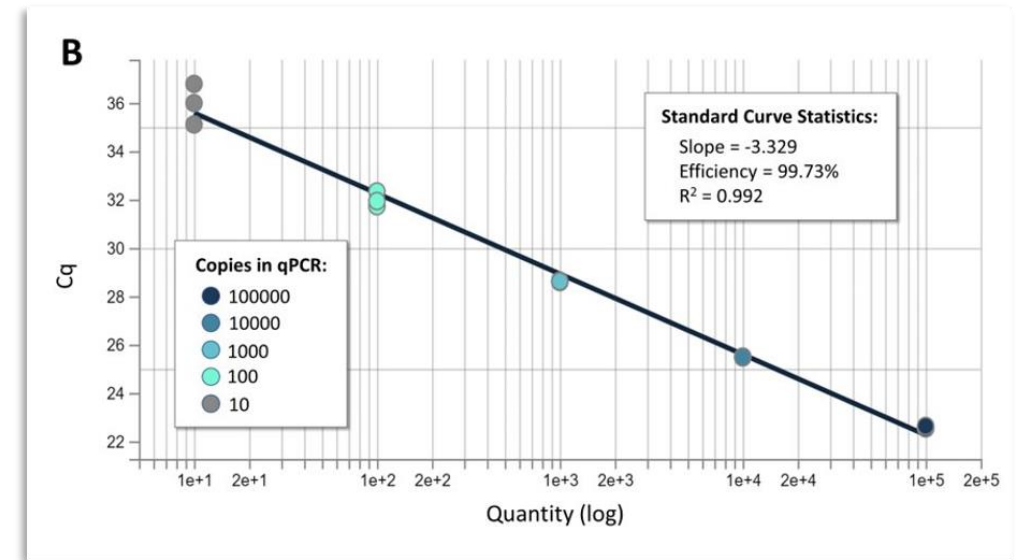
Link individual *enzymes* into *workflows* → Investment Oslo Lab

# Molecular Diagnostics

## Building product value

### Building product value through

- Complete MDx workflow with essential enzymes Reverse Transcriptase and *Taq* DNA Polymerase
- Customer-facing Application Data
- Link individual AZT products into complete workflow
- Significant value in formulations – buffer chemistries, blockers, enhancers, protocols. Ease of use.
- Expand read-out technologies – beyond qPCR
- Open to in-licensing/acquiring new technologies

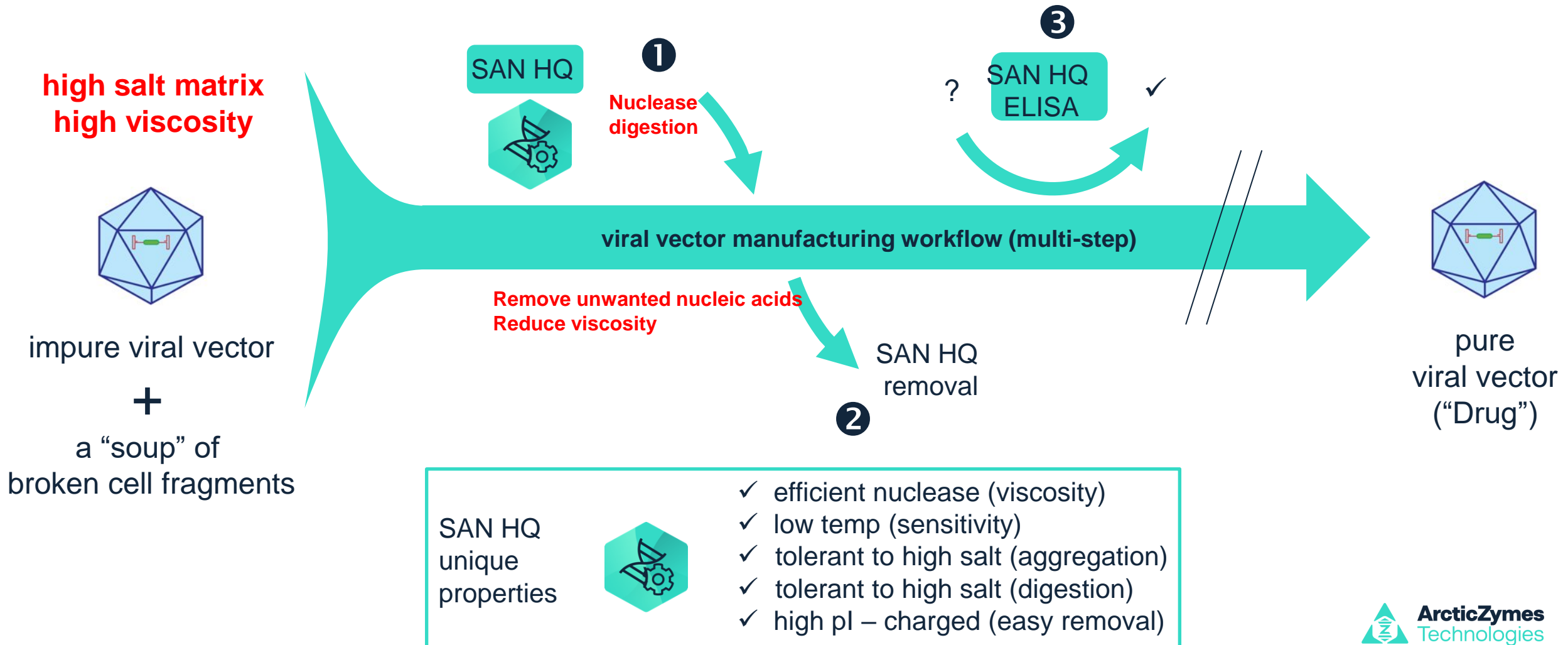


Showing performance of Reverse Transcriptase  
RNA Virus isolated from serum



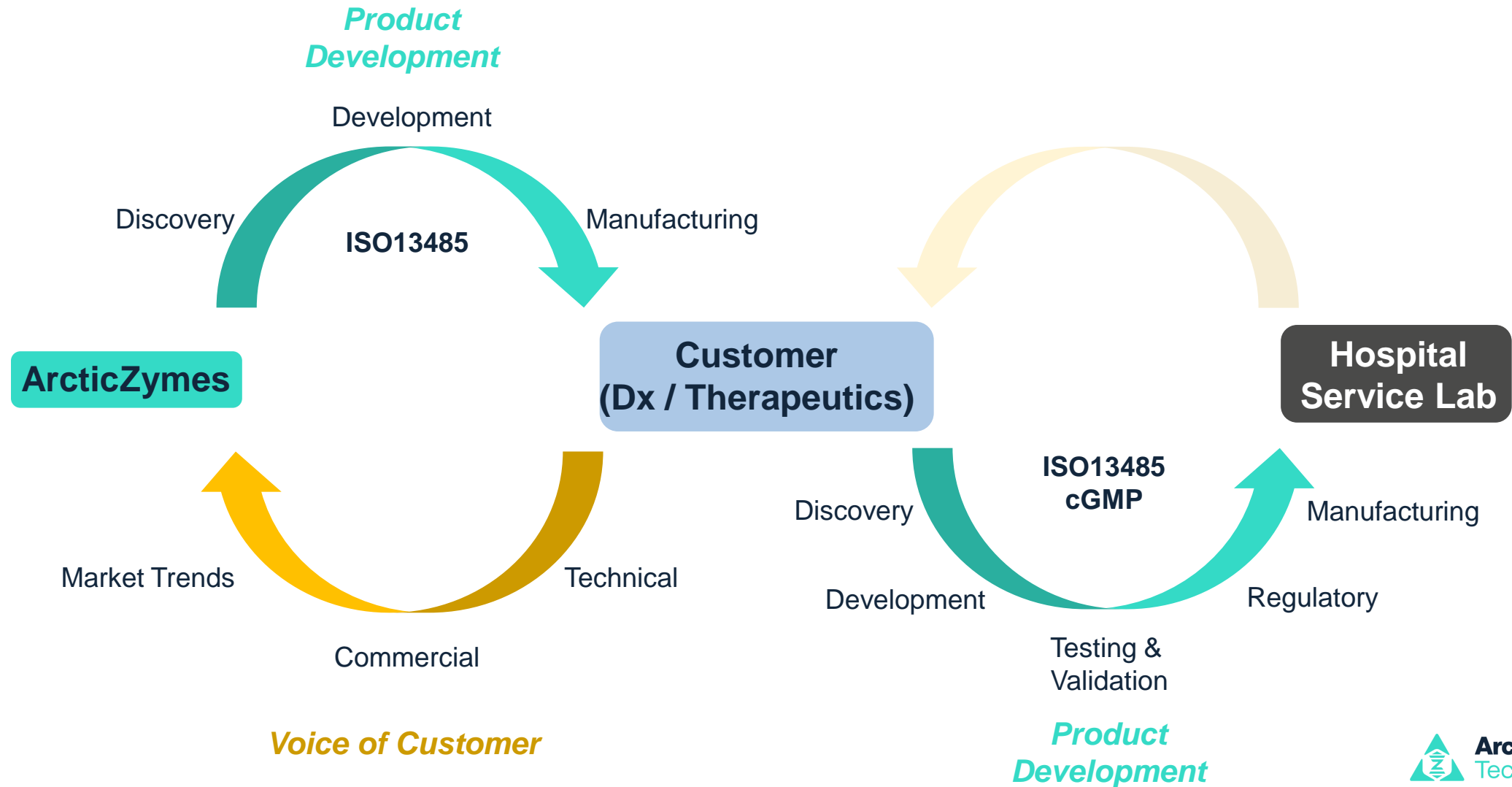
# Product Placement - Biomanufacturing

## Case Study – viral vector manufacturing (CGT)



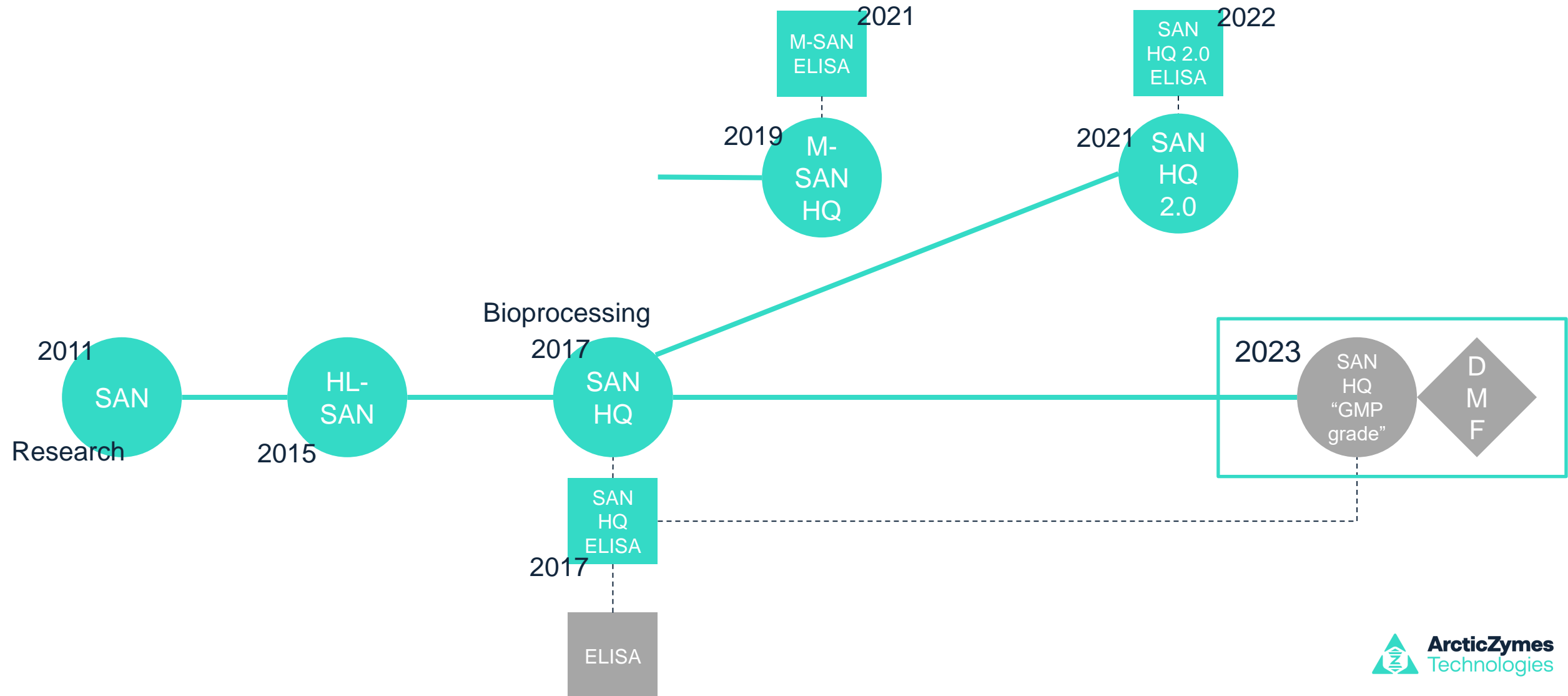
# Innovation Cycle

## How VOC and Product Dev work together



# Innovation Cycle

## Case Study – Evolution of the salt-active nuclease (SAN) product family



# Building out the product portfolio

## Retrospective Q4 2022 – new products

✓ **ArcticZymes Proteinase Glycerol Free  
(and Scale up ArcticZymes Proteinase)**

✓ **AZScript (Reverse Transcriptase)**

✓ **SAN HQ 2.0 ELISA**

- Very significant scale-up, lyophilization-friendly

- Critical enzyme for MDx, converts information from RNA to DNA ready for amplification technologies

- Essential companion product to SAN HQ 2.0 enzyme

# Building out the product portfolio

Looking to the near future – new products 2023

ArcticZymes Proteinase “bioprocessing grade” \*

Taq Polymerase

Salt Activated Nuclease - SAN “GMP grade”

- Building another pillar to our bioprocessing range

- Essential, the heart of molecular biology and MDx

- Premium SAN supported by DMF ‘drug master file’

\* names of new products subject to change

• late product development – but some residual risk

• non-exhaustive listing

# Building out the product portfolio

## Looking further ahead – beyond 2023

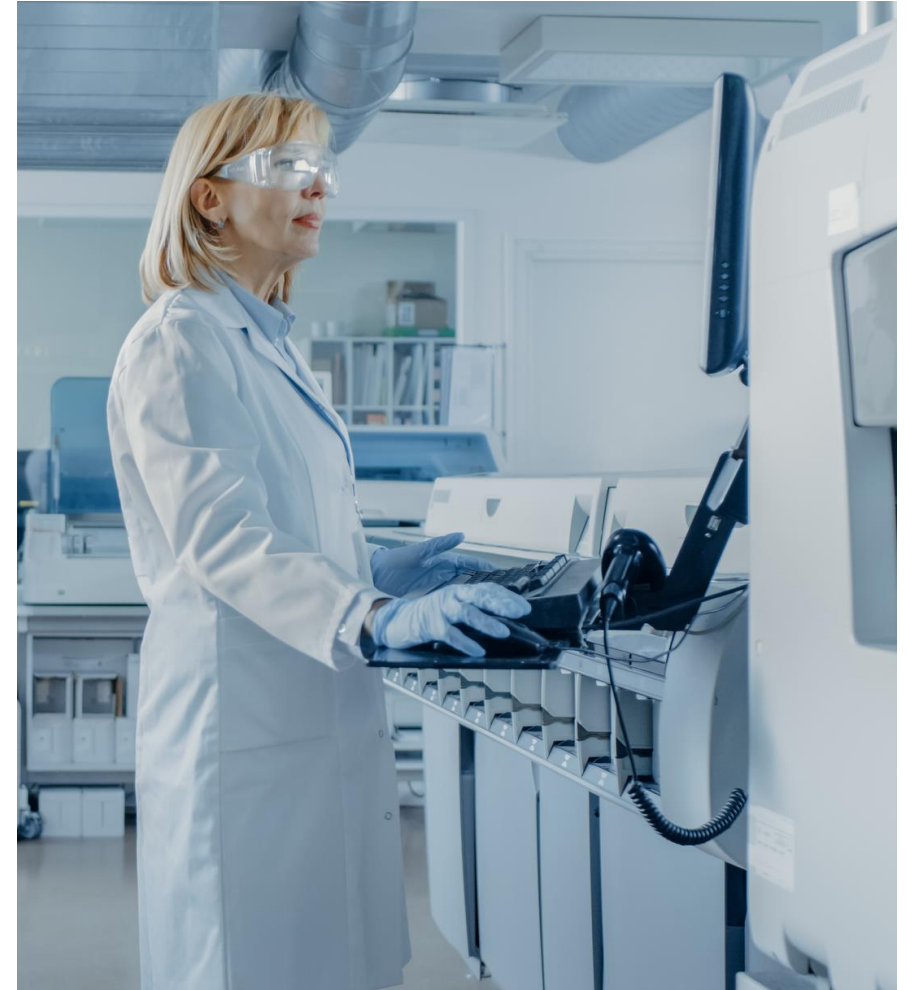
\*

### ❑ Expand Biomanufacturing capabilities

- SAN product lifecycle management
- Value through Quality – Transitions & DMF
- RNA therapeutics – generic & novel
- Two pillars – nucleases and proteinases

### ❑ Expand Molecular Tools capabilities

- Complete MDx workflow assembly
- Push new RT and Taq ++
- Hot Start / Formulations
- Expand to NGS variants



# Summary

## Drive Innovation

Leverage Discovery  
Understand the Market  
VOC-Product Lifecycle

## Expand the Portfolio

Novel unique products  
Fill in the workflow gaps  
Value through Quality

## Support the Products

Applications  
Technical relationships  
Work with customers



# Operations

Marit Sjo Lorentzen  
February 2023



# Operations

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**Organisation**

2

**Facilities, Equipment and Capacity**

3

**Scalability and Future Growth**

4

**Logistics**

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**Audits**

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**Summary**

# Organisation

## Personnel (15)

- Fermentation and Purification: 7.
- Filling and Shipments: 2
- Process Development: 2 – 3.
- Quality Control: 4.

## Recruitment

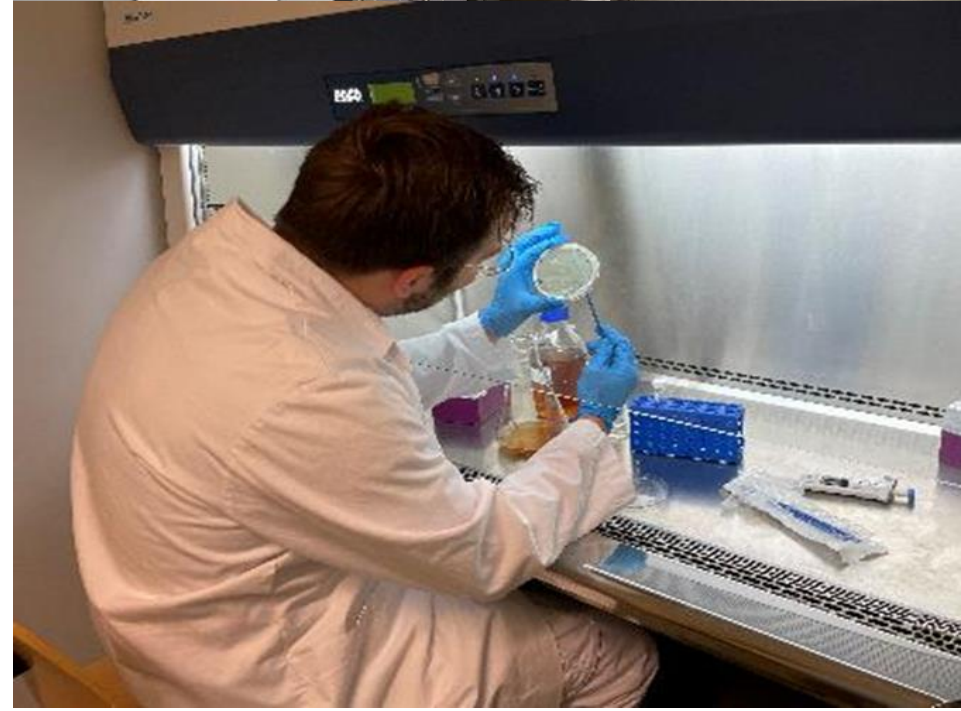
- Mainly University and University Hospital in Tromsø

## Competence

- Highly competent personnel
- Continuous internal competence building

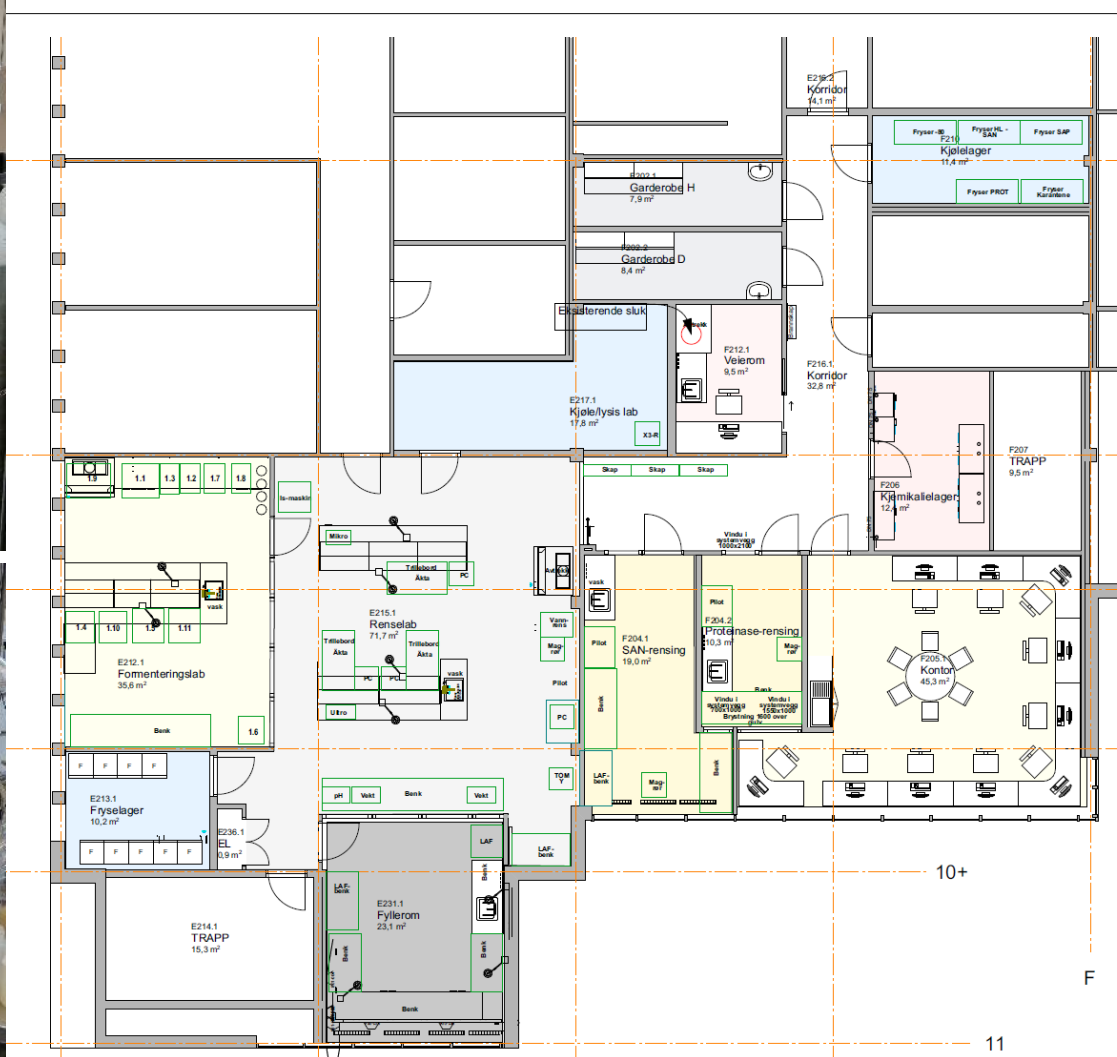
## QC department transfer to Quality Assurance during 2023

- cGMP requirements.



# Facilities

## Fermentation, Purification and Process Development



# Equipment and capacity

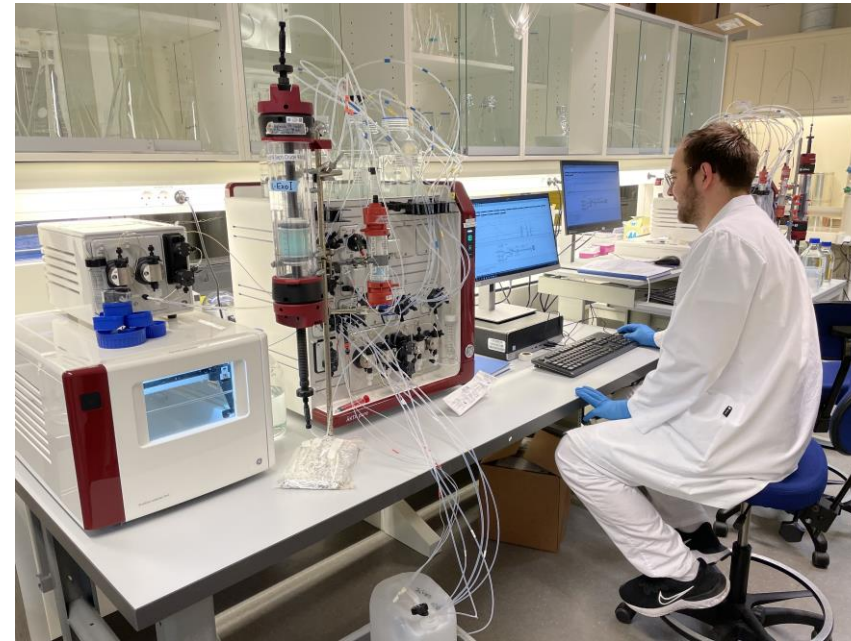
## Fermentation and purification

### Parallel lines

- Recombinant production in *E. coli* and *P. pastoris*.
  - Yield: kUnits – MUnits – BUnits (depending on product).
- Fermentors.
  - Internal and external (Contract Development Manufacturing Organisations).
- Purification systems.
  - Equipment dedicated Nucleases and Proteinase.
  - All downstream processes performed internally.
  - Backup systems: Qualified equipment in R&D.

### Capacity

- Currently at ~ 70 %.
- Shared equipment with Process Development.
- Well equipped for the next 2 – 3 years.
  - Possibility for growth internally.

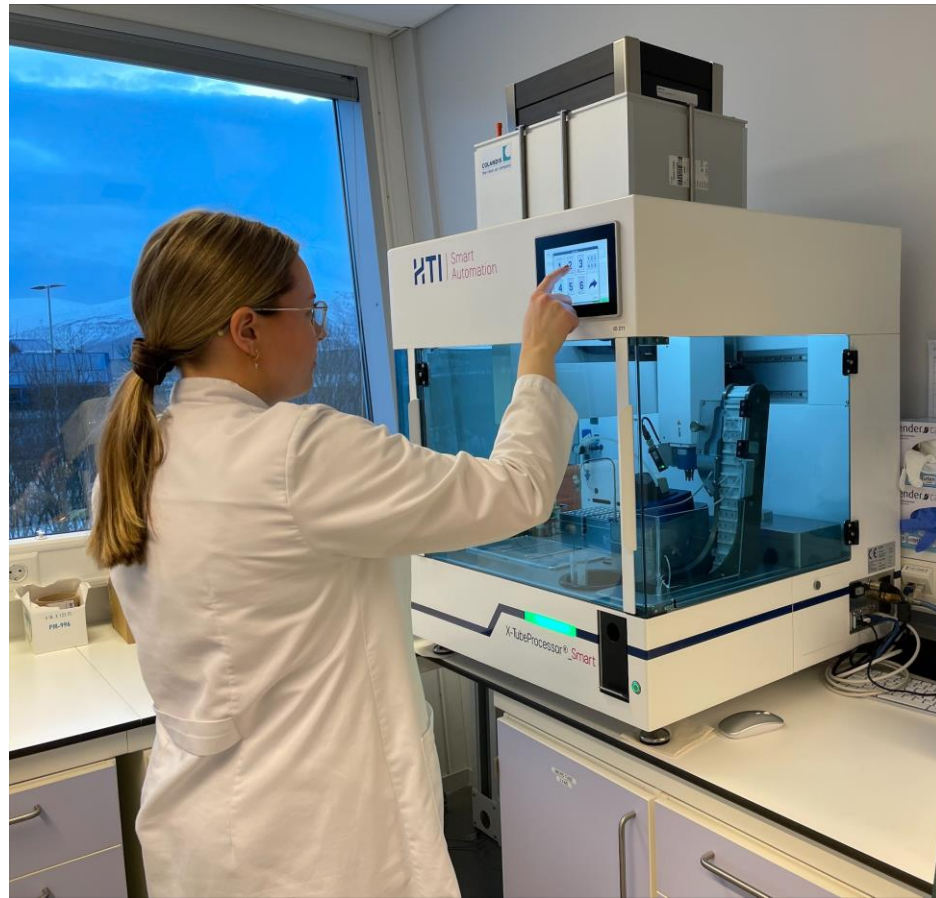


# Equipment and capacity

## QC and Filling

### Quality Control

- Separated from fermentation and purification.
- Shared equipment with R&D.



### Filling (always in Tromsø)

- Manual.
- Automated.

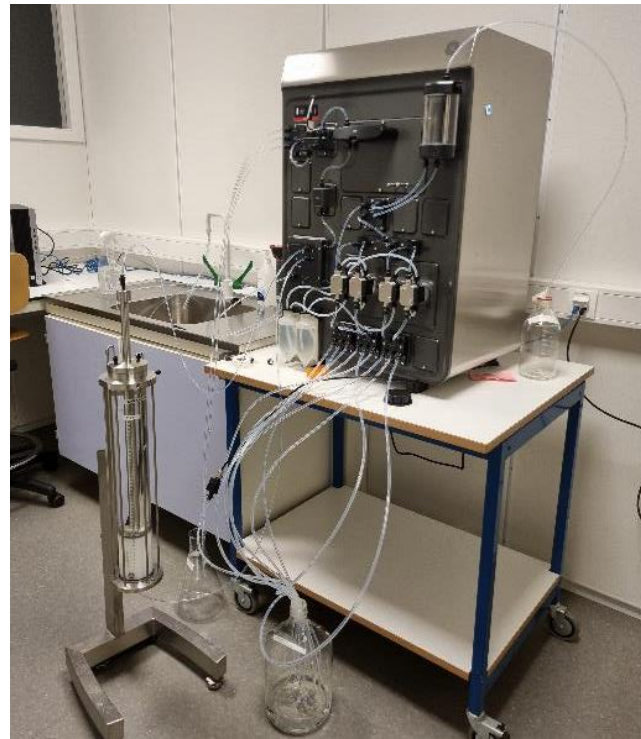
# Scalability

## Fermentation

- Up to 30 L in SIVA Innovation Centre (according to the Health Directorate).
- All products are scalable.
- rSAP and HL-SAN/SAN HQ/SAN HQ 2.0/M-SAN HQ at fermentation contractors (1 500 or 750 L).
  - Paras Biopharmaceuticals for SAN HQ.
  - Premises built for cGMP production.
  - Aiming at cGMP certification in 2024.

## Purification

- All products are scalable (internally).



# Future growth (fermentation)

## External CDMO's

- Pros:
  - No infrastructure or equipment investments.
- Cons:
  - Risk of compromising products (agreements in place).
  - Lack of complete control (cGMP requirements).

## Build own facilities

- Pros:
  - Complete control of premises, equipment and products.
- Cons:
  - Lack of competence.
  - Long timeframe.
  - Costs \$\$\$

## Buy ready to go facilities

- Pros:
  - Complete control of premises, equipment and products.
  - Competent personnel.
  - Up and running in short time.
- Cons:
  - Costs \$\$\$?



# Logistics

## Standard order

- Standard products shipped from AZ's warehouses.
  - Cryo Store in Joure, Netherlands, for EU and Asia.
  - Percorso in Philadelphia, USA for US and Japan.
  - Tromsø, primarily for Norway.

## Customer reply

- Within 48 hours.

## Packing and shipments to warehouses

- Regularly to
  - Netherlands, EU
  - Philadelphia, US

## Shipments to customers

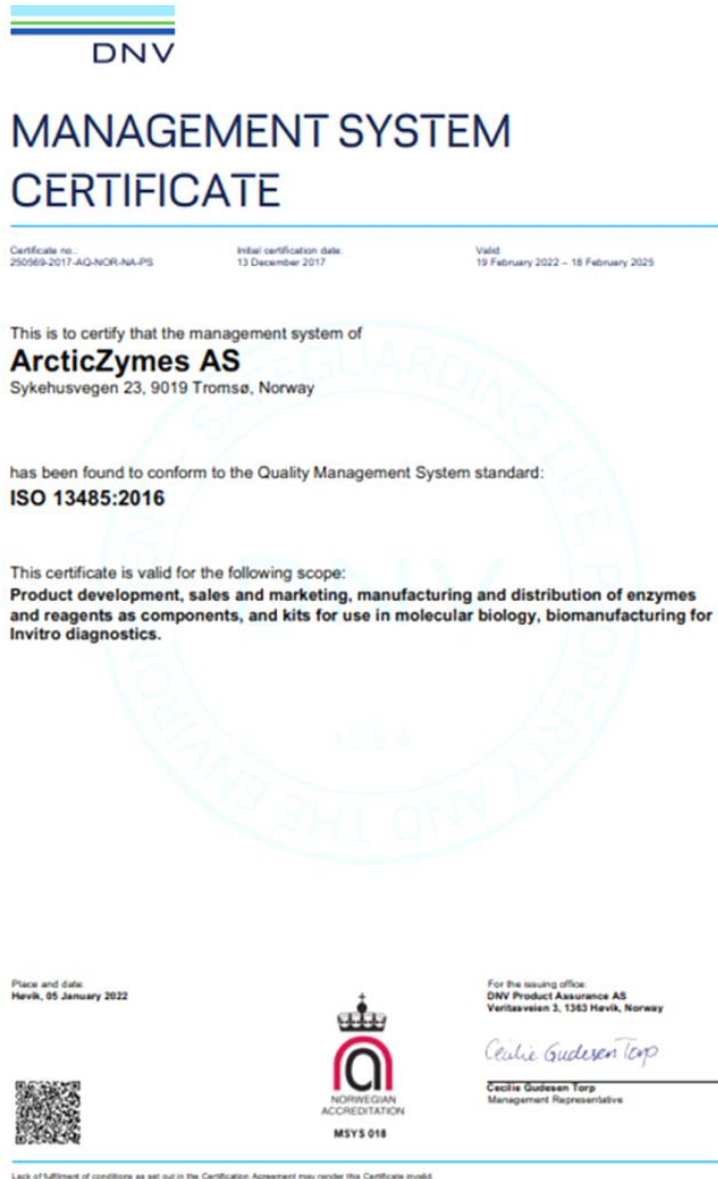
- Normally within one working day from external warehouses (Netherlands and US).

## Custom order

- Customised products and/or customised delivery methods.
  - Normally from AZ's head quarter.
  - Might require production of new dilution lots, quality controls and filling.



# Audits



## ISO 13485

- Recertification every 3<sup>rd</sup> year (last in 2021).
- Surveillance (December 2022).
  - No critical deviations.

## Customer audits (mainly for Bioprocessing)

- Ten audits last two years
  - ISO 13485 and relevant cGMP guidelines.
- Results
  - No critical deviations.
  - Continuous cGMP competence.
  - Continuous improvement of QMS.

# Summary

## Capacity

Facility  
Equipment  
Personnel

## Scalability

All products

## Future growth

Internally  
CDMO's  
Buy?



# Commercial

Dirk Hahneiser  
February 2023





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**Team**

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**Sales Cycle**

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**Areas for improvement in 2023**

4

**Sales by Geography 2022**

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**Market Potential**

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**Drug Master File (DMF)**

7

**Marketing & Sales Activities**

8

**Summary**

# Commercial Team

## Business Development



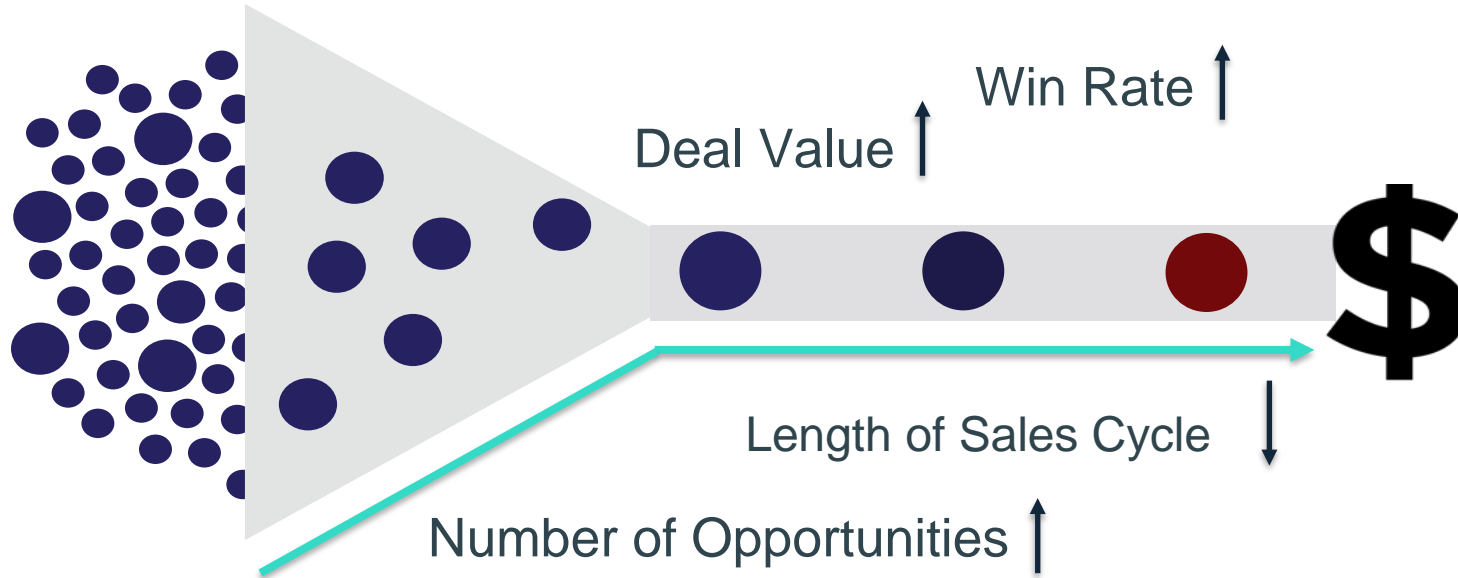
## Marketing & Customer Service



# The Sales Process & Cycle

## PIPELINE MANAGEMENT

## OPPORTUNITY MANAGEMENT



- Continuously feeding the pipeline
- Working with numerous customers in various stages of the sales cycle
- Rigorous Sales Management Process
- DMF & Application Data help accelerate cycle

**Lead Generation & Qualification**

On-Going

**Discovery**

6-18 Months  
Multiple Competitors  
Identifying Stakeholders  
Uncovering Needs  
Clarifying Technical Specs  
Regulatory (DMF)  
Application Data  
Pitching Value Proposition

**Trial/Audit**

1-12 Months  
Several Competitors  
Small - Mid Scale Sampling  
Technical Sales Support  
Auditing Supplier  
Application Data

**Validation/ Verification**

6-24 Months  
None to few Competitors  
Large Scale Batch  
Testing

**Negotiation**

1-3 Months  
Pricing  
Terms & Conditions

**Closed Won/Lost**

# Key areas to improve in 2023

## Commercial Excellence

- Execute price increase of **8.5%** from January 1, 2023
- Execute **Shipping & Handling** fee structure from Oct. 1, 2022
- Utilizing analytics in **Power BI**
- Drive **Opportunity Management** leveraging CRM
- Accelerate **sales cycle** & improve **conversion rate**
- Use **regulatory documentation** (DMF) as competitive advantage
- Continue to **build & invest** into a high performing team

## Demand Generation

- Laser sharp focus on generating new business with **Key Accounts**
- Aggressively **take share** in both, Biomanufacturing and Molecular Tools
- Update & leverage digital capabilities to **create leads**
- Attend selective trade shows to create **awareness and leads**
- Optimize **product launch** strategy and execution
- **Capitalize** on Asian opportunity
- Explore **new, adjacent markets**
- Hire **additional resource** for North America

## Collaboration

- Closer collaboration between **Market Development Managers and R&D** community
- Market Development Managers **key drivers** in new product launch initiatives
- Product ideation and development with **KOLs**
- Oslo lab to **improve and create** content around **workflows and applications**

# 2022 Sales by Geography

Even split between North America and Europe, Asia needs more attention



North America  
45%

Europe  
44%

Asia  
11%

# Market Potential

Our partners who profit from our expertise

## Biomanufacturing

Focus on Cell & Gene Therapies

### Market Size 2022 – 2030

13.85 - 75.6 Bil USD (CAGR 23.6% 2022-2030)

## Bio-manufacturers

Manufacturers of viruses for gene therapy and vaccines, cell therapy, and bio-products.



## Diagnostic Companies

Enzymes for driving assay technologies.

## Molecular Tools

Molecular Research & Diagnostics

### Market Size 2022 – 2027

23.2 – 30.4 Bil USD (CAGR. 5.4% 2022-2027)

# Marketing & Sales Investments & Activities

To support lead and demand generation

## Digital Marketing

- ◆ Transform web presence from informational to interactive and lead generation tool

## Trade Shows

- ◆ Participate at selected, most important trade shows to increase awareness and leads

## Improved Analytics

- ◆ Leverage Power BI and CRM tool to drive sales and pipeline/opportunity management

## Sales Process & Management

- ◆ Rigorous execution to drive all levers and close opportunities successfully

# Drug Master File

## What is it?

- A drug master file (DMF) is a **submission to the FDA** that contains confidential, detailed information about facilities, processes, or articles used in the **manufacturing, processing, packaging, and storing of one or more human drugs**. It is used to provide information to the FDA about these aspects of a drug product without revealing trade secrets to the customer.

## For which product do we submit?

**SAN HQ**

In short, the benefits of having a DMF are:

- Listen to voice of customer
- Improves AZT credibility and reputation
- Help customers streamline drug development and approval process
- Accelerate sales cycle
- Levels playing field against major competitors

# Summary

## Leverage Market Potential

- Grow with and take share in Molecular Tools & Biomanufacturing
- Tap into Asia (China)
- Explore new adjacent markets

## Prioritize Demand Generation

- Winning with Key Accounts
- Get in early with highly innovative incubators
- Improve lead generation through digital capabilities

## Accelerate Sales Cycle

- Continue to build opportunity pipeline
- Improve probability and speed of conversion
- Leverage DMF & Application Data to speed up cycle