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A Vision for the Future of Sterile Pharmaceutical Forms

The sterile pharmaceutical manufacturing landscape has been transformed, driven by COVID-19 and growing demand for biologics incorporating mRNA technologies. In 2023, Fareva made a significant change by reorganizing into Business Units, consolidating our pharmaceutical activities into a single entity encompassing the development, manufacturing, and packaging of active pharmaceutical ingredients (APIs, both conventional and sterile), oral solid dosage forms (OSD products), and injectables (standard and highly potent molecules). This end-to-end approach allows us to meet client demands for flexibility and comprehensive services. Here, we outline our strategic vision and measures for continued growth and leadership in this critical sector.

Navigating Market Dynamics

The COVID-19 pandemic, industry consolidation, and government sovereignty calls have highlighted the need for flexible, large-scale sterile drug production. These factors have reshaped the pharmaceutical manufacturing value chain, boosting innovation and emphasizing the role of contract development and manufacturing organizations (CDMOs). Fareva has ramped up its capabilities for swift, efficient production, leveraging our unique family-owned, financially independent model to better serve customers. Our accelerated COVID-19 vaccine development, mobilizing two sites, as well as our development group, effectively demonstrated our agility in addressing major health issues. We have also acquired thorough knowledge of mRNA manufacturing and its stringent logistics, including cold storage.

Strategic Initiatives

Increasing Demand for Biologics

In response to growing biologics and highly potent drug demand, Fareva launched a small-scale pilot for clinical batches (phases 1 to 3), including liquid and lyophilized products, ensuring we remain at the forefront of aseptic manufacturing.

Advanced Aseptic Processing Technologies

We invested in a new manufacturing and filling line at our high-potency facility using state-of-the-art isolator technology to enhance sterility and efficiency, meeting stringent quality standards for sterile products. Fareva's forward-thinking approach ensures that we remain leaders in aseptic manufacturing, providing safe and effective solutions to our clients.

Extension of Pharmaceutical Development Capabilities

In 2023, Fareva also invested in a new sterile GMP pilot facility, equipped with a filling line under isolator, connected to a lyophilizer with confinement for chemicals up to OEB5. This investment at Fareva Pau (South of France), completes the existing Fareva Development assets for OSDs (Farimea - France) and highly potent solid doses (Excella - Germany), to support development activities, clinical trials materials and small scale commercial batches.

Regulatory Stringency and Compliance

Fareva is upgrading aseptic practices to comply with revised EU GMP Annex 1 guidelines, ensuring our products meet high standards of quality and safety. We plan to invest over 30



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million euros in facility upgrades, underscoring our commitment to regulatory compliance and cutting-edge operations.

Growth in the Injectables Market

Fareva is expanding capacity with a new aseptic filling line in Valdepharm (France) for liquids and freeze-dried drugs, including fully automated packaging. This expansion aligns with market growth trends and demonstrates our ability to meet the rising demand for injectables. Our strategic investments enable us to position ourselves in order to capitalize on the growing market, ensuring efficient delivery of high-quality products. Rationalizing our portfolio and consolidating production have optimized our tools and added new capacities complying with Annex 1, ensuring agility and responsiveness to market demands. **With 20 aseptic lines dedicated to commercial injectables producing around 100 million units, Fareva's extensive footprint spans a broad range of sizes, forms (e.g., vials, PFS) and capabilities, reinforcing our position in the industry and ensuring comprehensive service delivery.**

Investment in Innovation

Fareva has established partnerships for new injection devices, combining BFS technology with "ready-to-use" syringe technology, positioning us as leaders in innovative solutions such as ApiJect™. Dedicated equipment and privileged partnerships with clients will soon allow us to offer efficient, economical solutions that can be produced on a large scale.

The US market for sterile injectable solutions is forecast to grow exponentially, by around +12% by 2030. Fareva has prioritized this market by investing in infrastructure and strengthening injectable expertise, positioning us as a key player in this dynamic landscape.

Sustainability and Eco-friendly Practices

Fareva is committed to corporate social and environmental responsibility, with certifications such as ECOVADIS and projects for decarbonization and alternative energy sources, as well as waste reduction through advanced treatment. Our sustainability efforts reduce our environmental footprint while maintaining high production standards.

Expansion of Capacity and Capabilities

Ongoing expansions in Fareva - Valdepharm, Pau, Riom, and Annonay demonstrate our commitment to meeting sterile product demand. Our BFS capacity will soon reach 1 billion units. We've also invested in a new Valdepharm facility for sterile API manufacturing, ensuring leadership in capacity and capabilities.

Human Resources Challenge

Attracting and retaining skilled talent is crucial in the competitive market for aseptic manufacturing. Fareva's proactive policies to build a skilled workforce ensure we maintain high standards and meet regulatory requirements. Our commitment to employee development and retention fosters a culture of excellence, driving innovation and maintaining our competitive edge.

Building Long-term Partnerships

As a family owned company, long-term partnerships with customers are essential in order to ensure in-depth customer understanding and optimal solutions. Fareva's strategic initiatives enhance service offerings and optimize supply chain costs, consolidating our position as a trusted pharmaceutical partner.

Fareva distinguishes itself as a key partner, close to its customers worldwide, responding to specific regional regulatory and cultural needs. Our agility and comprehensive range of technologies meet the diverse requirements of sterile pharmaceuticals.

Our global strategy

Fareva is committed to expanding capabilities, complying with regulatory standards, adopting advanced technologies, and building a skilled workforce. Our strategic vision and proactive measures position us strongly in the competitive sterile products market. We remain at the forefront, driving innovation and ensuring the highest quality standards. Our commitment to excellence, innovation, and sustainability sets us apart as leaders in pharmaceutical manufacturing, ready to meet future challenges and opportunities. ■

**SITE: FAREVA - EXCELVISION (FRANCE)
STERILE CORRIDOR LEADING TO FILLING ZONES**

