PHARMA network® magazine
N°54 - August 2022

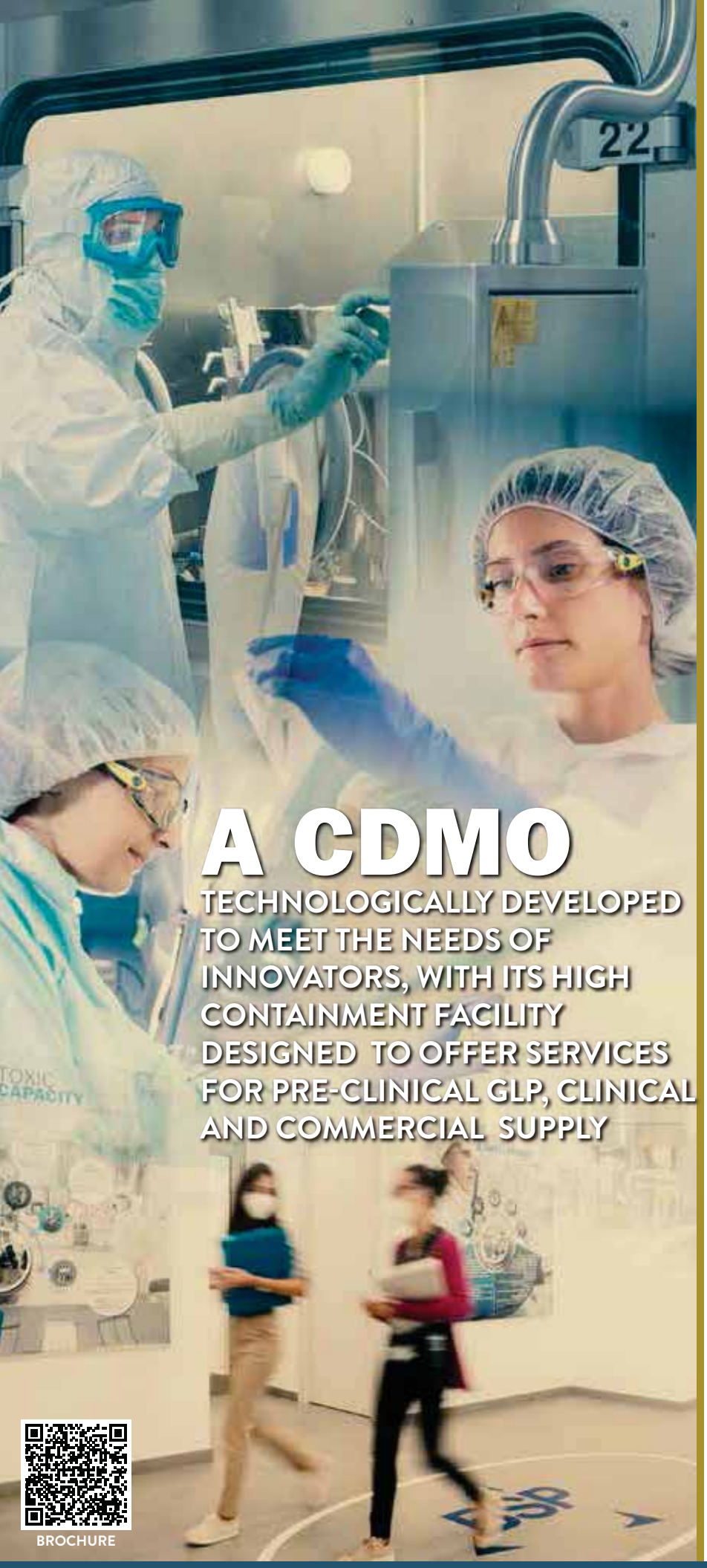
Approvals
Is the UK still "the place to be" for innovation and access to new medicines?

Health economics
Being ready for future pandemics

Finance
Strong first-half 2022 results for Big Pharma

Regulatory
Clinical trials in the European Union are subject to the new EU Regulation

CDMO CEOs:
Visions and strategies for 2022 and after



A CDMO

TECHNOLOGICALLY DEVELOPED TO MEET THE NEEDS OF INNOVATORS, WITH ITS HIGH CONTAINMENT FACILITY DESIGNED TO OFFER SERVICES FOR PRE-CLINICAL GLP, CLINICAL AND COMMERCIAL SUPPLY

BROCHURE

BSP PHARMACEUTICALS

INSPECTED BY:

EUROPE | USA | JAPAN | BRAZIL | KOREA | TAIWAN | TURKEY | SAUDI ARABIA | RUSSIA | IRAQ | KENYA | BIELORUSSIA

CYTOTOXIC

STERILE CAPABILITIES

7 Filling lines working in full containment, to produce liquid and lyo vials

Annual capacity: liq/lyo vials **31** Mill. units end 2022

NON-CYTOTOXIC

STERILE CAPABILITIES

7 Filling lines working in full containment to produce liquid and lyo vials

Annual capacity liquid/lyo vials:

Million units	9 **2022**	17 **2023**	26 **2024**	41 **2025**

DS MANUFACTURING

CAPABILITIES

Conjugation of ADC's
from development (10mg - 5g)
to clinical and commercial (20g - 5 Kg)

Liposomal Bulk Solutions

- **Annual capacity:** 410 Kg
- **Additional** 900 Kg by end of 2022

ORAL

CAPABILITIES

Dedicated manufacturing area for tabs, minitabs, capsule, LFHC

Development: 100g to 1000g

GMP Clinical and Commercial: 4Kg to 100Kg

Annual capacity: 50 Million units

QC ANALYTICAL

CAPABILITIES

Method validation and transfer

Full testing of small and large molecules

Stability and Photostability studies

DEVELOPMENT

CAPABILITIES

Preformulation and formulation development

Analytical methods Development

Process Development: oral solids, conjugation, liquid and lyo formulations, complex formulations

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CDMO CEOs

Jan Kengelbach
CEO Aenova Group

Aldo Braca
CEO, BSP Pharmaceuticals

Dr. Michael Quirmbach
CEO & President
CordenPharma

Alain Sainsot
CEO GTP Bioway

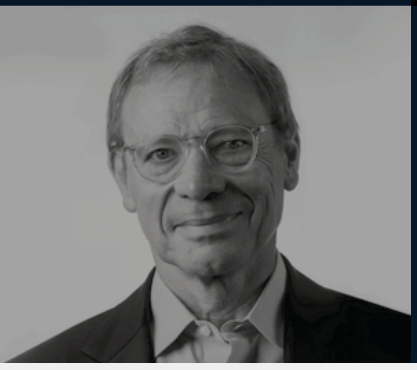
Peter Burema
CEO NextPharma

Pierre Banzet
CEO Pharmatis

Javier López-Belmonte
Vice President & Chief
Financial Officer ROVI

Wolfgang Wienand
CEO Siegfried

David Lescuyer
CEO Skyepharma



Eric Goupil
CEO Unither Pharmaceuticals

Thomas Otto
Managing Director Vetter

CDMO CEOs: Visions and strategies for 2022 and after

Rising labour costs, recruitment difficulties, increasing energy and commodity prices, and supply chain issues, have driven inflation much higher than was expected. Companies' profit margins are being squeezed to some extent. The first signs of a worldwide crisis are starting to spread fears on stock markets. Investors are worried about the consequences of inflation for demand and corporate profits. Never before have business leaders had to face a series of successive crises as that of Covid 19, war in Ukraine, and the risks of recession.

And yet, the biopharmaceutical sector experienced one of its finest moments in 2021 with its vaccine successes. Still in 2021, 5,500 scheduled new clinical trials started, up 14% on 2020 and 19% on 2019. The fundamentals remain sound for biopharmacy and health.

However, market access and getting financing to set up clinical studies are the main difficulties being encountered by start-ups. The big question of concern to investors at the moment is that of how far inflation might go. Biopharmaceutical companies in the launch phase are particularly vulnerable to any market turbulence, as they have few simple ways of generating income or reducing costs while conducting the required clinical trials.

In coming months, it is highly likely that some biotech firms might not manage to raise the funds they need to finalise their clinical trials. Such a situation could have a big impact on the activity of CDMOs specialised in this market.

For its September issue, PHARMAnetwork has asked the CEOs of major CDMOs in Europe and the US to give their reactions to this crisis and its (first) consequences for the strategy of their groups. Their testimonies are full of ideas for the future and, as such, exciting.

How are the heads of these CDMOs addressing the crisis? What decisions have been driven by the situation so far, and how will they change the way their companies are managed this year and in the future? What are the impacts of this crisis on the bio/pharmaceutical manufacturing value chain and more particularly on CDMO activity in 2022? What measures and organisations are they rolling out to boost the resilience of their companies and ensure that they grow on their markets? What strategies are being implemented and how are environmental issues incorporated into these strategies?

PHARMAnetwork would like to thank the following CEOs for their highly relevant insights: Jan Kengelbach, CEO, Aenova Group; Aldo Braca, CEO, BSP Pharmaceuticals; Dr. Michael Quirmbach, CEO & President, CordenPharma; Alain Sainsot, CEO, GTP Bioway; Peter Burema, CEO, NextPharma; Pierre Banzet, CEO, Pharmatis; Javier Lopez-Belmonte, Javier López-Belmonte, Vice President & Chief Financial Officer ROVI; Wolfgang Wienand, CEO, Siegfried; David Lescuyer, CEO, Skyepharma; Eric Goupil, CEO, Unither Pharmaceuticals ; Thomas Otto, Managing Director, Vetter.

Sheltered from stiff headwinds, BSP has designed a model driven by excellence to meet the need of innovators

Aldo Braca CEO BSP Pharmaceuticals

BSP has invested 410 million USD in cytotoxic and non-cytotoxic capacity confirming its position as a strategic partner in the CDMO space.

The increasingly uncertain economic environment has brought challenges for the CDMO industry by multiple fronts, from difficulties in hiring staff, long lead times of raw materials, logistical challenges, soaring energy costs.

BSP has approached these increasingly stiff headwinds against the trend.

As BSP has been the first CDMO to offer an integrated supply chain for ADCs, manufacturing drug substances in conjugation suites and drug products in fill finish suites, all into under the same roof and all combined with a superb quality system, now in a consistent way to its scope of business and mission, it intends to apply the same model of excellence to the second and third line of treatments, opening the largest capacity on the market (up to approx. 1250 Kg mAb/year and 72 million injectables) at the same facility to innovators with a focus on oncology and other relevant therapeutic indications.

With this aim, in 2020 BSP has decided to halve the then current time of execution of its strategic plan to be ready to offer capacity and capabilities adequate to sustain the actual demand of manufacturing of ADCs, as well as non-conventional formulations, like lipid based nano medicine, peptides, proteins, oligonucleotides, and nano medicines.

BSP Pharmaceuticals has continued investing 410 million USD in cytotoxic and non-cytotoxic capacity. The strategic decision to develop segregated facilities, both designed in full containment, for cytotoxic and non-cytotoxic compounds, defines BSP as a unique partner in the CDMO space. **This new cycle of investment will consolidate BSP's leadership in the manufacturing of innovative products.** In particular, the investment plans are focused in on the expansion of the newly built segregated facility until completion of up to seven sterile suites for the manufacturing of non-cytotoxic lyophilized and liquid vials, aimed at serving innovators in the Pharma arena of biologics and small molecule, as well as the completion of one additional sterile suite for the manufacturing of cytotoxic compounds and two brand new conjugation suites, both dedicated to both drug substance and drug product to sustain the growth of clinical and commercial candidates in the ADC and liposomal field. In January 2022, BSP has responded to the need of securing the supply chain with the commencement of the construction of a new warehouse to significantly increase storage capacity and cold chain management currently available on site, for oncology and biological compounds, with 7,500 pallet places at room temperature and about 1000 pallet places for refrigerated and deep-frozen materials, from 2-8°C to - 85°C.

In the last decade, BSP has built enriching collaborations with noted universities and research centers nationwide and internationally and designed courses tailored to business needs with the purpose of training a pool of talents, for complex professionals, ready to be hired with great timing, very often in advance of customer needs, by reducing training times and costs for personnel selection.

BSP is positioned as a center of excellence and a valued strategic partner among those small and large biopharmaceutical companies with an advanced outsourcing process, both in the development of new drugs and in their commercial production for strategic products with a high technological content.

By virtue of such a strategic partnership, BSP supports the growth of its customers, providing them development, clinical and commercial supply services with the same flexibility and reliability as their internal network, without exposing them to inconvenient situations, maintaining a sound financial position that never compromises business continuity, paying great attention to the environment, health and safety. ■