

## Press Release

### BIONIQUE TO EXPAND AFTER ACQUISITION BY ASAHI KASEI MEDICAL

**SARANAC LAKE, NY – December 15, 2021 – Bionique Testing Laboratories LLC** (Bionique; [www.bionique.com](http://www.bionique.com)), a global leader in mycoplasma testing services for the biologics and life-sciences industries, announced today that it has been 100% acquired by a subsidiary of Japan-based healthcare pioneer **Asahi Kasei Medical Co., Ltd.** (Asahi Kasei Medical). Bionique joins Austria-based viral and prion safety testing services expert ViruSure GmbH (ViruSure; [www.virusure.com](http://www.virusure.com)) as part of the global biosafety testing services unit of Asahi Kasei Medical's Bioprocess Division ([www.ak-bio.com](http://www.ak-bio.com)). Both Bionique and ViruSure will continue operations under their existing, widely respected brands.

Bacteria of the genus *Mycoplasma* are frequent and problematic contaminants of materials used in the production of biologics (medicines composed of, or derived from, biological materials). Bionique is a dedicated, FDA-registered provider of mycoplasma testing products and services. It is highly regarded for its comprehensive range of GMP testing services that are utilized by a broad variety of biologics companies during all stages of drug development and manufacture and is renowned for its unrivalled depth of expertise, arising from its specialist business experience of more than 30 years. In recent years, Bionique has become the provider of choice for clients faced with the complex CMC challenges pertaining to mycoplasma testing of emerging and rapidly growing treatment modalities such as cell and gene therapy products, and regenerative medicines. Similarly, Bionique's know-how has become indispensable to clients that span the industry, from top global biopharma companies, cell-culture media & sera suppliers, diagnostic test kit manufacturers, academic and research institutions to biotech start-ups.

The acquisition brings together the unique mycoplasma and viral safety proficiencies of Bionique and ViruSure, enabling Asahi Kasei Medical to offer clients expansive and exceptionally reliable biosafety testing support that is based on industry-leading scientific expertise, and is delivered via customized, trustworthy project partnerships. Asahi Kasei Medical is also actively investing in facility and employment expansion at various operating sites of both Bionique and ViruSure, to meet increasing demand for its testing services.

“Joining the Asahi Kasei group will enable Bionique to consolidate its leadership position in the global mycoplasma testing arena and afford our clients access to ViruSure's service portfolio,

satisfying their end-to-end biosafety testing needs from discovery through commercialization”, said Gladis Zamparo, CEO of Bionique.

“We are excited to have a strategic partner like Bionique as part of the Asahi Kasei group, and the expertise in mycoplasma testing that they bring will further strengthen our goal to better service our customers in all areas of biosafety testing” said Andy Bailey, CEO of ViruSure.

### **About Bionique Testing Laboratories LLC**

Bionique offers the full breadth of mycoplasma testing services from lot to final drug product release testing per regulatory guidelines, as well as a GMP-compliant Real-Time PCR assay to support clients’ needs from discovery to clinical trials. Bionique specializes in mycoplasma testing of cell therapies, cell banks, raw materials, unprocessed bulk harvest, and final drug products. Additionally, our highly experienced team has expertise in method development and validation to support the emerging applications of Rapid Microbial Methods (RMM) and commercialization for biopharmaceutical and cell & gene therapy products. Additional services such as regulatory and compliance consultancy add to Bionique’s unique position in this niche analytical testing space. Located in Saranac Lake, NY, Bionique’s facilities include two FDA-registered, GMP-compliant contract testing and contract R&D laboratories. Bionique aims at offering unsurpassed quality mycoplasma testing services, to meet the custom scientific and regulatory needs of each client and partner. Further information on Bionique can be found at [www.bionique.com](http://www.bionique.com).

### **About ViruSure GmbH**

ViruSure is an established CRO offering a wide range of services in the areas of virus and prion safety testing for biopharmaceutical products, cell banking and cell bank characterization services and *in vivo* biosafety studies (adventitious agent testing, tumorigenicity testing, oncogenicity testing) and molecular and potency testing, all required by pharma and biotech companies specializing on biological products (e.g. recombinant proteins, vaccines, human and animal derived biological products, cell based therapies). The company brings a wealth and breadth of expertise to ensure that biopharmaceutical companies meet all relevant pathogen safety testing requirements. Our goal is simple - to offer the highest level of quality, customer service and regulatory compliance for pathogen safety testing. Our state-of-the-art facilities located in Vienna, Austria are validated and certified to both GMP and GLP standards and all testing services are supported by a state-of-the-art risk-based quality management system which ensures we remain cutting edge partner dedicated to providing, first and foremost, a quality service to the biopharmaceutical industry. Further information on ViruSure can be found at [www.virusure.com](http://www.virusure.com).

**SOURCE**

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