Business segment overview* continued

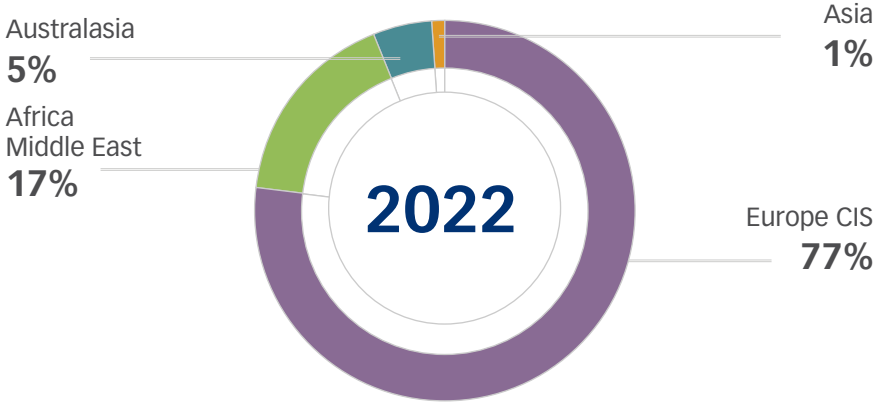
Manufacturing

Aspen has 23 manufacturing facilities across 15 sites. Our strategic manufacturing sites are widely accredited, holding international approval from some of the most stringent global regulatory agencies. We manufacture a wide variety of product types including steriles, oral solid dose, liquids, semi-solids, biologicals and APIs.

28% of Group revenue

12% of Group gross profit

Manufacturing revenue^



	2022 R'million	2021 (CER) R'million	Change %
Revenue			
API	**4 737**	4 849	(2)
API (Biochem)	**778**	1 161	(33)
FDF	**5 433**	3 307	64
Total	**10 948**	9 317	18
Gross profit percentage	**20,6%**	20,6%	

Performance

Performance in the Manufacturing segment was sustained as revenue increased 18% to R10 948 million, led by FDF growth of 64%. This included R1,4 billion in revenue from the fill and finish production of the Johnson & Johnson COVID-19 vaccine at the Gqeberha sterile manufacturing facility. This growth was partly diluted by the API business. Manufacturing in general was negatively impacted by supply-related constraints imposed by COVID-19 in the first half of the financial year and enjoyed a strong second half recovery, growing sales by 14% compared to the first half.

Gross profit at 20,6% was consistent with the prior year, even after dilution for the annualised impact of the supply agreements at low/no margin, related to disposal transactions. Excluding the impact of these disposal transaction-related supply agreements, gross margin increased in all segments. These improvements were achieved despite numerous operational and supply chain related challenges, as well as notable inflationary increases in operating and supply chain costs.

Prospects

Aspen has manufactured over 225 million doses of COVID-19 vaccine, predominantly for Africa. The decline in demand from Johnson & Johnson will have an unfavourable impact on Manufacturing performance in FY2023. We anticipate that any future COVID-19 doses in Africa will be pivoted to Aspenovax, in line with the regional procurement pronouncement and as committed by the African Union, COVAX and AVATT, but the extent of this demand is uncertain. Strong second half weighted revenue growth in FDF from our French facility is expected to more than compensate for the loss of revenue from the Johnson & Johnson COVID-19 vaccine and single-digit revenue growth is anticipated.

Aspen has continued to invest in the expansion of its sterile manufacturing capacity in Gqeberha to be used for vaccines and other steriles, including biological products. The commitment to an additional capital investment of R2 billion will be spread over financial years 2022 to 2024. The statement from the African Union, which called for support to achieve at least a 30% offtake of all

^ *Based on source of manufacture.*

* *All commentary in the Business segment overview reflects CER performance.*

Business segment overview* continued

vaccines from African manufacturers is a strong endorsement supporting this ongoing strategic capital investment. The signature of a long-term agreement with Serum Institute for Aspen to manufacture, market and distribute four Aspen-branded vaccines in Africa is an important milestone as Aspen seeks to optimise its sterile manufacturing capacity in Gqeberha.

Several other potential long-term opportunities are being explored with various multinational partners and Aspen's ambition is to secure these by the end of the 2023 financial year. The contribution from the manufacture of the Johnson & Johnson COVID-19 vaccine enhanced operating performance in the current year, but declining demand from Johnson & Johnson will have an unfavourable impact on Manufacturing performance in the 2023 financial year, unless substituted by orders for Aspenovax. Due to the technology transfer timelines, other sustainable long-term contracts and commercial manufacturing opportunities will only be realised from financial year 2024 onwards.

The four routine paediatric vaccines, Pneumococcal, Rotavirus, Polyvalent Meningococcal and Hexavalent vaccines, represent some of the most important vaccines to Africa and Gavi. Aspen will register its own marketing authorisation and Serum Institute will supply the drug substance to Aspen. It is anticipated that the registration process may be fast-tracked with transfers possibly from 12 to 24 months.

In addition to the agreement with Serum Institute, Aspen also anticipates receiving grant funding from each of the Bill & Melinda Gates Foundation and CEPI to support African regional manufacturing capacity for an affordable supply of vaccines to, among others, African countries and Gavi/UNICEF, as well as contributing to pandemic preparedness, through a share of Aspen's vaccine manufacturing capacity over a period of 10 years. These are both important endorsements of Aspen's sterile manufacturing capabilities and efforts to achieve enhanced access to medicines which is at the forefront of Aspen's ESG strategy.



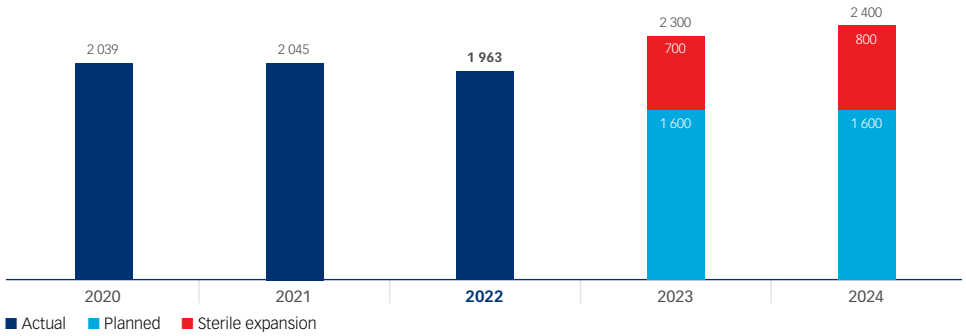
** All commentary in the Business segment overview reflects CER performance.*

Manufacturing operational overview

Our strategic objective of supplying high quality, affordable medicines is underpinned by our own manufacturing capabilities and the vertical integration of certain aspects of our supply chain. Our 23 manufacturing facilities provide a range of production capabilities and capacities, assisting us in the achievement of our current and future commercial objectives. These include steriles, oral solid, semi-solid, liquids, biologicals, vaccines and API manufacturing. Our niche and complex production capabilities provide a strategic advantage in an increasingly commoditised environment. Our sterile capacity and capability is a strategic advantage when considering the increased demand for vaccines and other steriles, including biological products.

During the last year, our strategic manufacturing projects continued to focus on the alignment of our facilities with our manufacturing and commercial strategies, enhancing technology as well as our quality and compliance standards, policies and procedures. Ongoing investment in the upgrading of our world-class manufacturing facilities, in addition to the implementation of state-of-the-art electronic systems and IT capability, support our ability to supply quality products, ensure ongoing compliance with GMP and create increased manufacturing capacity to meet both current and future operational requirements. Capital expenditure on the replacement and expansion of property, plant and equipment amounted to R1 963 million (2021: R2 045 million), with a further R2 300 million planned for FY2023 driven by the additional sterile manufacturing capacity to be used for vaccines and other steriles including biological products. The level of capital expenditure on these strategic projects is expected to reduce from FY2025.

Property, plant and equipment capital expenditure (R'million)*



* *Capital expenditure excludes interest on the cost of funding capitalised to the projects.*

Following the transactions with AstraZeneca AB and AstraZeneca UK, and GlaxoSmithKline Plc, which resulted in the acquisition of our Anaesthetics portfolio, we are transitioning supply from their manufacturing sites to our own sites and supply chain network, providing us with a strategic opportunity to pursue synergies. Significant capital projects are in progress at the Gqeberha, Notre Dame de Bondeville and Bad Oldesloe sites in order to effect these manufacturing transfers. First commercial production of these products at the Gqeberha and Bad Oldesloe sites has commenced, with production and subsequent commercialisation planned for FY2024 at the Notre Dame de Bondeville site.

Oral solid dose manufacturing

We remain focused on increasing the complex manufacturing capability at the Gqeberha site. This site has the ability to provide flexible high-volume manufacturing and packing capabilities for a variety of oral solids doses to several countries through the different regulatory approvals held by the respective units. Continuous improvement projects in respect of these sites are progressing well and delays due to the COVID-19 pandemic are in the process of being recovered, with key projects being:

Gqeberha, South Africa

- The Manufacturing Execution System implementation is progressing on schedule in facilities that require implementation prior to SAP go-live which is planned for March 2023.
- The implementation of the Laboratory Information System is on schedule for completion in all South African Operations laboratories by December 2022.
- The organisational redesign in the Quality Control laboratories is 90% completed and is yielding the required results. Further optimisation is performed as and when required.
- There is increased focus on initiatives to enhance competence at all levels across the site to ensure sustainable performance in the long term. Projects aimed at self-sufficiency in terms of water are completed. Projects aimed at self-sustainability in electricity supply have progressed to the point of readiness to conclude Power Purchase Agreements within the first quarter of the 2023 financial year with construction completed by January 2024. In the interim sufficient back-up power supply is available on a rental contract.

Semi-solid and liquid dose manufacturing

Bad Oldesloe, Germany

- The extension of the manufacturing and packing lines to accommodate the transfer of anaesthetic liquids, creams and ointments is almost complete. Two lines are already producing product for market supply and the process validation on another line is nearly completed.
- The project to install a new blow-fill seal line has been initiated. Construction of the building and the installation of all production machines have been completed and qualification has started. Remaining activities will be completed by early 2023. This line will provide competitive advantages and a production capacity of 120 million sterile single-dose poly ampoules per annum.

Manufacturing operational overview continued

Sterile manufacturing

Our facilities at the Gqeberha and Notre Dame de Bondeville sites provide us with extensive sterile manufacturing capability. Capacity expansion plans in respect of these sites have progressed well in the past year:

Gqeberha, South Africa

- Activities to introduce Anaesthetics production have commenced, a significant step in the evolution of this site. Phases 1 to 3 of the new infrastructure build component are complete and equipment is being installed and commissioned. The equipment that has already been installed is undergoing site acceptance testing. The first commercial batches were manufactured in March 2021. Validation batches for the balance of the products are underway, with completion of validation estimated for January 2023. The introduction of these new products is expected to see the export volume for the total South African Operations business move from 20% to over 50%, with more than 700 additional SKUs being added to the existing portfolio during the ramp-up phase over the next four years.
- The facility received a vaccine manufacturing licence from the South African Health Products Regulatory Authority in February 2021 and dedicated production of the Johnson & Johnson COVID-19 vaccine has been ongoing since first commercialisation in March 2021. Plans for expansion of the facility's vaccine manufacturing as well as lyophilization capacity has been approved and procurement of equipment is at an advanced stage. Construction of the required civil infrastructure is due to commence in FY2023. This includes the required support services such as packaging, cold storage and laboratories.

Notre Dame de Bondeville, France

- The new suite to manufacture anaesthetic dosage forms comprising polybags and poly ampoules is complete. Validation has started on the first line and the completion of the validation for the third line is targeted for the end of 2023.
- The new high-speed prefilled syringe filling line (60 000 syringes/hour) is ramping up with commercial production resulting in additional capacity for third-party business.
- The technical transfer for a further 80 000 prefilled syringes has commenced and commercial production is expected to commence in FY2024
- Installation of a new automatic visual inspection line for prefilled syringes is progressing with qualification and validation to commence commercial production in the third quarter FY2023.
- New autoclave investment for terminal sterilisation capabilities has been initiated to handle the growth of the diluent business at this site. Autoclaves will be installed and commissioned in FY2023.
- An extension of the warehouse with a cold chamber (approximately 1500 pallets) has been initiated to deal with the special requirements of vaccines storage. These works will be completed in FY2024.

API manufacturing

Our API network comprises seven owned sites; three located in the Netherlands (two in Oss and one in Boxtel), one in the USA (Sioux City), two in France (Notre Dame de Bondeville) and one in South Africa (Cape Town). In addition, we have two API manufacturing blocks situated at Laurus Labs in India. These sites provide Aspen with specialised API capabilities in respect of both our own as well as third-party commercial opportunities. The combination of the Oss and Sioux City sites with the Notre Dame de Bondeville site provides a fully integrated biochemical supply chain to support some of our Thrombosis portfolio of products. Initiatives to enhance our capacity and improve sustainability at the API sites have continued to receive focus as follows:

Oss, the Netherlands

- At the De Geer site, an automation upgrade is being prepared for all vessels to further reduce manual operator tasks.
- The upgrade of the process automation system in all the Moleneind site installations has been completed and preparative work for the Manufacturing Execution System implementation (both at the Moleneind and De Geer sites) is ongoing.
- At Moleneind, a new fire extinguishing installation has been installed in one of the production buildings, while three more buildings are in preparation. This mitigates business risk and reduces the size of the mandatory company fire brigade.
- A new storage location for stability samples and reference standards has been realised utilising existing space in one of the laboratory buildings.
- At the Moleneind site, several older facilities were demolished and obsolete installations removed.
- In the Biochem division, an investment in filter drier capacity provides support for a second-generation heparin process.
- At Moleneind, the partial automation of several vessels is planned to eliminate the possibility of a spill.
- An active footprint reduction programme aimed at concentrating activities in core buildings is ongoing at the different sites in the Netherlands as part of the transformation plan.

FCC in Cape Town, South Africa

- Additional steps have been taken to achieve further integration over the chemical supply chain. Additional production steps of intermediates in the rocuronium bromide synthesis have now been transferred from Oss to FCC as synergies across these two sites begin to be harnessed.
- FCC has been onboarded on the Oss SAP infrastructure. This was a major IT investment with impact on FCC's ways of working, but constituted a substantial step towards a further integrated API network/ supply chain.
- The full-scale commercial manufacture of API was initiated in the newly validated high containment/ high efficiency production block C2, in support of backward integration projects.
- The final validation of the recently installed high containment milling and micronising process centre was effected.
- The development and optimisation of an anaesthetic API, which will also support backward integration into the Aspen portfolio of products, was concluded.
- A new water treatment plant for the use of alternate underground water supply during times of constrained local municipal supply was commissioned and validated.
- A new hazardous aqueous waste treatment plant and a solvent recovery unit are being finalised, with both being installed and commissioned in the current financial year, resulting in significant long-term cost savings.
- The upgrade and expansion of fire prevention and control systems in line with regulatory requirements has continued.

More details of our manufacturing capabilities are available online

Manufacturing operational overview continued

External supply manufacturing network

Our FDF manufacturing network also comprises supply from numerous contract manufacturing organisations situated globally, several of which are located in Europe. A number of the products manufactured in the external network have been earmarked for transfer to our own manufacturing sites over the next five years. This move will enhance ongoing supply sustainability. We have an internal team of supply chain and quality experts who ensure that all the requisite controls are in place to facilitate supply, on time and in full, and in compliance with our required quality standards.

Cost containment and increased efficiencies

We have a strong focus on continuous improvement initiatives and savings plans to enhance production efficiencies and optimise economies of scale across the Group. Comprehensive, detailed, multi-year savings plans, covering all aspects of the operations, are progressing to plan and the improvements to the South African Operations, the Oss and the Notre Dame de Bondeville sites are poised to deliver important future cost savings to the Group.

The cost-reduction initiatives fall into two distinct categories: procurement and organisational design. The savings plans have a phased implementation and should be complete by the end of the next calendar year. In addition to the procurement and organisational changes, structural process efficiency initiatives are ongoing and will have both an economical and an ecological improvement, supporting the Group's sustainability goals.

The progress made in achieving these plans across the Group Operations is monitored on a regular basis. By owning our strategically important manufacturing capital, we are able to better manage our product quality, production efficiencies and cost competitiveness to ensure responsive management of the supply chain. This, in turn, supports the maintenance of Group margins.

