



Briefing regarding Life Sciences Business March 10, 2023 (TOKYO)

# Legends



- BPM: Bioprocess Materials
- CRO: Contract Research Organization
- CDMO: Contract Development and Manufacturing Organization
- IVD: in vitro Diagnostics
- CLIA: Clinical Laboratory Improvement Amendments
- PDX: Patient derived xenograft
- CDx: Companion Diagnostics
- cGMP: Current Good Manufacturing Practice
- mAb: Monoclonal antibody
- IND: Investigational New Drug

# Agenda



- Summary
- Mid-term Policy for Life Sciences
- CDMO
- CRO

# Summary of Management Policy



#### Vision

- Create value for all stakeholders through sustainable growth
- Strengthen the resilient business structure by responding to changes in the environment

#### **Business Portfolio**

Digital Solutions (especially SEMI) and Life Sciences as the center of our business portfolio



## **Business Target**

ROE more than 10%

**Exceed Prior**Core OP Peak

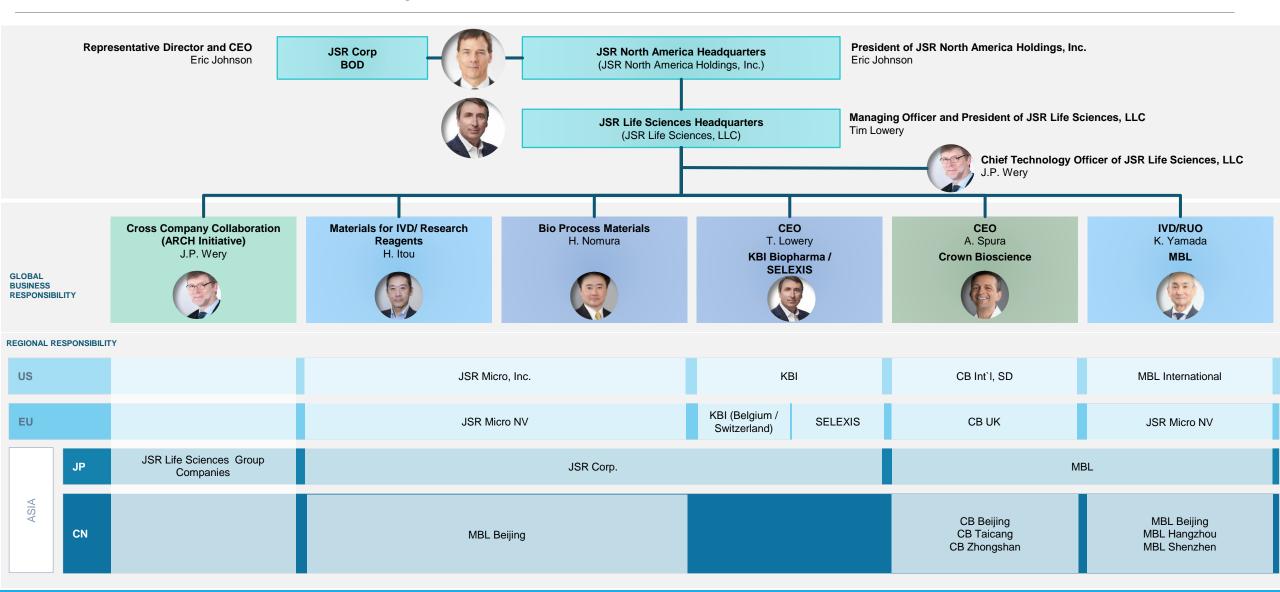
more than 60 billion yen Digital Solutions & Life Sciences

#### **Structure**

# Resilient infrastructure

Innovation
Digitalization
ESG commitment
Employee engagement

# Global Leadership Team



# Mid-term Policy for Life Sciences

# Summary



	Performance results	Over the past few years, sales have grown from 50 billion yen to over 100 billion yen. We have established a competitive position in the biopharmaceutical development space from drug discovery to clinical manufacturing and commercialization.
LS Strategy	Mid term plan (MTP)	• The sales target for FY24 is expected to achieve in FY22. We've completed upfront investment to allow for further growth. With the 20% OP margin target within reach, we will focus our efforts on increasing the efficiency of all businesses.
	Long term vision	We have started formulating the future business projections for the long-term expansion and value creation for JSR Life Sciences.
CDMO Segment	Strength	• Our strength is our technical acumen, which leverages our ability to analyze complex proteins to provide consistent support from non-clinical and early-phase to commercialization of candidate drugs.
	Track record	• The number of development programs, which will be the source of future earnings, increased by +20% YoY, and the order backlog increased by +10% YoY. (As of December 2022)
	Outlook	• The commercial ramp-up of the new KBI facilities is now progressing well, heading towards full production in H2 FY23. We aim to achieve OP 20% during the MTP by controlling cost increases and implementing intensive measures to improve profitability.
CRO Segment	Strength	• Market leader position in drug discovery support services in the oncology area. We have advanced disease-related platforms from the world's largest number of PDX models to organoids. Second largest sales sub-segment after CDMO in LS segment. (excl. antigen test kit)
	Track record	• Approx. 40% of new cancer drugs in the US (2021) were provided with Crown's drug discovery support services. Out grew the market by leveraging Crown's distinctive strengths.
	Outlook	• Going forward, we expect double-digit sales growth and stable profit growth. Furthermore, with our recent M&A, we expect to expand our business and regional portfolio, including the biobank business and CLIA business and expansion into the European and Japanese markets.

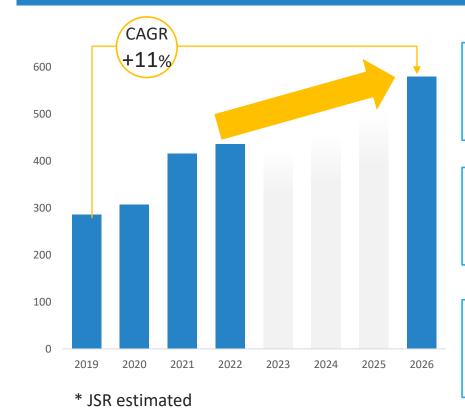
## Life Sciences: Market



#### **Opportunity gets stronger**

#### Our playing field gets stronger





Aging society

Personalized medicine

Efficiency improvement of drug development

#### JSR Life Sciences in this space

#### **Our Segment**

#### **Life Science Services (LSS)**

- Key enabler of Pharma market
- ~25-30% of Pharma value pool
- Attractive growth and returns

#### **Our Business**

#### High end services and inputs

- Contract services (CRO, CDMO)
- Materials (purification media, diagnostic kits, beads)

#### **Our Customers**

#### Innovators across the lifecycle

- Bio Pharma
- Virtual Biotech
- Academia

## Who We Are



We are committed to become a high-performing life science services (LSS) provider

#### Vision of JSR Life Sciences

Being **the partner of choice** to innovators by delivering reliable, innovative and technically differentiated **services & products** essential to advancing customers' assets

#### Mission of JSR Life Sciences

Empower our customers to improve human health.

We do this by engaging the finest scientific talent, upholding the highest quality standards, and relentlessly pursuing innovation.

We strive to **accelerate** and **de-risk** drug discovery & development to help realize a world where **every patient gets the right treatment at the right time**.

# Our Portfolio Today



#### We have built a competitive advantage in the LSS space

<u>Discovery</u> <u>Preclinical</u> <u>Clinical</u> <u>On-Market</u>







(Service)





- Advanced disease models, eg. PDX, Organoid and other model platforms
- Premium oncology sample access service



(Material/product)



"One Stop Shop" services for IVD/CDx products in Japan







- Complex biologics process development and manufacturing
- Advanced modality development



(Material/product)



**BPM** 

 Innovative bioprocessing separation product and service

"Right patient, right treatment, and right time"

- Personalized Medicine

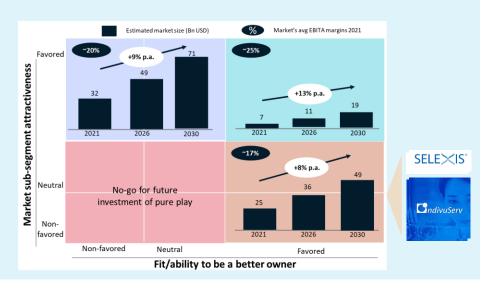
## Outlook: What is Next



We will stepwise expand our LSS ecosystem to enhance the leadership and double down on creating value from our portfolio

## Expansion of ecosystem

- Developed LSS portfolio expansion roadmap
- Prioritization exercise based on market attractiveness and fit to JLS
- Prioritized segments for expansion, worth ~\$140
   Billions out of ~\$300 Billions total LSS market in 2026



## Rigor in value creation

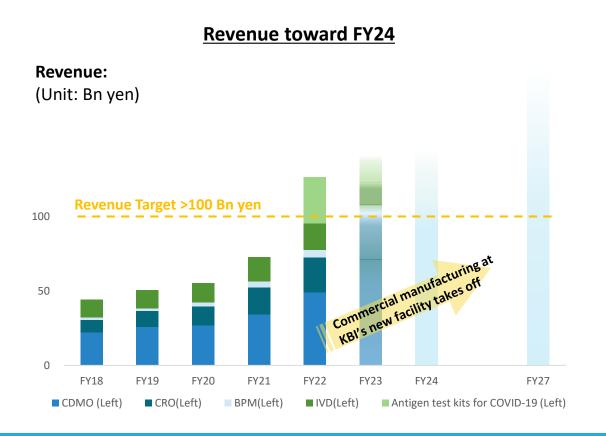
- Disciplined portfolio management and excellence in targeted M&A
- Value-focused (financial) management system to safeguard our resources for growth and innovation
- Upskilling and leverage talent across the ecosystem
- Centralized support to enable affiliates to excel in their core (delivering superior service and innovate their offerings)
- Leveraging JSR Digital capabilities to build valueadding new offerings, service model and customer experience
- Goals and objectives aligned with profitable growth at industry standard for all affiliates

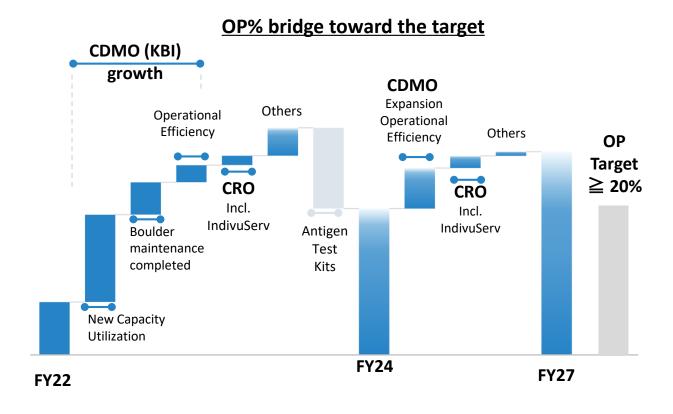
# **Progress of Business Targets**



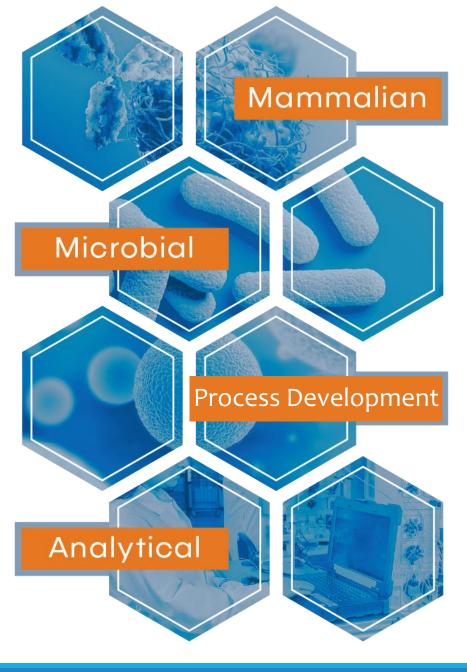
#### FY24 Target: Revenue growth to > 100 billion yen and achieve more than 20% ROS

- Expected to achieve the revenue target ahead of time in FY22.
- ROS target is within range in FY24 by the takeoff of CDMO's commercial manufacturing and expansion and efficiency gains from overall our portfolio businesses.





# CDMO



- Selexis' specialized high-titer mammalian cell line development technologies and services
- KBI's cGMP bulk drug manufacturing for clinical and commercial requirements





- Cell line development, tox material, clinical, and commercial bulk drug manufacturing
- Unique expertise fixates on manufacturability; enables the expression of "difficult-to-refold" products.
- Extensive immunotherapy experience
- Industry-leading analytical characterization capabilities
- Comprehensive services for autologous and allogeneic cell therapy products
- 3300+ projects completed
- Extensive cell-based assay support and product stability
- Process support from development to validation
- Formulation experience on 100+ molecules; concentration ranges from 1-300 mg/ml
- Industry-leading large molecule particle characterization capabilities



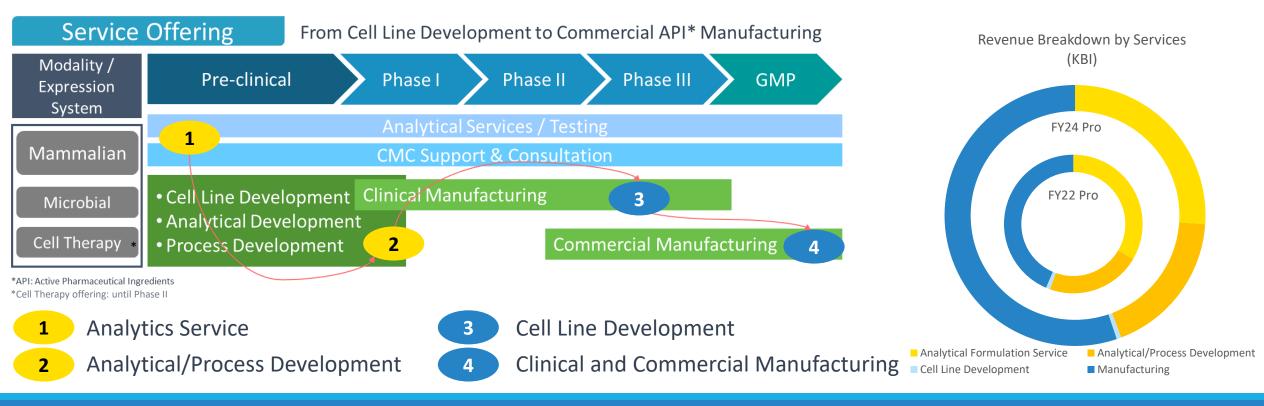
## Serving Clients in Our Worldwide Facilities



# KBI's Uniqueness as CDMO



- Strength in Analytical service (protein characterization) and Analytical/Process
  Development established capability of Clinical/Commercial manufacturing of
  difficult-to-express molecules
- These capabilities feed into manufacturing programs, which is growing now



# KBI's Origin: Analytical Service



- KBI started as an analytical service provider
- An Industry-Leader in Analytical services has given KBI the strength to deal with difficult molecules.

#### **PERFORMANCE**

- **KBI** is The Industry-Leader in **Protein Analytics**
- **17** years Of Leadership in Formulation Development
- **3300+ Projects Completed**

#### MORE HIGHLIGHTS

**Industry leading array of analytical** equipment and scientific expertise

- 160+ Formulation development projects to date
- Multiple dosage forms: Intravenous, Subcutaneous, Intramuscular Intravitreal, Topicals
- Product concentrations ranging from 10μg/mL to 300mg/mL
- 200+ active product stability studies
- (GMP & non-GMP)

#### **Experience Across All Biologics**

IgG1

Conjugates

• IgG2

Peptides

• IgG4

- Polyclonals
- Bispecific
- Biosimilars

Fc and

- IgM
- Fab
- ADC

- other Fusion **Proteins**
- Highly
  - **Glycosylated**

**Proteins** 

- Enzymes Cytokines
- Protein
- Growth

factors

- vaccines
- AAV
- PEGylated proteins

# Another Strength: Analytical/Process Development

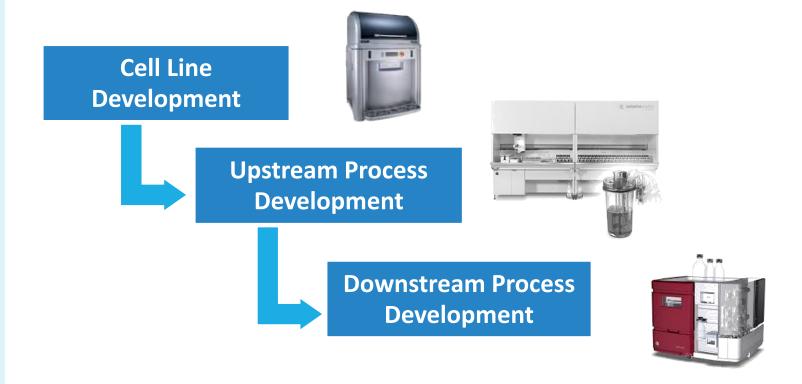


KBI has developed the processes for various molecules

#### **Process Development Focus Areas**

- Support upwards of 40-50 programs annually
- Collaboration with Selexis on >48 programs
- Including PhI PhIII dev and PC & PPQ support
- Process development for mAbs, bispecifics, Fc-fusions, and recombinant targets
- Platform for mAbs and complex bispecifics
- 10+ peer reviewed publications

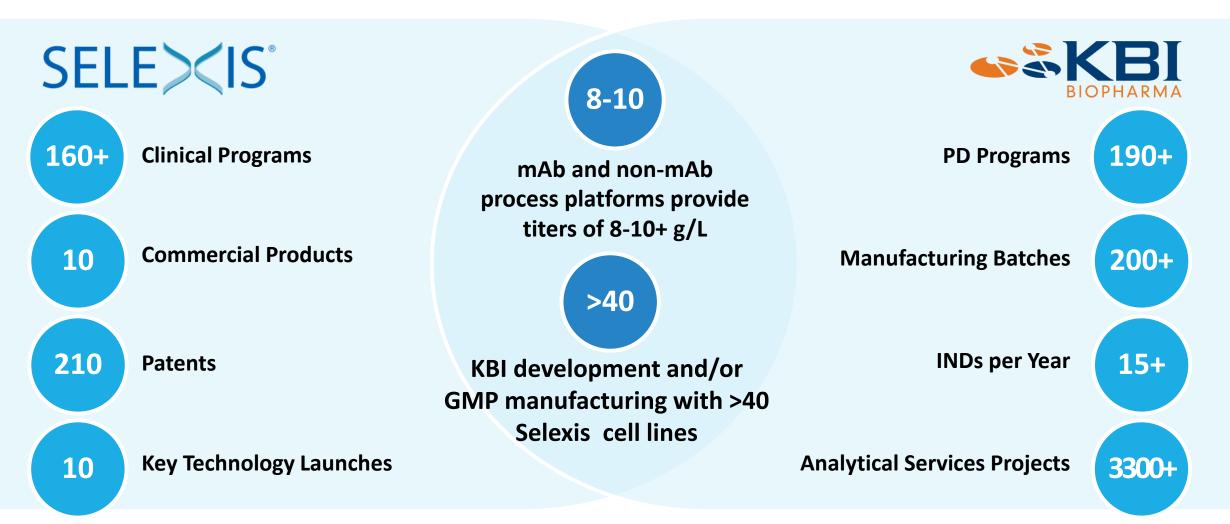
**Process Development** delivers the process and robustness data needed to enable successful scale up to GMP manufacturing



## Manufacturing: Best-in-Class End-to-End Mammalian Offering



Synergy between Selexis and KBI strengthens the mammalian offering



## Track Record



#### **KBI**

50

-150

FY19

 Expanding in both revenue backlog and # of programs, strongly reflecting technical capabilities

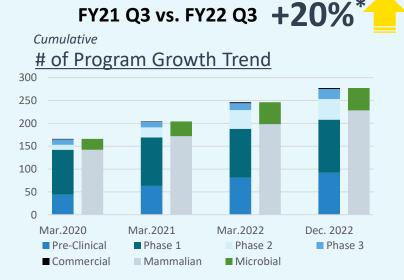
Increasing # of multi-year manufacturing contracts contributed to increased Backlog. New Booking at the end of Q3 FY22 has already reached 85% of FY21 total

Strong increase was seen in mammalian with increased # of Phase 2 and Phase 3 programs

# Booking 85%\* Backlog 110%\* Booking Growth Trend New Booking Revenue Backlog 450 April 1988 Revenue Backlog

FY20

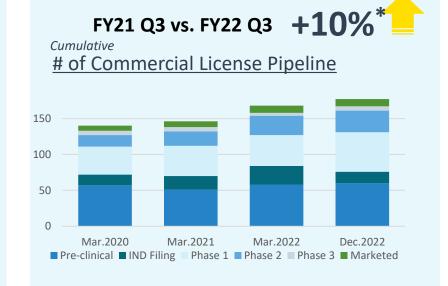
FY22 O3Ytd



#### **SELEXIS**

 Constantly increasing # of Commercial Licenses

Commercial license is a potential future revenue source through milestone payment and running royalties



\*Numbers are approximate. 2

# KBI Profitability Improvement



 FY23 marks a turning point with the combination of the successful launch of commercial manufacturing in NC and well managed cost control

#### **Ongoing Objectives**

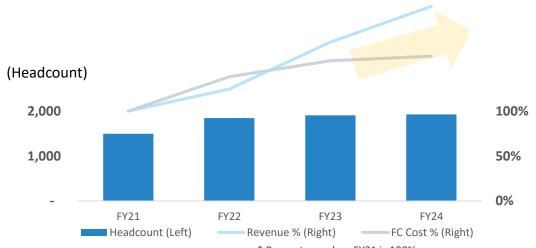
In addition to the successful launch of the commercial manufacturing facility, we are following continuous efforts strengthen the profitability.

- 1. Ensuring commercial excellence
- 2. Unlocking operations and filling capacity
- 3. Improving productivity
- 4. Optimizing external spending
- 5. Implementing an enhanced network strategy
- 6. Collaboration with a leading transformation consulting firm to further drive improvements

These efforts are going to continue throughout MTP period to maximize profitability.

#### **Revenue vs Cost**

- From FY23, the commercial MFG revenue in NC will grow significantly together with other service growth.
- Staffing level which satisfies the growth has been mostly onboarded in FY22
- Only limited incremental increase in staffing will be required in FY23-24.



# Identified items for KBI's Profitability Improvement



 Preliminary analysis has already identified significant number of items for profitability improvement



## Virtual Plant Tour



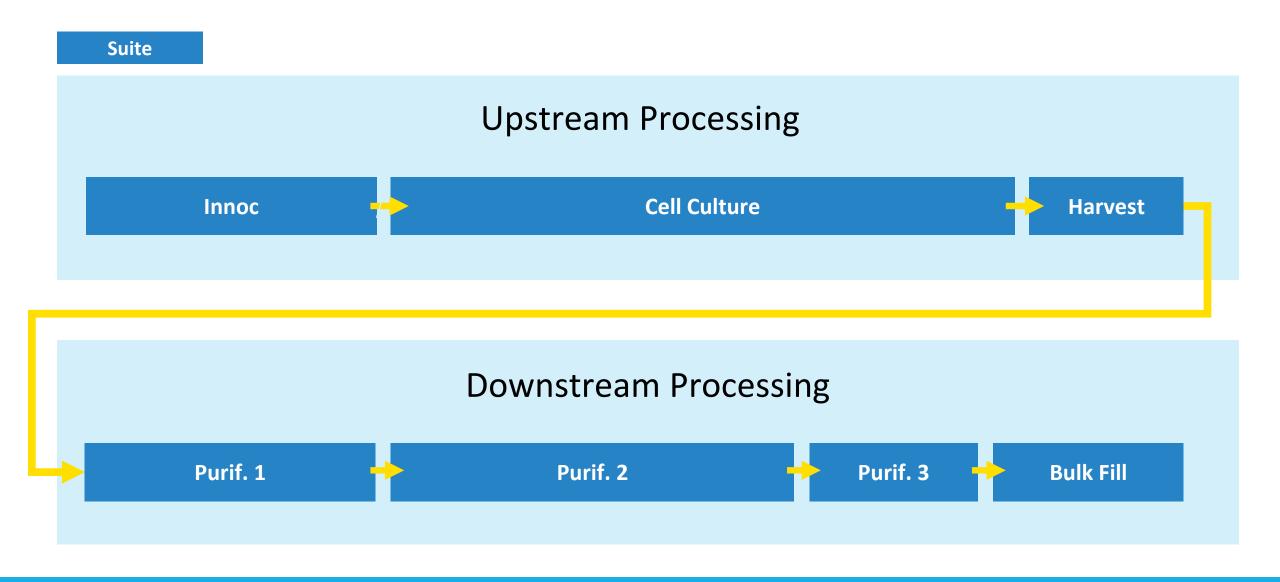
Patriot Park Facility in North Carolina



- Since: 2022
- Location: Research Triangle Park, NC
- Usage: Commercial manufacturing
- Feature:
  - 150,000 square-foot commercial manufacturing facility for Mammalian
  - 2000L bioreactor: 6
  - Campaign operation: 24x7
  - Purification rooms: 3
  - Significant future space

# Production Process at Patriot Park Facility in North Carolina USR

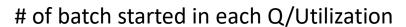


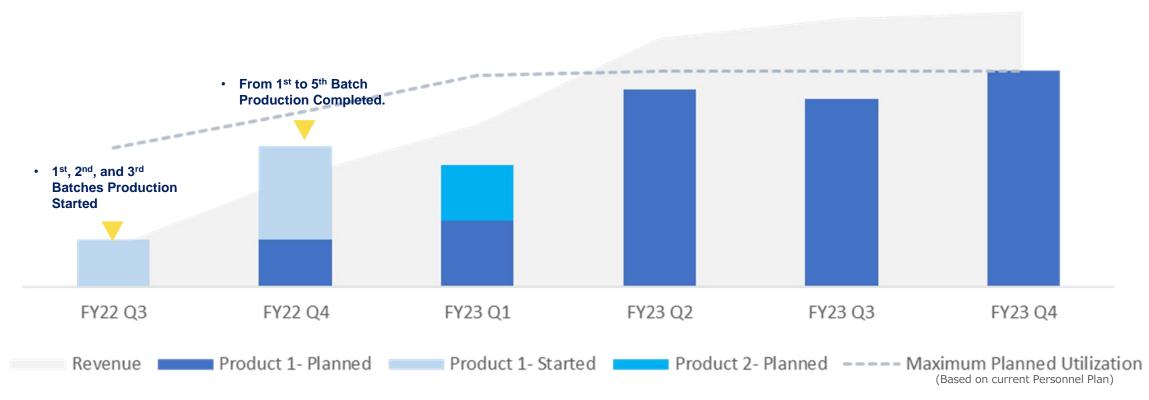


# Production Schedule of Patriot Park Facility: UPDATED



Ramp Up Utilization and Achieve Full Utilization through Q4 FY23





<sup>\*</sup>The above production plan is subject to change as it is reviewed from time to time. No major changes from Q3 FY22 results.

<sup>\*</sup>As of the end of February 2023.

# CRO

# Crown Bioscience is primarily active in discovery and early **pre**-clinical phases



# Major Life Science Service (LSS) value streams Crown Bioscience is engaged in

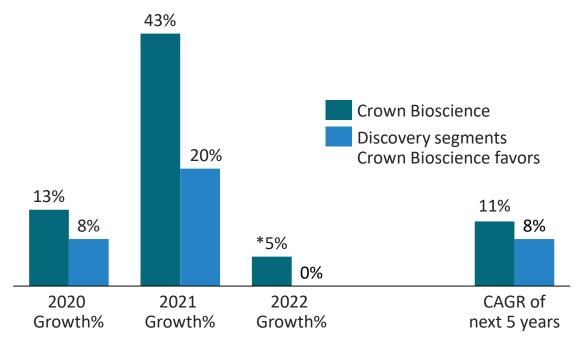
Discovery	Preclinical	Clinical	Commercial
Identify & validate the right targets			
Identify & optimize to right molecules	he		
Biomarker discovery, validation and development		Clinical trial biomarker testing Con	mpanion Diagnostics CDx
	Enable the IND	Show the clinical evidence and file with authorities	
CROWN BIOSCIENCE	Make the drug substance i	n right quality and scale ! I	Drug product manufacturing, F&F

- Estimated market size of these three value streams is at \$17.5 Billion in 2023 and grows at 5% CAGR through 2026.
- Crown Bioscience does not offer service for all segments within the three streams today. Estimated total accessible market size of Crown Bioscience would be >\$1.2 Billion.

# Crown Bioscience has consistently outperformed in the oncology pharmacology market

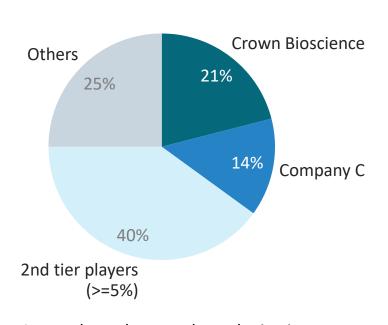


# Crown Bioscience has exceeded market growth and expects this trend to continue



- 2022 market contraction was attributed to decline of fund raising in public markets and VC spend, particular in early stage biotech
- The future market outlook remains attractive because:
  - Outsourcing penetration is set to increase
  - Pharma R&D spend is estimated to increase by 2.6% pa through 2028.
  - At the same time, pharma are reducing their R&D labor force., driving up outsourcing needs

# Crown Bioscience is the market leader in the oncology pharmacology market as of 2022

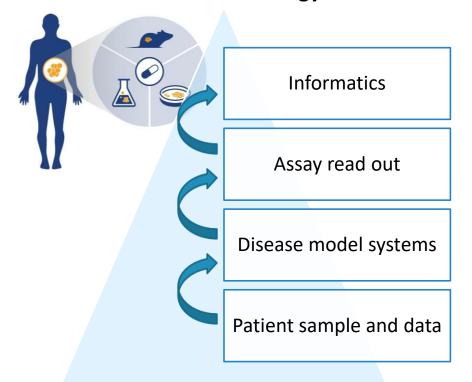


In oncology pharmacology, the in vivo market represents a majority of the overall market, with in vitro and ex vivo markets contributing <50%

# Crown Bioscience's comprehensive portfolio of translational biology services is a key differentiator for customers



# Major foundations enabling full translational biology service



# Crown Bioscience has advanced capabilities in each of the four foundations

#### Multi-Omics platforms

- 2<sup>nd</sup> generation NGS, Illumina and BGI
- 3<sup>rd</sup> generation NGS, PacificBio
- Bionano platform for structural variants
- Hypothesis free proteomics
- 10X single cell RNA and spatial biology
- Digital pathology

#### Hu**Base**™

The world's largest and annotated PDX library

- 3,000 PDX models, ~10k users and 40k access yearly
- 15,000 treatment datasets

#### In house data science team

- Going beyond data generation CRO service to insight generation
- Partner with Cambridge Quantum Computing (CQC) to employ quantum technology to identify multi-gene biomarker for oncology drug

## Acquired Ocello to become a leading Organoid model system CRO in 2021

 FDA animal reduction act announced in 2022 could turbocharge the organoid CRO demand

**43 novel drug** approvals by FDA since Nov 2019, **17 novel oncology drug** approvals, Crown Bioscience directly contributed to **7** of them (~41%).



# A global operations network ensures on time project delivery while maintaining consistent quality and competitive price



Global operations network with strong presence in Asia, allowing Crown Bioscience to manage both cost structure and operational sustainability

#### An illustration of Crown Bioscience site network as of Feb2023



Most Important factors when Choosing a CRO to Work With

- 1. Depth of resources to support quick project initiation and turnaround
- 2. Quality of work
- 3. Pricing

IndivuServ business unit acquisition from IndivuMed announced on Jan 25<sup>th</sup> 2023, estimated closing time Apr. 1

Will have Certified CLIA\* labs in EU and US
 \*CLIA: Clinical Laboratory Improvement Amendments

Opened Crown Bioscience's
Singapore operation on Feb 10<sup>th</sup>
2023 in collaboration with A\*STAR Agency for Science, Technology and
Research to hedge against China
risks and US costs



# Indivumed acquisition will boost translational biology service and premium oncology sample access service



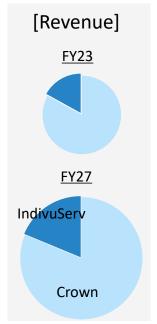


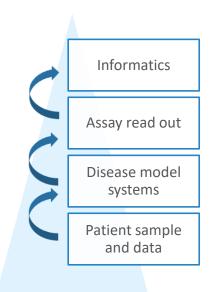


- IndivuServ is a business unit of Indivumed and will be acquired by JSR in this transaction.
- A market leader in prospective oncology high quality sample access service.
- Acquisition includes biomarker testing labs in US and Germany

# Strategic rational 1 - Enter a high growth service subsegment driven by personalized medicine

Entering premium oncology sample acquisition biobanking service market with total addressable market size \$0.5 Billion and projected to grow at low double digits through 2026. Strategic rational 2 - Highly complementary to translational biology service capability of Crown Bioscience





#### Value creation opportunity of the deal to Crown Bioscience

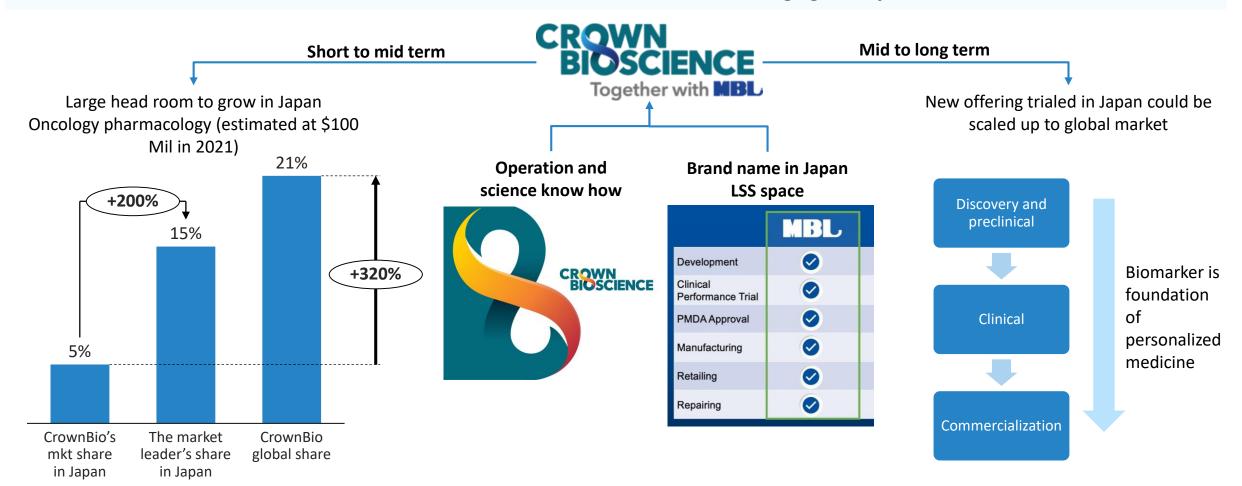
	Synergy rating	Unmet customer needs	Benefit to Crown Biosciences
	L		<ul> <li>Upsell more data analysis service because of strong data generation capabilities</li> </ul>
	Н	Availability and quality of biospecimens prolong the biomarker project timeline	<ul> <li>Streamlined bioassay validation and testing attracts more customer</li> <li>CLIA lab and regulatory know how</li> </ul>
	Н	More translational models to minimize clinical stage failure	<ul> <li>Offer patient sample based ex-vivo assay</li> </ul>
	Н	Samples paired with deep characterization data	<ul> <li>Faster expansion of model repository</li> </ul>

# By leveraging JSR's Japan heritage, we can gain a competitive advantage in the LSS market of Japan



Strategic rational 1 – Unlock full potential of Crown Bioscience in Japan market

Strategic rational 2 – Could be a launchpad for new service offerings globally



Source: LEK, Crown Bioscience management estimation

## Future portfolio expansion strategies of Crown Bioscience



Discovery	Preclinical	Clinical	Commercial
Identify & validate the right targets  Identify & optimize right molecules	2 the 12		
Biomarker discovery, v	alidation and development	<b>•</b>	Companion Diagnostics
	Enable the IND 2	Show the clinical evidence and file with authorities	

- Defending market leading position of Crown Bioscience's core business
- 2. Expanding the accessible market size of Crown Bioscience in the preclinical space
- 3. Strengthening the preclinical CRO portfolio with the goal of becoming preclinical and clinical CRO specialized for personalized medicine





# Thank You