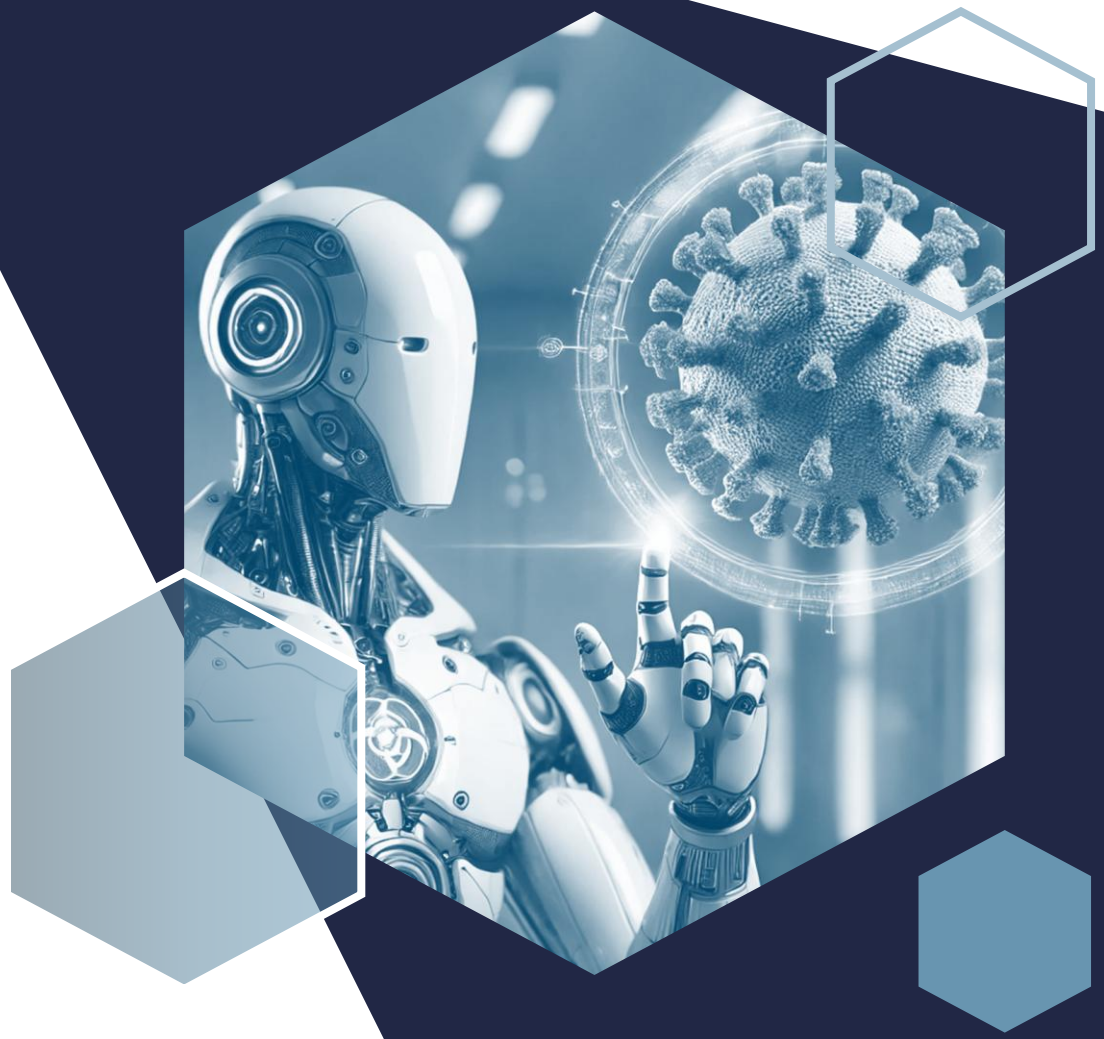
RoLink BIOTECHNOLOGY



ART OF THE KILL

Rapid Response UV inactivation

Roland Heténi MD

CEO

Problem Statement

Rapid Response

need for vaccines

$ $ $ $ $ $

R&D reagents

Low Yield

Chemical/heat inactivation

$ $ $ $ $ $

80% loss

proteins/RNA/DNA damaged

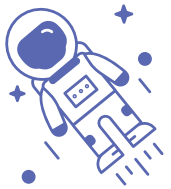
BSL-4

☣ ☣ ☣ ☣ ☣

$ $ $ $ $ $

51

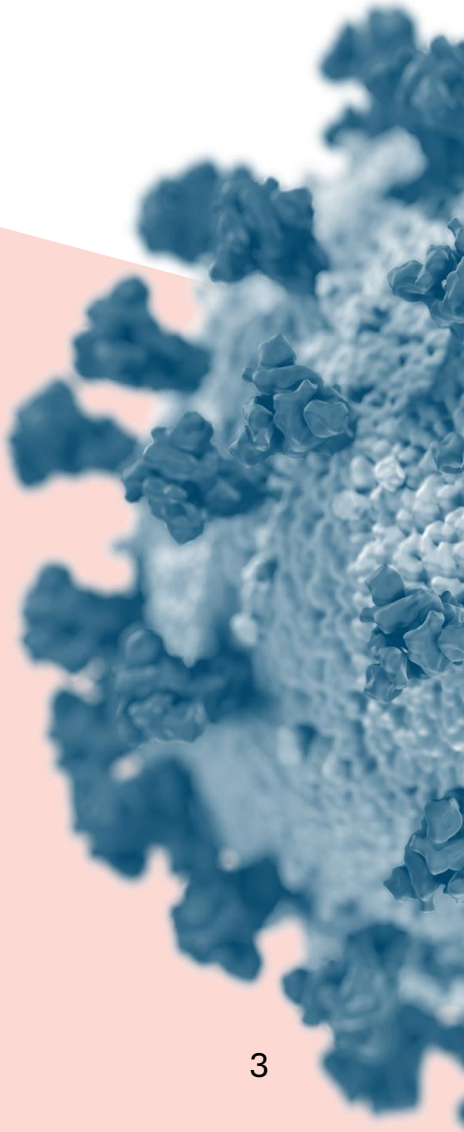
Ebola, Marburg
Nipah, CCHFV



BSL-4 operators are rarer than astronauts — RoLink makes them scalable.

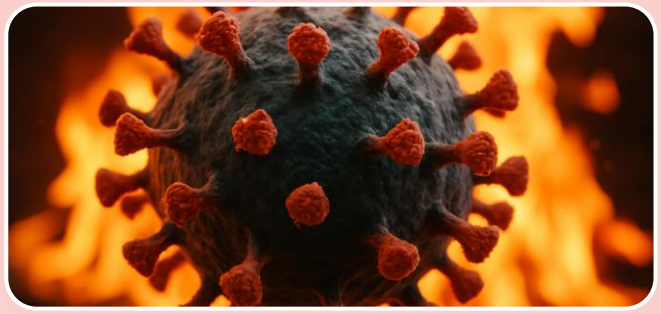
Market Need

We need viruses.
Safely.
But cheaply. Efficiently.
In large quantities.



Market Opportunity

RoLink BIOTECHNOLOGY



Viral Inactivation Market

$0.72B (2024)

→

$1.4B (2030)

CAGR: 11.6%

Virus-Like Particles (VLPs)

$3.9B (2024)

→

$10.5B (2034)

CAGR: 10.4%

Total Addressable Market

Vaccine Development – $63.2B

Diagnostics – $21.3B

Virology Research – $5.6B

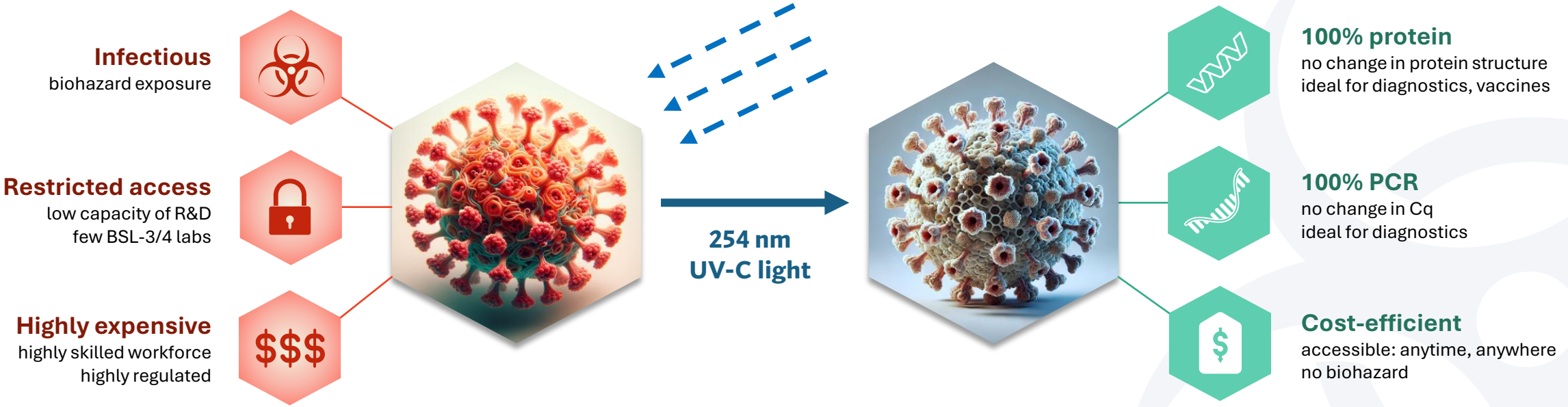
Biotech & Pharma – $4.8B

TAM: $94.9B

The Insight Partners, Donaldson, Univercells

Our Solution

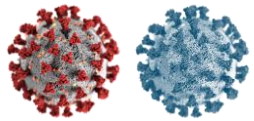
Complete inactivation, 100% intact virus



IP: PCT/HU2025/050010 + 1 new

Figure 1. UV-C Light Inactivation of Viruses for Safe Research and Vaccine Development. UV-C light inactivation of viruses at 254 nm effectively turns "off" the infectious properties of the virus while preserving the structural integrity of viral proteins. The illustration demonstrates the transition of an active, infectious virus (left) being exposed to UV-C light, resulting in an inactivated virus (right) suitable for safe use in research and vaccine development. This process ensures the virus is rendered non-infectious, marked by the "OFF" switch, while maintaining the critical proteins necessary for vaccine efficacy, as indicated by the intact structure on the right.

Intact proteins



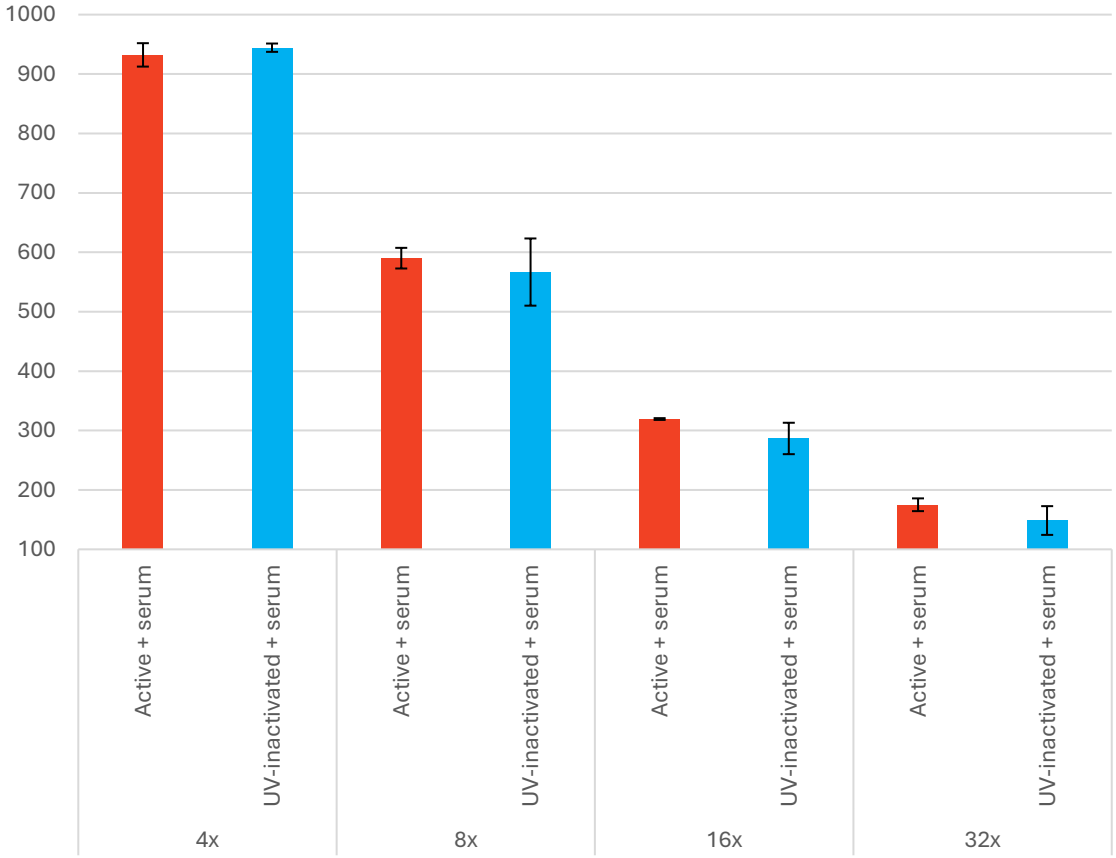


Figure 2. Comparison of ELISA Reactivity Between Active and UV-Inactivated SARS-CoV-2 RBD Antigen Across Serum Dilutions. The bar chart presents a comparison of Enzyme-Linked Immunosorbent Assay (ELISA) results measuring the concentrations of the Receptor Binding Domain (RBD) antigen from active and UV-inactivated SARS-CoV-2 virus in serum samples. The data is organized by the dilution factor of the serum (4x, 8x, 16x, and 32x). It shows the antigen concentration for samples with active virus and serum and those with UV-inactivated virus and serum, across the different dilution factors. Error bars indicate the variability or standard deviation of the measurements ($p<0,05$).

The bar chart illustrates that the Receptor Binding Domain (RBD) antigen from both active and UV-inactivated SARS-CoV-2 virus can be detected at comparable concentrations across various serum dilutions. This suggests that UV inactivation preserves the antigenic structures relevant for ELISA detection, indicating that the structural proteins remain intact and immunologically recognizable post-UV treatment.

This finding is significant for several applications in virology and immunology. It implies that UV-inactivated SARS-CoV-2 can reliably be used for the development of diagnostic assays, such as ELISA-based tests, which depend on the detection of viral antigens. Furthermore, because the relevant proteins are not denatured by UV inactivation, they could potentially be used in vaccine development, where the induction of an immune response to these proteins is crucial. This data supports the use of UV-inactivation techniques in the safe handling of viruses for research and vaccine production, without compromising the structural integrity of key viral proteins. RoLink, 2021.

Intact PCR

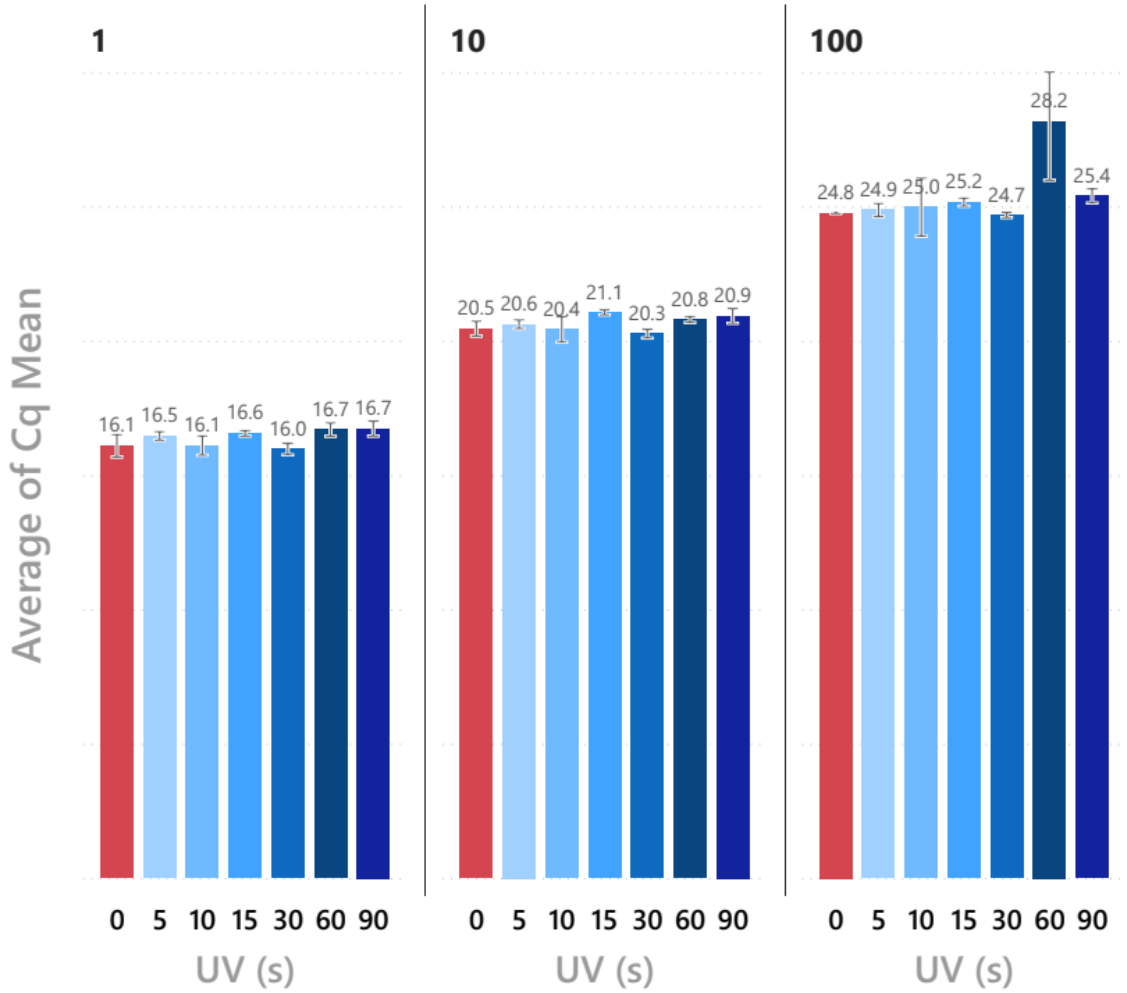


Figure 3. Impact of 254 nm UV Irradiation on SARS-CoV-2 Delta Variant RNA Integrity as Assessed by qPCR. This bar chart with 1 standard deviation error bars delineates the average cycle threshold (Cq) values from quantitative PCR analysis of RdRp gene after exposure to varying durations of 11 W UV-C light (0, 5, 10, 15, 30, 60, 90 seconds) across dilution factors of 1, 10, and 100. Despite different UV exposure times, the Cq values remain relatively consistent, **suggesting no significant degradation of viral RNA**.

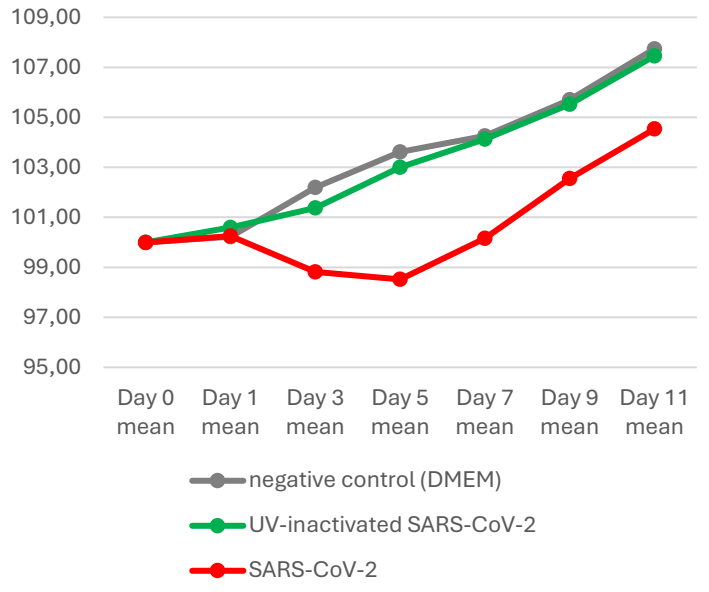
In conclusion, our investigation into the effects of UV irradiation on SARS-CoV-2 Delta variant RNA integrity, using comprehensive qPCR analysis, reveals that the viral RNA remains largely intact across a spectrum of UV exposure times. The absence of a significant dose-response relationship, as evidenced by OLS regression analysis (R^2 = 0.007, p = 0.367), and the consistency of Cq values in Welch's t-tests (p-values ranging from 0.549 to 0.986), suggest that within the limits of our experimental conditions, UV irradiation does not substantively degrade viral RNA. Furthermore, ANCOVA analysis reinforces the notion that the initial viral load does not substantially affect RNA integrity after UV treatment. These findings imply that UV irradiation can be a reliable method for viral inactivation that is compatible with subsequent molecular diagnostics and research applications. However, they also highlight the importance of optimizing UV irradiation conditions to achieve effective viral inactivation for public health safety, without compromising the analytical integrity of viral RNA.

Experiment ID: UV-071-1, RoLink, 2023.

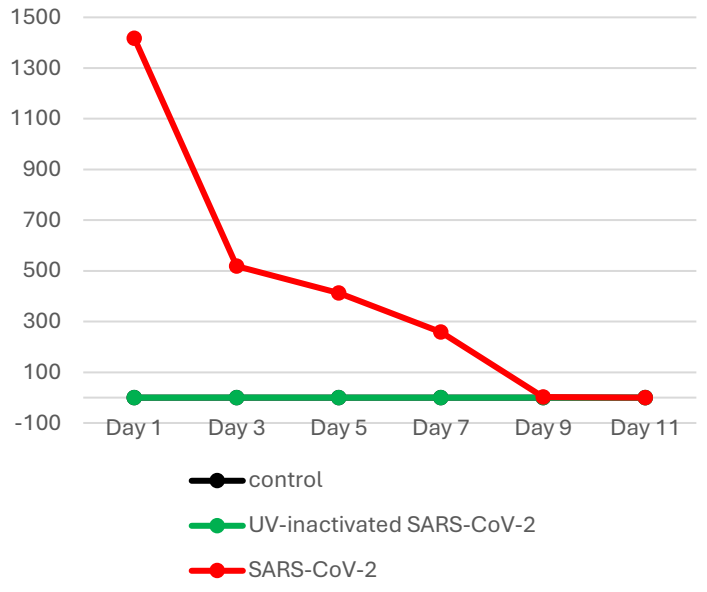
UV-inactivated virus: SARS-CoV-2

RoLink BIOTECHNOLOGY

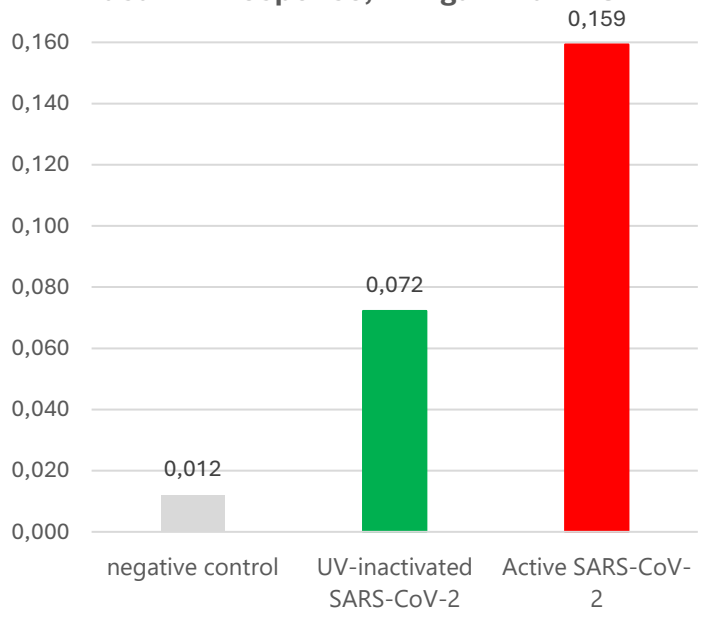
1. body weight change (%)



2. nasopharynegal ddPCR



3. nasal Th1 response, IFN-gamma ELISA



Evaluation of a UV-inactivated SARS-CoV-2 vaccine in a Syrian hamster model: Safety profile, lack of viral replication, and induction of a Th1-biased immune response. The experiment validates the safety and immune efficacy of a UV-inactivated SARS-CoV-2 vaccine. Hamsters maintained stable health post-vaccination, indicating good tolerability. Absence of viral replication post-vaccination, as shown by ddPCR analysis, suggests effective viral inactivation. Furthermore, the vaccine stimulated a Th1 immune response, which is critical for cellular immunity and long-term protection. These promising results support further development and trials of the vaccine. The overall findings suggest that the UV-inactivated SARS-CoV-2 vaccine is a promising candidate for preventing COVID-19. It demonstrates a favorable safety profile, absence of viral replication (signifying efficacy), and induces a Th1-biased immune response which is crucial for long-term immunity and vaccine success. RoLink, 2021.

Business Model

UV inactivation pipeline TRL-7

Technology
Manufacturers
Vaccines
R&D reagents
Diagnostics, Assays

Direct Sales
RUO
Big Pharma/R&D /academic

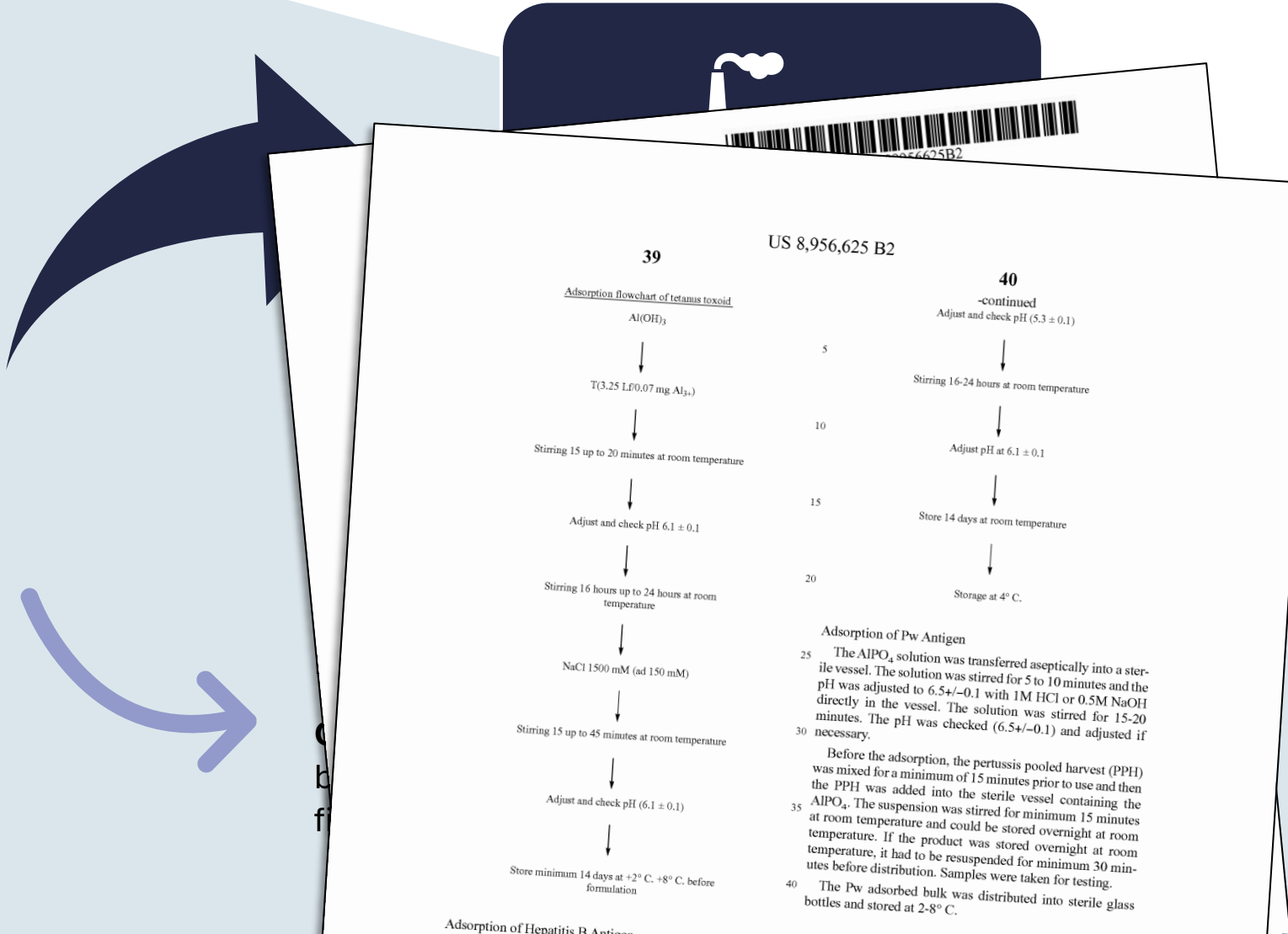
CBRN research
biodefense projects/training
field exercise

Business Model

RoLink BIOTECHNOLOGY

UV inactivation pipeline

TRL-7



US 8,956,625 B2

39

Adsorption flowchart of tetanus toxoid

$Al(OH)_3$

↓

T(3.25 Lf/0.07 mg Al_{3+})

↓

Stirring 15 up to 20 minutes at room temperature

↓

Adjust and check pH 6.1 ± 0.1

↓

Stirring 16 hours up to 24 hours at room temperature

↓

NaCl 1500 mM (ad 150 mM)

↓

Stirring 15 up to 45 minutes at room temperature

↓

Adjust and check pH (6.1 ± 0.1)

↓

Store minimum 14 days at +2° C. +8° C. before formulation

40

-continued

Adjust and check pH (5.3 ± 0.1)

↓

Stirring 16-24 hours at room temperature

↓

Adjust pH at 6.1 ± 0.1

↓

Store 14 days at room temperature

↓

Storage at 4° C.

Adsorption of Pw Antigen

The $AlPO_4$ solution was transferred aseptically into a sterile vessel. The solution was stirred for 5 to 10 minutes and the pH was adjusted to 6.5+/−0.1 with 1M HCl or 0.5M NaOH directly in the vessel. The solution was stirred for 15-20 minutes. The pH was checked (6.5+/−0.1) and adjusted if necessary.

Before the adsorption, the pertussis pooled harvest (PPH) was mixed for a minimum of 15 minutes prior to use and then the PPH was added into the sterile vessel containing the $AlPO_4$. The suspension was stirred for minimum 15 minutes at room temperature and could be stored overnight at room temperature. If the product was stored overnight at room temperature, it had to be resuspended for minimum 30 minutes before distribution. Samples were taken for testing.

The Pw adsorbed bulk was distributed into sterile glass bottles and stored at 2-8° C.

Adsorption of Hepatitis B Antigen

Business Model

Vaccine Manufacturer

license/exit

💰 Charles River → **$100M acquisition** of Distributed Bio

💰 AstraZeneca → **$838M acquisition** of Icosavax

Direct Sales

RUO

Big Pharma/R&D /academic

💰 25 K USD → 18 000 K USD (one batch)

💰 7.5 M USD (Y5)

CBRN research

biodefense projects/training

field exercise

💰 EDF calls ($1B (2025)

💰 **CBRN market size** $21.5B (2024)

Successful projects

RoLink BIOTECHNOLOGY

Ceva Santé Animale

FLUART
INNOVATIVE VACCINES Kft.

UNIVERSITY OF PÉCS
NATIONAL LABORATORY
OF VIROLOGY

EUROPEAN DEFENCE FUND
EUROPEAN UNION

A HAZÁÉRT
MAGYAR HONVÉDSÉG

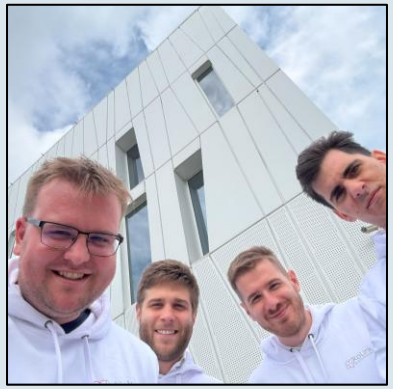
ThermoFisher SCIENTIFIC

Zatloukal Innovations

PROJECT FINANCED FROM THE NRDI FUND

Social Impact

School



PhD programs

Berlin Embassy

Defence Projects

Promoting Grants

Meeting a Nobel laurate

Social Events

Biosafety Conference

Investment Ask

✓ **Grant Money**

€350K non-dilutive grant

(COVID grant) +

€750K non-dilutive grant
(GYORSÍTÓSÁV)

European Defence Forces

★ **€60K** ★

+

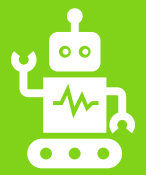
Investment

SEED

1M USD

equipment, hiring,
go-to-market, BSL-4

What do we achieve?



Industry ready technology

Full technological line at TRL-7 from virus production to end product, tested and validated for 4+ viruses

Stockpile

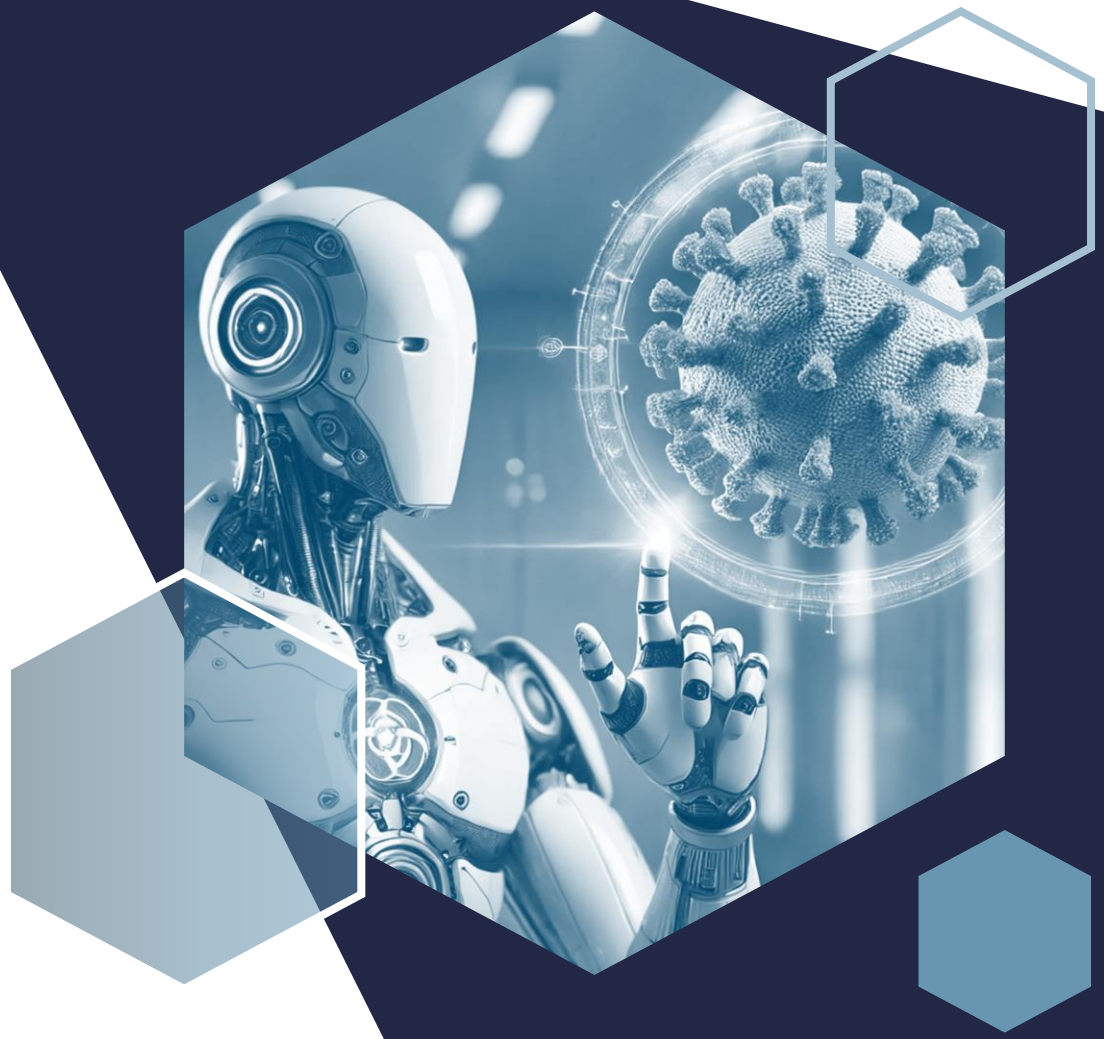
A stockpile of 4+ relevant UV-inactivated viruses, 500 doses each (0.5-12 m USD worth of stock)

Revenue

We aim to achieve at least a 1000% annual net revenue by 2028.

We aim for at least 5 relevant business endeavors by the end of 2028.

RoLink BIOTECHNOLOGY



ART OF THE KILL

Rapid Response UV inactivation

Roland Heténi MD

CEO

Appendix

ART OF THE KILL

RoLink Biotechnology Kft.

dr. Roland Heténi
CEO, medical doctor

UV inactivation
Virus purification
Vaccine development
Cellular immune response
Humoral immune response
Graphic Design

dr. Dániel Hanna
Co-owner, medical doctor

UV inactivation
Virus purification
Vaccine development
Cellular immune response
Magnetic beads
Data analysis
Statistics

In response to the first wave of the COVID-19 pandemic in 2020, Dr. Roland Heténi and Dr. Daniel Hanna, newly graduated doctors, founded RoLink Biotechnology Ltd. with the mission to bolster pandemic defense through rapid domestic innovation. With a grant of 350,000 EUR from the COVID Fund, we swiftly provided critical data to the Ministry within a month. As a key strategic partner of the National Laboratory of Virology, the only BSL-4 laboratory in the central EU region, we developed five innovative technologies applicable to any virus. Our groundbreaking achievement includes the UV inactivation of the coronavirus at the laboratory level, addressing the severe capacity constraints of BSL-4 facilities. Additionally, we devised a diagnostic procedure for convalescent plasma therapy and demonstrated in animal experiments that UV-inactivated coronavirus can serve as a viable vaccine base. We successfully navigated university-industry collaboration under challenging conditions and are now in advanced negotiations with major biotech companies, including CEVA Hungary, for vaccine technology development, and ThermoFisher, for the commercialization of our technologies. Furthermore, we serve as a subcontractor for the European Defence Fund, contributing to the rapid response and building of a European biodefense system. Our collaboration with the Hungarian Military positions them as both a key collaborator and a future customer for our technologies.

Team: Board

dr. Tibor Héjj, MBA, PhD
lead advisor, co-owner

- 25+ yrs experience in strategic and management consulting
- Former country manager, Boston Consulting Group, HU
- Former international vice president at A.T. Kearney
- Founder of PMC innovation management

dr. János Matuz
legal advisor, IP management

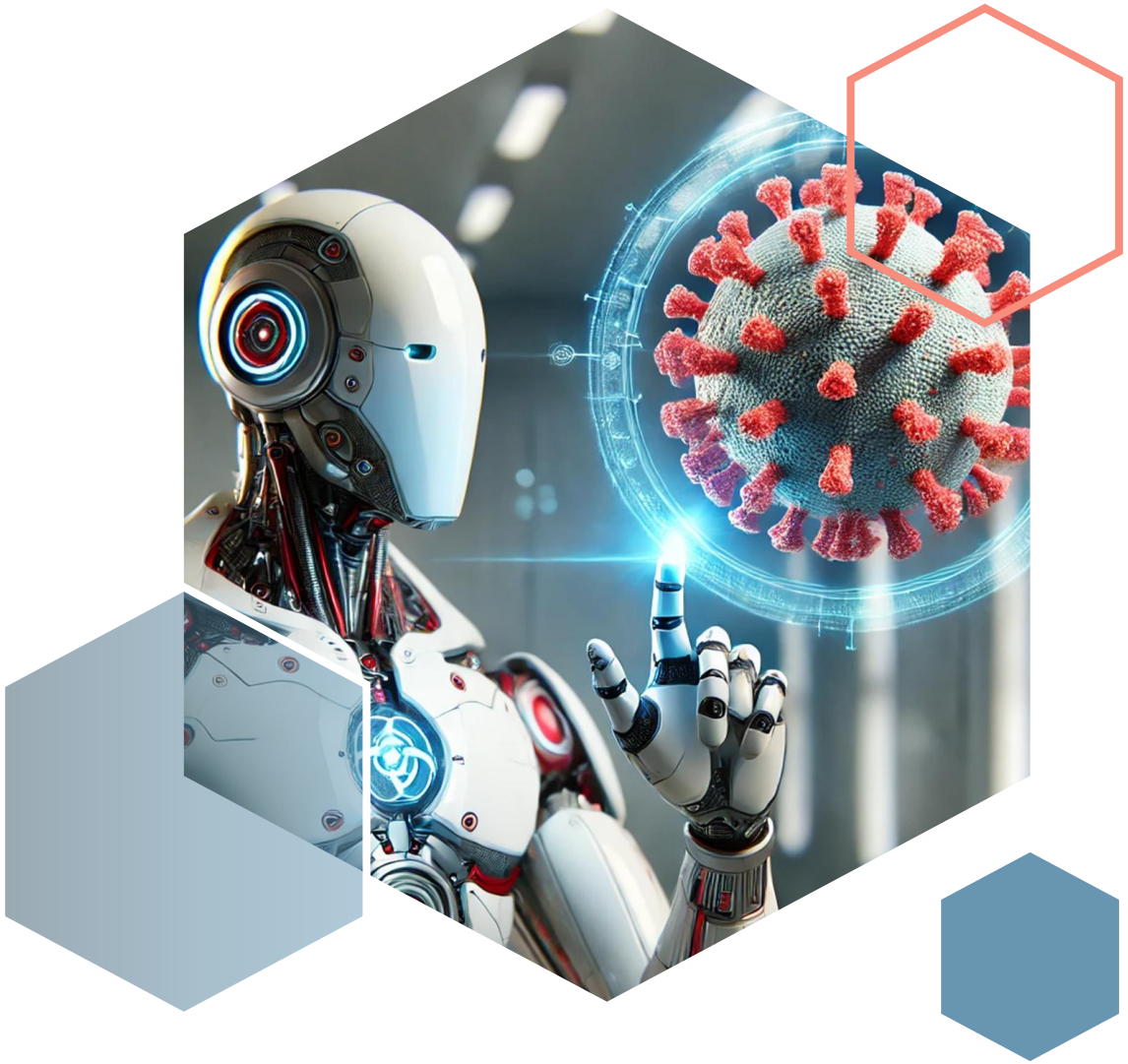
- Expert in innovation management with a focus on R&D support
- Years of experience in the Hungarian and EU grant systems
- Extensive experience in the energy sector
- Experience in energy, healthcare, biotechnology social innovations

Péter Gebhardt
sales management, chief representative

- Former financial data analyst at PRK Global
- Founded a business in Spain in 2018, returned to Hungary in 2022 as head of BTL's cardiology division
- Expertise in R&D, institutional communication, healthcare IT, procurement, and international relations

UNIVERSITY OF PÉCS
NATIONAL LABORATORY
OF VIROLOGY

RoLink
BIOTECHNOLOGY



296 117 320 Ft

Grant Won and Approved
(2023-1.1.2-GYORSÍTÓSÁV)

Art of the Kill

UV inactivation in Biotechnology

Védelmi képességfejlesztés a járványok korában: UV-inaktiváció

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Problem

Biosafety Levels (BSL)

BSL-2
☣
$
~10 000
influenza Zika, Hepatitis B

BSL-3
☣ ☣ ☣
$ $ $
409
SARS-CoV-2 mpox, West Nile

BSL-4
☣ ☣ ☣ ☣ ☣
$ $ $ $ $ $
51
Ebola, Marburg Nipah, CCHFV

Biosafety Levels (BSL)

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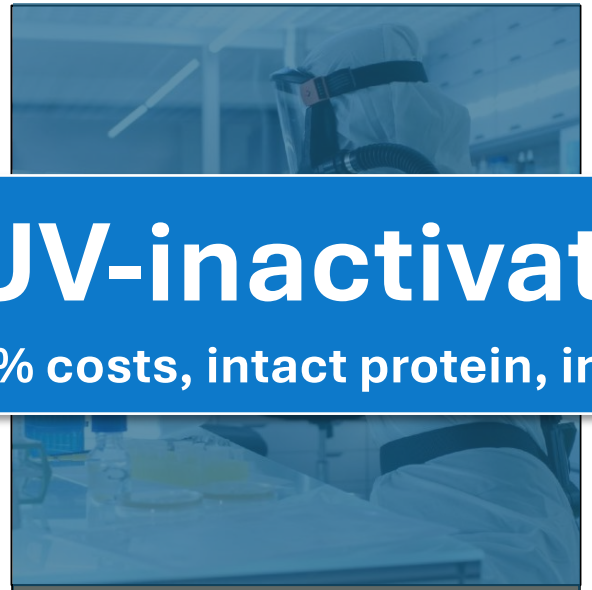
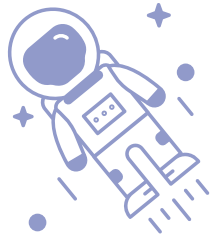


UV-inactivation

-90% costs, intact protein, intact PCR

BSL-2	BSL-3	BSL-4
☣	☣ ☣ ☣	☣ ☣ ☣ ☣ ☣
$	$ $ $	$ $ $ $ $ $
~10 000	409	51
influenza Zika, Hepatitis B	SARS-CoV-2 mpox, West Nile	Ebola, Marburg Nipah, CCHFV



BSL-4 operators are rarer than astronauts — RoLink makes them scalable.

Regional Racer

This project is based at Central Europe's leading university based **BSL-4 laboratory**, setting the benchmark for exceptional biosafety standards. This distinction elevates the laboratory's **strategic value**, positioning it as a key hub for **high-pathogenicity pathogen research and education**.

As the **only university-affiliated** facility of its kind, it offers **unmatched R&D capabilities** and specialized training, backed by a team of top-tier experts with strong **international collaborations**. Its significance extends beyond national borders, fulfilling **critical infrastructure needs** for cutting-edge research in Central Europe while also providing **global advantages**.

Moreover, Western European laboratories may view this facility as a **cost-effective** and **efficient alternative**, presenting opportunities for strategic partnerships in biosafety research and innovation.

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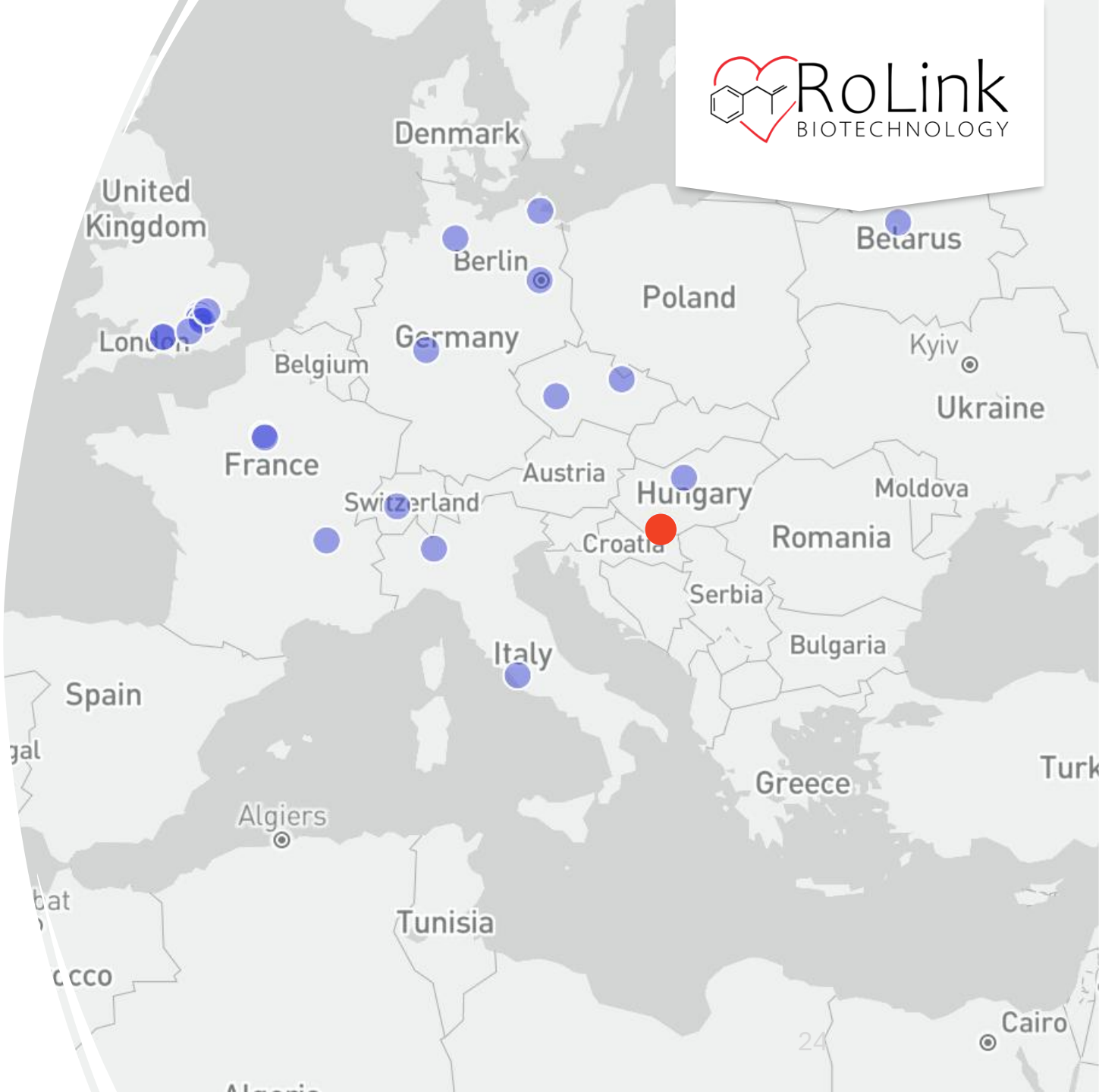
NATIONAL LABORATORY
OF VIROLOGY



Risk

Use High Containment When absolutely <u>needed</u>

3R Principle in HCLs – Replace, Reduce, Refine

Replace high-risk live pathogens with UV- inactivated models where possible.

Reduce the number of necessary high-containment experiments.

Refine procedures to minimize risks and optimize efficiency.

How Many Experiments Can Be Batch-Processed with One Entry into BSL-4?

RoLink BIOTECHNOLOGY

Maximizing Efficiency in BSL-4 Labs

Single-entry planning can support multiple experiments.	**UV-inactivated samples** allow pre-testing before BSL-4 entry.	**Risk minimization** through strategic batch experiments.
1	**PRE**	**MIN**

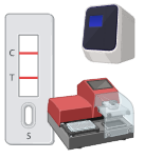
3 L UV-inactivated virus

Application & Benefits

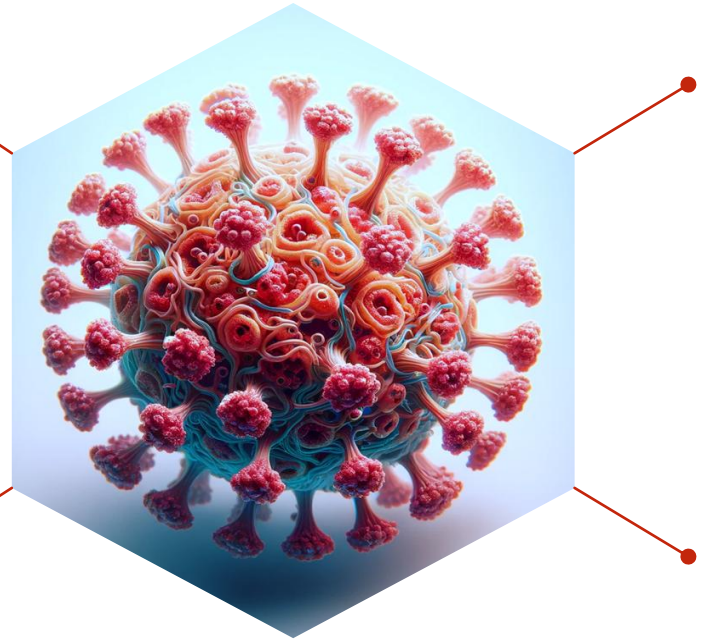
accessible and inexpensive research and public health

-90% cheaper virological research and development
any lab or field application
no need to wait for BSL-3/4 capacity
COVID-19, Crimean-Congo, Ebola, Marburg, Lassa fever MERS-CoV, SARS, Nipah and henipaviral, Rift Valley fever, Zika
“Disease X”

diagnostic assay development



rapid response PCR
ELISA, rapid test, Luminex



pharma industry

antivirals
rapid response vaccine development,
compatible with GMO vaccine prodction

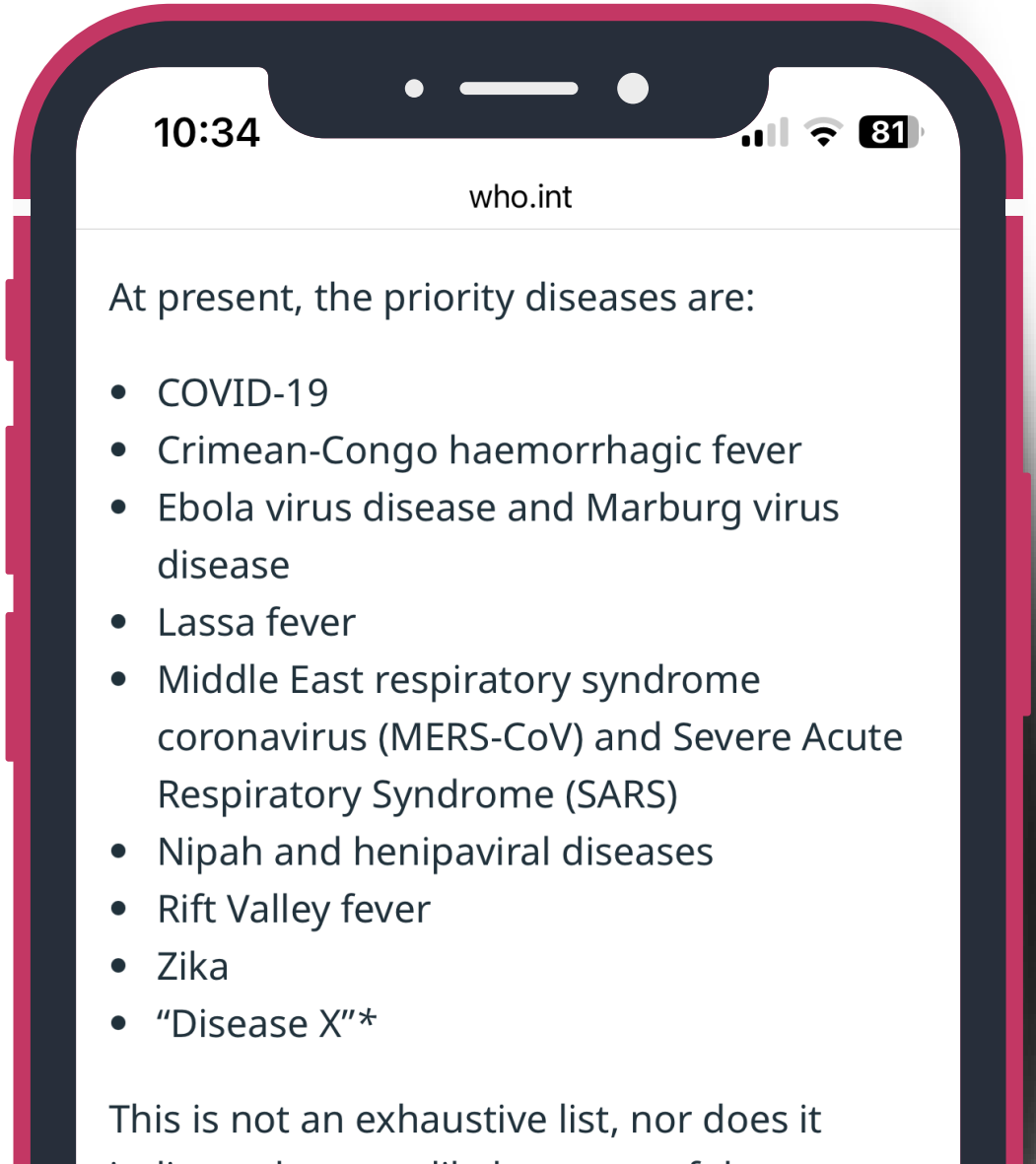
CBRN research

biodefense training
field exercise
EDF projects

Unlocking BSL-3 and BSL-4 Limits

UV inactivation accelerates timelines, boosting productivity and progress.

Market Demand



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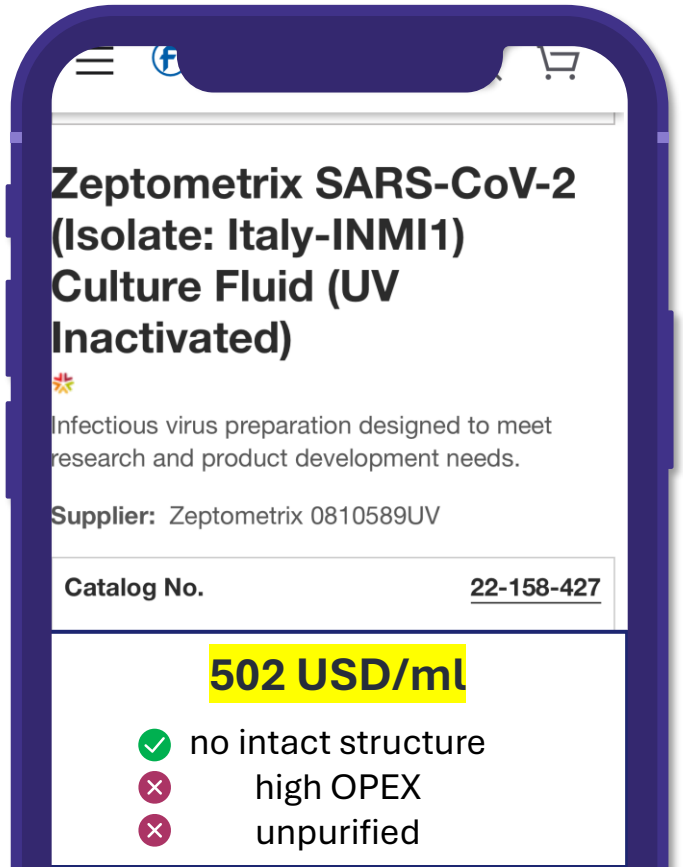
World Health Organization

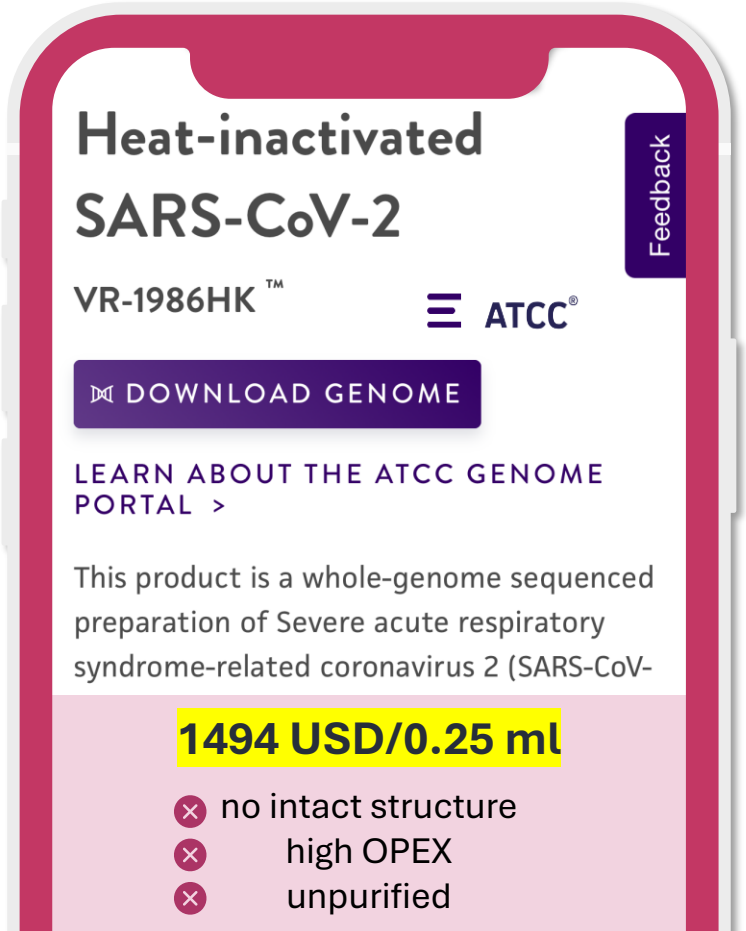
ISIDORe

EVAg
European Virus Archive Global

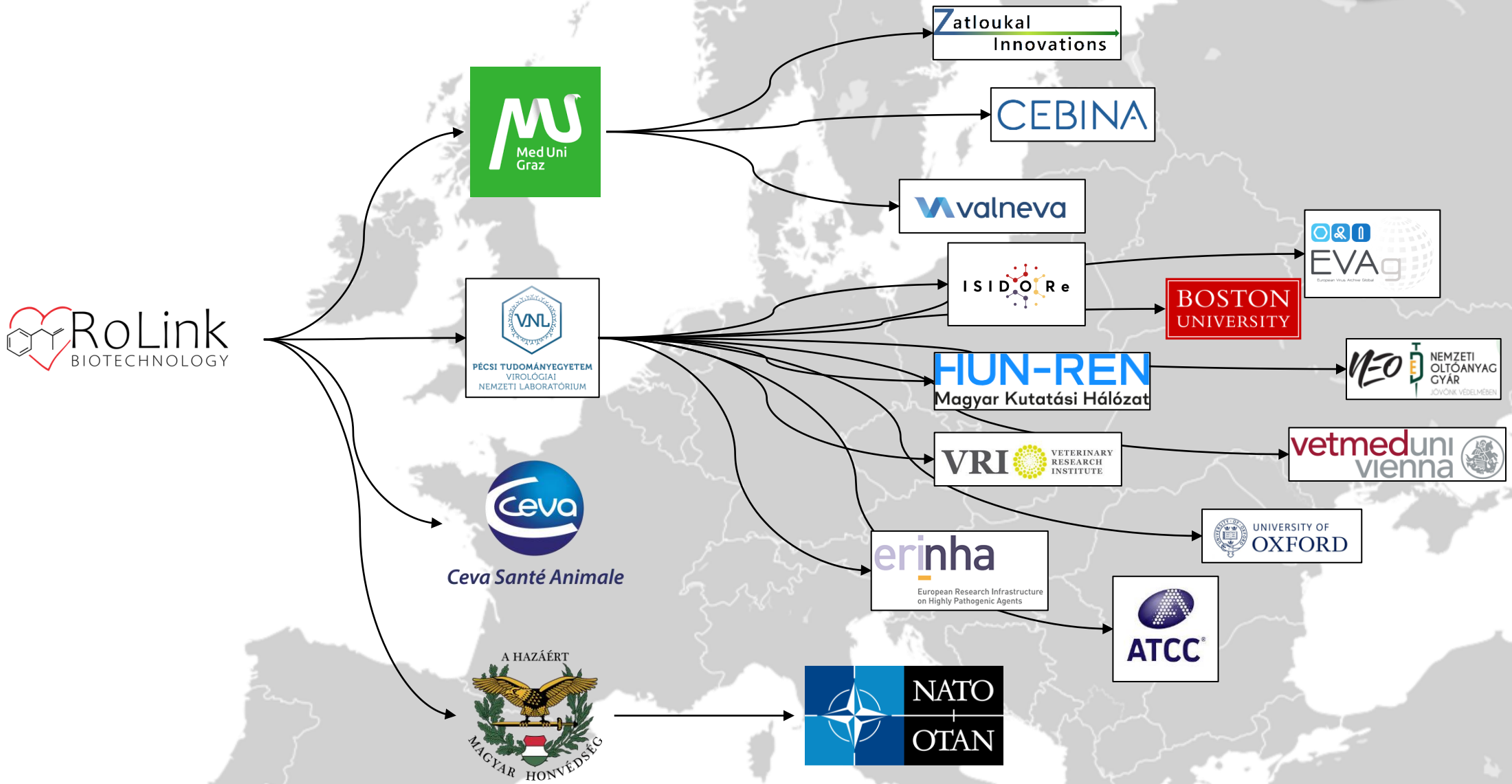
Unlocking a Billion-Dollar Market

Competitor analysis





Go-To-Market


RoLink BIOTECHNOLOGY
Med Uni Graz
PÉCSI TUDOMÁNYEGYETEM VIROLÓGIAI NEMZETI LABORATÓRIUM
Ceva Santé Animale
A HAZÁÉRT MAGYAR HONVÉDSÉG
Zatloukal Innovations
CEBINA
valneva
ISIDORe
BOSTON UNIVERSITY
EVAg
HUN-REN Magyar Kutatási Hálózat
NEO NEMZETI OLTÓANYAG GYÁR
VRI VETERINARY RESEARCH INSTITUTE
vetmeduni vienna
UNIVERSITY OF OXFORD
erinha European Research Infrastructure on Highly Pathogenic Agents
ATCC
NATO OTAN

Exit Strategy

- **Charles River Laboratories Acquisition of Distributed Bio** [23]
  - **Company Profile**: Distributed Bio, a biotech company founded in 2016, specialized in next-generation antibody discovery. New modality and TRL-7 tech bought. Inactivation.
  - **Funding History**: Secured $9.7 million in grants by 2019.
  - **Revenue at Exit**: Approximately $15 million annual revenue.
  - **Acquisition Details**: In 2020, Charles River Laboratories acquired Distributed Bio for approximately **$100 million**.
- **AstraZeneca Acquisition of Icosavax** [24]
  - **Company Profile:** Icosavax, a clinical-stage biopharmaceutical company, specialized in virus-like particle (VLP) vaccines targeting respiratory syncytial virus (RSV) and human metapneumovirus (hMPV).
  - **Lead Product:** IVX-A12, a Phase III-ready bivalent VLP-based vaccine candidate for RSV and hMPV.
  - **Acquisition Details:** In December 2023, AstraZeneca announced its acquisition of Icosavax for $838 million upfront, with potential milestone payments bringing the total deal value to **$1.1 billion.**
  - **Strategic Rationale:** The acquisition strengthens AstraZeneca's pipeline in vaccines and immune therapies, addressing unmet needs in infectious diseases for vulnerable populations.

23 *Charles River Laboratories Acquires Distributed Bio*, <https://ir.criver.com/news-releases/news-release-details/charles-river-laboratories-acquires-distributed-bio/> (2024).

24 AstraZeneca. *AstraZeneca to acquire Icosavax, including potential first-in-class RSV and hMPV combination vaccine with positive Phase II data*, <https://www.astrazeneca.com/media-centre/press-releases/2023/astrazeneca-to-acquire-icosavax-including-potential-first-in-class-rsv-and-hmpv-combination-vaccine-with-positive-phase-ii-data.html> (2023).

Comparative advantage

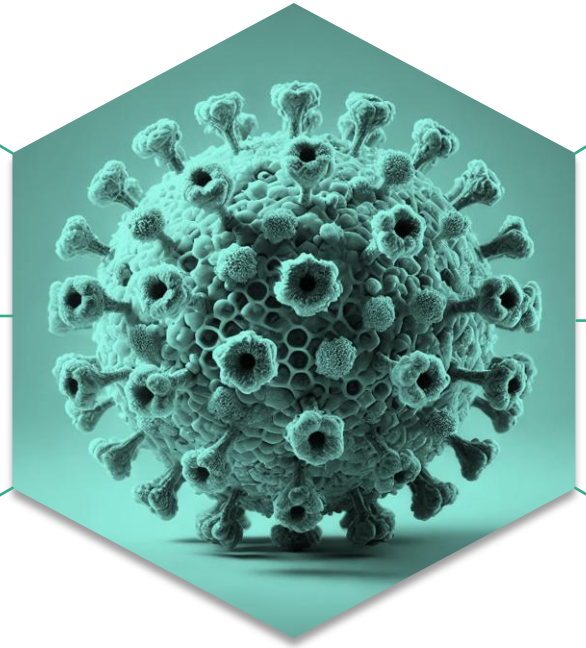
UV-Inactivated, purified virus suspension

500-6000 USD/ml

-90% CAPEX
low expense compared to benchmark tech

-80% CoGs
very efficient Cost of Goods Sold, high profit margin

-90% utilities
compact, modulated



automated
GMP-ready, modulated

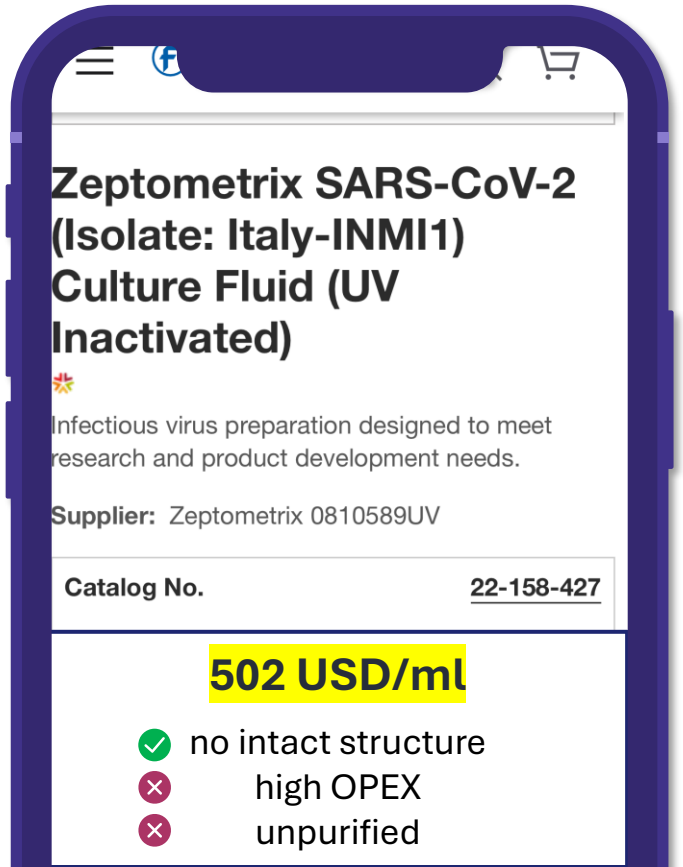
ISO35001
unique biorisk managament
quality control

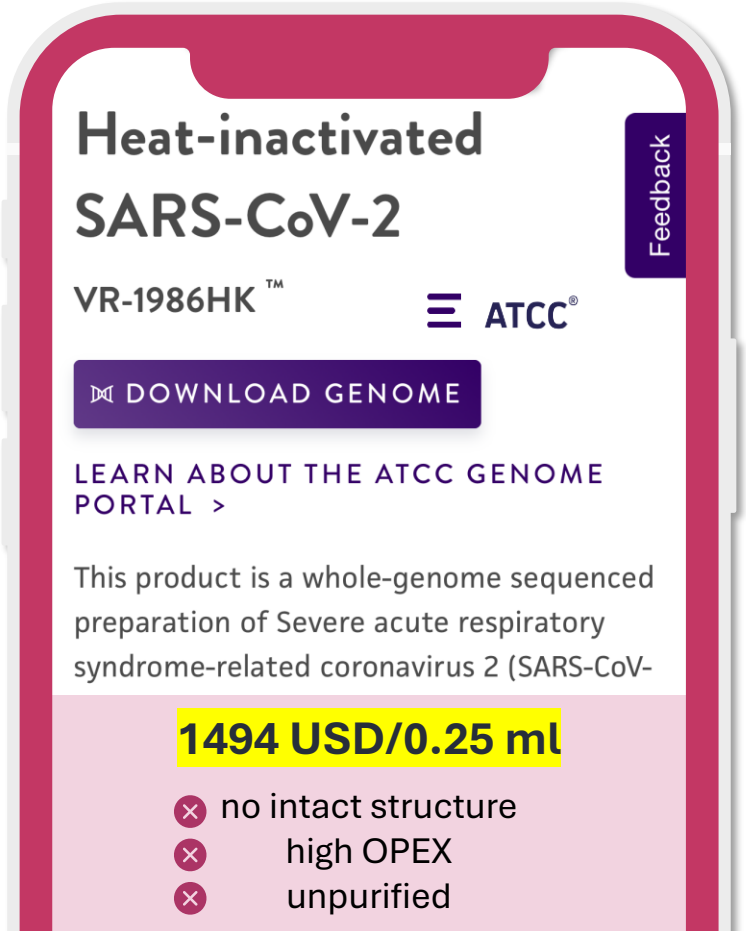
intact virion
intact protein and viral structure

Our UV-inactivated virus production process is highly automated, ensuring containment and safety, and adheres to ISO35001 standards for reliability. Designed for quick adaptability in response to epidemics, our system promises both efficiency and a smaller operational footprint, making it suitable for biosafety cabinet integration. Automated and standardized isolation processes yield high-quality virus products, significantly reducing costs: CAPEX by 90% and CoGs by 80%, with utility consumption down by 92.8%.
The production line boasts an impressive capacity of 22 batches per year. Quality control is stringent, utilizing metagenomic sampling and intact protein ELISA, with an eye towards further advancements under ISO13485 standards. The sIPV model exemplifies the process's efficiency with a purification yield of 57%, demonstrating our commitment to setting industry standards in both innovation and sustainability.

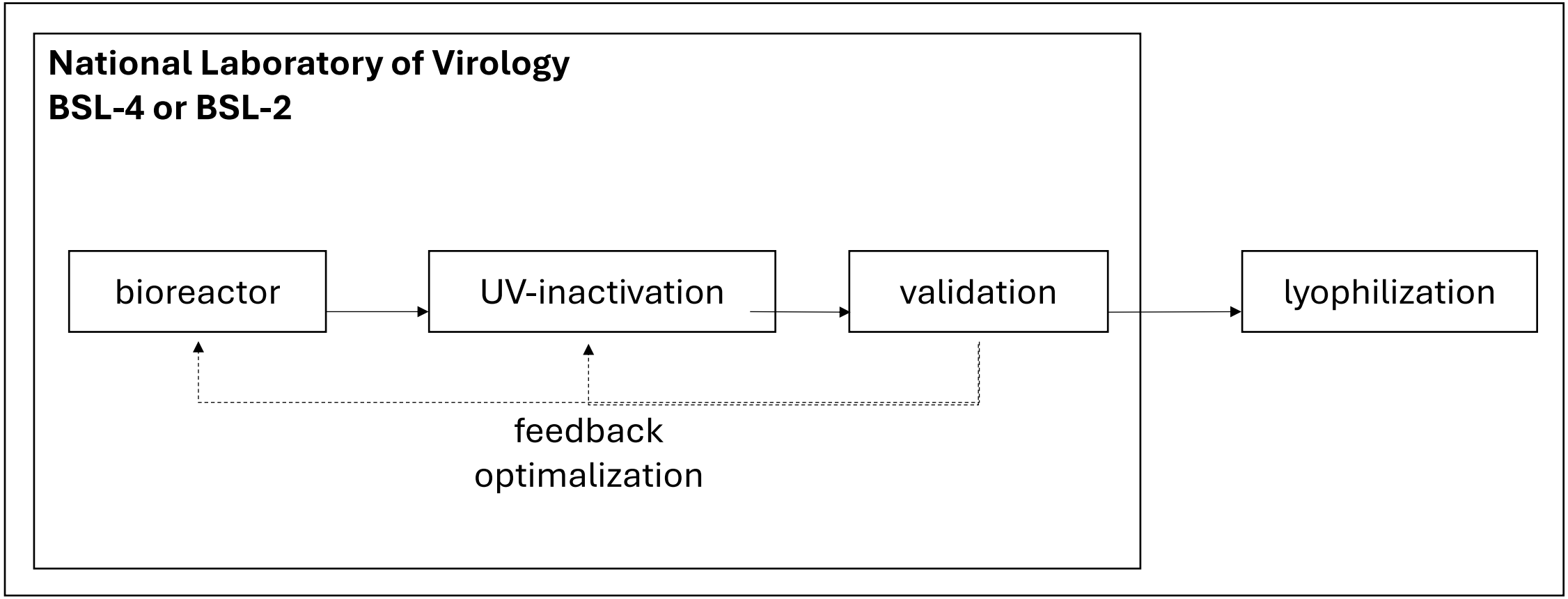
Unlocking a Billion-Dollar Market

Competitor analysis





Taking the leap!



Closed system, GMP-ready, 1-5 L single batch

From Prototype to Platform

- **TRL Progression**: TRL-4 → TRL-7 by 2026
- Supported by Vapourtec UV-150 and E-Series modular flow chemistry systems
- Output scalability: from **2–5 batches** to **50 batches/year**
- **Fully automated**, **low-footprint**, **GMP-ready** architecture

Closed system, GMP-ready, 1-5 L single batch

UV Reactor – Key Features Enabling Scale

- **Continuous flow** UV inactivation with 254 nm precision
- Temperature control: -20°C to +80°C
- Light sources:
  - 150W medium pressure mercury lamp
  - LED alternatives for narrower wavelength tuning
- Safety: Enclosed system with real-time spectral analysis
- Result: Up to **5g/hour/module** of UV-treated material in validated reactions, 10 ml/min = **14,4 L/day/module**

Advantages

Unlike traditional batch UV setups or chemical inactivation methods, our **flow-based configuration** ensures:

- Uniform photon exposure,
- Minimal shear stress,
- Preservation of whole virion structure, critical for vaccine efficacy and diagnostic use.

- GMP-compliant, sterile-grade outputs, suitable for direct formulation into inactivated vaccines,
- High reproducibility, with 2–4× higher virion yield than conventional methods,

Our Flow Setup for Viral Inactivation

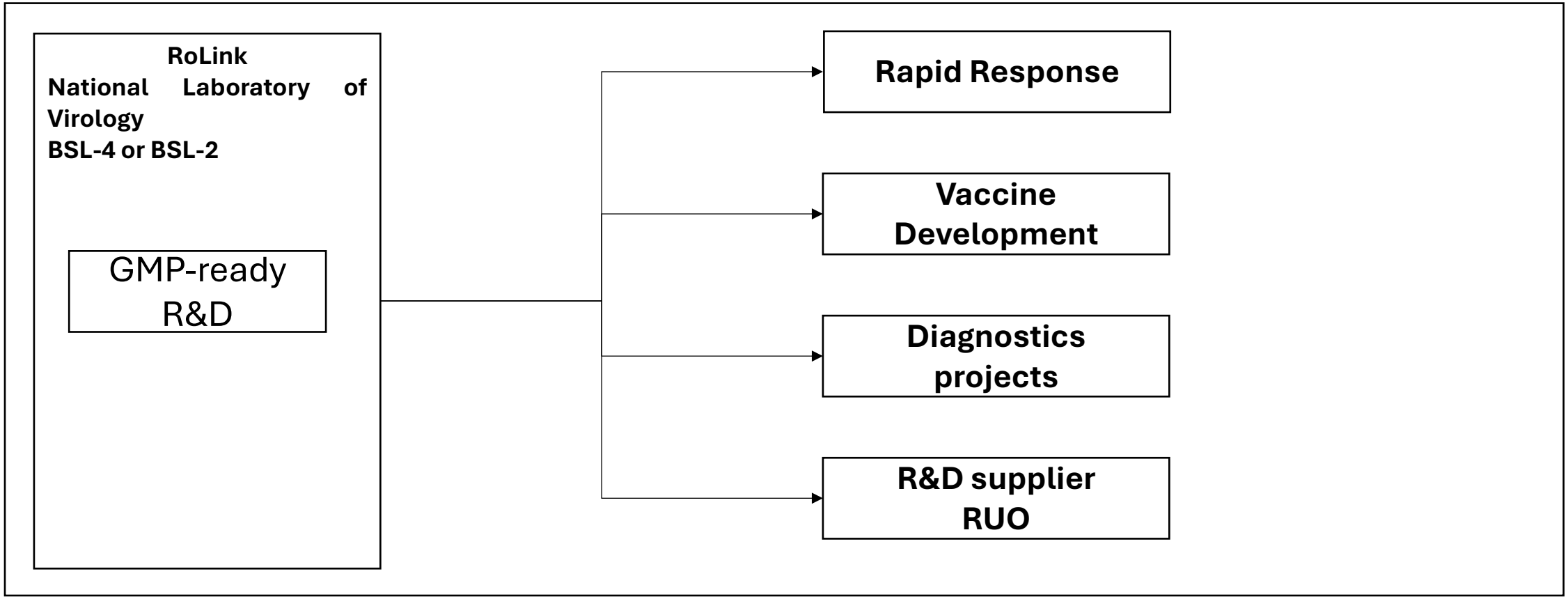
- **UV reactor**
  - Flow rate: 0.1–10 mL/min
  - Pressure: Up to 10 bar
  - Modular compatibility with purification units
- **Tubing capacity**: 10 mL reactor coils, user-rewindable
- **Process Integration**:
  - Virus propagation →
  - Tangential flow filtration →
  - Ion exchange chromatography →
  - UV-C inactivation →
  - Lyophilization-ready output

Production Scaling Model

Stage	Year 1	Year 3	Year 5
Batch capacity	22/year	35/year	50/year
Output (R&D reagent)	~5–10 L	~25 L	40–60 L
Revenue Potential (€)	390K–1.4M	2.75M	13–25M

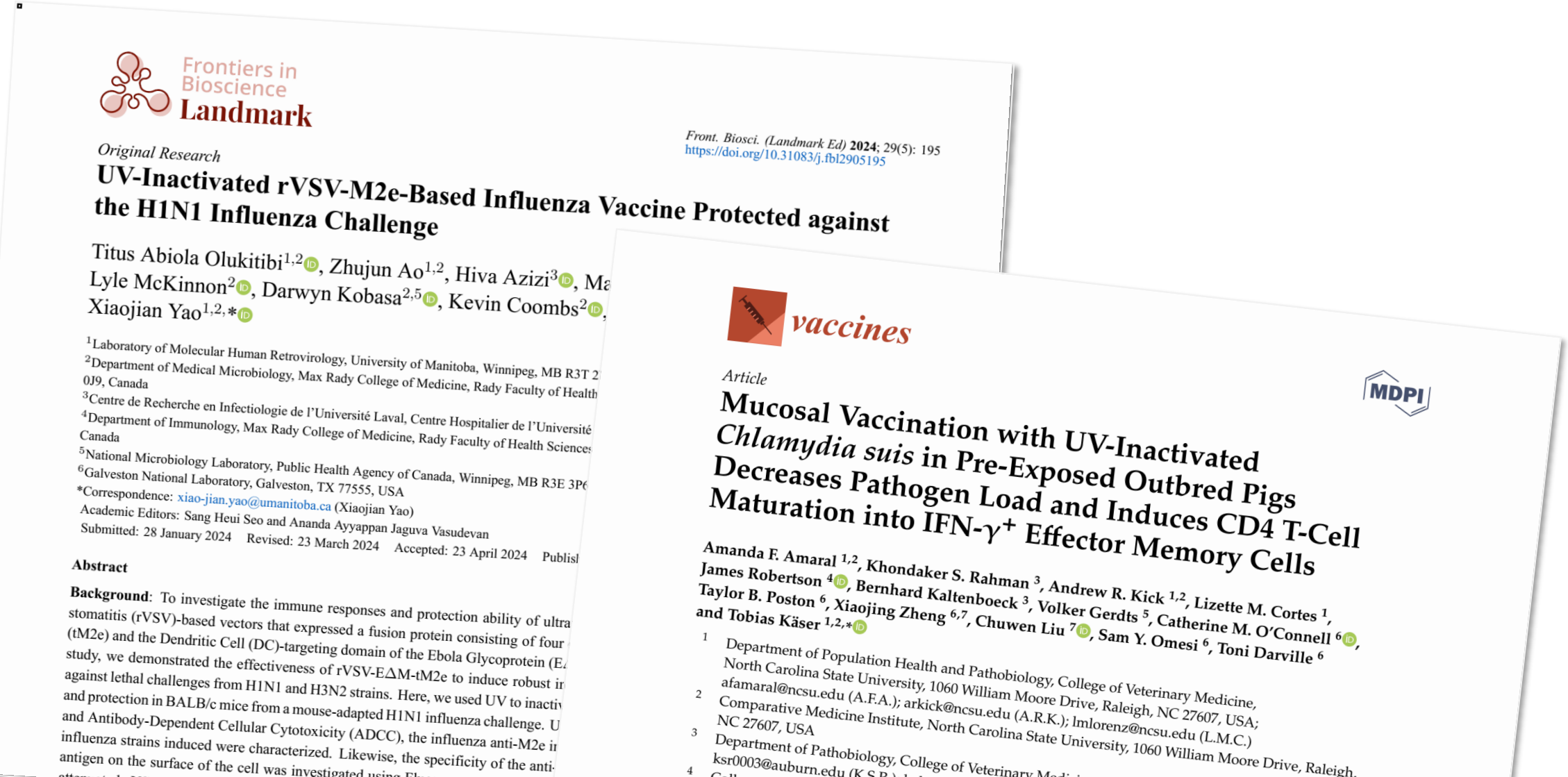
Market Price $500–$6000/mL

Business Model



UV inactivated vaccines

RoLink BIOTECHNOLOGY



Frontiers in Bioscience Landmark

Original Research

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https://doi.org/10.31083/j.fbl2905195

UV-Inactivated rVSV-M2e-Based Influenza Vaccine Protected against the H1N1 Influenza Challenge

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Abstract

Background: To investigate the immune responses and protection ability of ultra
stomatitis (rVSV)-based vectors that expressed a fusion protein consisting of four
(tM2e) and the Dendritic Cell (DC)-targeting domain of the Ebola Glycoprotein (E
study, we demonstrated the effectiveness of rVSV-EΔM-tM2e to induce robust i
against lethal challenges from H1N1 and H3N2 strains. Here, we used UV to inacti
and protection in BALB/c mice from a mouse-adapted H1N1 influenza challenge. U
and Antibody-Dependent Cellular Cytotoxicity (ADCC), the influenza anti-M2e i
influenza strains induced were characterized. Likewise, the specificity of the anti
antigen on the surface of the cell was investigated using

vaccines

Article

MDPI

Mucosal Vaccination with UV-Inactivated *Chlamydia suis* in Pre-Exposed Outbred Pigs Decreases Pathogen Load and Induces CD4 T-Cell Maturation into IFN-γ⁺ Effector Memory Cells

Amanda F. Amaral [1,2], Khondaker S. Rahman [3], Andrew R. Kick [1,2], Lizette M. Cortes [1], James Robertson [4], Bernhard Kaltenboeck [3], Volker Gerdts [5], Catherine M. O'Connell [6], Taylor B. Poston [6], Xiaojing Zheng [6,7], Chuwen Liu [7], Sam Y. Omesi [6], Toni Darville [6] and Tobias Käser [1,2,*]

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