

BRAIN Biotech AG

Creating a #BiobasedFuture

BRAIN CMD 2024

Alexander Pelzer, VP Head of Research & Development

Andrew Ellis, VP Fermentation & Technology

Unique technology & production platform

Zwingenberg, December 12th, 2024



WE SUPPORT



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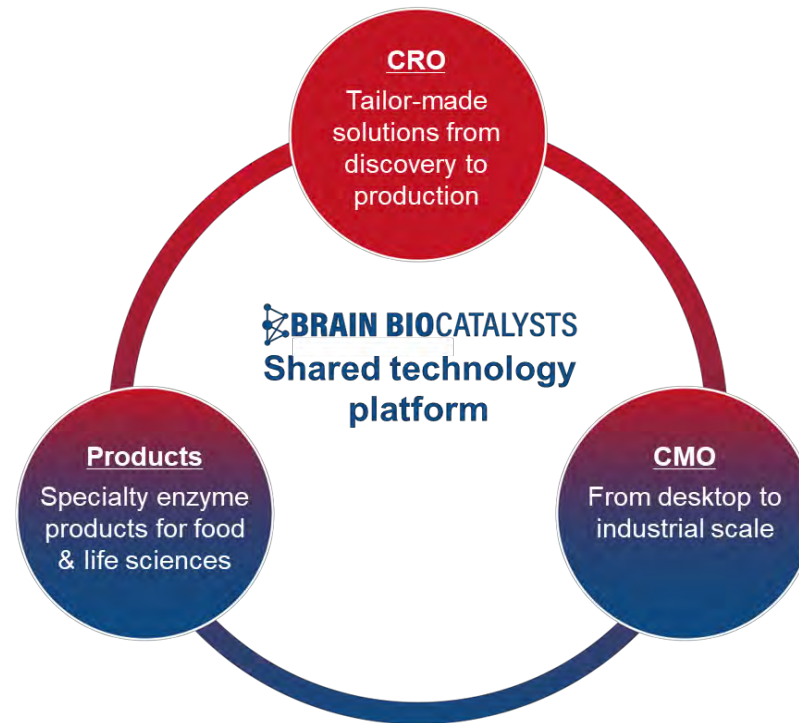
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A Shared Technology Platform as the Engine of Business

the foundation of BRAINBiocatalysts' unique customer offering



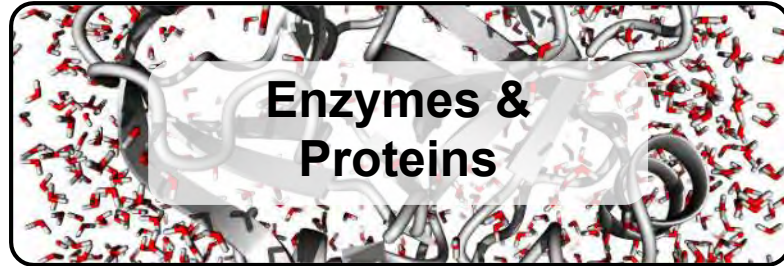
Advanced Research & Development Platform

Tailor-made solutions from discovery to production



Research & Development Focus Areas Drive Innovation

advanced technology portfolio designed to deliver Biosolutions



Enzyme Technology

Enzyme discovery
Enzyme engineering



Microbial Strain Development

Bioprospecting
Strain engineering
Production strain development



Bioprocess Development

Fermentation development
Downstream process development

Bioinformatics | Analytics | QM | IP

Our inspiration

More than 3.5 billion years of innovative solutions in nature



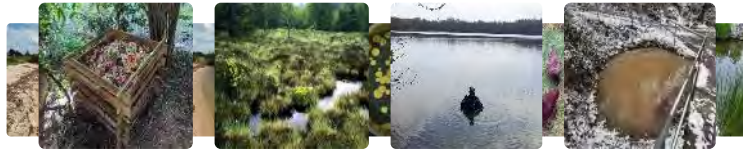
The future is digital

Nature is the role model. The methods are digital.



MetXtra™ – A Highly Sophisticated Technology Platform for New Enzymes

streamlined process for the identification of novel enzymes for application



Digitized biodiversity that continuously evolves

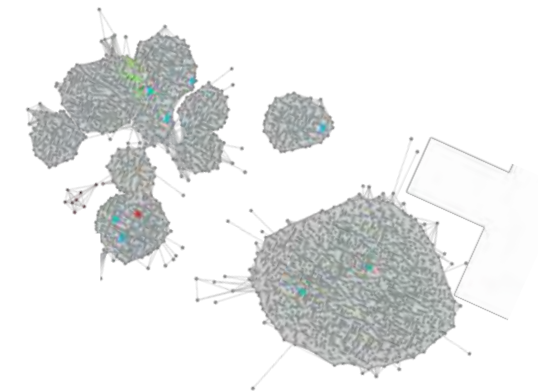
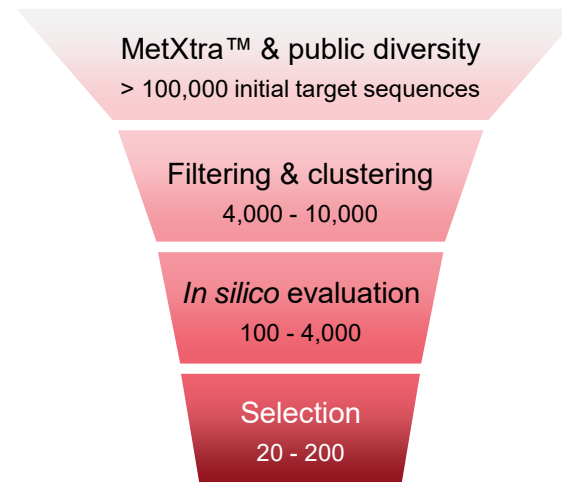
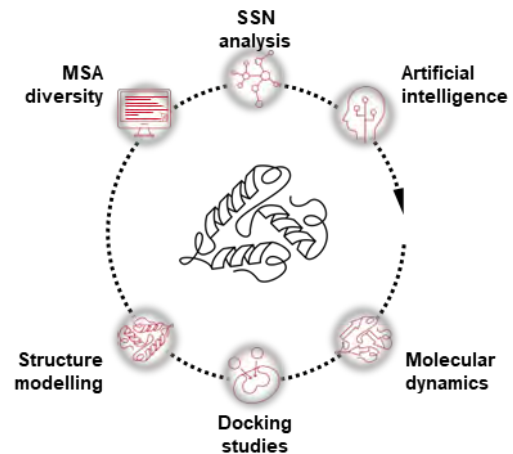
99.8 % of the protein sequences are novel

MetXtra™
enabling enzyme solutions



Toolbox for AI generated enzymes

Enzyme fine tuning via MetXtra™ database



▶ **Advanced technology for discovering novel natural & synthetic enzymes for application**

Case study: Truly New Enzymes Discovered in MetXtra™

discovery of a proprietary CRISPR Cas-like genome editing tools



Powerful tool for production strain development



Industrial enzyme production strains:

- *Escherichia coli*
- *Bacillus subtilis*
- *Komagataella phaffii* (*P. pastoris*)
- *Aspergillus niger*



Industrial biomolecule production strains:

- *Saccharomyces cerevisiae*
- *Kluyveromyces lactis*
- *Torulaspora delbrueckii*
- *Pseudomonas sp.*

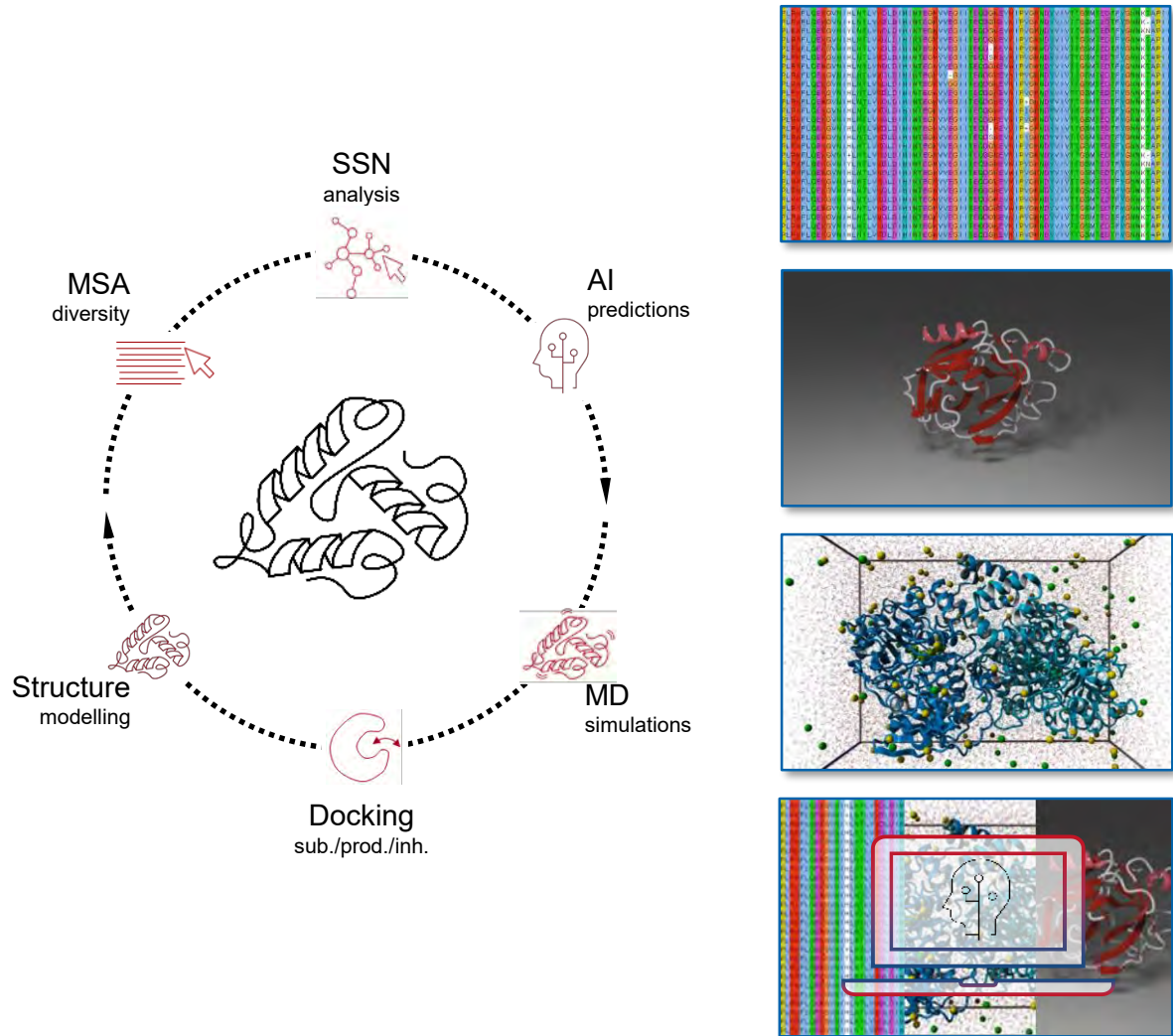


▶ **Genome editing tool BMC enables precise & fast production strain development**

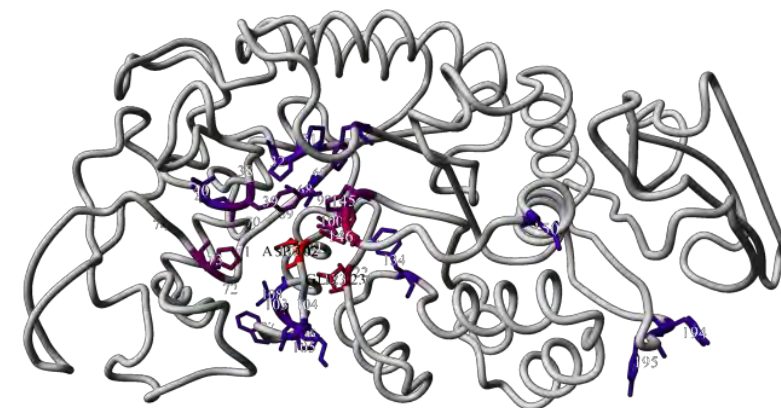
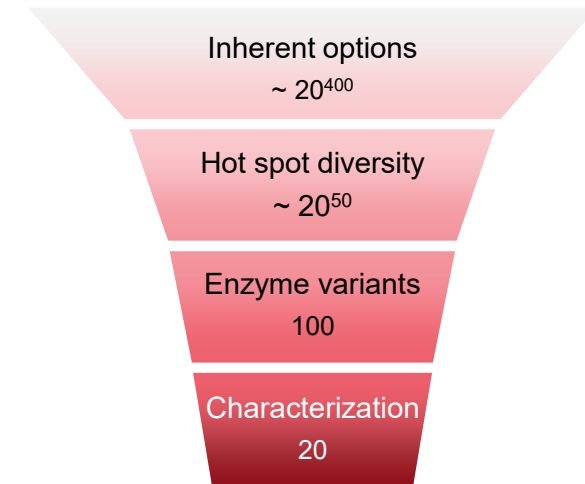
▶ **Significantly reduces production strain development time**

Optimization of Enzymes for New & Improved Applications

bioinformatics-guided approach for efficiently creating improved enzyme variants



Reducing possibilities to what is beneficial

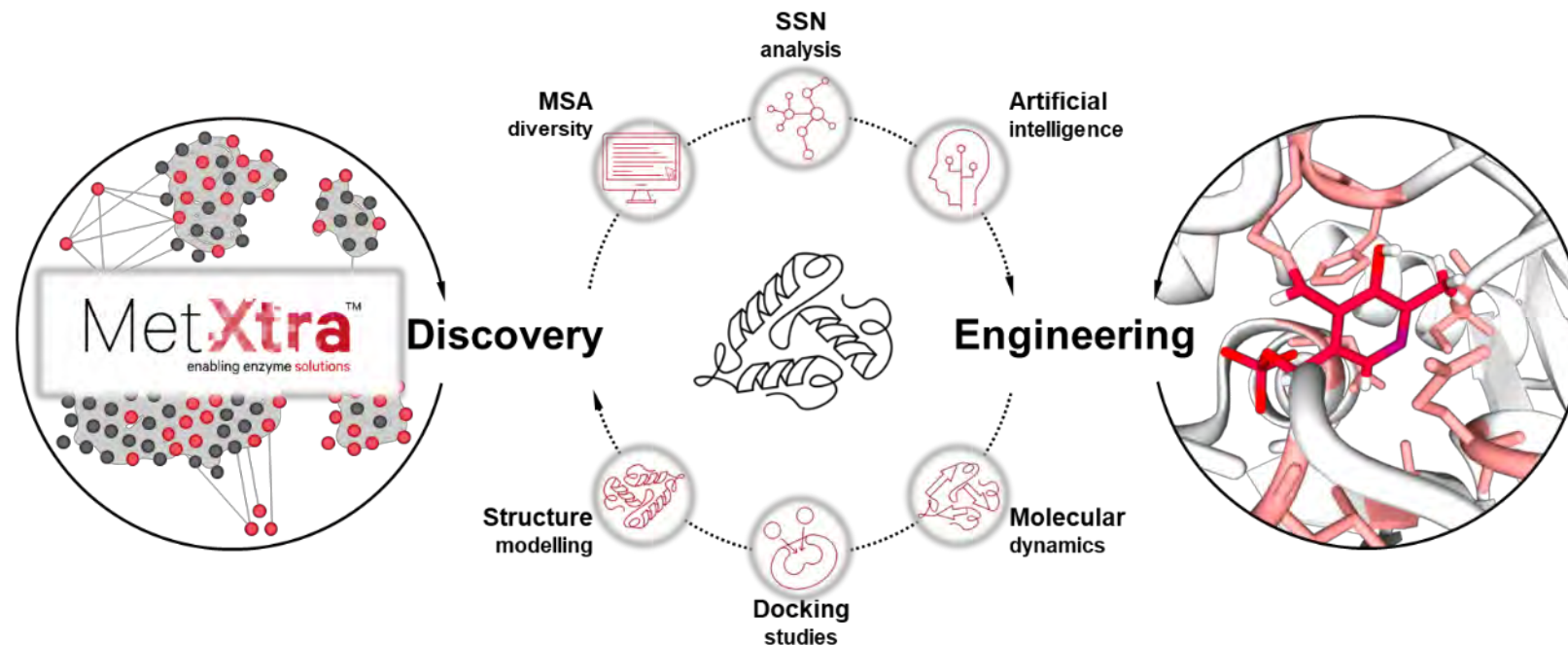


Red/purple are the best positions to achieve enzyme optimizations

Integration of Enzyme Discovery & Engineering Drives Success

providing the best enzyme - regardless of the method

- ▶ Enzyme discovery & engineering are equally powerful tools for providing novel enzymes
- ▶ Having both available greatly increases the chances of success

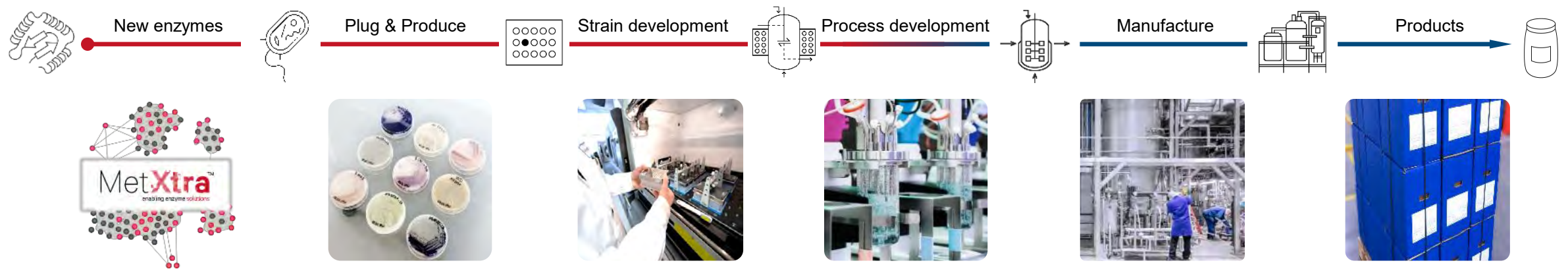


- ▶ **Integrated strategy to fuel enzyme innovation & produce market-leading enzyme solutions**

Industrial Enzyme Production Designed from Start to Finish

end-to-end solution for enzymes

- ▶ Even the most exceptional enzymes must be producible at scale
- ▶ Powerful industrial production strains & bioprocesses are the door opener for commercial enzyme production



- ▶ **Enzyme development is considered in a comprehensive and end-to-end manner**

Development of Robust Industrial Production Strains & Processes

an integrated platform for production strains & bioprocess development

Industrial enzyme production strains

A. niger HE

Bioprocess development platform



Plug & Produce:

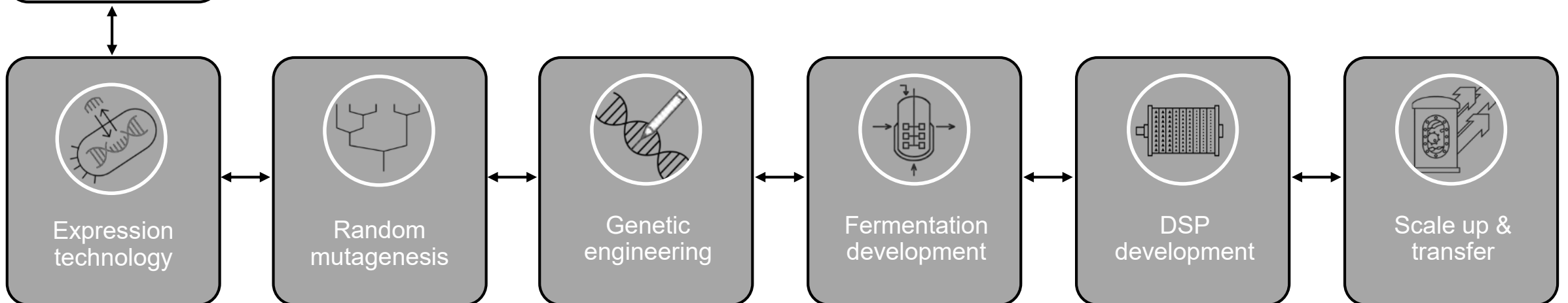
- Rapid testing of enzyme producibility

Production strains:

- Bacteria: *E. coli*, *B. subtilis*
- Yeast: *P. pastoris*, *Y. lipolytica*
- Fungi: *A. niger*

Process design & development:

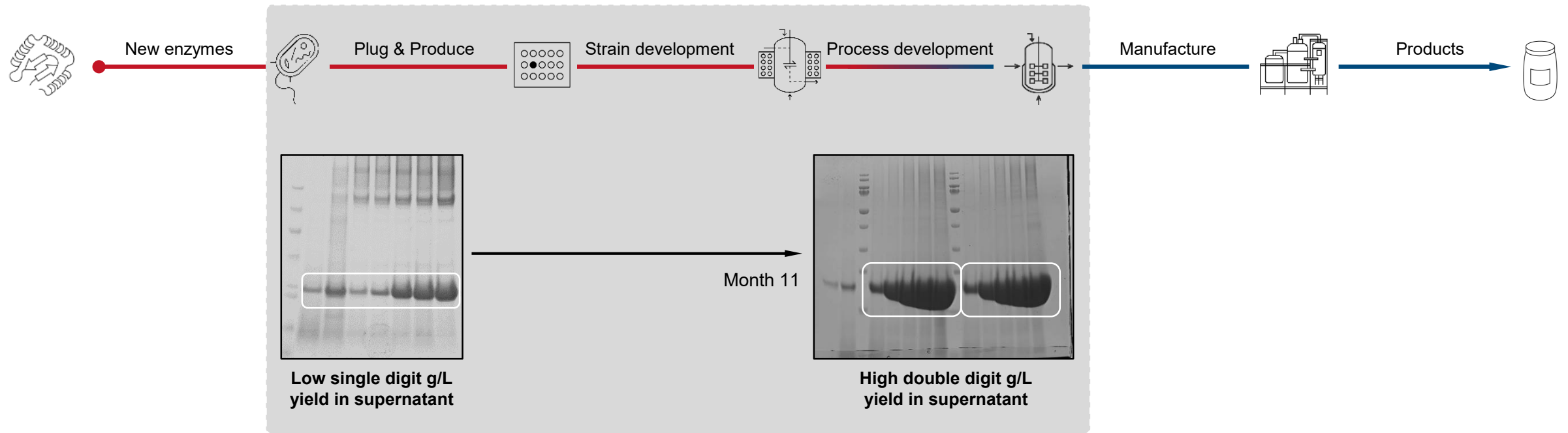
- 1 mL to 200 L fermenters
- DSP development & product purification
- Full analytical support
- Experience: wide range of production strains
- Extensive knowledge of industry regulatory & quality requirements



Case Study: Integrated Platform for Strains & Bioprocess Development

development of robust industrial production strains & processes


- ▶ Targeted & product-specific optimization to achieve high production yields

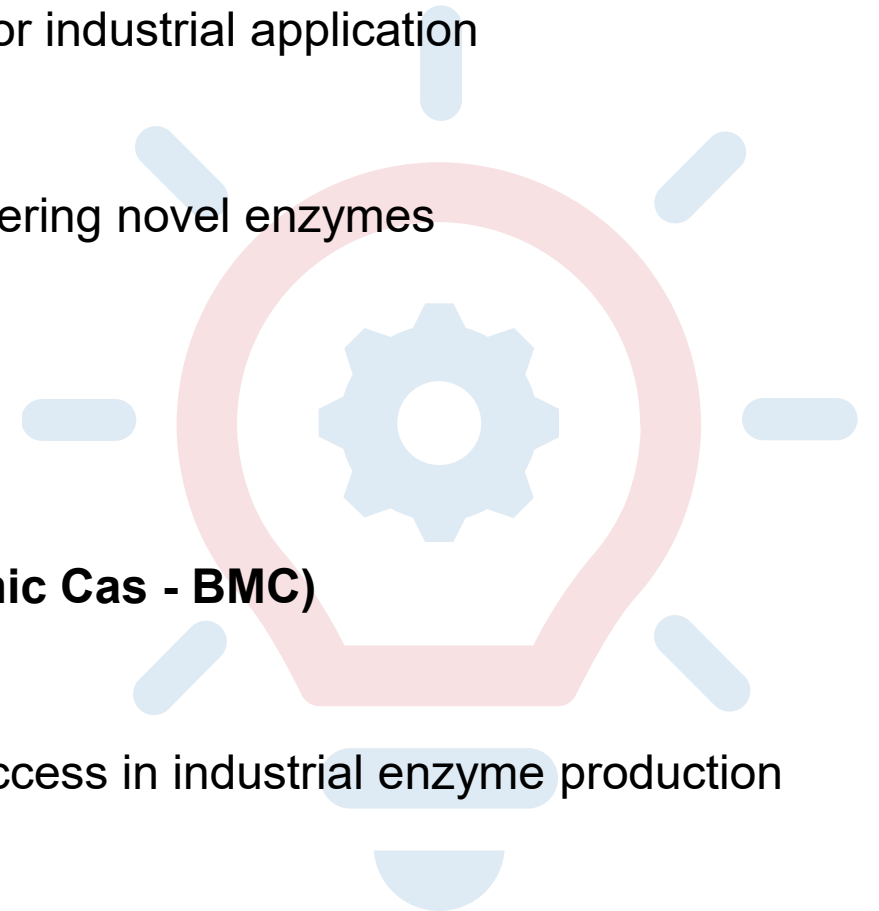


- ▶ The integrated platform for production strains & bioprocesses leads to high enzyme yields

Core Strengths of the Research & Development Platform

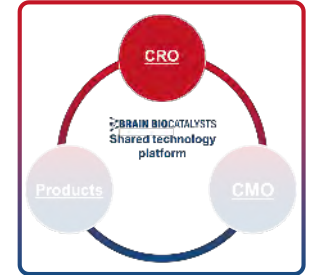
Highlights

- ▶  **MetXtra™**: Identification of **unique, high-performance enzymes** for industrial application
- ▶ Integrated **enzyme discovery & engineering** drive success in delivering novel enzymes
- ▶ High-yield **industrial production strains**
- ▶ Unique tools for production strain development (**BRAIN Metagenomic Cas - BMC**)
- ▶ Integrated **production strain & bioprocess development** drive success in industrial enzyme production



Contract Research Services – Range, Modularity & Flexibility Make it Special

delivering tailor-made solutions across various industries



Fermentation Manufacturing Platform

From desktop to industrial scale

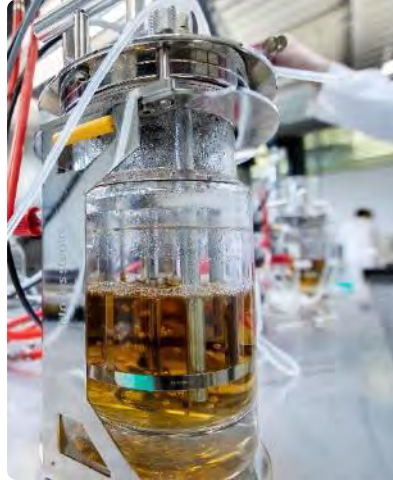


State-of-the-art Manufacturing Capabilities

perfectly suited to speciality enzymes

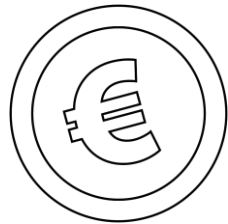
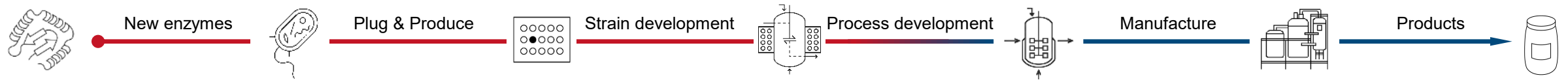
Capabilities:

- Pilot scale fermenters (≤ 750 L)
- Manufacturing scale (2×10 m³)
- Subcontractor network (15 - 50 m³)
- Comprehensive down-stream processing
- Sophisticated chromatography systems
- Compatibility with multiple strains
- Options for product stabilisation
- Talent: scientists, engineers & technicians

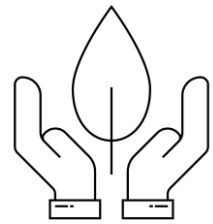


Design-for-Manufacture Framework

a key competitive differentiator for BRAINBiocatalysts



Process Economics



Sustainability



Regulations



Intellectual Property



Quality

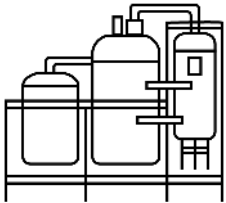


Time

Fermentation: Maximising Product Margins

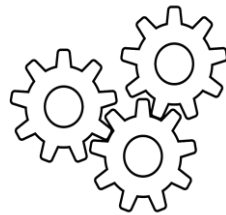
a critical success factor for driving EBITDA growth

Capacity



- Two fully functional 10 m³ fermenters with recent breakthroughs in increasing throughput
- Flexibility through an expanding range of EU fermentation partners

Productivity



- Strain development is essential for maximising product margins
- Continuous fermentation optimisation is a key enabler
- Down-stream process optimisation is another important driver

2023/24 productivity increase target:

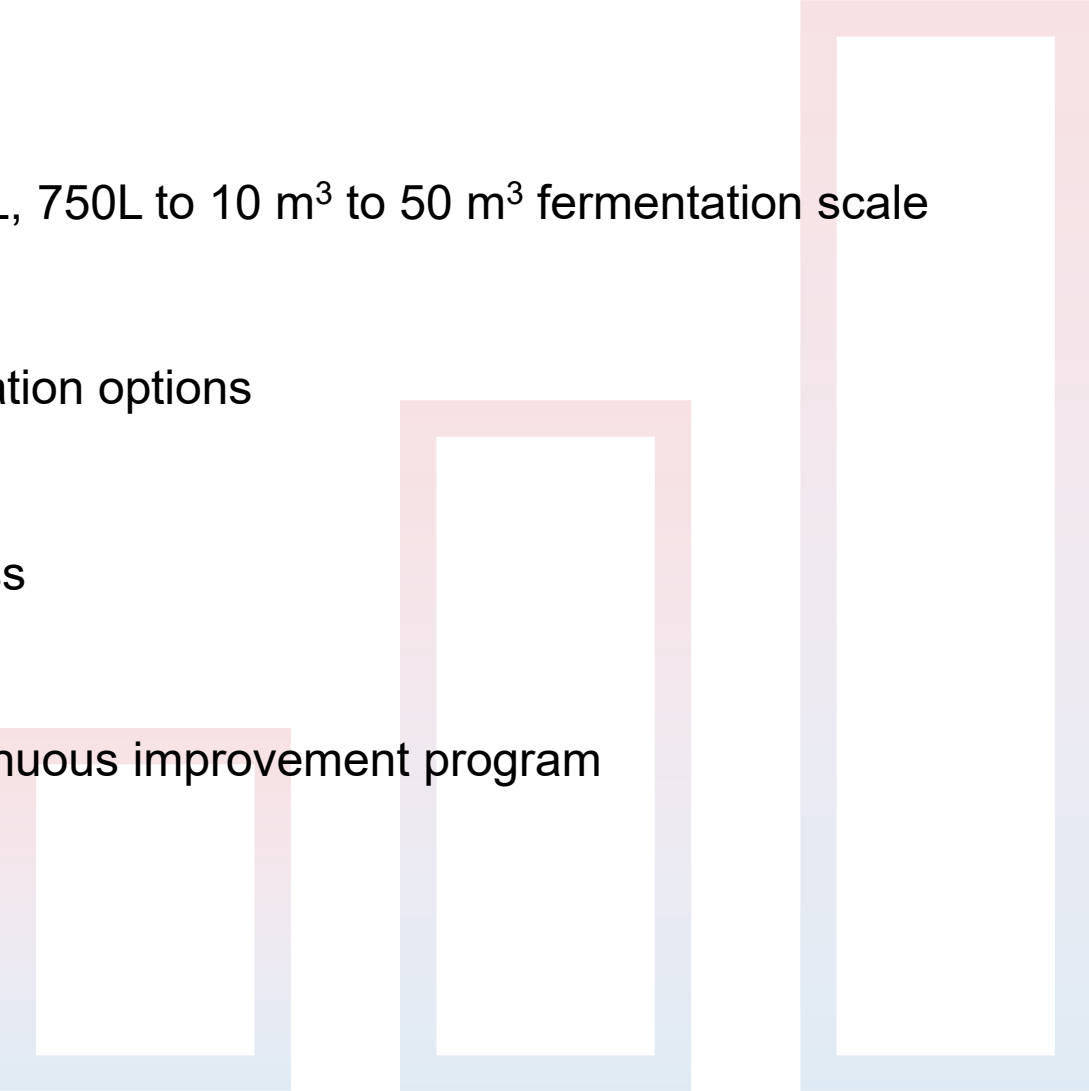
- ✓ > 10% reduction in fermentation material cost
- ✓ > 25% increase in process productivity

2024/25 and beyond:

- ✓ Ongoing focus programs to drive productivity

Core Strengths of the Fermentation Manufacturing Platform

Highlights

- ▶ State-of-the-art **manufacturing capabilities** utilizing 50L, 750L to 10 m³ to 50 m³ fermentation scale
 - ▶ Extensive **downstream processing** and product purification options
 - ▶ **Design-for-manufacture framework** maximises success
 - ▶ A strong focus on **margin improvement** through a continuous improvement program
- 

Shared Technology Platform Drive Revenue Streams

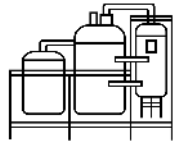
monetizing our R&D and fermentation capabilities

▶ Contract Research (Organization) Services (CRO)



- Using the R&D platform to develop tailor-made biotech solutions for customers
- Project revenues and license deals

▶ Contract Manufacturing (Organization) Services (CMO)



- Development & scale-up of fermentation process for individual customers
- Leading to routine enzyme manufacture

▶ BRAINBiocatalysts Product Development



- Development of specialty enzyme products for market niches
- Exciting and extensive pipeline of new enzyme products

Case Study

Hydrolase enzyme product for production of a speciality carbohydrate [CRO/CMO]



Customer need

- A customer requirement for development of an enzyme to modify a low-cost carbohydrate to a high-value fibre ingredient

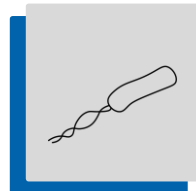


Development approach



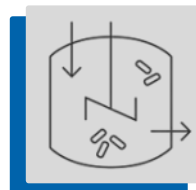
Enzyme discovery

Enzyme identified from the MetXtra™ technology platform



Strain development

Bacterial strain successfully developed by BRAINBiocatalysts



Bioprocess development

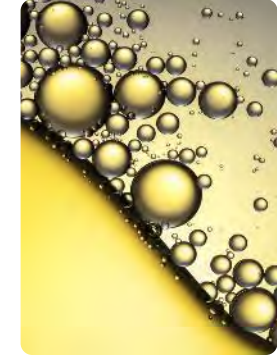
Fermentation and DSP optimised for scale up by BRAINBiocatalysts

Results

- Exclusivity and commercialisation agreement in-progress

Case Study

Lipase product for use in manufacture of a speciality food ingredient [Product Development]



Market need

- A market requirement for an enzyme to modify a lipid substrate to produce a speciality food ingredient

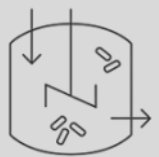


Development approach



Strain development

Yeast strain developed for production of the lipase identified using bioinformatics



Bioprocess optimisation

Fermentation and DSP strategy optimized for 10 m³



Regulatory approval

Submission of US FDA GRAS notice and product launch







Results

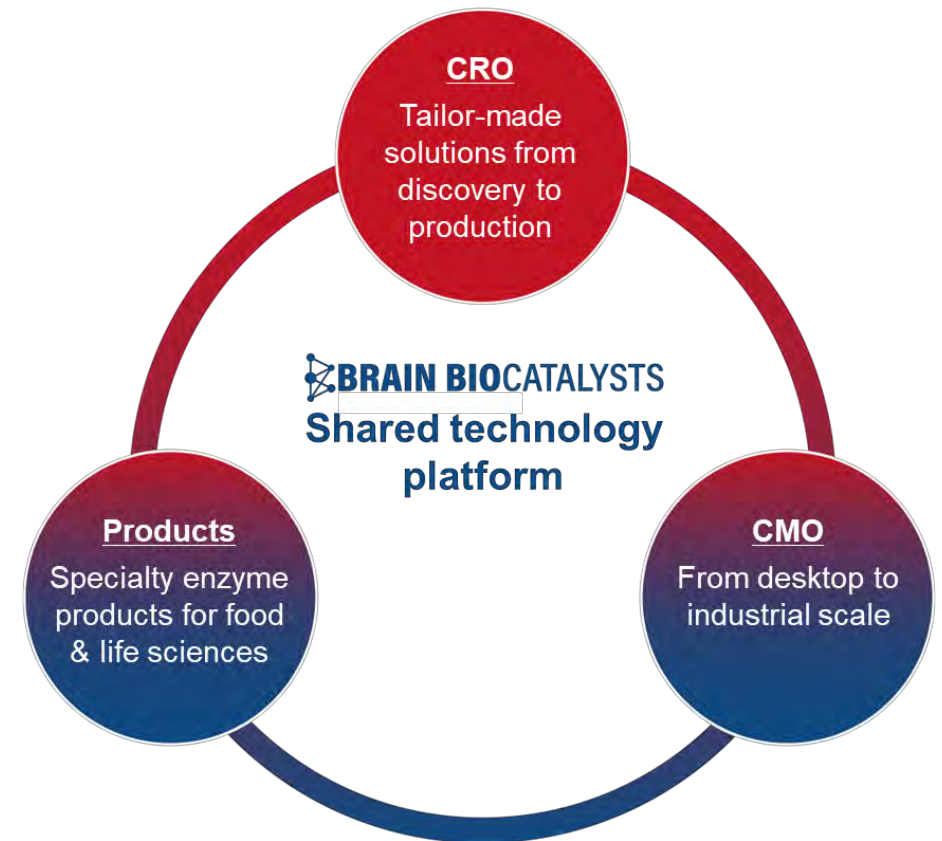
- Lipase product launched to customers in multiple countries

A Shared Technology Platform as the Business Engine

the foundation of BRAINBiocatalysts unique customer offering



-  **Enzyme discovery & engineering**
-  **Industrial production strains & strain engineering**
-  **Bioprocess development & scale-up**
-  **Extensive fermentation capability**
-  **Enzyme product development**
-  **Quality & regulatory expertise**



Thank you very much for your interest.



BRAIN Biotech AG

Darmstädter Straße 34–36
64673 Zwingenberg, Germany
+49 (0) 6251-9331-0
www.brain-biotech-group.com

Biocatalysts Ltd.

Unit 1, Cefn Coed,
Parc Nantgarw, Cardiff
CF15 7QQ, Wales, UK
+44 1443 843712
www.biocatalysts.com

Your contacts:

Alexander Pelzer, VP Head of
Research & Development

Andrew Ellis, VP Fermentation &
Technology

Martina Schuster, IR
+49 (0) 6251-9331-69
IR@brain-biotech.com

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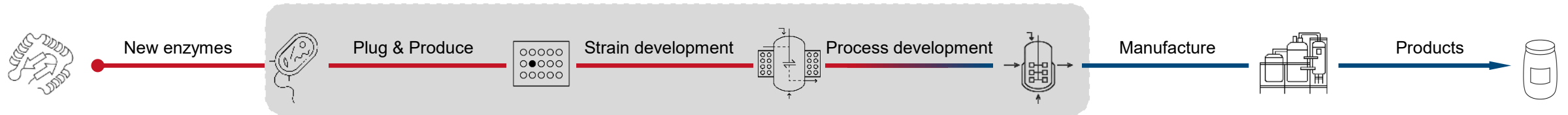
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Case Study: Integrated Platform for Strains & Bioprocess Development

development of robust industrial production strains & processes

- ▶ Targeted & product-specific optimization to achieve high production yields

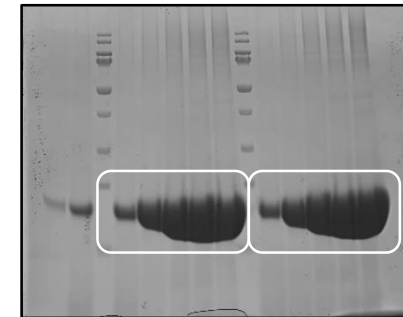
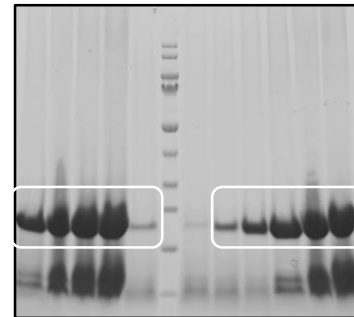
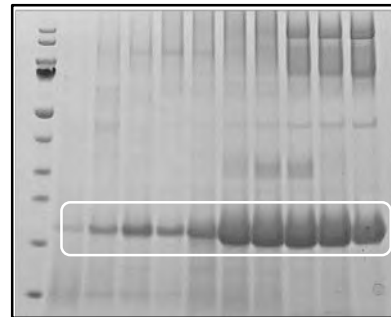
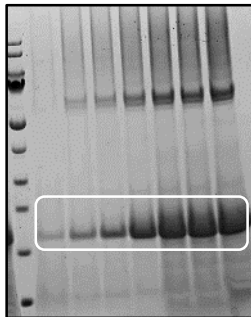
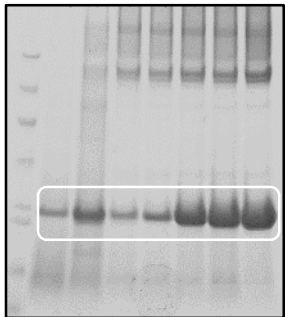


Month 1

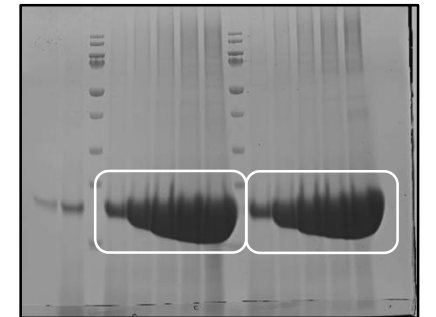
Plug & Produce *A. niger* - Strain generations

Month 10

Single digit g/L in supernatant



Double digit g/L in supernatant



- ▶ The integrated platform for production strains & bioprocesses leads to high enzyme yields