STELLENCE
PHARMSCIENCE LIMITED

456, Road 3, Industrial Area,
Jigani, Bangalore South – 562106
Karnataka, India

NOTICE TO READER

The statements in this business plan represent the intentions, plans, expectations, and beliefs of the company Stellence Pharmscience Limited (SPL) and Avigna Chemitech Pvt Ltd (ACPL) and are subject to risks, uncertainties, and other factors, of which many are beyond the control of the Company. These factors could cause actual results to differ materially from such forward-looking statements. These factors include and are not restricted to: regulatory approvals; the timing and size of contracts, acquisitions and other corporate developments; the ability to attract and retain qualified employees; market competition in the generic pharmaceutical industry; general economic and business conditions, foreign exchange and other risks as well as assumptions regarding the foregoing.

No representation or warranty is made as to the accuracy or completeness of any part of the information contained in this business plan or any other written or oral communication transmitted in the course of the evaluation of Stellence Pharmscience Limited or ACPL. The only legal obligations of the corporation will be those contained in a definitive written agreement.

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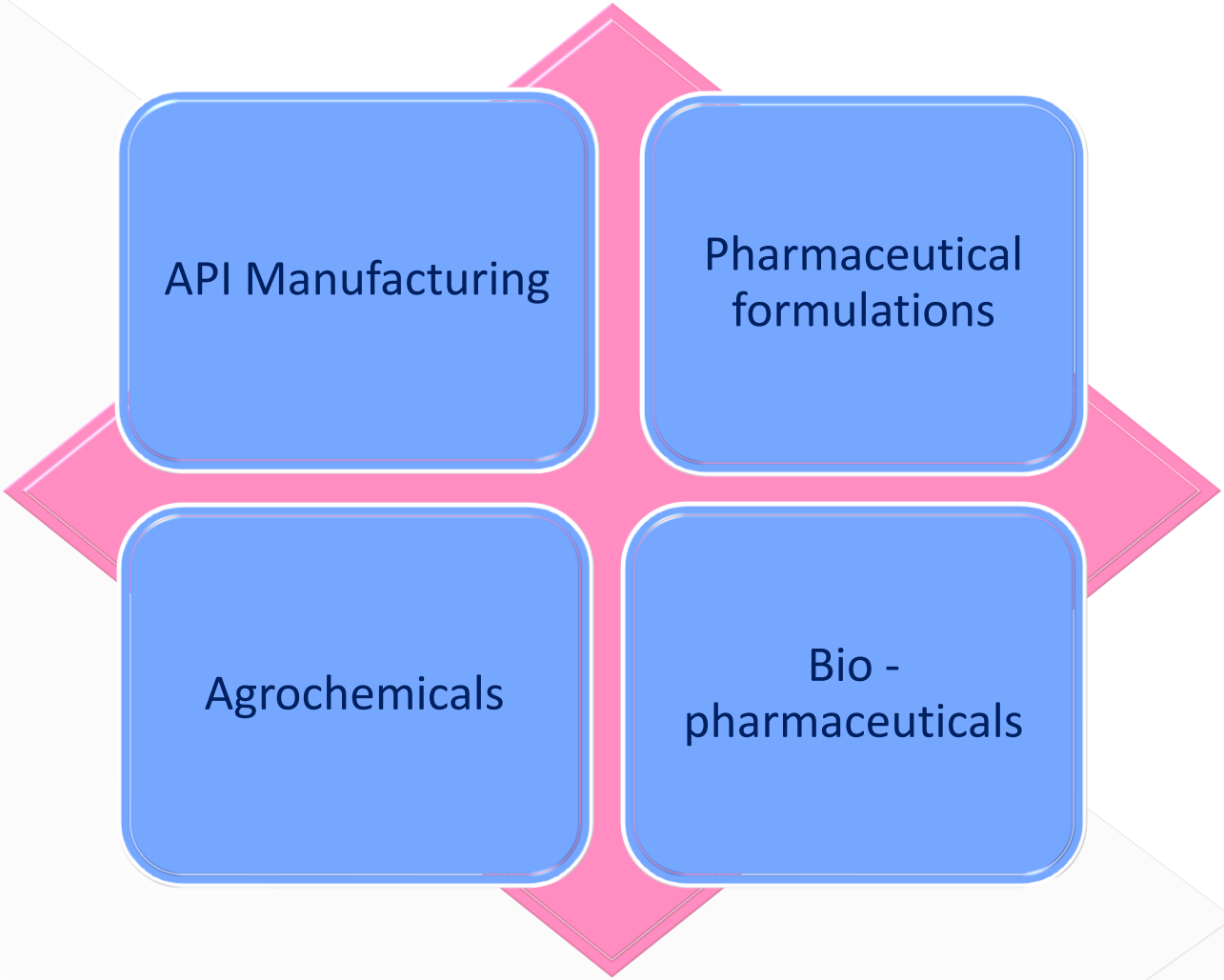
Stellence Pharmscience Limited,
456, Road #3, Industrial Area,
Jigani, Bangalore South 562 106.
To the attention of:
Managing Director.

COMPANY PROFILE

- *Established in the year 2005, Bangalore, Karnataka, India as a leading company for the manufacturing of Niche Pharmaceutical products like contrast media agents.*
- *Company is promoted by extensively experienced entrepreneurs of the pharmaceutical industry.*
- *The company has cGMP certified state -of –the- art manufacturing facility.*
- *Stellence Pharmscience Limited (SPL) is committed to develop a centre of excellence for NDDS (New Drug Delivery Systems).*
- *SPL has established a DSIR (Department of Scientific and Industrial Research) recognized R&D facility.*
- *SPL believes in nurturing and promoting talents and therefore and it has an excellent pool of scientists recruited from industry and academia.*

CORE COMPETENCE



Mission Statement: Our Belief and Promise

WE STRONGLY BELIEVE.....

- *that, as a corporate entity in an industrial environment, our responsibilities extend way beyond day to day management of our company and its environs.*
- *in unequivocal excellence spanning all functioning areas and across all levels of our Company with clearly measurable evidence of success.*
- *in continuous innovation with a clear emphasis on Science and it will be our endeavor to perform even ordinary tasks extra ordinarily. We shall do so with complete honesty and integrity.*
- *that, being a corporate entity, generation of profits is an integral and essential part of our sustenance and growth. We will achieve it, by ensuring that all our products (actions) reflect our intrinsic values while providing distinctive societal benefits.*

VISION 2015:

- ***Stellence Pharmscience Limited*** *to be amongst the top five manufacturers of non-ionic Contrast Media in the world.*
- ***Stellence Pharmscience Limited*** *to be the best API and Contract Development and Manufacturing Company in Karnataka State, that has all equipments and systems in place. This will enable our Research teams to function in a manner conducive to providing full fledged support to Medicinal and related Chemistry activities of the company.*
- ***Stellence Pharmscience Limited*** *to be the preferred choice Contract Manufacturer for intermediates for our partner companies.*
- ***Stellence Pharmscience Limited*** *will have an enviable Team in place to achieve this vision.*

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QUALITY POLICY

- *We shall develop and manage our business to ensure that all our activities are based on established processes and every product manufactured by us will more than meet the specified quality standards.*

- *All our operations will be carried out by fully complying with all regulatory and statutory requirements, ethically and with complete integrity.*

- *We shall always meet all our commitments and will constantly strive to enhance the satisfaction of all interested parties in the value chain.*

OUR FOCUS

- *Partnership with global players in exciting chemistries*
- *Contract Manufacturing - long term relationship based on integrity and timely deliveries and respect for IPR's*
- *Work with clients from the research stages, through process development and commercialization*
- *Continuous improvements in process efficiencies, product quality over the life of project.*
- *Sustainable products.*

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THE DIFFERENTIATORS

- *All manufacturing facilities and controls are designed to comply with global regulatory requirements – Systems oriented*
- *Process Research Capabilities*
- *cGMP Compliant Manufacturing Facility for APIs*
- *Interesting and difficult chemistry/reactions capability in-house at lab, pilot and plant level.*
- *Quality, Consistency, Timely Delivery and Customer Delight!*

REACTION CAPABILITIES

- *Hydrogenation*
- *Friedel Crafts*
- *Reaction*
- *Alkylation*
- *Chlorination*
- *Nitration*
- *Bromination*
- *Grignard*
- *Diazotization*
- *Esterification*
- *Vilsmeier Reaction*
- *Oxidation*
- *Reduction*
- *Resolution*
- *Asymmetric Synthesis*

FACILITIES

- *Non GMP Intermediate/ Fine Chemicals Manufacturing :*

  Laboratory Capacities : Small Volumes 100 Gms to 5 Kgs

Fume Cupboards	6 nos
Vessel Capacities	50 ml to 20 lts
Nutsche Filters	50 Gms to 5 Kgs
Driers	Fluid Bed and Vacuum Tray Driers
Hydrogenator	10 lts – 100 Kgs Pressure

FACILITIES

❖ *Non GMP Intermediate/ Fine Chemicals Manufacturing :*
Pilot Capacities : 5 Kgs to 50 Kgs

Glass Lined Reactors	300 to 500 lts
SS Reactors	600 lts
Nutsche Filters	30 to 50 Kgs
Centrifuges	36 “
Driers	Tray driers, RCVD glass lined

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FACILITIES

❖ *Non GMP Intermediate/ Fine Chemicals Manufacturing.*
Large Scale Capacities : 50 Kgs to 500 Kgs

Glass Lined Reactors	1500 to 3000 lts
SS Reactors	1000 to 6000 lts
Nutsche Filters	100 to 400 Kgs
Centrifuges	36’ & 48”
Driers	RCVD, Tray Driers
Hydrogenator	2000 lts 40 Kgs pressure

FACILITIES

- *Large Scale Manufacture of APIs under c GMP conditions: Capacity : 100 to 500 Kgs*

Glass Lined Reactors	1500 lts
SS Reactors	2000 to 3000 lts
Centrifuges	48”
Driers	Rotary Vacuum Driers, Fluid bed driers
Particle Size modification equipments	Multi-mill, Compactor, Sifter

QUALITY ASSURANCE & REGULATORY

- *Manufacturing systems and Documentation complying to cGMP, ICH Q7A guidelines*
- *Regular Internal Audits*
- *Stringent change control systems*
- *Validation Master Plans :*
  - *Process Validation*
  - *Cleaning Validation*
  - *Equipment Qualification*
  - *Extensive Product Release Controls*

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QUALITY ASSURANCE & REGULATORY

- *Drug Master Files for APIs in CTD format*
- *Stability Data Support*
- *Analytical Method Validation*
- *Process Validation*

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QUALITY CONTROL AND ANALYTICAL SUPPORT

- ***Sophisticated Analytical Lab with:***
  - *HPLCs, GCs , FTIR & UV Spectrometers, Autotitrators, LCMS, NMR...*
  - *Validated and calibrated systems*
  - *Methods Development, Standardisation and Validation*
- ***Analytical Development, Specification Development***
  - *API / API Intermediate specifications complying to ICH*
  - *CMC guidelines*
- ***Method Validation as per ICH guidelines***
- ***Qualified and Experienced Man power***

SAFETY HEALTH AND ENVIRONMENT (SHE)

SHE Programs:

- *Personal Safety*
- *Process Safety*
- *Environmental Safety*

- ***Risk Analysis***
- ***On Site Emergency Plan***
- ***Environmental Management Programme***

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Thank You……..