RRPV Member Spotlight

Q: Provide some insight into your company's history, core business areas, focuses, or key ideas that you wish to describe.

A: Versatope Therapeutics is a clinical-stage biotechnology company developing a transformative class of immunotherapeutics and vaccines. The platform utilizes advanced synthetic biology to engineer nano-sized recombinant bacterial extracellular vesicles (bEVs), also known as recombinant outer membrane vesicles. Licensed from Cornell University, these vesicles are derived from the outer membranes of genetically engineered, detoxified probiotic strains. The platform serves a dual purpose by driving robust immune system activation for infectious disease targets and serving as a customizable vehicle for targeted, intracellular delivery of therapeutic peptides and ribonucleic acid payloads to cancer or inflamed tissues.

A core innovation of the bEV platform is its capacity to address highly mutable pathogens by capturing genetic diversity on a single vehicle. Traditional vaccine modalities are often restricted to single-strain targets, limiting the breadth of protection. In contrast, Versatope's technology allows for the simultaneous display of multiple viral variants on a single vesicle surface. This multivalent presentation forces the immune system to recognize highly conserved epitopes, driving broad, cross-protective, and durable immune responses. The company's advanced candidate pipeline demonstrates this therapeutic logic through VT-105, which is a universal influenza A vaccine candidate entering Phase One clinical testing. Additionally, the company is engineering pan-coronavirus formulations to provide cross-strain protection against evolving coronaviruses, alongside active discovery and development pipelines applying vesicle surface modification to malaria parasitic antigens.

From an operational standpoint, the bEV platform resolves two major historical bottlenecks in vaccine deployment by addressing cold-chain dependency and manufacturing scalability. By leveraging the naturally robust, durable structures of

bacterial outer membranes, Versatope generates formulations that remain stable at room temperature for months. These vesicles can also be lyophilized, completely eradicating rigid cold-chain logistics and maximizing global deployment capabilities.

Furthermore, traditional vaccine production is often constrained by the slow doubling times and complex line-screening associated with mammalian or egg-based cell lines. Versatope utilizes standard, highly efficient bacterial fermentation protocols instead. This workflow yields exponentially higher production volumes and offers low-cost, high-yield scalability. This rapid-response architecture allows manufacturing to pivot from antigen discovery to mass production within weeks, matching the strategic demands of pandemic preparedness and biodefense thresholds.

Versatope Therapeutics showcases a highly scalable, rapid-response medical countermeasure platform alongside an advanced pipeline of broad-spectrum candidate vaccines.

Core Platform Technologies

- Recombinant bEVs (rOMVs): Proprietary synthetic biology platform that leverages genetically engineered, probiotic-derived nanovesicles to deliver targeted vaccines and immunotherapies.
- Vesicle Surface Display Engineering: Breakthrough molecular engineering capability that allows the simultaneous display of multiple diverse viral antigens and strain variants on a single nano-sized vesicle.
- Thermostable Formulation Platform: Formulation technology that ensures vaccine candidate stability at room temperature for months, entirely eliminating traditional cold chain infrastructure dependencies for rapid global deployment. •
- Targeted Therapeutic Delivery: Precision drug delivery technology engineered to carry custom biochemical payloads—such as nucleic acids, RNA, and peptides—exquisitely targeted to specific cells or oncology indications.

Product Pipeline

- VT-105 (Universal Influenza A Vaccine): Lead clinical-stage asset displaying diverse Matrix-2 (M2) viral variants to provide multi-strain, cross-protective, and durable immunity against seasonal and pandemic influenza.
- Bi-specific Malaria Vaccine: Preclinical-stage vaccine candidate backed by NIH/NIAID SBIR funding utilizing a dual-acting target designed to simultaneously block initial infection and transmission.
- Clostridioides difficile (C. diff) Vaccine/Therapeutic: Early-stage pipeline candidate utilizing recombinant nanovesicles for the prevention of disease.

Q: What specific capabilities or strengths does your company offer?

A: Versatope Therapeutics offers a highly versatile, clinical-stage delivery platform and deep expertise in synthetic biology to member organizations requiring rapid, scalable, and cross-protective medical countermeasures.

Core Scientific & Technical Capabilities

- bEV Platform Engineering: Advanced capability to design and genetically engineer proprietary bEVs/rOMVs as highly immunogenic vaccine carriers.
- Surface Display Expression: Multi-antigen display technology allowing the simultaneous expression of diverse viral or bacterial proteins on a single nano-sized vesicle to combat highly mutable pathogens.
- Thermostable Drug Delivery: Formulation expertise creating candidate vaccines that remain stable at room temperature for months, radically simplifying deployment and eliminating traditional cold chain requirements.
- Targeted Intracellular Payload Delivery: Precision engineering of nanovesicles capable of encapsulating and delivering diverse biochemical payloads—including nucleic acids, RNA, and peptides—directly to targeted cell types.

Development & Operational Strengths

- Clinical-Stage Pipeline Asset Management: Proven capability to advance a biological candidate from initial discovery through rigorous preclinical evaluation and into Phase 1 clinical development (Lead Asset: VT-105 Universal Flu Vaccine).
- Federal Contract Compliance: Experienced in managing multi-million-dollar, milestone-driven federal development programs, backed by a $17.9M NIH/NIAID contract award.
- High-Yield, Scalable Upstream Processing: Established, high-efficiency bacterial fermentation protocols that allow for rapid manufacturing scale-up compared to traditional mammalian or egg-based cell cultures.

Q: Are there any specific partnership opportunities you're seeking with other members in the industry? What kinds of expertise or resources would be beneficial for your company to explore through partnerships?

A: To maximize the impact of our bEV platform and accelerate the deployment of medical countermeasures, Versatope seeks strategic partnerships with member organizations possessing expertise in the following areas:

Clinical & Regulatory Execution

- Infectious Disease Clinical Research Organizations (CROs): Partners with established infrastructure to design, manage, and execute Phase 1 and Phase 2 global clinical trials.
- Regulatory Affairs for Biologics: Advisors with deep expertise navigating FDA Fast Track, Emergency Use Authorization (EUA), and BARDA regulatory pathways.

Advanced Manufacturing & Formulation

- Large-Scale Biomanufacturing (CDMOs): Organizations capable of high-yield, cGMP-compliant fermentation and purification of bEVs.
- Novel Formulation & Lyophilization: Experts in dry-powder stability or advanced drug delivery systems to further optimize the room-temperature shelf life of our assets. Antigen Discovery & Preclinical Testing
- Computational Structural Biology: Partners utilizing AI/machine learning to identify highly conserved, cross-reactive epitopes for emerging viral and bacterial threats.
- High-Containment In Vivo Testing: Facilities with BSL-3 or BSL-4 capabilities to conduct advanced efficacy, challenge, and toxicology studies for pandemic threats.

Government Contracting & Logistics

- Prime Government Contractors: Organizations with extensive experience managing complex, multi-million-dollar DoD, BARDA, or HHS program requirements.
- Global Distribution Networks: Supply chain partners specializing in rapid vaccine distribution to low-resource settings or strategic national stockpiles.

Q: What trends or innovations do you foresee shaping the future of the industry, and how is your company preparing for those changes?

A: The biomanufacturing industry is undergoing a critical paradigm shift toward ultra-rapid, scalable production platforms. This evolution is driven by modern biosecurity needs, which demand medical countermeasure platforms capable of pivoting from antigen discovery to mass production in weeks rather than years. Traditional egg-based and complex mammalian cell culture systems are inherently slow and logistically constrained. Consequently, they are increasingly viewed as ill-suited for the rapid-response timelines required to counter emerging pandemic threats. Versatope Therapeutics addresses these legacy limitations through its proprietary bEV platform. By leveraging highly efficient upstream bacterial fermentation protocols, Versatope bypasses the bottlenecks associated with traditional methods.

Bacteria exhibit exponential growth rates and require significantly simpler, lower-cost infrastructure than mammalian systems, translating into a quantifiable manufacturing

advantage. The operational discrepancies between these two methodologies are distinct across several key metrics:

Upstream Culture Cycle: Traditional mammalian and egg systems require weeks to months of development due to slow cell doubling times and complex clonal line screening. Conversely, the bEV platform compresses this cycle to mere hours or days by capitalizing on rapid bacterial doubling.

Platform Scalability: Conventional manufacturing imposes high capital costs and fixed capacity constraints, relying heavily on specialized facilities and bioreactors. In contrast, Versatope's standard fermentation processes offer a low-cost, high-yield alternative that is easily adaptable to varying production volumes.

Infrastructure Footprint: Legacy systems depend on specialized, heavy-footprint facilities and rigid cold-chain logistics. The bEV workflow mitigates these vulnerabilities by utilizing highly adaptable, localized, and thermostable manufacturing processes.

By shifting away from standard mammalian cell lines, Versatope is positioning its lead asset, VT-105, for rapid scaling at the threshold of an emerging pandemic. This architecture completely sidesteps traditional egg-allocation dependencies and bioreactor bottlenecks. Ultimately, the platform aligns with the strategic goals of the Rapid Response Partnership Vehicle (RRPV) to deliver secure, accelerated medical countermeasure deployments during global health crises.

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Project Spotlight: VT-105, a Universal Influenza A Vaccine Candidate for Pandemic Preparedness

Q: Brief Description of the Project, Achievement, or Success Story.

A: The VT-105 project by Versatope Therapeutics is a clinical-stage universal influenza A vaccine candidate. It utilizes proprietary bEV technology to deliver a single, nano-sized recombinant vesicle displaying multiple viral variants. This design focuses on providing broad-spectrum, cross-strain protection against both seasonal epidemics and potential global pandemic influenza A strains. Unlike standard annual vaccines that focus on the highly mutable head of the virus, VT-105 targets the Matrix-2 (M2) protein ion channel and incorporates diverse viral variants on a single nano-sized vesicle. This design allows it to provide durable, broad-spectrum cross-protection against seasonal and pandemic influenza A strains.

Milestone & Success Story: Clinical Transition

- What Was Achieved: The project successfully completed its rigorous iterative preclinical screening, identifying VT-105 as the company's optimized lead candidate. Backed by a $17.9 million National Institutes of Health (NIH/NIAID) development contract, Versatope officially launched its dedicated Clinical Development Team to steer the asset directly into Phase 1 clinical human trials.

Key Impact Categories

- Technology Advancement: Breakthrough genetic engineering allows the vesicle to mimic viral presentation, triggering a stronger and longer-lasting immune response compared to current commercially available flu vaccines.
- Improved Efficiency & Deployment Success: The bEV platform is inherently thermostable, meaning it eliminates traditional cold chain storage dependencies and radically simplifies mass production scale-up.

Q: Key Outcome or Impact.

A: Standard annual flu shots suffer from diminished efficacy if health organizations misjudge which strains will dominate each season. Because VT-105 targets the highly conserved Matrix-2 (M2) protein and aggregates diverse strain variants on a single vesicle, it has the potential to eliminate the need for a reformatted annual flu shot. This advancement represents a critical paradigm shift for vulnerable global populations and pandemic preparedness.