AURIGENE
PHARMACEUTICAL SERVICES

# HPAPI molecules development to market

# HPAPI molecules from development to market

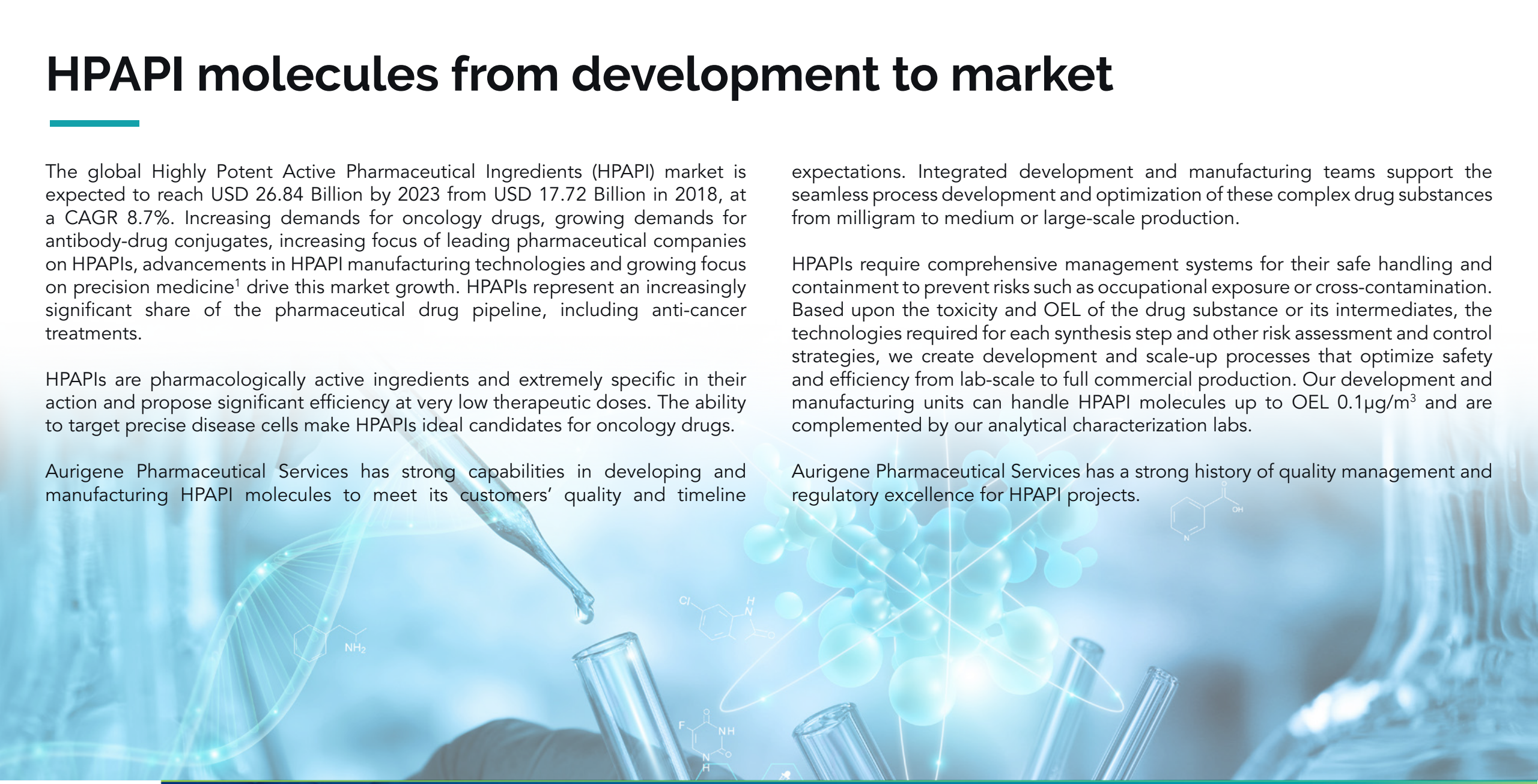
The global Highly Potent Active Pharmaceutical Ingredients (HPAPI) market is expected to reach USD 26.84 Billion by 2023 from USD 17.72 Billion in 2018, at a CAGR 8.7%. Increasing demands for oncology drugs, growing demands for antibody-drug conjugates, increasing focus of leading pharmaceutical companies on HPAPIs, advancements in HPAPI manufacturing technologies and growing focus on precision medicine[1] drive this market growth. HPAPIs represent an increasingly significant share of the pharmaceutical drug pipeline, including anti-cancer treatments.

HPAPIs are pharmacologically active ingredients and extremely specific in their action and propose significant efficiency at very low therapeutic doses. The ability to target precise disease cells make HPAPIs ideal candidates for oncology drugs.

Aurigene Pharmaceutical Services has strong capabilities in developing and manufacturing HPAPI molecules to meet its customers' quality and timeline expectations. Integrated development and manufacturing teams support the seamless process development and optimization of these complex drug substances from milligram to medium or large-scale production.

HPAPIs require comprehensive management systems for their safe handling and containment to prevent risks such as occupational exposure or cross-contamination. Based upon the toxicity and OEL of the drug substance or its intermediates, the technologies required for each synthesis step and other risk assessment and control strategies, we create development and scale-up processes that optimize safety and efficiency from lab-scale to full commercial production. Our development and manufacturing units can handle HPAPI molecules up to OEL 0.1µg/m$^3$ and are complemented by our analytical characterization labs.

Aurigene Pharmaceutical Services has a strong history of quality management and regulatory excellence for HPAPI projects.



# HPAPI capabilities

- Self-equipped high potency chemical development lab with fume hoods (with negative pressure), barrier isolation, balance connected with isolator
- Isolator consisting of sample dispensing, one reaction set up, isolation and drying process
- Multi-purpose solids handling suites
- High potency analytical labs with dedicated equipment connected with pass box
- Analytical instrumentation supporting development; impurity profiling and characterization based on spectral methods
- Validation documentation (DQ/IQ/OQ)
- Biometric access control system
- Lab scale of operation: Up to 50 g per batch
- Scientists trained to handle HPAPI of various molecular architecture viz., heterocyclic, nucleosides, steroids, carbohydrates
- Proficient in handling standard organic chemical transformations, organo-metallic reagents, metal-catalyzed cross-coupling reactions, oxidations, reductions and cryogenic reactions
- HPAPI dispensed and  sifted in isolator
- Charging of blend using SBV, from bin blender
- Contained automatic coater

# Cytotoxic Drug Product: Type of Containments

- Primary containment:  non-exposure of potent product from equipment
- Secondary containment: Secondary containment revolves around processing areas excluding equipment
- Emergency containment provisions

## From route scouting to commercial manufacturing

Our scientific team has a track record of designing cost-effective and scalable routes for process scale-up and kilogram production, our cGMP manufacturing sites CTO-1 (Capacity 63L to 2500 L), CTO-6 (Capacity 63 L to 2000 L), CTO-SEZ (Fully automated 160 L to 1000 L) are equipped with dedicated blocks for commercial manufacturing. Clinical NCE's for oral solid dosage forms and injectables can be provided by FTO-7 with a capacity for solid oral dosage forms of 40 million  units/annum (1 Kg to 25 kg batch size) and small-volume parenteral capacities of 7 million  units/annum (5 L to 100 L batch size). Our in-house lyophilization capabilities are 0.3 million units/annum.

1. High Potency APIs /HPAPI Market, MARKETS AND MARKETS

# Thank You

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https://www.aurigeneservices.com/form/contact

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