



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



UNIVERSITÀ
DEGLI STUDI
DI TORINO

BSP PHARMACEUTICALS

COMPANY OVERVIEW

June 4th, 2021



- **CDMO FOUNDED ON 2006**
- **High Containment and Explosion Proof** manufacture facilities
- Located in Italy (40 miles South of Rome)
- Business offices (BSP USA Inc.) Princeton, NJ
- **Segregated** facilities for cyto and non cyto products
- Facilities designed to handle **Small and Large Molecules, ADCs, Peptides, and Nano Medicines** from **DS to Fill/Finish**, from **Development to Commercial** supply as well.
- Supplying > 70 Countries

CONJUGATION of ADCs

MICRO/NANO EMULSION

TABS, MiniTABS

CAPS, LFHC

LYO-LIQUID VIALS



CAPABILITY OVERVIEW

LYO VIALS

LIQUID VIALS

INJECTABLES

DS MANUFACTURING

ORAL

INJECTABLES

HIGH POTENT & CYTOTOXIC

Small and Large
Molecules
Pre-Clinical, Clinical &
Commercial Supply

NON CYTOTOXIC

START UP 2021

Small and Large Molecules,
Pre-Clinical, Clinical &
Commercial Supply

COMPLETION

Q2-2023

VISUAL
INSPECTION

WAREHOUSE

DEVELOPMENT LABS

THENA BIOTECH
RESEARCH LAB

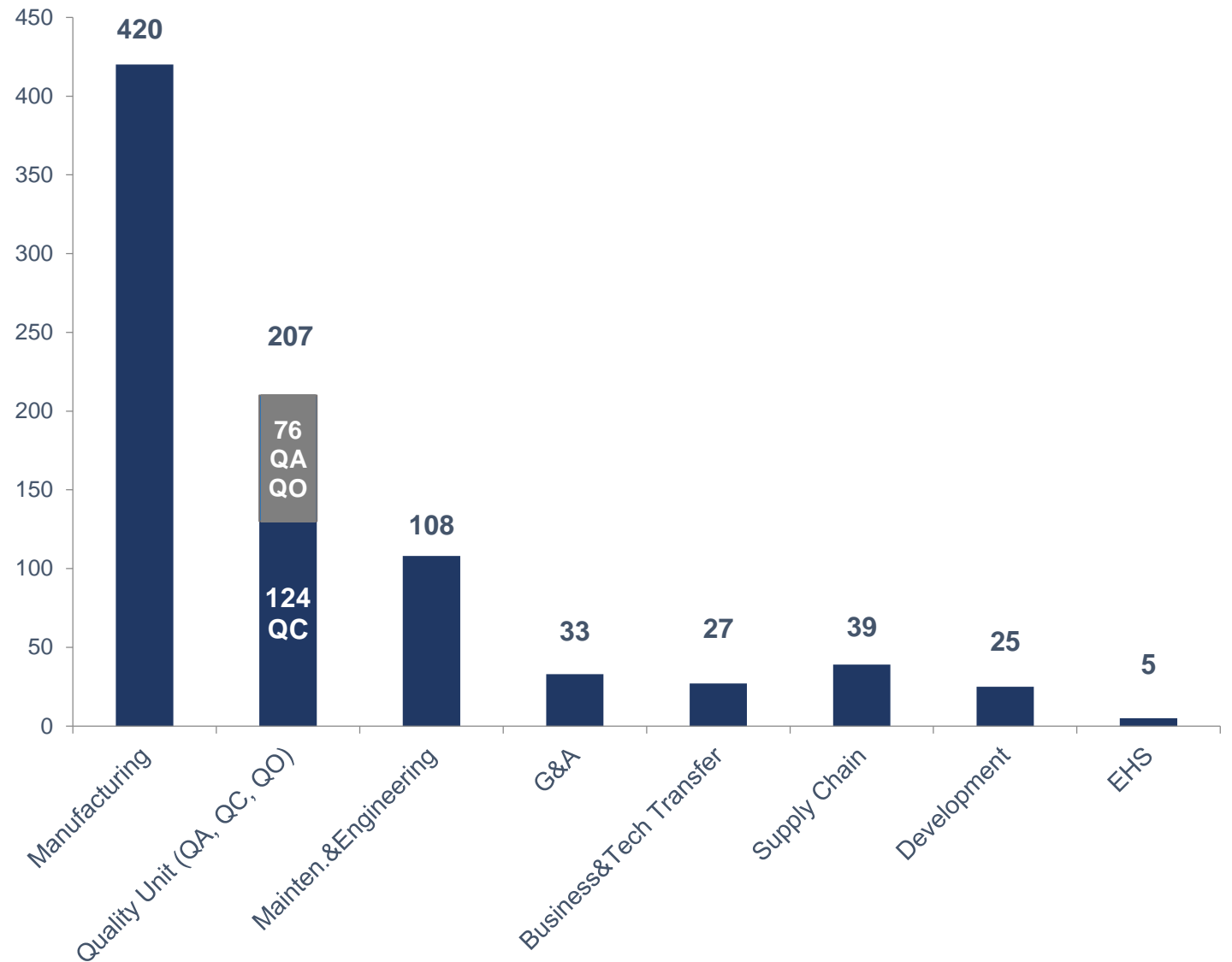


EMPLOYEES

Total: 867

(updated to Apr. 2021)

47% of the employees are graduated from University



SERVICES AND CAPABILITIES

SPECIAL CAPABILITIES

- **ADC PRODUCTS**
Conjugation & Fill Finish
- **LIQUID Filled Hard GELATINE Capsules**
- **PEPTIDES**
- **OLIGONUCLEOTIDES**
- **NANO ENCAPSULATED drugs**
- **LIPID BASED Formulations**
- **ORGANIC Solvent Based Formulations**

DEVELOPMENT

CLINICAL
SUPPLY

COMMERCIAL
SUPPLY

ANALYTICAL
SERVICES

REGULATORY
SERVICES

• **TABLETS**

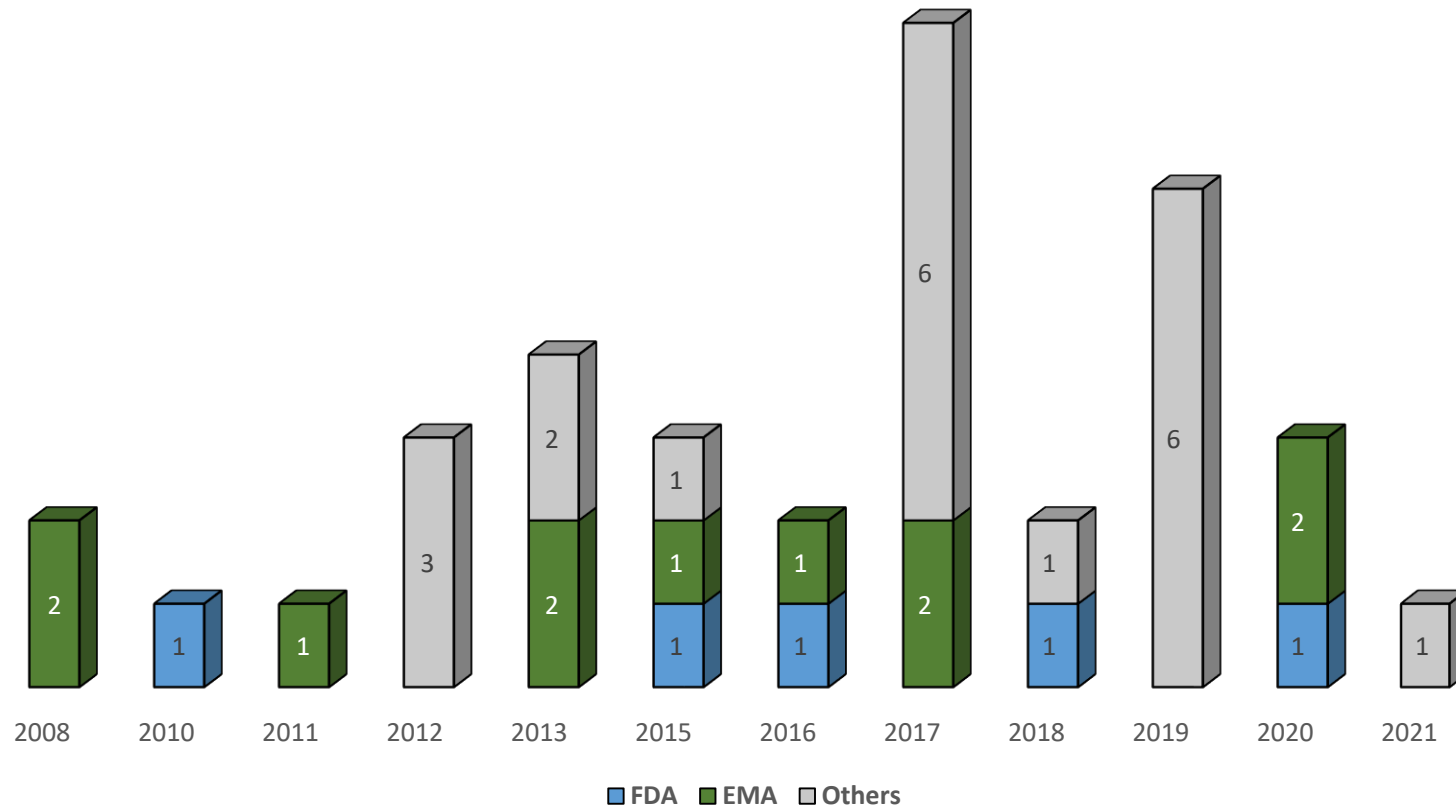
• **CAPSULES**

• **LYOPHILIZED VIALS**

• **LIQUID VIALS**

CONVENTIONAL CAPABILITIES

REGULATORY HISTORY



Regulatory Agencies inspecting BSP on a regular base

-  • EMA
-  • FDA
-  • PMDA
-  • ANVISA
-  • TURKISH
-  • KFDA
-  • SAUDI ARABIA
-  • RUSSIA
-  • TFDA
-  • IRAQ
-  • KENIA
-  • BIELORUSSIA

Expertise

Our Technology Transfer History



78

ADCs PROGRAM SUCCESSFULLY
TRANSFERRED

25

ADCs SUPPORTED WITH
INTEGRATED DS & DP
MANUFACTURING

CLINICAL SMALL
MOLECULES

61

CLINICAL LARGE
MOLECULES

98

COMMERCIAL LARGE
MOLECULES

28

COMMERCIAL SMALL
MOLECULES

43

230

TECH
TRANSFER
2008-2021

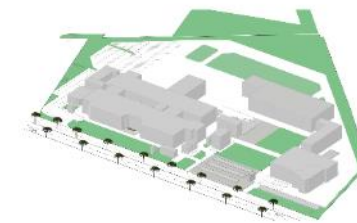
PLANT CONTAINMENT POLICY

The plant has been designed
to achieve the following
Occupational Exposure Limit
(OEL) : <10 nanograms/m³



CONTAINMENT GRANTED BY:

- **INSULATING SYSTEMS**
isolators, active cRABS, Containment valves
- **PRESSURE CASCADE FROM OPERATIONAL** to surrounding areas
- **CONTINUOUS MONITORING**
of differential pressure and related alarm systems
- **DEDICATED** air handling systems
- **100% Exhaust air** no recirculation
- **ABSOLUTE FILTER** of exhaust air
- **CONTAMINATED WASTE WATER**
Segregation, Inactivation and Disposal



BSP CAMPUS



LEADERSHIP AWARDS 2019
CAPABILITIES, EXPERTISE, RELIABILITY, SERVICE

LEADERSHIP AWARDS 2018
CAPABILITIES, COMPATIBILITIES, EXPERTISE
RELIABILITY, QUALITY, DEVELOPMENT

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STERILE
SUITES

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INJECTABLE CAPABILITIES CLINICAL AND COMMERCIAL SCALE

- **DOSAGE FORMS:** Lyophilized and Liquid vials
- **VIAL SIZE:** from 2ml to 100ml
- **CRYOGENIC FREEZE-DRYERS**
- **AUTOMATIC** Loading & Unloading System (ALUS)
- **COMBI DOSING** in all the filing lines (peristaltic and rotary piston pumps)
- **MANUFACTURING LINES** designed under active cRabs
- **100% CCIT TEST BY FMS**
- **VISUAL INSPECTION** – Manual, Semi-Automatic & Automatic
- **SECONDARY PACKAGING** - for Commercial supply

APPROX. 2866 SQF LYO SURFACE

Sterile 1



- Liquid and Lyo vials
- 2 x 107 sqf LYO (GEA)
- Bosch Filling line, statistical weight check inline

Sterile 2



- Liquid and Lyo vials
- 1 x 16 sqf LYO (GEA)
- DF Filling line, statistical weight check offline

Sterile 3



- Liquid and lyo vials
- 2 x 323 sqf LYO (Telstar)
- Corima Filling line, statistical weight check inline

Sterile 4



- Liquid and Lyo vials
- 2 x 215 sqf LYO (GEA)
- Steriline Filling line, 100% weight check inline

Sterile 5



- Liquid and Lyo vials
- 2 x 215 sqf LYO (Telstar)
- Corima Filling line, 100% weight check inline

Sterile 6



- Liquid and Lyo vials
- 2 x 65 sqf LYO (Telstar)
- Steriline Filling line, 100% weight check inline

Sterile 7



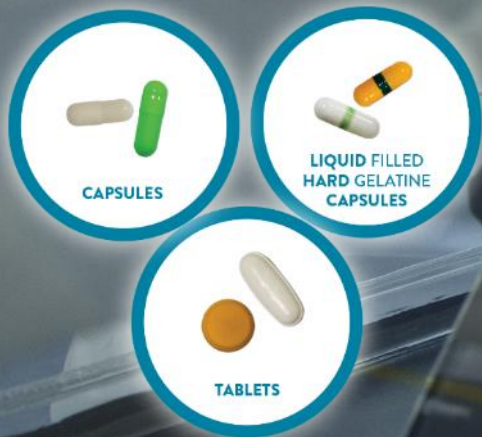
- Liquid and Lyo vials
- 2 x 323 sqf LYO (Telstar)
- IMA Filling line, 100% weight check inline

Available by
end 2021

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ORAL MANUFACTURING

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ORAL CAPABILITIES

CLINICAL AND COMMERCIAL SCALE

TECHNOLOGIES:



- Wet granulation (aqueous and organic solvent based)
- Dry Granulation by rolling compactor
- Film coating (aqueous and organic solvent based)
- Dedusting / Metal check
- Weight sorting
- Visual Inspection
- Banding for liquid or powder filled capsules



DOSAGE FORMS:

- Tablets
- miniTabs
- Capsules
- Liquid Filled Hard Gelatin Capsules

PRIMARY PACKAGING

- Blisters & Bottles

DEVELOPMENT

100-1000 g

CLINICAL

4-20 Kg

COMMERCIAL

12-100 Kg

“
mAb's CONJ &
Nano medicine
DS Preparation
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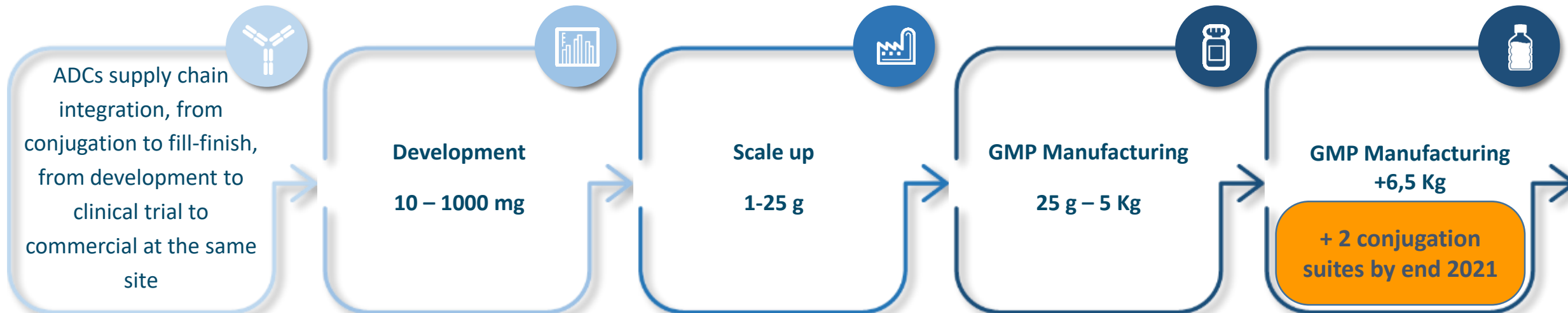
CONJUGATION CAPABILITIES DEVELOPMENT, CLINICAL AND COMMERCIAL SCALE

3 Class C suites already available and 2 additional suites under construction for Drug Substances with a capacity increase from 410 Kg to approx. 1250 Kg annum

Wide range of batch size: Up to 100 g scale, Up to 1,5 Kg scale, Up to 5 Kg scale, Up to 6,5 Kg scale of mAb

Diafiltration systems, Chromatography system, Storage @ 2-8°C, frozen conditions (up to < -80°C)

Release and Stability Testing (including “Specific Cytotoxicity and Direct Binding”).



Annual Capacity: approx 410 Kg mAb
Additional 840 Kg mAb starting by 2021*

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ANALYTICAL SERVICES

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Analytical services

**METHOD DEVELOPMENT
& OPTIMIZATION**

**METHOD VALIDATION
& TRANSFER**

**CLEANABILITY
& COMPATIBILITY
STUDIES**

**CLEANING METHODS
DEVELOPMENT AND
VALIDATION**

**STABILITY &
PHOTOSTABILITY
STUDIES**

IN PROCESS CONTROL

**RAW MATERIALS
TESTING**

FINAL RELEASE





“ DEVELOPMENT SERVICES ”

N.2 MAIN LABORATORIES
of approximately 3100 sqft
completely separated but
fully integrated with cGMP
Manufacturing areas.

Development services

A group of scientists that works in tight connection with manufacturing personnel, represents a unique combination of knowledge, skills and competences that can be make the difference in moving the product quickly to clinic and to the market.

**PRE-FORMULATION
STUDIES**

**DOSAGE FORM
SELECTION**

**COMPATIBILITY
STUDIES**

CLEANABILITY STUDIES

**STABILITY &
PHOTOSTABILITY
STUDIES**

**FORMULATION AND
PROCESS
OPTIMIZATION**

**PROCESS
CHARACTERIZATION
AND SCALE-UP**

**ANALYTICAL METHODS
DEVELOPMENT AND
OPTIMIZATION**





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NON-CYTO
FACILITY

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LOOKING TO SATISFY NEW DEMAND OF CAPACITY & CAPABILITIES

- BSP built a new plant, segregated from the current plant, by using “**FULL CONTAINMENT**” technology to meet the needs of Innovators.

This plant will host **6 sterile manufacturing suites** to handle **IMMUNO-ONCOLOGY** drugs (mAbs, checkpoint inhibitors, synthetic vaccines), **IMMUNOTHERAPY** drugs, as well as other **INNOVATIVE** products as small and large molecules.

- The concept is to provide Clients with a full package of services from Development to Commercial, pre-Clinical GLP, Clinical, Commercial production for both Liquids and Lyo products.

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APPROX. 1747 SQF LYO SURFACE

Implementation Plan

Sterile 11

- Liquid and lyo vials
- 1 x 65 sqf LYO SURFACE
- Steriline Filling line
- Telstar freeze dryer

Sterile 13

- Liquid vials
- IMA Filling line

Sterile 12

- Liquid and lyo vials
- 2 x 323 sqf LYO SURFACE
- IMA Filling line
- Telstar freeze dryer

Sterile 16

- Liquid vials
- IMA Filling line

Sterile 14

- Liquid and lyo vials
- 2 x 323 sqf LYO SURFACE
- Order ongoing

Sterile 15

- Liquid and lyo vials
- 2 x 215 sqf LYO SURFACE
- Order ongoing



THANK YOU FOR YOUR ATTENTION

WE ARE A CDMO
TECHNOLOGICALLY
DEVELOPED TO MEET THE NEEDS OF
INNOVATORS

www.bsppharmaceuticals.com

