**START-UP PROPOSAL**

**Novel silk & silk protein topicaldermal formulations with augmented functionality**

1. ***Personal Information***

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1. ***Abstract of the Proposal (200 words)***

Through this startup proposal we intend to develop and commercialize novel formulations containing silk / silk proteins as an active excipient that impart added properties to the dermal formulations.

Micronized silk granules absorb UV rays. These granules and silk protein (sericin) are also good absorbents forming gels and have anti-inflammatory & antiseptic properties. The silk and its components are biocompatible and are safe after absorption. As an excipient they impart potent advantage as adjuvant to the main API action, some examples of which are underscored below:

One such condition is mucositis and mouth ulcers. These are ubiquitous but the conventional treatment by Cap B Complex & glycerine is neither effective nor scientifically validated. Routine mucositis and mouth ulcers are self limited but those associated with chemotherapy / local radiotherapy is a medical issue and has serious effect on quality of life and diet reduction further compounding the health issues. Many generic anti-ulcer gels are available. We are in the process of developing oral gels for mucositis that contain silk gel as the excipient base.

The second set of formulations contain antiseptics like povidone iodine or chlorhexidine in silk base. This will be used in all conditions of wounds and burns where antiseptic ointments are indicated. Currently the base is paraffin or hydrogels.

The third set of formulations contain topical antibiotics like framycetin or neomycin in silk gel base. These are used as dressing for infected wounds and burns.

The forth set of formulations contain topical steroids like hydrocortisone or beclamethasone in silk gel base. These may be used in inflamamtory autoimmune diseases like eczema & allergic dermatitis.

Based on successful preliminary developmental &scintigraphy human data , we shall be developing the following for comparative clinical trials and implementation

* Silk gel based anti-UV creams
* Silk gel based antiseptic cream
* Silk gel based antibiotic cream
* Silk gel based steroid cream

***Introduction to Ideation***

* 1. *Broad Industry Sector:*

Novel topical formulations

* 1. *What is the Product / Service*
* New more effective and safe topical formulations for various applications basehydrogeld on silk gel
  1. *Who is the beneficiary of Product / Service*
* UV-A & B exposure
* Radiation dermatitis
* Skin inflammatory conditions
* Wounds and burns
* Skin autoimmune conditions
  1. *What is the idea / innovation*
* Use of silk gel and silk proteins as active base of dermal / topical formulations
  1. *Is it an Idea or you have validated any proof of concept*
     1. Silk gel has been developed
     2. Formulations have been developed
     3. Safety data, stability data&Pk databeing collected in humans using scintigraphy
  2. *If you have started any work on it, has it generated some revenue?*

No.

* 1. *What experiments will you like to do*
     1. Complete pK profile
     2. Animal safety studies as per need
     3. Human Scintigraphy
     4. Short clinical trials as proof of concept in 04 diseases / conditions
  2. *What will be requirement to get idea conceptualized*
     1. Funds
     2. Tie-up with GMP facilities
     3. Tie up with JH / DIPSRU& INMAS for completion of developmental data.
     4. Administrative module with defined role of incubator & mentors. Internal financial & administrative rule book/SoP
     5. Office space
     6. Interphase with clinical trial partners, regulatory bodies
     7. Back up exit plan: ToT of the technology to a bigger player

1. **Startup Plan**
   1. *Who are the targeted founders/cofounders/promoters*
      1. The core team consists of 04 young entrepreneur. Biodata of the founder members is attached.
   2. *Specify role of each promoter/mentor*

There are 04 mentors:

* Dr Ashok Salhan, (Sc G, Retd, from DIPAS, DRDO): 30 yrs experience in device innovations and implementation.
* Ms.AnuradhaBhavnani (Group head, Asia, Burmah Shell, responsible for setting up viable rural startups in India. More than 25 yrs experience).
* Prof RuchikaKuba, Medical Doctor, School of Health Sciences, IGNOU.
* Dr AseemBhatnagar, Sc G, INMAS. 28 yrs experience in product development, scintigraphy & clinical trials

Dr Salhan is providing technical and scientific mentoring, Ms AnuradhaBhavnani is providing financial and administrative mentoring. Dr Kuba shall help with dispute resolution and documentation. Dr Bhatnagar shall provide scintigraphy & clinical trials mentoring.

* 1. *Since how long have you been working together on this idea*

01 years. We have reached the stage of formulation development &Pk (under work).

1. **On Your Business Idea**
   1. *What is the financial viability plan for start-up*

* The formulations are easy to get manufactured without much capital investment.
* Not much expenses on safety studies expected as silk is already shown to be biocompatible.
* The market is big and appears to be ready for such innovative products based on sound logic.
* All advantages accruing to start-ups will be incorporated.
* Company SOP will be created as an official document.
* Provision of shared patents with incubator & user defence agencies (who contribute by way of trials and specifications fine tuning) will be a stated policy of the company.
* **Seed money need estimate: Rs25 L**
* Operations from home for 02 yrs to cut down expenses. Official address may also be provided by the incubator: DIIF
* Travel will be largely local.
* Talks, presentations and poster presentation in industrial conference will be the mainstay of advertisement.
* Advertisement will also be done through personal and social network, with a small budget on brochures etc.
* Specifications will be sealed with participation of mentors.
* A bigger pharma establishment that can absorb the products at near mature status shall be identified.
* Rs 15 lakhs expenditure expected in the first 18 months on industrial prototyping, trials, licensing and production. Rs 05 lakhs will be needed for user appraisal / 3rd& 4rth batch production thereafter. Rs 05 lakhs will be kept as reserve for ‘May Day’.
* Return on investment expected at the end of 15-18 month period.
* Break even expected at 18-24 months period.
* Continuation of the startup or ToT to a bigger company will be a consensus decision at the end of 24 month period.
  1. *What are the sources of funds from self / other cofounders / anticipated from the incubation centre*
     1. Team leader: Rs 1 lakh (personal or bank loan)
     2. Other cofounders: Rs 1 lakhs from 4 other cofounders.(personal or bank loan)
     3. **Rs 20 lakhs from incubator**
  2. *Anticipated competition and current industry position with respect to your idea*
     1. No such product exists in the market.
     2. Conventional treatment exists for all these treatment but there is scope of improvement, and there is a scope of innovation, both medical and commercial.
  3. *Uniqueness of your start-up with respect to the product /service*
* Only we are privy to the technology (apart from DRDO) as we conceived it.
* Team members have themselves worked on the concept and the products academically
* Team has young members , but they already havestartup experience. Mentors have more than 08 decades of cumulative experience covering all areas where mentorship will be needed.
* Team members have complimentary abilities, that cover Science & technology, Product development, management & administration experience.
* Team members know each other for more than 1years, and association with mentors is > 2 months.
* Product idea has matured, prototypes are made. Data generation is in progress, suggesting seriousness of approach.
* ‘Make in India’ approach through student startups
  1. *How do you view your technology / idea with respect to sustainability*
* Products are niche, innovative, relevant & cost effective. These are not ‘Me Too’ products.
* Items are required for ‘need areas’ of medicine. These have potential to enhance capability of APIs in the entire field of dermal medical & cosmetic products and are capable of improving QOL substantially.
* No same / similar indigenous product in Indian market
* Industry partner / mentors already in loop.
* Infusion of our own funds and bank loans will ensure that the team will put all efforts towards success of the venture.
* Feasibility worked out in terms of
  + Local availability of sub-systems.
  + QC parameters
  + Field trials
  + Demand & cost re-appropriation
  + Fund management
  1. *Target Market (customer segment) identification; market size and trend, how much market share you can gain over next 03 years*
* Hospitals, OPD & home management: mouth ulcers, mucositis, wounds & burns, dermal inflammatory, autoimmune or infective conditions
* we expect the following market upfront at the end of 1st year &3 yrs:

|  |  |  |
| --- | --- | --- |
| Item | 1st batch | 3rd batch |
| Silk based oral gel & lip balm | 5000 units | 1 lakh units |
| Silk based antiseptic topical hydrogel | 5000 units | 2 lakh units |
| Silk based antibiotic topical hydrogel | 5000 units | 2 lakh units |
| Silk based steroid topical hydrogel | 5000 units | 1 lakh units |
| Silk based anti-UV cream | 10000 units | 1 lakhs units |
|  |  |  |

1. **Strategy**
   1. *What if you do not get the incubation support from DIIF*

* The project will be delayed by 06-12 months for want of funds
* We shall have to look for similar incubators
* The team leader will be under stress to keep the flock together.
* Market will have to wait for 05 QOL improving/ important therapeutic medical items for several months despite commercial and medical value
  1. *What if you get the incubation support from DIIF*
     1. The above stated process will be kick-started immediately.
     2. We shall apply for loans from banks / put in our funds to initiate the process immediately
     3. Administrative work to initiate startup and technical work for pre-production shall be initiated immediately, even ahead of actual funding, on the basis of written commitment from the incubator
     4. We shall have a meeting with incubator mentors immediately to make a work plan by consensus.
     5. With consensus, a PhD scholar from DIPSARU shall be involved in the research work.
  2. *How do you plan to scale up your startup*
* Initially, we shall go for job contract or jnt development with 1-2 GMP companies
* Later on, we may share equity with the GMP facility or enter into a long term contract with the GMP as part of scale up plan.
* As part of Plan B for manufacture, standby production units will be kept in loop so that smooth substitution can be done in case things do not work out with the original fabricator.
* With time, a small facility may be taken on lease.
  1. *What are the challenges you are facing now and you foresee in the next 2 years*
* These are new products. It will need time for the market to form opinion
* Business and incubation opportunities are limited in reality inspite of efforts being made by various organs of the government.
* The rule book is too heavy for new startupswho are fresh and need to concentrate on technology maturation rather than running around to govtdepts for approvals.
* Startups, particularly those funded by government, today face a bad name and credibility issue because of high failure rate failure to return the investment. To convince authorities that our startup effort is genuine and approach balanced and technically sound is a challenge.
* Market survey not done presently.

1. **Requirements**
   1. *Infrastructure required*

* Office space needed. Meetings will also be positioned at GMP collaborating establishments since these are formal agencies.
* Use of QC equipment. Initially it will be done at incubator establishment. Later on, equipment will be purchased or 3rd party certification shall be hired.
* Secure storage space (about 10 M3) needed temporarily for upto 104weeks.
* *Justification: a)* Allowed as per Incubator concept note, b) Upfront / hire charges can be managed from the seed fund as per rules / norms.
  1. *Requirement of the meeting room (frequency of meeting / month)*
     1. No formal meeting in the first 3 months.
     2. Monthly / 2-monthly meeting with prospective technology buyers / distributers in presence of mentors and incubator officials between 06-18 months.
  2. Incubator Funds required in maximum 02 instalments within the first 09 months. Justification: major expenses are in the initial phase only
  3. Incubator & mentor assistance required upto 02 years.
  4. Return on investment & joint patent guidelines may kindly be clarified

1. **Expected Milestones (every 06 months)**
   1. Submission of SOP of company to incubator cell within 01 months of approval.
   2. Submission of letters of demand / letter of Intent from prospective GMP partners and MOU with feeder industries within 01 months of sanction letter.
   3. Industrial prototype and demo of functionality : 09 months.
   4. Clinical trials : 09-24 months
   5. Ploughing back of funds for perpetual production: 15-24 months.
   6. Report preparation and maturation of startup function: 21-24 months.