

PROMOTING INNOVATION FOR AFFORDABLE PRODUCT DEVELOPMENT







### DBT – BIRAC Innovators Compendium: 2012



### In association with



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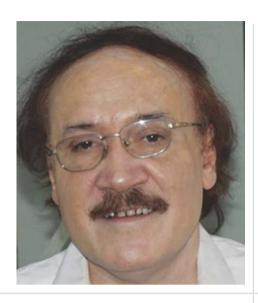
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# DBT-BIRAC Innovators Meet-Compendium

It gives me great satisfaction to note that Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India and Biotechnology Industry Research Assistance Council (BIRAC) have through a critical due diligence process identified and supported innovative nationally relevant ideas / products / processes for further development and commercialization.

This support to industry innovation research through public private partnership is aimed at developing innovative technologies aimed for affordable product development.

This compendium is an effort to share the highlights of these innovation efforts with the researchers and the Biotech Community at large. I hope that this document would facilitate knowledge networking and collaborations desirable for strengthening the capabilities of our national Biotech Sector and give us a sense of how well we are doing and what aspects need redesigning.

I wish the researchers success in their endeavors towards innovation research.

**Dr. M. K. Bhan**Secretary, DBT & Chairman, BIRAC



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# DBT-BIRAC Innovators Meet-Compendium

he Department of Biotechnology, under the Government of India, has been supporting industry innovation research through various schemes such as Small Business Innovation Research Initiative (SBIRI), Biotechnology Industry Partnership Programme (BIPP) and the recently launched Biotechnology Ignition Grant Scheme (BIG). The effort has been to promote and nurture innovation research in the biotech enterprise with special focus on promoting industry academia interaction. The Contract Research and Services Scheme (CRS) launched early this year is also aimed in this direction.

The recently setup Public Sector Organization of Department of Biotechnology (DBT)-Biotechnology Industry Research Assistance Council (BIRAC) aims at empowering and enabling the biotech innovation ecosystem for affordable product development. One of the key strategies of BIRAC is fostering innovating capabilities in all places of research, with a focus on Startups and SMEs.

BIPP is a government partnership with Industries for support on a cost sharing basis for path-breaking research in frontier futuristic technology areas that have major economic potential, making the Indian industry globally competitive. It is focused on IP creation with ownership retained by Indian industry. Over the last few years through this support, a large number of innovations have resulted in some important technologies and products. Nearly 100 agreements have been signed with approximately 90 different companies including more than 50 startups and SMEs. Nearly 30 academic research institutes and universities are involved in collaborative projects.

A total investment of US\$ 150 million has been committed with approximately US\$ 65m coming from Government of India and a contribution of US\$ 95m coming in as private sector contribution.

Through this compendium we have compiled the various innovations highlighting the uniqueness, novelty, national and societal relevance and market potential of the technologies and products developed and under development. We hope this compendium would provide useful information with regard to the innovation research being conducted by the Biotech Industry through Government support and we wish the researchers success in their present and future endeavors.

**Dr. Renu Swarup**Adviser, DBT and MD, BIRAC







nti-cancer compounds, immunogens against H1N1, detection kits for autoimmune diseases, cheap recombinant human insulin, stem cell research, stress tolerant rice, enzyme production from agri-waste, enhancing ethanol yield, biomass production and conversion to fuel, bio-hydrogen production, nano pesticide manufacture - the Indian biotech industry is in the thick of it all. India is amongst the top-12 biotech destinations in the world and ranks second in Asia, after China. The largest producer of the recombinant Hepatitis B vaccine in the world, India is globally recognised as a manufacturer of economical, high-quality bulk drugs and formulations. Scientists believe that India can leapfrog into the biotech future shaped by materials like bacterial

rope and DNA chips. Bacterial ropes essentially consist of certain mutant bacteria that have the ability to grow into spaghetti-like structures. When impregnated with certain metal ions, these can be stronger than steel but much lighter and biodegradable. DNA chips, as part of predictive medicine, will enable monitoring and predicting the possibility of diseases, thereby instituting preventive measures or treatments. Genetically engineered plants will show the way towards production of monoclonal antibodies for diagnosis and therapy. All these can be developed with the available knowledge and skills.

But for all these to happen, the country needs to invest big time in research and development (R&D). While we know the importance of R&D, most large organisations in







India are not very forthcoming in committing large budgets in R&D and prefer to buy knowhow or are happy to work as a franchisee of an original inventor from abroad. On the other hand, there are large number of small companies and entrepreneurs, bubbling with innovative ideas but very little fund to bank on. Fortunately, in the field of biotechnology, which has many promising sub-segments, the government of India through the Department of Biotechnology has extended its helping hand. The DBT, through several government entities, has launched many schemes to foster innovations.

#### Making a difference

It is in this context that the Biotechnology Industry Research Assistance Council (BIRAC) has been set up expressly to support innovation and provide infrastructure and services to the Indian biotechnology sector, especially the SMEs. Set up as a Section 25 company, BIRAC addresses sector needs by providing a suitable environment to promote and support high-end innovation. Registered under India Companies Act 1956, it has been set up as Department of Biotechnology's interface agency, which serves as a single window for the emerging biotech industries. BIRAC is guided by an Independent Board of Directors comprising senior professionals, academicians, policy makers and industrialists.

BIRAC has a financial assistance scheme called Biotechnology Industry Partnership Programme (BIPP) which is a unique initiative with industry for support on a cost sharing basis for a development of novel and high-risk futuristic technologies in key areas of national importance and public good. The DBT is operating this scheme to promote and nurture innovation research in biotech enterprises, specially start-ups and SMEs. The BIPP scheme, started in December 2008 has called for proposals 21 times so far till March 2012. During this period BIRAC has received 551 proposals and has approved more than 90 different companies with 50 of them being SMEs or start-ups. At the last count these approved proposals together have committed Rs 750 crore worth of investment, of which Rs 475 crore came from companies and Rs 275 crore from BIPP scheme in the form of grants and loans.

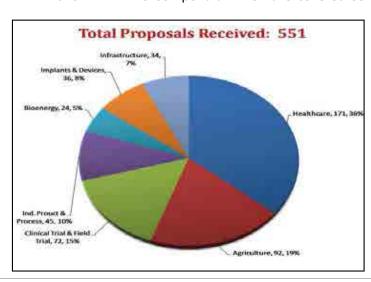
"The BIPP scheme is focused on IP creation with ownership retained by Indian industry. Over the last few years, through this support a large number of innovations have resulted in some important technologies and products. Nearly 30 academic research institutes and universities are involved in collaborative projects," said Dr Renu Swarup, Adviser, DBT and MD, BIRAC.

According to the data obtained from BIRAC sources, of the total 93 approved schemes under BIRAC-BIPP umbrella, there are 57 products/processes under the broad healthcare segment; 21 under agriculture; 3 Industrial; 9 under Energy; 4 under infrastructure capacity building; and one under Bio-informatics. The range is clearly indicative of the reach of BIRAC while a look at the firms will reveal that not only many SMEs have availed the benefits, there are many big names like Biocon, Mahyco, Avesthagen, Cadilla, Serum Institute, Bharat Biotech, Stempeutics, Strand Life Science, and others who have also got financial assistance from BIPP. Not only is this proof of BIRAC's strengths but also of the sore need for such an agency.

Given the poor reach of healthcare services in India and the huge need to make healthcare affordable and well penetrated for the vast population in the country, BIRAC has rightly emphasised its assistance focus. The sector-wise distribution of assisted companies indicates the dominance of healthcare sector with 62 per cent of the total approved projects.

The agriculture sector, another important segment in Indian economy supporting nearly 60 per cent of the population, received 16 per cent of the approved projects. The remaining 22 per cent of the projects was shared by infrastructure, bioenergy, industrial and bioinformatics segments. One interesting achievement of the BIRAC-BI-PP initiative is the successful development of Inactivated H1N1 Split Virion Influenza Vaccine (Pandy Flu) developed by Panacea Biotec. In this project Rs 10 crore was funded by the DBT while the company invested Rs 29 crore. Another example is development of Micro PCR Diagnostic Platform by Bigtec Labs at an investment of Rs 8 crore shared equally by DBT and the company.

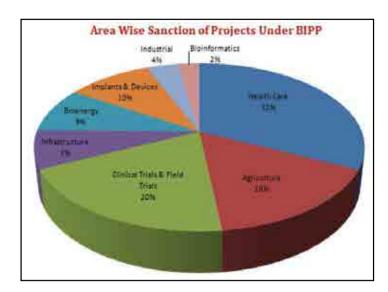
In this DBT-BIRAC Compendium we have covered 53











companies based on answers provided to a fixed questionnaire. The BIRAC-BIPP assisted companies have provided detailed information on innovation, its progress, technology collaborator (if any), market potential, risk factors, national/ societal relevance, potential for IP generation, etc. Interestingly, projects under healthcare dominated the study with 30 companies (57 per cent), followed by agriculture sector with 15 companies. We hope this compendium would provide useful information with regard to the innovation research being conducted by the biotech industry through Government support.

BIRAC will also launch a Grand Challenges Programme, offering researchers and scientist opportunities to innovate and work on scientific and technological solutions for affordable product development to meet national needs. The program will have the goal to create scientific and technological tools to overcome hurdles and find solutions for novel affordable products of national relevance. High level of innovation, new tools and transformative ideas would be supported. These could be in health care, agriculture and energy. In the last section of this report we have done a detail impact analysis collated from the companies under the Compendium section. Based on the information we have done sector wise analysis on innovative elements, national relevance of the projects, risk factors, market potential, etc.

#### **Growth trajectory**

The Indian biotechnology sector is presently divided into five segments of bio-pharmaceuticals, bio-services, bio-agriculture, bio-industrial and bio-informatics. Data obtained from the Department of Industrial Policy and Promotion (DIPP) shows that the drugs and pharmaceuticals

sector attracted an impressive level of FDI worth USD 3,208 million between April 2011 and January 2012.

One of the fastest growing knowledge-based sectors in India, the biotech sector is expected to play a key role in shaping the nation's rapidly growing economy and emerge as a key global player. Not surprising, given the many advantages it has, like knowledge, skills and cost effectiveness. Increasing R&D and infrastructure investments from the private and public sectors, strong position in small-molecule generics, clinical capabilities in drug discovery and low-cost manufacturing have aided the market growth.

Going by the trends, the industry is on track. It grew threefold in five years to report revenues of US\$ 3 billion in 2009-10, according to the eighth annual survey conducted by the Association of Biotechnology-Led Enterprises (ABLE) and BioSpectrum. The biopharma sector contributed nearly three-fifth to the industry's revenues at US\$ 1.9 billion, a rise of 12 per cent, followed by bioservices at US\$ 573 million and bioagri at US\$ 420.4 million. The remaining revenue came from the bioindustrials US\$ 122.5 million and bioinformatics US\$ 50.2 million segments. The last three have remained focussed largely on domestic operations. The industry-sponsored Phase II, Phase III clinical trial sites in India have grown by over 100 per cent in the last couple of years.

A total of 350 companies operate in the biotechnology sector in India. Some of the successful biotechnology companies in India, to name a few, are Biocon, Serum Institute of India, Panacea Biotech, Nuziveedu Seeds, Bharath Biotech, Reliance Life Sciences, Quintiles, Rasi Seeds, Novo Nordisk, Shantha Biotechnics, Venkateshwara Hatcheries, Amrita Therapeutics, Indian Immunologicals, TransAsia Biomedics and Mahyco.

As per the Association of Biotechnology Led Enterprises (ABLE), the sector fetched a record turnover of over USD 4 billion in 2011. The Indian biotechnology industry is expected to garner revenues of USD 11.6 billion by the year 2017. Future growth is expected to come from the country's strong position in biosimilars while molecular diagnostics and personalized medicine are also promising areas, according to a market report from Ernst & Young (beyond borders – Global Biotechnology Report).

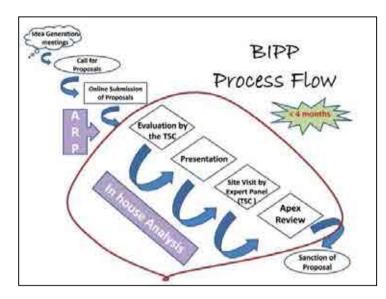
#### Scope for improvement

There is, however, a growing chasm between big, established players and small and early stage start-ups with regard to the funds. Pre-commercial stage projects depend









on years of funding to support the development of new drugs. This is a stumbling factor for the Indian biotech sector, where the bulk of the industry consists of small and medium enterprises.

The biotechnology industry in India is at a critical juncture. While the industry has been growing at a CAGR of 19 per cent rate over the last five years, it has also been facing diverse challenges that have prevented the industry from reaching the next level, says an Ernst & Young report.

As an incentive for in-house R&D, the government does provide 200 per cent weighted tax deduction, which has been extended till 2017. In terms of infrastructure, several biotech parks have been set up in India in the last five years with public private partnerships. But most of these are weighted in favour of biotech services and diagnostics firms rather than biotech manufacturing companies, feel experts in the industry. What is required is land at subsidized rates, uninterrupted power at competitive prices, good quality water supply and effluent treatment facilities to improve the efficiency and productivity of pharmaceutical companies.

While contract service providers in bioinformatics, early discovery, pre-clinical, CRAMS and clinical research, etc., have been very important to the growth of biotech opportunities in India, they have not been able to generate commercially valuable intellectual property and are at the lower end of the value chain because they do not engage in fundamental basic research to develop new types of drugs for the global market.

Innovation has taken a beating with companies that have focused on innovation facing funding constraints.

The investor community has shied away from investing in early stage ventures. In a developing nation where millions still eke a survival, innovation becomes crucial in delivering affordable solutions across the sector. Dependence on foreign innovations is an expensive proposition given the monopolistic MNC pricing.

Looking at environmentally friendly products, addressing pollution, optimising and exploring clean energy, cheap and effective vaccines and treatment, water treatment, ensuring food security through sustainable crop production, these are a few areas where the country has to spur innovation.

#### **BIRAC** objective

Clearly, the stage was set for the government to step in to create an ecosystem for innovation through financial & technological assistance from the DBT. It is in this perspective BIRAC is playing a major role to support innovation and provide infrastructure and services to the Indian biotechnology sector, especially the SMEs.

To nurture industry R&D while setting aside 30 per cent budget on PPP (public private participation), BIRAC aims to strengthen and empower the sector by enabling services for promoting the innovation ecosystem. It looks at strategic research that addresses nationally relevant product development to make India globally competitive in biotech innovation and entrepreneurship, as well as for creation of affordable products for the largest section of the society.

Among its mission are promotion of academia – industry collaboration, international linkages and techno entrepreneurship, and enabling creation and sustainability









of viable bio-enterprises with global competitiveness. Its mandates encompass Knowledge, Technology Mapping and Management, Technology Transfer, Licensing and Acquisition. BIRAC is an organization with three unique verticals to support its mandate: Foster innovation and Enterprise Building; Provide enabling services for promoting the innovation ecosystem; and Build Strategic Alliances.

Entrepreneurship Development & Enterprise Building is a critical component of BIRAC. Creation of start-ups which are the fuel for innovation is a priority. BIRAC addresses key areas of creation of enterprises, giving access to mentors and providing hand-holding schemes. The needs are diverse - from access to early stage funds, understanding business plans to Intellectual Property and other information such as market analysis & competition.

Providing essential need based research and innovation services to the industry, particularly start-ups and small and medium industry is a critical requirement for promoting the innovation ecosystem. Specialized services such as IP management, project management, legal and contract services for licensing, capacity building for skill augmentation and other innovation support services, particularly for regulatory product evaluation, are supported and facilitated.

### **Special strength**

BIRAC's special strength is its ability to network and partner with like-minded organisations to reach out to all its stakeholders and accomplish its mission effectively. Leveraging national and international strength and partnering with other stakeholders is BIRAC's key philosophy in promoting and nurturing innovation research, technology validation and product development. These partnerships and alliances are an important tool to build on the existing expertise and work together for achieving a common goal of affordable product development.

Beginning with igniting new and big ideas, through its Biotech Ignition Grant (BIG) Scheme, to early stage research for concept validation through Small Business Innovation Research Initiative (SBIRI) and from there to partnership with industry for high risk discovery led innovation research via the Biotechnology Industry Partnership Programme (BIPP) and finally, facilitating technology validation and development through Contract Research Scheme (CRS), the BIRAC programmes provide series of funds at every stage of a company's growth curve. The BIPP is for existing companies, the SBIRI for smaller companies, BIG schemes for start-ups and creating world class quality incubation space (bio-incubators) for entrepreneurs and start-ups through the Bio-Incubator Support Scheme (BISS).

For instance, under the BIPP path breaking research in technology, economic potential is identified and facilitation of government partnership with industries is empowered. Products of high, national relevance as well as high risk, high value IP are identified. Some success stories under BIPP are affordable products like H1N1 pandemic influenza vaccine named PandyfluTM, developed by Panacea Biotech, Delhi; Japanese Encephalitis (JE) vaccine whose Phase III clinical trials have been successfully concluded by Biological E, Hyderabad; Phase I studies completed for a novel molecule TRC150094 for the treatment of cardiovascular (CV) risk factors by Torrent Pharmaceuticals, Ahmedabad; Phase-III clinical trial of oral Rota virus vaccine developed by public sector, being implemented by three public sector organisation and coordinated by Bharat Biotech India, Hyderabad.

Under BISS, strengthening and upgradation of existing bio-incubators is the objective. These include creation of world class quality Incubation space (Bio-incubators) for entrepreneurs and start-ups. Also, creating common service facilities in public and private sector to serve the needs of Start Ups, schemes that facilitate the acquisition or license of innovative technology and technology mapping for identifying patentable technology at national or international level and creating capacity in various fields, are the other aspects addressed and undertaken.

BIRAC in-house IP Cell provides assistance to SMEs,





# **Biotechnology Industry Partnership Programme-BIPP**

### Purpose:

- ·Govt. partnership with Industries
- · Cost sharing basis
- · For path-breaking research in frontier futuristic technology areas having major economic potential.
- Focused on IP creation
- IP ownership retained by Indian industry/collaborating scientists.

### Support:

- For high risk, highly innovative accelerated technology
- ·For nationally and socially relevant areas, with no assured market. \
- Provides for product evaluation and validation through support for field trial for agriculture products and clinical trials (Phase I, II, III) for health care products.
- Supporting research project for novel IP generation.

### **Target:**

- Indian Biotech companies registered under Indian Company Act 1956
- •51% Indian shareholding (including NRI's)
- DSIR recognized R&D
- Apply independently or in collaboration with companies, not for Profit organisation or academics partners

Start-ups and Academia for prior art, patentability and freedom-to-operate searches. It also gives guidance and advisory services on the Patent filing, IP Policy and IP management to academia and research institutes. BIRAC organizes various workshop/conferences on IPR to build IP awareness.

BIRAC conducts an IP due diligence for all the eligible proposals received under various funding schemes of DBT like BIPP, CRS etc. The IP cell also does patent landscape analysis to identify patenting activities in different domains.

As a first step to enhance the proportion of Life science invention that can be translated, BIRAC has initiated technology mapping of DBT institutes. IP services are also rendered to DBT and Universities. Apart from the various IP services, the IP cell also analyses Patent Policy of India vis-a-vis other countries.

BIRAC plays a pro-active role to ensure smooth flow of knowledge from public sector to industry. Mapping of both knowledge and technologies in organisations involved in innovation research is essential. For this BI-RAC has initiated Technology mapping at National level & International level. In order to acquire new important technologies either nationally or globally BIRAC plans to launch a Technology Acquisition Fund. These are aimed at novel and affordable products.

The BIRAC Legal and Contracts Cell provides all the support required for formulation and execution of various schemes, agreements & contracts for industry research funding, technology transfer, licensing, agreements related to Intellectual Property, collaborative research, contract research and other associated activities.

The Cell also provides the required services to the industry as per their specific needs and on case to case basis.

Capacity building efforts includes a broad range of approaches, e.g., grant writing, grant management training and development for IP management, technology licens-







### How does BIRAC accomplish its Mission

### **Ensuring Entitlements**

- Ignite new Ideas- Biotech Ignition Grant Scheme (BIG)
- Support early stage research for proof of concept validation – Small Business Innovation Research Initiative (SBIRI)
- Partnership with industry for high risk discovery led innovation research – Biotechnology Industry Partnership Programme (BIPP)
- Facilitating technology validation and development – Contract Research Scheme (CRS)

### Empowering for Achieving Excellence

- Create world class quality Incubation space (Bio-incubators) for entrepreneurs and star-ups.
- Create common service facilities in public and private sector to serve the needs of Start Ups.
- Create Schemes that facilitate the acquisition or license of innovative technology and technology mapping for identifying patentable technology at national or international level.
- Create capacity in various fields required for successful Bio enterprises.

ing and transfer. BIRAC helps the industry by conducting capacity building activities in partnership with other agencies in varied fields required for successful Bio-entrepreneur creation.

#### **Hand-holding innovators**

Often small companies may not have the management bandwidth. It could be a researcher with a great idea, but without the financial resources or contacts to test it and take it to the next level. A new entrepreneur has to deal with multiple agencies, for concessional lab space, capital, loans etc. This involves interacting with bankers, lawyers, HR professionals, et al. For an entrepreneur this can be a bewildering process. Where BIRAC steps in is as an agency that nurtures feasible plans up to the break-even point in an environment that encompasses all the elements. The BISS scheme and the other services like the IPR and technology evaluation cells, etc. can meet this need. BI-RAC's advantage is its flexibility of operation and being an excellent instrument for managing the PPP programmes. BIRAC's role is significant because, while DBT is focussed on funding biotech research in the public sector, BIRAC's brief is to support and manage all PPPs and nurture startups and small companies, or in short, to be a lifeline to budding entrepreneurs. When it comes to sanctioning project proposals, the focus is on innovation, inventiveness, collaboration—knowledge economy partnership. Each proposal submitted is examined thoroughly to discern potential hiccups in research/commercialisation and regulatory requirements.

Evaluation of the proposals by Technical Screening Committee comprising scientists and academicians involve due diligence of the technical and financial aspects, besides site visits. An Apex Committee then recommends the proposal for DBT sanction. The fund instalments are released in 30, 20, 20, 20, 10 percentages across the five milestones with rigorous monitoring throughout. As is evident, the BIRAC process is rigorous, efficient and transparent.

The coming days will see how the biotech industry utilises the funds and expertise of the BIRAC to pole vault into the future and turn from a global player into a global leader.



DBT – BIRAC INNOVATORS
PROMOTING INNOVATION FOR AFFORDABLE PRODUCT DEVELOPMENT

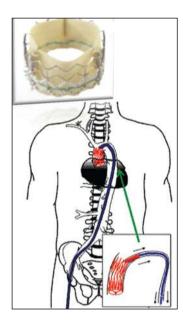






# birac ignite innovate incubate

**HEALTHCARE** 



#### Team Members: (including collaborators)

- 1. Dr. Mohan Thanikachalam
- 2. Dr. Naresh Kumar
- 3. Dr. George Joseph
- 4. Dr. R K Ramanathan
- 5. Ms. Kiruthigha Shanmugham
- 6. Ms. Ranjitha Jeevan

#### **Company Address:**

**Agada Medical Technologies** No.104/5, Arihant VTN Square, G.N. Chetty Road, T. Nagar, Chennai - 600017

# **AGADA MEDICAL TECHNOLOGIES**

#### **Description of Innovation:**

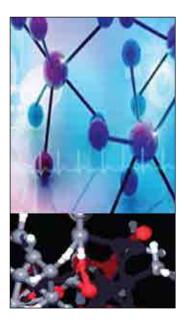
Percutaneous Aortic Valve Replacement–Transcatheter Aortic Valve Replacement (TAVR). Develop a percutaneously implantable stented aortic valve to treat aortic stenosis. The innovation lies in the unique stent and valve design. The stented aortic valve is intended to replace traditional open-heart surgery associated with the repair of the stenotic aortic valves.

#### Collaborating Partners (if any):

None

- **1. Stage of Development:** The percutaneous aortic valve technology is a proof -of-concept project that aims to develop a percutaneously implantable stented aortic valve to treat aortic stenosis. Design analyses through computer simulation and valve fabrication are in progress, with a concept prototype having been fabricated.
- 2. Innovative Elements: The innovation lies in the unique stent and valve design. The PAV comprises of a Biological Aortic Valve supported by a metallic stent. The procedure involves accessing the femoral arteries in the leg by a small incision, through which the stent with the valve, preloaded in a catheter, is delivered to the target site in the heart under fluoroscopic guidance. Designing a stent that conforms to the aortic root dimensional changes during systolic and diastolic phases, identifying a bio-material which will act as a sealant by adhering to the stent and aortic annulus and the development of a low-profile deployment system, are the other innovations dealt with.
- **3 Market Potential:** The stented aortic valve is intended to replace traditional openheart surgery associated with the repair of the stenotic aortic valves. The proposed percutaneous technology which is unique and commercially not available globally, if successfully developed, could be used both in and abroad with the potential to capture 46 per cent of the current aortic valve market besides expanding the same market by 30 per cent through extension of treatment to high risk patients who are currently denied surgery.
- 4. **Risk Factors:** Potential complications are bleeding during incision at the groin, stent migration leading to occlusion of coronary ostium, dislodgement of calcified plaque during deployment leading to stroke, infection and thrombus formation. Designing a stent that conforms to the aortic annulus with least amount of trauma, identifying a bio material that will act as a good sealant and the development of a low profile deployment system will minimize or eliminate these potential complications.
- 5. National/Societal Relevance: The technology being new, its development would put India onto the forefront of worldwide cardiac implant technology development. The technology means good news for patients with co-morbidities, while translating into the reduction of procedural costs associated with an open-heart surgery.
- **6. Potential for IP Generation:** Once developed an international patent for the same would be obtained.
- 7. **Progress Quantifiers:** Independent third-party evaluators will validate final design parameters. Bench testing as per the established standards to test the hydrodynamic performance of PAV under steady and pulsatile flow conditions will be performed.
- **8. Plans to take up innovation further:** The success of this proof-of-concept project would result in subsequent animal trials and commercialization.
- **9. Self-satisfaction level:** (On a scale of 1 to 10): 7





#### Team Members: (including collaborators)

- 1. Dr. Sunilkumar Sukumaran
- Dr. Shalaka Samant
- Dr. Ganesh Sambasivam
- Subbulakshmi Karthikeyan
- Dr. Kannan Thanukrishnan
- Dr. Santanu Datta
- Dr. Anand Anandkumar

#### **Company Address:**

**Anthem Biosciences Pvt Ltd.** #49, Canara Bank Road, Bommasandra Industrial Area Phase I, Bommasandra, Hosur Road Bangalore - 560099, Karnataka

## **Anthem Biosciences Pvt. Ltd.**

#### **Description of Innovation:**

Ketoreductases-whole cell biotransformation for chiral chemistry. According to the New Drug Policy and FDA guidelines, chiral drugs should be enantiometrically pure and the use of racemic mixtures as drugs is forbidden unless it can be shown that both the chiral forms are active.

#### Collaborating Partners (if any):

Cellworks Research India Pvt. Ltd.

- 1. Stage of Development: The innovation is currently under Proof-of-concept stage.
- 2. Innovative Elements: The application of Biocatalysts such as ketoreductases in the production of pro-chiral alcohols has undergone a revolution in the past few years. Deficiency of sufficient co-factors is known to be detrimental in large scale biotransformations. In an effort to subvert this, Anthem proposes a novel approach based on predictive modeling of micro-organisms, of deleting specific genes whose products extensively utilize essential co-factors. The company also proposes to clone and express certain ketoreductases for carrying out whole cell reduction of 5 commercially relevant pro-chiral ketones and high value pharmaceutical intermediates.
- 3. Market Potential: Ketoreductases (KRED's) yield products has a current market value of US\$ 5 billion. It is projected that this amount is set to increase to about \$60 billion by 2020. With such a high rate of growth for the KRED segment, it makes obvious business sense. This proprietary technology could potentially enable India attain the status of a technology leader in the field of Green Chemistry.
- **4. Risk Factors:** The basic assumptions of the project that if we can knockout the high flux non-essential cofactor utilizing pathways, then the enriched co-factors could be channeled and utilized solely for the synthesis of chiral intermediates. This is still an untested hypothesis. It might be difficult to convert some prochiral molecules into the chiral form. This may be due to the low solubility, low permeability and toxicity issues. Additionally, modeling of the host organism may not be able to take into account all effects of metabolic re-arrangement that may lead to chromosomal instability at high volumes.
- 5. National/ Social Relevance: Production of chiral alcohols in India is carried out mainly using chemical means. The development of indigenous cutting edge whole cell bio-transformations to synthesize chiral alcohols is of national importance because they are easily scalable, can reduce process costs and provide for a safe approach to the same goal by avoiding the use of toxic and/or hazardous substances, thereby promoting "Sustainable technologies". Moreover, our project will create a high value IP by methodologies of insilico and wetlab techniques.
- 6. Potential for IP Generation: Targeted genetic deletions in E. coli to facilitate optimal use of cellular NADH/NADPH to give enhanced yields following whole cell reduction is novel and patentable.
- 7. Progress Quatifiers: Of the 4 objectives listed in our proposal, we have completed the first 3 (75% achieved). We are currently evaluating the possibility of enhancing the chiral reduction yields of 5 industrially relevant ketones using our co-factor enriched E. coli strains overexpressing different ketoreductases.
- 8. Self-satisfaction: 8





#### **Team Members:**

(including collaborators)

- 1. Manoj M.N
- 2. Manjula J

#### **Company Address:**

Bigtec Labs Pvt. Ltd., Society for Innovation and Development (SID) Indian Institute of Science Campus, Bangalore - 560012

### **BIGTEC PRIVATE LIMITED**

#### **Description of Innovation:**

Validation of disease detection on handheld microPCR device. The battery-operated microPCR device enables detection of infectious diseases such as malaria and dengue in resource-limited settings where laboratory infrastructure is not available.

#### Collaborating Partners (if any):

None

- 1. Stage of Development: Bigtec had developed tests for diseases of relevance to India (Malaria, Dengue, Salmonella, amongst others). Through BIPP-DBT support, these tests were internally and externally validated for use in clinical settings. They were standardized according to CLSI Nucleic Acid Testing guidelines. They were also independently validated at leading hospitals and research institutions like the National Institute of Malaria Research.
- 2. Innovative Elements: The battery-operated microPCR device enables detection of infectious diseases such as malaria and dengue in resource-limited settings where laboratory infrastructure is not available. The test is performed on a microchip that has the entire test reagents stored on it, ready for use. A minimally trained operator can run the test. This development allows healthcare authorities to now use PCR - a very sensitive detection mechanism, at a fraction of the cost of commercially available PCR tests.
- 3. Market Potential: Cost of Bigtec's microPCR is one twentieth of the real-time machine. With diagnostic results available in few minutes, it is ideal for use in clinics, primary health centres, airports. Based on estimates done by Frost and Sullivan, its market size is US \$ 39.7 billion. Currently there is no equivalent PCR device/test available in the market for infectious disease detection.
- 4. Risk Factors: No patient risk factor envisaged as samples collected will be used along with routine diagnosis samples. Risk with respect to assay will be mitigated as the assay will be tested for various performance parameters.
- 5. National /Societal Relevance: As India has many cases of diseases like Malaria and Dengue annually, Bigtec's microPCR tests would contribute to reduction in disease burden through rapid identification and treatment besides curbing the spread of disease and preventing epidemics. Infectious diseases account for 30 per cent of the Disability adjusted life years world over calling for a cost-effective rapid infectious disease diagnostic device. Nucleic Acid testing is the gold standard in infectious disease detection and the current device provides for Nucleic Acid testing at Point of
- **6. Potential for IP Generation:** Bigtec's microPCR device disease-specific microPCR tests are the subject of patent applications worldwide.
- 7. Progress Quantifiers: The microPCR device and tests will be launched in India in 2012.
- 8. Plans to take up innovation further: Bigtec will be looking towards standardising and validating assays for different infectious diseases in accordance with mentioned timelines. It will also apply for CE marking approval for each validated assay.





### **BIOCON LTD**

#### **Description of Innovation:**

A Multicenter, Randomized, Double-Blind, Placebo Control study of IN-105 tablets [oral insulin] in patients with Type 2 Diabetes Mellitus who have inadequate Glycemic Control on Optimal doses of Extended Release Metformin Tablets.

#### Collaborating Partners (if any):

None

#### Higlights of the innovation:

- 1. Stage of Development: IN-105 (a oral insulin), is a novel insulin analogue which is being developed for oral delivery for the treatment of diabetes mellitus.
- 2. Innovative Elements: The drug product has a major advantage as short acting profile. This is useful for controlling the prandial glycemic surges in diabetic patients. The short acting profile has significant benefit in terms of reduced risk of hypoglycemia and weight gain which is a common problem in type 2 diabetes patients. The IN-105 molecule can be used for the treatment across the diabetes continuum.
- 3. Market Potential: India leads the world with the largest number of diabetics, earning the dubious distinction of 'diabetes capital' of the world. According to data published by International Diabetes Association the number of diabetes in India is around 41 million and expected to rise to 70 million by 2025 unless urgent prevention measures are taken.

This molecule IN 105 can be used for the treatment across the diabetes range. Since an oral Insulin product can help initiate insulin therapy early in the diabetes progression and can potentially slow down the progression of diabetes, even those at the early stages of the ailment will find the product useful.

- 4. Risk Factors: The oral delivery of insulin has several developmental risk. The biggest risk is of failure of the Phase 3 study which can delay the product coming to the market.
- 5. National/ Social Relevance: Since India has a very large percentage of population suffering from diabetics, the expected lower cost of oral insulin is likely to reduce the therapy costs of chronic diseases like diabetes, cancer and autoimmune diseases by leveraging India's cost advantage to provide access to affordable treatment to patients worldwide.
- 6. Potential for IP Generation: The molecule is completely novel and has a strong IP protection.
- 7. Plans to take the innovation further: Further studies are being planned to understand the mechanism of failure based on which further long term studies can be conducted to bring the product to market.

#### Team Members: (including collaborators)

- 1. Dr. Harish lyer
- 2. Dr. Manish Verma
- 3. Dr. Sharmitha Krishnamurthy
- 4. Arthur Augustine

#### **Company Address:**

Biocon Ltd. 20th K M Hosur, Road, Electronic City, Bangalore - 560100 Andhra Pradesh







#### **Team Members:**

#### (including collaborators)

- 1. Dr. Anand Anandkumar
- Dr. Shireen Vali
- 3. Dr. Anita Chugh
- Dr. Santanu Datta
- 5. Ms. Shweta Kapoor

### **CELLWORKS RESEARCH INDIA PVT. LTD.**

Description of Innovation: Therapy Design and in vivo proof-of-concept for novel, combination therapy for non-small cell lung cancer (NSCLC). The objective is to design a novel, efficacious and affordable combination therapy for non-small cell lung cancer (NSCLC) by the use of the Cellworks in-silico platform.

Collaborating Partners (if any): Syngene International Limited, Bangalore, India

#### Higlights of the innovation:

- 1. Stage of Development: The primary objective of the project is to design a novel, efficacious and affordable combination therapy for non-small cell lung cancer (NSCLC) by the use of the Cellworks in-silico platform. Currently it is in the stage of hypothesis testing, from Insilico through Invitro to Invivo POC, on Cellworks' prediction of Synergistic Fixed dose combination.
- 2. Innovative Elements: Cellworks has developed a functional proteomics based predictive in-silico model of an epithelial tumor cell. The technology, the only one of its kind, is a dynamic pathway network incorporating comprehensive coverage of signalling and tumor metabolism pathways related to apoptosis, metastasis, cell cycle, metabolism, tumor microenvironment including the interplay between the growth factor receptors, kinases and other molecules. Further, the platform can be customized to match different cell lines and patient profiles by overlaying key mutations on the control cell to generate a dynamic disease state.
- 3. Market Potential: Lung cancer forms more than 15 per cent of all cancer occurrences in India with 80 per cent of incidences in rural males, translating into a major affordable healthcare need. Prone to late diagnosis, lung cancer is difficult to treat and a serious public health problem even in industrialized countries, calling for optimal and efficacious treatment regimens that work across patient profiles. The current economic cost of treatment is substantial with total worldwide market size in excess of \$10 billion for treatment of NSCLC.
- 4. Risk Factors: Correlation of animal data with human clinical data remains a risk factor though it is minimized through use of drugs that have gone through man before to avoid any PKPD surprises. Further, the accuracy of drugs modelled through functional proteomics based experimentation is dependent on information available on drug primary mechanism of action. Unknown drug to drug interactions which impact drugs absorption and distribution is yet another risk factor.
- 5. National/Societal Relevance: Lung cancer has reached epidemic proportions in India with a major cause being smoking besides specific occupational environments related to asbestos, arsenic etc. Lung cancer forms 15 per cent of all cancers in India with dominant occurrence in rural males. It accounts for 7 per cent of total cancer Disability Adjusted Life Years (DALY), highest among all cancer types. Current therapies are expensive and are resistant in a large subset of NSCLC patients. Hence, finding efficacious and affordable therapy for NSCLC has significant social relevance.
- 6. Potential for IP Generation: Novel mechanism of action of fixed dose combination for NSCLC, based on existing drugs that are 'repurposed' for new indication holds key potential for IP generation.
- 7. Progress Quantifiers: With the work having started a year back, the first milestone has neared completion.
- 8. Self-satisfaction level (On a scale of 1 to 10): 9

#### **Company Address:**

#### **Cellworks Research India Limited-R&D Center**

3rd floor, West Wing, "Neil - Rao Tower"118, Road # 3, EPIP, Whitefield, Bangalore - 560 066





#### Team Members: (including collaborators)

- 1. Dr. Taslimarif Saiyed
- 2. Dr. Anil Prabhakar
- 3. Dr. Sudip Mondal
- 4. Dr. H. Krishnamurthy
- 5. Dr. Vishnu

#### **Company Address:**

#### **Centre for Cellular and Molecular Platforms**

NCBS-TIFR, GKVK Post, Bellary Road, Bangalore 560065

# **CENTRE FOR CELLULAR AND MOLECULAR PLATFORMS (CCAMP)**

#### **Description of Innovation:**

Miniaturized microfluidic flow analyzer. The miniature flow analyzer technology for CD4 cell counting has its main application in HIV testing at point-of-care locations. The novel technology incorporates a microfluidic component to miniaturize the device, hence reducing the cost of device for affordability. The technology as a whole aims to make quantitative HIV testing an affordable and accessible exercise.

#### Collaborating Partners (if any):

**IIT-Madras** 

#### **Higlights of the innovation:**

- 1. Innovative Elements: The innovative elements of this product has many interesting angles. Its microfluidic device uses 2D focusing coupled with opto-electronic system and embedded lens fiber. Currently HIV diagnosis is carried out using enzyme-linked immunosorbent assay or through conventional flow cytometry techniques. However, a major drawback of these is that they are not quantitative and cannot detect the level of infection. Using the CD4 cell counting method it is possible to ascertain CD cell count which increases during the immune response.
- 2. Market Potential: The main market for this technology is the HIV/AIDS Screening Tests market, which at the present time generates around US\$1.5 billion/year in revenue. By 2015, the HIV/AIDS monitoring test market is projected to reach US\$1.7 billion.
- 3. Risk Factors: The product will encounter competition because it is in a competitive technological market. The timely conversion of the idea into production will be a key factor for success.
- 4. National/ Social Relevance: HIV is one of the most serious infectious diseases with nearly 33.3 million infected individuals worldwide in the year 2009. Out of these infected individuals, 2.5 million are below 15 years of age with 14.6 million people estimated to be in need of antiretroviral therapy (ART). People with a cell count lower than 350 are usually administered ART.

In AIDS patients, HIV causes a significant reduction in CD4 cells that initiate the body's immune response. Hence, an effective way to study AIDS severity is to measure CD4 cell proportion in blood samples of patients, which is then used to detect, initiate and monitor the therapy for HIV. Patients need to be monitored every 3-6 months to verify the progression of the disease.

In order to make frequent health monitoring a common practice, there is a need for less expensive, user friendly and disposable flow cytometers that can not only detect HIV but also give quantitative information such as the level of infection. This need is even more apparent in developing countries where point-of-care-testing (POCT) is not easily available.

- 5. Potential for IP Generation: The company has filed for a provisional patent last year around its novel fluid flow technology using 2D hydrodynamic focusing and coupled to a microfluidic component.
- **6. Progress Quatifiers:** Targets & milestone accomplished.
- 7. Plans to take the innovation further: Currently discussing possible licensing deal with a couple of companies.
- 8. Self-satisfaction: 8-9







#### **Team Members:** (including collaborators)

- 1. Dr. Sreenivasu K
- 2. Mr. Muralidhar Reddy
- 3. Mr. Vijay Babu G
- 4. Mr. Anil Kumar Reddy C
- 5. Mr. Vijay Nag

#### **Company Address:**

#### Clonz Biotech Pvt. Ltd.

Plot No 15A, Biotech Incubation Center (BTIC), Alexandria Knowledge Park, Genome Valley, Shamirpet Mandal, Turkapalli Village, R.R Dist., Hyderabad - 500078, Andhra Pradesh

### **CLONZ BIOTECH PVT LTD**

#### **Description of Innovation:**

Production of Ranibizumab, a recombinant humanized anti-VEGF monoclonal antibody fragment (recombinant huFab V2) expressed in Hansenula polymorpha. Ranibizumab binds to and inhibits the biologic activity of human vascular endothelial growth factor a (VEGF-A). Ranibizumab is used for treating a serious eye condition known as age-related wet macular degeneration.

#### Collaborating Partners (if any):

None

- 1. Stage of Development: The humanized anti-VEGF antibody was cloned into the Hansenula yeast vectors and transformed into Hansenula host. Screening for the best clone is going on.
- 2. Innovative Elements: The protein expression of Ranibizumab in yeast as secreted into the medium is novel. Ranibizumab is used for treating a serious eye condition known as age-related wet macular degeneration. The medication can slowdown or even reverse macular damage and vision loss. The innovator is Gentech Inc, and the drug is sold in India at a very high price. To make it economically accessible to Indian patients the Clonz Biotech will make the product available at lower than 50 per cent of the cost of the current innovator price, the company said in its proposal.
- 3. Market Potential: Total estimated cost for Ranibizumab treatment is estimated to be Rs 13 lakh for 20 doses at Rs.65,000 per dose. With Clonz Biotech's product expected to be launched at half the cost of the innovator drug, the market penetration would be easier as this is a price sensitive market. Since there is no Indian player offering this drug in India, the company has the potential to penetrate the market further.
- 4. Risk Factors: Since the product is expressed in Yeast for the first time, there could be some un-known risk factors involved.
- 5. National/ Social Relevance: Age-related macular degeneration (ARMD) is the most common cause for visual impairment in the elderly in western countries. The prevalence in India varies from 2.7% (early ARMD) to 0.6% (late ARMD) in South India 4 to 4.7% in North India. Yearly financial burden of AMD patients is approximately Rs 8,000 crores. Direct and indirect costs will further add to this economic burden. The 60+ year's age group is at risk for ARMD and constitutes 7.5% of the Indian population (75 million). About one million of them will suffer from ARMD (considering 1.5% prevalence). Wet ARMD will constitute about 10% of these cases (0.1 million) and will require treatment. Considering that about 18 to 22% of the Indian population is below the poverty line, they cannot afford these treatments.
- 6. Potential for IP Generation: The product process has good potential for IP generation.
- 7. Progress Quatifiers: The target and first milestone for proof of concept is achieved as protein expression was confirmed by the Western blot. The process needs to be optimized for high protein expression.
- 8. Self-satisfaction (on a scale of 1-10): 8







### Team Members: (including collaborators)

- 1. Dr. Ashwini Nangia (Crystalin)
- 2. Dr. Jitendra Kumar (lkp)
- 3. Dr. Dinesh Kumar (NIN)

# **CRYSTALIN RESEARCH PVT LTD**

#### **Description of Innovation:**

Pharmaceutical Cocrystals of anticancer drug Temozolomide – pre clinical trials. The objective was to start animal and human clinical trials to test the efficacy of temozolomide cocrystals.

#### Collaborating Partners (if any):

None

#### Higlights of the innovation:

- 1. Stage of Development: Validation of novel drug cocrystals in cancer cell lines and then animals. The plan was to do clinical trials on animal and human to test the efficacy of temozolomide cocrystals. In vitro results of solubility, dissolution and stability are all positive.
- 2. Innovative Elements: The solubility of this drug, Temozolomide, was measured and it was found that cocrystals have comparable or superior solubility and also better stability than reference drug. So the company wanted to carry out clinical trials to establish this.
- 3. Market Potential: The company, in its summary proposal said that the global market for temozolomide is US\$1billion and patent for parent drug will expire in 2014. It is around this time the company wants to launch its product.
- **4. Risk Factors:** Since temezolomide is an approved drug, the risk factor is minimal. The conformers are safe for human consumption. At the last stage of drug development there is no change in drug molecule.
- 5. National/ Social Relevance: Cancer is one of the biggest killer disease in the world. An improved version of temezolomide of higher efficacy will mean lower dosage, faster treatment and better healthcare. The company is in the process of stabilizing anti-cancer drug Temozolomide for tropical/ humid conditions.
- **6. Potential for IP Generation:** The company has filed for Indian patent application.
- 7. **Progress Quantifiers:** Cell lines experiments are ongoing as per milestones and timelines. Animal testing of drug cocrystals will be carried out in next 3-4 months.
- **8. Plans to take the innovation further:** Next stage is animal trials, and then human clinical Phase I trials.
- **9. Self-satisfaction:** 8-9 as the project is more than 50% complete in 8 months of first year.

#### **Company Address:**

Crystalin Research Pvt. Ltd. Plot 81 A/C, Unit D, MLA Colony, Road No. 12, Banjara Hills, Hyderabad - 500034 Andhra Pradesh





#### **Team Members:** (including collaborators)

- 1. Dr. Navin Khanna, ICGEB
- 2. Dr. Kim Pettersson University of Turku

### **DESIGNINNOVA**

#### **Description of Innovation:**

Design and development of an affordable Fluorescence Reader for Point-of-care diagnostics. The aim of the project is to develop a reader device for Lateral Flow (LF) assays utilising up-converting phosphor (UCP) technology. Its low power battery operated, portable and affordable design can be adapted for field applications. As it uses novel up-conversion phosphors technique as a detection system, which uses infrared low energy signal for excitation and emits light in the visible range, the design ensures there is no-auto-fluorescence from biological samples.

#### Collaborating Partners (if any):

ICGEB & (DBTU) University of Turku

#### Higlights of the innovation:

- 1. Stage of Development: The project is currently at the discovery/Proof-of-Concept stage.
- 2. Innovative Elements: As it uses novel up-conversion phosphors technique as a detection system, which uses infrared low energy signal for excitation and emits light in the visible range, the design ensures there is no-auto-fluorescence from biological samples. This offers very high signal to noise ratios. It is a solid-state design with micro actuator as scanning LF cassette, thus ensuring its robustness, making it adaptable for various POC diagnostics LF formats. Its low power battery operated portable and affordable design can be adapted for field applications.
- 3. Market Potential: This platform design has an immense potential for the point of care diagnostic applications, both in the developing and developed nations. The use of novel up-converting phosphors (UCP) has the potential to remove the bottleneck of lower sensitivity associated with lateral flow systems and can be adapted for tests for detection of HIV, HCV, HBV, Syphilis and Tuberculosis infections. Use of UCP has the potential to provide inexpensive option for disease testing.
- **4. Risk Factors:** Since this design is in its discovery phase, it may have its inherent risks. However, this design is being continuously evaluated with several scientists from university of Turku, Finland, who strongly believe in the design with respect to UCP technology.
- 5. National /Societal Relevance: This affordable portable fluorescence reader will be of immense social value. It will help to detect multiple infections simultaneously in remote settings. If the biology component is successful, one could imagine carrying out a pre-screening from a finger prick (Instead of post screening after collection of a bagful of blood) of blood donors for the presence of HIV, HCV, HBV and Syphilis infections. This will reduce medical waste in blood banks. The use of up-conversion phosphors developed by University of Turku, has the potential to enhance the sensitivity of these POC multiplexed tests, similar to the sensitivity and specificity required by WHO.
- 6. Potential for IP Generation: Portable UCP Reader for POC holds potential for IP generation.
- 7. Progress Quantifiers: The Company has already achieved 55 per cent of the targets set under the project.
- 8. Plans to take up innovation further: The Company plans to enhance the applicability of the novel readers to ELISA strips or other LF formats.
- 9. Self-satisfaction level (On a scale of 1 to 10): 9

#### **Company Address:**

### **DESIGNINNOVA**

Phase 1, A-12 Naraina Industrial Area, Naraina, New Delhi





#### **Team Members:**

#### (including collaborators)

- 1. Dr. K.M.Cherian
- 2 .Dr. Soma Guhathakurtha
- 3. Dr. Balasundari Ramesh
- 4. Dr. Ravi Agarwal.

#### **Company Address:**

Frontier Lifeline Pvt. Ltd. R.30 C Ambattur. Industrial Estate Road, Mogappair, Chennai - 600101 Tamil Nadu

### FRONTIER LIFELINE PVT LTD.

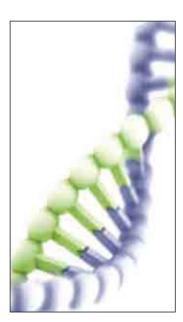
Description of Innovation: Porcine Pulmonary Xenograft as a versatile conduit in cardiovascular surgery. The project aims to minimize the dilatation of decellularized and processed porcine pulmonary artery by coating with biodegradable electrospun nanofibers. It addresses the issue of perfect biological conduit to restore anatomical continuity from the heart to the pulmonary artery and aorta. The currently available product of the Company is applicable for the right side of the heart but improvisation by nanotechnology would make it versatile.

Collaborating Partners (if any): None

- 1. Stage of Development: The project aims to minimize dilatation of decellularized and processed porcine pulmonary artery by coating with biodegradable electrospun nanofibers. Various polymers such as PCL (Poly Caprolactone), PLLA (Poly L-Lactic acid), Collagen (Bovine skin and Umbilical cord) and Blended polymer of PCL-Collagen, PLLA-Collagen and PLLA -PCL were evaluated. Parameters such as Voltage, Temperature, Viscosity, Flow rate, Distance between needle and collector, Rotor speed was standardized and optimized for each polymer. Solubility, Wettability (Fluid uptake), Stability, Mechanical strength, cytotoxicity, Fatigue testing, DSC, FTIR and various microscopical studies were performed to determine the suitable polymer.
- 2. Innovative Elements: Electrospun biopolymer nanofiber reinforced biological conduit of porcine origin is the innovation addressed. Involves post decellularization nanocoating and innovative method of cross linking. About 40 per cent of complex congenital heart disease patients require this kind of conduit across the world.
- 3. Market Potential: Currently, the country imports almost 100 per cent of its requirement of biological implants for cardiovascular applications. This lucrative market is currently controlled by global market leaders because of lack of availability of a biological conduit. This has skewed, both market availability as well as price of life saving devices such as valved conduit to a supplier detailed market. The current device of this project is expected to be delivered at one-third the prevailing market price, with better quality.
- 4. Risk Factors: In vivo large animal experimentation is required to confirm the efficacy of nanocoated porcine valve. Further investigation is necessary to prove longer life span of processed tissue in human system and its resistance to immunologic interference along with its growth propensity.
- 5. National /Societal Relevance: The project is first of its kind in whole of South East Asia offering better properties than existing imported ones. This will not only be versatile both in the left and right side of the heart but also affordable. This could also be a potential solution for patients with valvular heart diseases as processed vascular conduits could be a suitable replacement. The project would give an edge to enter the global biological devices market in a big way.
- **6. Potential for IP Generation:** It is a step further in realising the dream of making a patented nanocoated porcine xenograft for clinical use.
- 7. Progress Quantifiers: Already attempted coating with 3 kinds of biopolymer with favourable results which are undergoing validation. Phase I clinical trials showed 89 conduits functioning adequately without improvisation in the right side of the heart.
- 8. Plans to take up innovation further: Large animal study involving implantation under the skin and subcutaneous tissue in the jugular vein as an interposition graft and explanation after six months histological and immunohistochemistry evaluation.
- 9. Self-satisfaction level (On a scale of 1 to 10): 10







#### Team Members: (including collaborators)

- 1. Dr. Sujay Singh
- 2. Dr. Ashok K. Patra
- 3. Dr. Prashant K. Maiti
- 4. Longjam P. Singh
- 5. Javed Akhtar

## IMGENEX INDIA PVT. LTD.

#### **Description of Innovation:**

Development of high expression plasmid vectors for production of biosimilar Herceptin and other recombinant proteins and antibodies in mammalian cells. The development of biosimilar antibodies or recombinant proteins depends on a high-expresser plasmid vector to keep production costs low. Company's plasmid vector can be used for this purpose.

#### Collaborating Partners (if any):

None

#### **Higlights of the innovation:**

- 1. Stage of Development: Imgenex has generated a novel vector containing two copies of a chromatin-organizing element and one copy of a post-transcriptional regulatory element near the gene of interest. These two elements and the gene under the control of CMV promoter can be used for high-level expression of any recombinant proteins including monoclonal antibodies.
- 2. Innovative Elements: Comparative higher-level expression of recombinant EPO was achieved in CHO-DG44 cell line by using this vector. Such enhancement of expression level established the proof of concept that with the combination of above-mentioned elements high-level of gene expression can be achieved. Combination of a plasmid vector containing MAR and WPRE elements and CHO cell line stably transferred with MAR elements is an inventive step.
- 3. Market Potential: The company's initial interest is to produce Herceptin, a monoclonal antibody for treatment of breast cancers, which has immense market potential of more than 6 billion US dollar worldwide annually. Herceptin, a breast cancer drug which reduces the risk of relapse by 50 per cent in case of women with a fast-growing type of tumor. As many drugs are going out of patents, biosimilars have a tremendous manufacturing potential in India.
- 4. Risk Factors: There is a chance that the recombinant Herceptin may have different post-translational modifications, which may affect biological functions. The company will carefully analyse such possibility in its work plan.
- 5. National/Social Relevance: Incidence of breast cancer is rising in India with almost 75,000 new cases every year. According to medical experts in every 13 minutes breast cancer kills one patient in India. Patients die due to lack of affordable therapeutic medications. Since Herceptin currently is an expensive drug, the company's goal is to develop high-expresser mammalian cell line that can significantly lower the treatment cost.
- 6. Potential for IP Generation: The company plans to use a two-prong approach of utilizing this genetic elements and the modified bioprocess to enhance the expression level of recombinant proteins.

#### **Company Address:**

Imgenex India Pvt. Ltd. E-5, Infocity, KIIT Post Office, Bhubaneswar - 751024, Orissa



### birac Ignite Innovate Incubate

**HEALTHCARE** 



# **INBIOPRO SOLUTIONS PVT. LTD**

#### **Description of Innovation:**

Process development of a recombinant therapeutic protein used for the treatment of Multiple Sclerosis. Multiple sclerosis (MS) is an autoimmune disease that affects the brain and spinal cord (the central nervous system. MS affects women more than men. The disorder is most commonly diagnosed between ages 20 and 40, but can be seen at any age. MS is caused by damage to the myelin sheath, the protective covering that surrounds nerve cells. When this nerve covering is damaged, nerve signals slow down or stop. (Interferon Beta 1B improves the integrity of the blood-brain barrier (BBB)—which generally breaks down in MS patients, allowing increasing amounts of undesirable substances to reach the brain).

#### Collaborating Partners (if any):

None

#### Higlights of the innovation:

- 1. Stage of Development: Proof of concept
- 2. Innovative Elements: Interferon beta 1b will be the first biosimilar produced in India. Interferons are manufactured commercially in large quantities by recombinant DNA technology. Interferon beta 1b was approved for the treatment of multiple sclerosis by the United States Food and Drug Administration in 1993

Interferon beta 1b brings down the therapy cost for patients (over two million patients globally). Interferon Beta 1B when compared to the other two interferons used in MS, is used only once a week in the treatment regimen at 250mcg.

- **3. Market Potential:** Interferon beta 1b was one of the first FDA approved drug for MS. It provides long term treatment with high dosage when compared to other types of interferon. This regimen follows a once weekly schedule of 250mcg. Other advantage is that the biological actions of interferon Beta 1B comprise of antiviral activities, cytokine modulation and alteration of dysregular T cell function in MS. This makes the drug's multi functionality role, disenable in all approaches in all markets.
- **4. Risk Factors:** Though the process pathway is clear, being a biosimilar, the regulatory pathway and extent of biosimilarity to be ascertained follows a linear approach. Post clinical trials, the method of commercialization and market authorization would follow a regular biosimilar therapeutic route but new formulations could be challenging.
- 5. National/ Social Relevance: Incidence of MS in India goes undetected due to lack of relevant testing methods. The calculations based on the hospital data suggest an approximate prevalence rate of 0.17 to 1.33 per one lakh population in different parts of India. Since MS patients in India struggle with the high price of the innovator drug for longer periods of time -- MS is a non- curable disease, it is very imperative that a biosimilar version of betaseron comes to the market soon.
- **6. Potential for IP Generation:** New Process that gives better productivity and yield.
- **7. Progress Quatifiers:** Clone is ready and the company needs to start process development.
- **8. Plans to take the innovation further:** Yet to be planned.
- 9. Self-satisfaction: 9

#### Team Members: (including collaborators)

- 1. Mrs. Kavitha Iyer Rodrigues
- 2. Mr. Satishbabu.G
- Mr. Rajanarendrareddy G
- 4. Mr. Prathap kumar.S
- 5. Ms. Divya Unnikrishnan

#### **Company Address:**

**Inbiopro Solutions Pvt. Ltd.,** KIADB Industrial Area Peenya 3rd Phase, Bangalore – 560058





#### **Team Members:** (including collaborators)

- 1. Srikant Viswanadha
- 2. Swaroop Vakkalanka
- 3. Uday Kumar
- 4. Prashant Bhavar.

#### **Company Address:**

Incozen Therapeutics Pvt. Ltd. Phase-1 SP Biotech Park, "Spectrum" Discovery Zone SP Biotech Park, Turkapally, Shameerpet, Hyderabad – 500078

### **INCOZEN THERAPEUTICS PVT. LTD.**

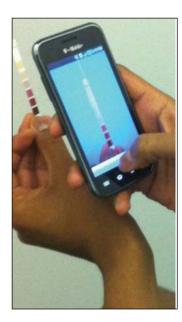
Description of Innovation: Discovery and development of Potent, Selective, and Novel c-Met kinase inhibitors in Cancer. Current cancer treatment regimens involve use of platinum-based combination chemotherapy or single agent treatment with third generation drug such as gemcitabine or taxanes. Majority of patients stop treatment because of the toxic effects of chemotherapeutic drugs. Tyrosine Kinase inhibitors represent a less toxic therapy, extending potentially beneficial treatment to a greater proportion of patients with tumours.

Collaborating Partners (if any): None

- 1. Stage of Development: A series of novel scaffolds have been designed, synthesized, and tested in enzyme and various cell-based assays. Lead compound has been identified based on in vitro, pharmacokinetic and efficacy data. Further efficacy testing along with toxicological evaluation is in progress.
- 2. Innovative Elements: Amongst several tyrosine kinase inhibitors currently under evaluation, c-Met has immense potential in regulating downstream events. C-Met is a proto-oncogene that encodes the protein c-Met with intrinsic tyrosine kinase activity. Modulating the c-Met signalling cascade via kinase inhibition represents a novel approach at alleviation of tumour growth and increasing progression-free survival of patients without any adverse effects. Tyrosine kinase inhibitors represent targeted therapies that are intended to have specific effect on cancerous cells rather than a mass effect on a tissue or organ.
- 3. Market Potential: Human protein kinases are intriguing drug targets given their role in regulation of a variety of signaling pathways, including more than 500 distinct protein molecules. There has been a steady growth in approvals of kinase inhibitors over the recent years. The largest segment receptor tyrosine kinase inhibitors market was nearly \$9.4 billion in 2008; which increased to \$10 billion in 2009. This is expected to rise to \$13.1 billion in 2014, registering a compound annual growth rate of 5.5 per cent. Given the large population, there is a huge burden of cancer in India, spelling immense market potential.
- 4. Risk Factors: Drugs inhibiting other kinases apart from c-Met kinase could potentially display increased toxicities. Treatment could therefore be restricted to patients diagnosed with tumours displaying aberrant c-Met kinase signalling.
- 5. National /Societal Relevance: The number of cancer patients in the country is expected to increase by 8 lakhs every year. Lack of diagnostic facilities resulting in late stage deduction is one of the chief reasons for fatalities amongst cancer victims. The high cost of therapy further compounds this. This warrants the development of safer, cost effective and efficacious drugs to address the disease. Besides, the currently available chemotherapeutic drugs have extensive toxic side effects. Tyrosine Kinase inhibitors represent a less toxic therapy, extending potentially beneficial treatment to a greater proportion of patients with tumours.
- **6. Potential for IP Generation:** Not available
- 7. Progress Quantifiers: The project is currently on track based on the projected time-
- 8. Plans to take up innovation further: The Company anticipates moving a lead compound to GLP toxicology evaluation in 2013.
- 9. Self-satisfaction level (On a scale of 1 to 10): 8







### JANACARE SOLUTIONS PVT LTD

#### **Description of Innovation:**

DXPhone - Mobile Phone Platform for Blood Glucose Analysis. Jana Care's software platform -DXPhone turns mobile phone into a diabetes monitoring platform, enabling lay users like health workers and patients to analyse blood glucose test strips using phone's camera, track symptoms and lifestyle data, and transmit data to a physician for follow up.

#### Collaborating Partners (if any):

AIIMS, Narayana Hrudayalaya

#### Higlights of the innovation:

- 1. Stage of Development: Janacare has validated the technology with a total of 101 patient blood samples against a laboratory analyzer and plan to perform IRB approved clinical validation by Jan 2013 and consequently submit for US FDA approval.
- 2. Innovative Elements: The core idea is to make use of the mobile phone's processing power to analyze test strips for different parameters, such as glucose, hemoglobin, cholesterol, HbA1c, urine albumin, creatinine etc. DXPhone will use the phone's camera to automatically detect the colour of the blood glucose test strip instead of relying on comparison to a reference colour chart by the patients. The innovation is to place a patch of a known colour on each strip that will allow the software to normalize for illumination and automatically compare against a reference colour chart stored in the memory.
- 3. Market Potential: The company will initially target Type I and II diabetes patients who use private specialists clinics in India. According to its earlier estimate there are about 10,000 Diabetologists, Endocrinologists and Internal Medicine Specialists who cater to 10 million diabetes patients. Base on this the addressable market potential was estimated at \$500 million for glucose monitoring in India by 2015.
- 4. Risk Factors: The initial customer base is expected to be small because of lower penetration of smart phones. The company is planning on porting platform to basic SymbianOS based phones to cover nearly 72 per cent of the phones in India.
- 5. National/Social Relevance: Diabetes is one of the leading causes of death around the world and in India there are nearly 50 million diabetic patients, which is expected to rise to 80 million by 2020. There is a large unmet clinical need to provide an affordable, simple and easily accessible blood glucose monitoring solution to patients, especially in the rural areas.

#### Team Members: (including collaborators)

- 1. Sidhant Jena
- 2. Michal Depa
- 3. Dr. Nikhil Tandon

#### **Company Address:**

Janacare Solutions Pvt. Ltd. 17 Teen Murti Marg, New Delhi - 110001





#### **Team Members:**

#### (including collaborators)

- 1. Pankaj Sharma
- 2. Dr. Sundeep Dugar
- 3. Dr. Frank Hollinger
- 4. Dr. Narayana
- 5. Dr. Kanury Rao

## SPHAERA PHARMA

#### **Description of Innovation:**

Novel combination therapy for treatment of resistant and non-responsive cancers.

#### Collaborating Partners (if any):

Leadinvent Technologies Pvt. Ltd., ICGEB

### Higlights of the innovation:

- 1. Stage of Development: Proof-of-Concept.
- 2. Innovative Elements: Involves a combination therapy that targets important synergistic onco proteins.
- 3. Market Potential: The innovation is aimed at a multi-million dollar market potential.
- 4. Risk Factors: The program has standard drug discovery and clinical stage related risk factors.
- 5. National /Societal Relevance: Patients with resistant and non-responsive cancers have limited therapeutic options available under current marketed therapies. The program is aimed at providing viable treatment option to such patient population.
- 6. Potential for IP Generation: IP creation is the central core of this program and a series of patents is expected to be generated around the outcome of this work.
- 7. Progress Quantifiers: The first year milestones have been successfully achieved with consistent progress made towards further development of this program.
- 8. Plans to take up innovation further: The focus is currently on the next stage of the project with the aim to create a combination of compounds with clinical goals.
- 9. Self-satisfaction level: (On a scale of 1 to 10): 9

#### **Company Address:**

Sphaera Pharma R & D Pvt. Ltd., 31, Sector 5, Manesar - 122051 Haryana





#### **Team Members:**

#### (including collaborators)

- 1. Dr. Lily Verma
- Prof. G.K. Khuller
- 3. Dr. J.N. Verma
- Dr. Nalini Vemuri
- 5. Dr. Samir Malhotra
- 6. Dr. Nusrat Shafiq

### LIFECARE INNOVATIONS PVT LTD

#### **Description of Innovation:**

Production of poly-(lactide-co-glycolide) nanoparticles (PLG-NP) and poly-(lactide-co-glycolide) nanoparticles encapsulating anti-tubercular drugs (rifampicin, isoniazid and pyrazinamide) (PLG-NP-ATDs) in GMP facilities. The novel polymer based nano-drug is formulated for treatment of Mycobacterium tuberculosis infections with the objective of improving the existing chemotherapeutic regimen by specifically reducing the dose frequency and improving patient compliance.

#### Collaborating Partners (if any):

None

#### Higlights of the innovation:

- 1. Innovative Elements: These are novel polymer-drug with the potential of replacing the daily oral dosage of free ATDs with a weekly half the therapeutic dose or alternatively, with a full therapeutic dose which can be given every 10th day. This is expected to improve patient compliance and reverse the rising trend of MDR and XDR tuberculosis with better TB control. It is also expected to improve the logistics of control programs such as DOTS, replacing the daily visits that span over 6-12 months with every 7th /10th day visits.
- 2. Market Potential: Being a superior alternative to current conventional drugs regime, the product would have huge demands both within and outside India.
- 3. Risk Factors: No risk is foreseen. The Nano-TB drug PLGA-NP-ATDs was found to be safe in pre-clinical studies. Polymer (PLG) and ATDs are USFDA approved.
- 4. National /Societal Relevance: A novel polymer-based nano-drug is formulated for treatment of Mycobacterium tuberculosis infections with the objective of improving the existing chemotherapeutic regimen by specifically reducing the dose frequency and thereby improving patient compliance. The Phase I clinical trials that have been completed hold promise for effective control of TB and reversal of the rising trend of MDR and XDR Tuberculosis.
- 5. Potential for IP Generation: No new I.P. is anticipated from the proposed project.
- 6. Progress Quantifiers: The Company has setup GMP facility to produce nanoparticles (PLG-NP) of rifampicin, isoniazid and pyrazinamide (PLG-NP-ATDs).
- 7. Plans to take up innovation further: Plans are underway to conduct Phase I clinical trials with poly-(lactide-co- glycolide) nanoparticles encapsulating anti-tubercular drugs (rifampicin, isoniazid and pyrazinamide) (PLG-NP-ATDs) in healthy volunteers.
- 8. Self-satisfaction level (On a scale of 1 to 10): 7

#### **Company Address:**

Lifecare Innovations Pvt. Ltd. B-589, Sushant Lok Phase - I Gurgaon-122 002







#### Team Members: (including collaborators)

- Dr. Manivannan.M
- 2. Dr. Thillai Rajan. A
- 3. Mr. Varun Durai.S.I
- Ms. K. Kanakapriya
- 5. Mr. Abhijit Biswas
- 6. Miss. Ajitha
- 7. Mr. Prabhu

# **MERKEL HAPTIC SYSTEMS PVT. LTD.**

#### **Description of Innovation:**

Hi-Fidelity Affordable Mannequin for Effective CPR (Cardiopulmonary Resuscitation) Training. Addresses preventing brain damage after cardiac arrest due to lack of medical intervention. Involves development of CPR mannequin for training in CPR.

#### Collaborating Partners (if any):

Indian Institute of Technology Madras

#### Higlights of the innovation:

- 1. Stage of Development: Proof of Concept.
- 2. Innovative Elements: Preventing brain damage after cardiac arrest due to lack of medical intervention requires general/non-medical public to perform CPR. This calls for training. The main aim of this project in Touchlab at IIT Madras is realising that the exact skill needed for CPR training is compressing depth of 1.5 to 2 Inches (for Adult) and also how to train the hand-eye coordination with minimum resources possible. The research output is the design of our CPR mannequin.
- 3. Market Potential: The CPR mannequin is a full body, interactive and affordable at school level. It allows training and periodic retraining and comes with interactive animation in regional languages to improve learning and is applicable to even the uneducated. The target segment comprises of all the corporate offices, IT offices, colleges (NSS and NCC cadres) schools and elderly homes.
- 4. Risk Factors: A foreign company could customise a mannequin specifically for Indian market, similar to the Auto/Car industry.
- 5. National/Societal Relevance: None of CPR mannequins are made in India and none customized for Indian population as they are imported mostly from US. Know-how of this technology is still absent. Our CPR mannequin fills this gap for the first time.
- **6. Potential for IP Generation:** Not as on date.
- **Progress Quantifiers:** Design in progress.
- **Plans to take up innovation further:** Not applicable.
- 9. Self-satisfaction level: (On a scale of 1 to 10): 8

#### **Company Address:**

#### Merkel Haptic Systems Pvt. Ltd.

Touchlab, MSB-356, Biomedical Engineering Group, Applied Mechanics, Indian Institute of Technology (IIT) Madras, Chennai - 600036





### **Team Members:** (including collaborators)

- 1. Mr. Sameer Sawarkar (Project Coordinator and Key Investigator)
- 2. Dr. Ravikumar Banda (Collaborator & Key Investigator)
- 3. Dr. Rajneesh Joshi (Collaborator & Key Investigator)

#### **Company Address:**

#### **Neurosynaptic Communications** Pvt. Ltd.

#6, 29th Main Road, BTM Layout II Stage, Bangalore - 560076

# **NEUROSYNAPTIC COMMUNICATIONS** PVT. LTD.

#### **Description of Innovation:**

Rural Primary Care Diagnostic Device. The device uniquely combines automated microscopy, multiwavelength colorimetry and centrifuge, with image processing techniques and dry chemistry, to suit the solution to the limited rural skill set and infrastructure. With the help of the device, a range of core tests will be addressed including glucose, hemoglobin, total/differential blood counts, UTI, Malaria, TB amongst several others.

#### Collaborating Partners (if any):

XCyton Diagnostics Private Limited, World Health Partners

- **1. Stage of Development:** The project is currently in the Proof-of-Concept stage.
- 2. Innovative Elements: The Company has developed and patented the affordable Remote Medical Diagnostics technology through which patients get access to city or town doctors from their village with price points below US \$ 1 per consultation.
- **3. Market Potential:** With the existing channel of rural entrepreneurs and lab assistants through e-Healthcare platforms, as well as other channels, the device has the potential market of US\$ 280 Million annually in India and would result in a 65-70 per cent saving in cost for the patient. The public health system in India which caters to 20 per cent of the health needs in the system, serves as a huge market with the device being designed to be operated by the village operator. This solution is scalable to similar settings in the developing world. Further, considering the generic nature of the device, more diagnostic tests could be added, resulting in higher coverage and revenues.
- **4. Risk Factors:** Some of the challenges that are likely to be faced include: Certification and validation of the device, its system integration and calibration & consistency, training the operators, besides integration into the public health system and service delivery.
- 5. National /Societal Relevance: Access to basic diagnostic tests remains a critical problem for rural patients with an average 15 Kms travel over rough roads to reach diagnostic labs. Besides, the travel costs often feature beyond the patient's ability to pay. Skilled personnel are scarce and devices are expensive for point-of-care due to low volumes. The proposed device uniquely combines automated microscopy, multi-wavelength colorimetry and centrifuge, with image processing techniques and dry chemistry, to suit the solution to the limited rural skill set and infrastructure. It addresses a range of core tests including glucose, hemoglobin, total/differential blood counts, UTI, Malaria, TB amongst several others.
- 6. Potential for IP Generation: One patent application has already been filed for this innovation and a few more patents are expected to be filed during the project duration.
- 7. Plans to take up innovation further: The Company plans to develop a device that combines motorized microscopy, colourimetry and can be used in the villages to carry out a set of defined tests at affordable costs accurately.





#### **Team Members:**

(including collaborators)

- 1. Dr Sanjay Trehan
- 2. Dr Goutam Ghosh

### PANACEA BIOTEC LTD.

#### **Description of Innovation:**

Development of safe and highly efficacious 13-Valent Pneumococcal Conjugate vaccine against Streptococcus pneumoniae infections.

This vaccine will address the pathogen estimated to cause 16 million deaths every year, including up to one million children below 5 years.

#### Collaborating Partners (if any):

None

#### Higlights of the innovation:

- 1. Stage of Development: The Company has prepared and characterized research cell banks for all strains. The fermentation process was developed initially at a small scale and later scaled up to 15-L for most of the serotypes. Concurrently, purification process was also established and characterization is now in progress for most of serotypes. The fermentation and purification process has also been established for the carrier protein and scale up has been initiated. Simultaneously, conjugation and formulation work is in progress for proof-of-concept studies.
- 2. Innovative Elements: The project proposes to develop fermentation strategies for production of robust 13 polysaccharides from 13 S. pneumoniae serotypes. It will also develop purification and conjugation strategies for production of highly immunogenic conjugated polysaccharides vaccine from 13 serotypes of S. pneumoniae. Further, the Company will design and develop a formulation for a conjugate Pneumococcal vaccine and confirm the immunogenicity.
- 3. Market Potential: The vaccine has a market potential of Rs 930 crore with very less risk as the demand is huge with currently only two suppliers in the Indian market. S. pneumoniae continues to be a major cause of morbidity and mortality in developing countries like India. The emerging resistance to some common antibiotics compounds the problem. There arises a need to monitor the resistance pattern and map serotype distribution in different geographic locations.
- 4. Risk Factors: Preclinical studies need to be carried out to evaluate the safety and efficacy of the vaccine.
- 5. National /Societal Relevance: The vaccine has national and societal relevance as it will address the pathogen estimated to cause 16 million deaths every year, including up to one million children below 5 years. The incidence is highest in developing countries, making it all the more relevant to this part of the world.
- **6. Potential for IP Generation:** The process developed has some unique aspects and is considered for patents.
- 7. Progress Quantifiers: The development of the vaccine is currently in the right direction. Most of the milestones and proposed targets have been achieved with some of them being in advanced stages of progress.
- 8. Self-satisfaction level (On a scale of 1 to 10): 10

#### **Company Address:**

#### **Panacea Biotec Ltd**

B-1 Extn./ A-27, Mohan Co-op. Industrial Estate, Mathura Road, New Delhi -110044







### RASAYANI BIOLOGICS PVT. LTD.

#### **Description of Innovation:**

The innovation is to develop Platinum Nano-particles for treatment of hormone refractory Prostate Cancer. Develop & test Anticancer intervention based on bare platinum nanoparticles in both, in vitro and in vivo models for anti-cancer application. Bioplatin is proposed to be fed orally and is the first home grown active pharmaceutical intervention.

#### Collaborating Partners (if any):

None

#### Higlights of the innovation:

- **1. Stage of Development:** Proof of concept and Validation.
- 2. Innovative Elements: Bioplatin, proposed for the management of malignancies, is an oral, platinum based metallic complex produced by environmental friendly process using herbs to generate the nano size particles. They have undertaken animal toxicity studies as per the norms of OECD which prove the non toxicity of Bioplatin.
- 3. Market Potential: All metastatic tumors treatment market in India and overseas. The current cost of extending life for 1 year of 550 thousand American cancer patients is \$440 billion. With the burgeoning cancer cases there exists a market potential of \$7 billion in India for the indicative and palliative treatment at the reduced costs.
- **4. Risk Factors:** The risks are the toxicity of the drug and the required regulatory approvals for selling. Going by the industry average of success and failure new drug development is fraught with more failures than success, hence it is risky.
- 5. National/ Social Relevance: Rasayani Biologicals intends to provide chemotherapy and palliatiative care at affordable cost. Fully indigenous product, cost effective treatment & affordable. The product is of high social relevance in our country as it will help increase life and also help improve quality of life of cancer patients.
- **6. Potential for IP Generation:** Patents obtained in US and EU.
- **Progress Quatifiers:** Effort towards Phase-I trials, 90 per cent completed so far.
- **8. Plans to take the innovation further:** Plans to Conduct Phase-I clinical trials
- 9. Self-satisfaction: 9

#### **Company Address:**

Rasayani Biologics Pvt. Ltd. B-1 Amrutkumbha, Laxmi Park Society, Navi Peth, Pune - 411030





# **RAVINDRANATH GE MEDICAL ASSOCIATES PVT. LTD.**

#### **Description of Innovation:**

Functional evaluation of autologous cell based therapy in cardiovascular diseases - Molecular Imaging (An innovative non-invasive technology). This innovation addresses the real time visualization of stem cell delivery, homing proliferation and differentiation capacity along with functional assessment, safety and efficacy issues of imaging technology.

#### Collaborating Partners (if any):

None

### Higlights of the innovation:

- 1. Stage of Development: : Proof-of-Concept
- 2. Innovative Elements: Designing MRI and PET probes for addressing the stem cell homing, cell distribution, proliferation
- **3.** Market Potential: The World market size of molecular imaging is about \$4.75 billion. The innovation is a hugely potential commercial product. The company's proposal is relevant for investigating cell fate monitoring with new imaging technologies for short term and long term safety and efficacy.
- 4. Risk Factors: Risk factors are high. Although, some of the risks are general to surgical transplantation and may not be reduced, the potential risk of tumor formation and inappropriate cell migration must be minimized before obtaining a true benefit to risk calculation with this innovation.
- 5. National/ Social Relevance: Modern imaging tools make possible the non-invasive visualization of cellular and molecular processes in living subjects. For cell-based therapy to truly succeed, it is important to track the locations of delivered cells, the duration of cell survival, and any potential of adverse effects. Analysis on the stem cell therapy using bioluminescence imaging indicates that about 90% of cells die within first 3 week of delivery and stated as one of the reasons of short term improvement of cardiac function. The problem of cell death is particularly troublesome and may limit the overall efficacy of stem cell-based therapy, making the current proposal more relevant into investigating the cell fate monitoring with new imaging technologies for short term and long term safety and efficacy.
- 6. Potential for IP Generation: High
- **Progress Quatifiers:** MCR 1 Completed
- 8. Plans to take the innovation further: Planning for pre-clinical and clinical applications.
- 9. Self-satisfaction: 9

#### **Team Members:**

(including collaborators)

- 1. Prof. K.S.Ratnakar
- 2. Dr. Lakshmi Kiran Chelluri
- 3. Dr. Aluri Ravi Kumar
- 4. Dr.V.Sritharan

#### **Company Address:**

Ravindranath GE Medical Associates Pvt. Ltd.,

**Global Hospitals** 6-3-1070/1 to 4, Lakdi-ka-pul, Hyderabad - 500 004, Andhra Pradesh







#### **Team Members:**

#### (including collaborators)

- 1. Dr Ravi Chandra Beeram
- 2. Dr Alka Rao
- 3. Siva Atchuth Kumar Y
- 4. Sagarika K
- 5. Ramanjaneya Prasad E
- 6. Keerthi

#### **Company Address:**

**Revelations Biotech Pvt Ltd** LSI, IKP Knowledge Park, Genome Valley, Turkapally, Shameerpet, Hyderabad - 500078

### **REVELATIONS BIOTECH PVT. LTD.**

#### **Description of Innovation:**

Nucleic acid detection and quantification is one of the most reliable ways of disease diagnosis. However, technological limitations and cost factors involved in nucleic acid quantification for routine molecular diagnosis using quantitative PCR has prompted the innovation for a low cost rapid quantitative PCR for molecular diagnosis.

#### Collaborating Partners (if any):

Dr Alka Rao (CSIR-IMTECH, Chandigarh)

- **1. Stage of Development:** The company has established the proof of the concept.
- 2. Innovative Elements: Revelations Biotech is developing a unique technology platform by which quantitative PCR can be performed easily and rapidly using a simple PCR machine without real time module. The technology does not involve fluorescent dyes, expensive real time PCR module or great technical expertise. A genetically engineered protein scaffold is capable of detecting and reporting each amplicon in solution after PCR amplification. Their protein scaffold is unique and designed in an innovative manner by integrating multiple biological principles.
- 3. Market Potential: The total Indian healthcare sector which is currently valued at \$34 billion and is projected to grow to nearly \$40billion by 2012 and diagnostic and pathology market is around 2% of the overall health care market. The diagnostic market has been growing at 15-20 percent and by all indications shall continue to grow for another 10 years at this rate. The future growth in the diagnostic market is expected to come from Oncology testing, Genetic testing and pharmacogenomics testing.
- 4. Risk Factors: The risk in developing such futuristic technology is about being able to deal with all the technological and regulatory hurdles. Sensitivity and selectivity have been the major issues for any novel diagnostic technology.
- 5. National/ Social Relevance: The cost burden in public health care because of the quantitative real time PCR is steadily increasing. General PCR based diagnostics are also becoming very popular in the country. However, the cost of a typical PCR based diagnostic test to the tune of few thousands and poses huge burden on public and private health care system. The proposed innovation aims at bringing down the national burden for higher quality of diagnostics and makes the technology affordable and getting quick results.
- 6. Potential for IP Generation: They have generated valuable IP and plan to commercialize the technology at the earliest.
- 7. Progress Quatifiers: They have completed about 70% of the project and making efforts to improve the sensitivity of the system.
- 8. Plans to take the innovation further: They are progressing rapidly to establish their innovation towards commercially viable technology.
- 9. Self-satisfaction: 6







### **SERUM INSTITUTE OF INDIA LTD.**

#### **Description of Innovation:**

Development of Quadravalent HPV Vaccine. The present proposal involves the scale up development and GMP development of the 1L process technology sourced from Rhein Bitotech Germany for the manufacture of HPV vaccine. The purified VLP would be formulated using adjuvant to develop a vaccine providing high degree of seroconversion and protection.

#### Collaborating Partners (if any):

None

#### Higlights of the innovation:

- 1. Stage of Development: The expression of VLP in Hansenula polymorpha has been successfully achieved by Rhein Biotech, Germany. The capsid protein was demonstrated to form VLPs which were highly immunogenic and biochemically
- 2. Innovative Elements: Using the Hansenula polymorpha expression system one can successfully manufacture millions of doses of HPV vaccine in a small sized reactor. This cost efficient expression system would make the vaccine available to the masses at a very affordable cost of a few dollars per dose. The Methylotrophic yeast Hansenula polymorpha is a suitable, regulatory-accepted host organism and has become a preferred microbial organism for the production of recombinant proteins on an industrial scale. Product examples range from vaccines and therapeutics such as hepatitis B vaccines and human insulin as well as industrial enzymes.
- 3. Market Potential: The HPV vaccine market is expected to reach \$1 billion in the near future. The four strain HPV vaccine would be made available to public at an affordable rate of few dollars per dose.
- 4. Risk Factors: Presently there are two HPV vaccines, Gardasil and Cervarix, marketed. The side effects listed in Gardasil include headache, dizziness, nausea, slight pain and pyrexia. The side effects of Cervarix include upper respiratory tract infection, headache, dizziness, nausea, vomiting, diarrhoea, abdominal pain, itching, rash etc.
- 5. National /Societal Relevance: Cervical cancer is one of the leading causes of cancer mortality across the globe. An estimated 470,000 new cases are reported with 230,000 deaths occurring every year, with 80 per cent of the cases featuring in the developing world. The four strain HPV vaccine is expected to provide 90 per cent protection against cervical cancer, thus bringing down the mortality rate significantly.

#### **Team Members:**

#### (including collaborators)

- 1. Mr. Umesh Shaligram
- Dr. Zbigniew Janowicz
- Dr. Amuel Carsten
- Mr. Harish Rao

#### **Company Address:**

Serum Institute of India Ltd. Off Soli Ponawalla Road. 212/2, Hadapsar, Pune - 411028 Maharashtra









#### **Team Members:**

#### (including collaborators)

- 1. Mr. Umesh Shaligram
- Mr. Scott Maguire
- 3. Dr. Sajjad Desai
- Mr. Manish Gupta

### **SERUM INSTITUTE OF INDIA LTD.**

### **Description of Innovation:**

Clinical development of Polysialylated Erythropoietin-- Polysialylated Erythropoietin is a conjugate of Erythropoietin and biodegradable polymer Alfa 2-8 linked Polysialic acid. Polysialylation, Lipoxen is a proprietary process by which the natural polymer polysialic acid is covalently attached to protein and peptide drugs, can overcome such shortcomings and improve drug formulation stability, pharmacokinetics and pharmacodynamics in a natural way. Polysialylation also increases the molecular mass of polypeptides, reduces loss through the kidneys, shields them from proteolytic enzymes.

### Collaborating Partners (if any):

### Higlights of the innovation:

- 1. Innovative Elements: It is sought to explore the application of polysialylation to produce an improved form of rHuEPO that will require lower frequency of injection and will have a slower onset of action than rHuEPO, potentially averting some of the side effects that have been noted for rHuEPO. Polysialylation allows the disadvantages of proteins and peptides to be addressed effectively leading to improved pharmacokinetics and pharmacodynamics while minimising the potential for toxicity as compared to PEG and other delivery systems.
- **2. Market Potential:** This is estimated to be around 5-6 billion dollars wordwide.
- 3. Risk Factors: Some of the adverse events observed are hypertension, increased risk of thrombosis, injection-site pain and headache which incidentally are very common. The stabbing migraine pain can be indicative of hypertensive crisis. Hyperkalaemia, seizures, thrombocytosis, influenza-like symptoms, dyspnoea, PRCA and anaphylaxis are however rare events.
- 4. National /Societal Relevance: Chronic kidney disease (CKD) is a worldwide health problem with kidney and urinary tract diseases contributing to nearly 850,000 deaths per year globally according to WHO and 115,010,107 disability adjusted life years. With an expected 40 per cent of diabetic and hypertension patients in the country prone to developing CKD and end stage renal diseases, the burden on healthcare is evident. India has the dubious distinction of being the diabetic capital of the world with the current number of cases registered at 40.9 million and slated to go up to 69.9 million by 2025.

The cost of Erythropoietin is \$400 per month resulting in only 30 per cent of the Hemodialysis receiving Erythropoietin therapy. Anaemia resulting from insufficient production of Erythropoietin is a common consequence of CKD. If left untreated, renal anaemia can result in fatigue, cognitive dysfunction and impaired quality of life, with increased risk of cardiovascular disease and mortality in the long run. The development of improved therapy like Polysialylated Erythropoietin which has potential to improve the convenience of administration, improve patient compliance, potential to increase the efficacy and reduce adverse events, is desirable for patients and healthcare providers.

5. Plans to take up innovation further: A clinical study to assess safety of Polysialylated Erythropoietin when given by intravenous route is planned.

### **Company Address:**

Serum Institute of India Ltd. Off Soli Ponawalla Road, 212/2, Hadapsar, Pune - 411028 Maharashtra





### **Team Members:**

(including collaborators)

- 1. Dr Pawan Gupta, MD, DNB, PhD
- 2. Dr Anish S Majumdar PhD
- 3. Dr Anoop CH, MD.

### **Company Address:**

Stempeutics Research Pvt Ltd. 9th Floor, Manipal Hospital 98,Old Airport Road, Rustom Bagh Bangalore - 560017

### STEMPEUTICS RESEARCH

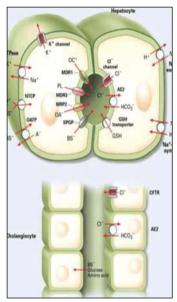
Description of Innovation: An end point evaluation, multicentre, dose escalation, phase – II study assessing the safety and efficacy of intra-arterial (Hepatic) ex-vivo cultured adult Allogeneic Mesenchymal stem cells in patients with Alcoholic Liver Cirrhosis. Alcoholic cirrhosis develops in 15% of individuals who drink heavily for more than a decade. Cirrhosis represents a late stage of progressive hepatic fibrosis characterized by distortion of hepatic architecture and formation of regeneration nodules. Adult stem cell therapy may offer a cure or regression of the disease for such group of patients. However, potential benefits are hampered by many drawbacks. Stempeutics technology is to upscale the bone marrow derived allogeneic mesenchymal stem cells derived from few donors and produce stem cell product (stempeucel).

Collaborating Partners (if any): None

- 1. Stage of Development: Validation
- 2. Innovative Elements: Human mesenchymal stem cells are being used in cases of endstage liver disorders to prevent further degeneration of hepatocytes through their (a) immunomodulatory properties that turn off allogeneic T cell activation and chronic inflammatory process through paracrine activity. Human mesenchymal stem cells also have ability to generate new hepatocytes from the remaining progenitor cells and possibly to reverse the process of degeneration by virtue of their regenerative ability in the diseased livers.
- 3. Market Potential: Liver cirrhosis is a health problem worldwide and is very difficult to treat. Stempeutics has the technology to upscale the bone marrow derived allogeneic mesenchymal stem cells derived from few donors and produce stem cell product (stempeucel) sufficient for 10000+ patients. Stem cells can be developed as an offthe-shelf cryopreserved product which can be infused into the patients as and when required.
- 4. Risk Factors: There is a potential risk in this type of novel stem cell technology based clinical trial as this may not have drastic impact on the progression of the disease process.
- 5. National/ Social Relevance: Alcoholic cirrhosis develops in 15% of individuals who drink heavily for more than a decade. Prevalence of alcoholics in India is found to be 21% in adult males. This ranges from as low as 7% in western state of Gujarat to 75% in northeastern part of the country. The standard treatments available do not offer a cure for the disease. Adult stem cell therapy may offer a cure or regression of the disease for such group of patients. However, potential benefits are hampered by many drawbacks such as relative shortage of donors, operative risk, post-transplant rejection, recidivism of the pre-existing liver disease, high cost and several complications. This technology will enable us to bring down the cost of stem cell therapy.
- **6. Potential for IP Generation:** Yes
- 7. Progress Quatifiers: Ongoing phase II clinical trials using allogeneic MSCs (stempeucel) in critical limb ischemia and osteoarthritis have shown that MSCs are safe and may likely to be efficacious.
- 8. Plans to take the innovation further: Stempeutics is aiming to be the pioneer in the field of stem cells in India once the ongoing phase II clinical trial is successful. The study is progressing as planned and it is expected to end the 60 patient's recruitment by Mar 2013.







### **Team Members:** (including collaborators)

- 1. Kalyanasundaram Subramanian
- 2. Sonali Das
- 3. M.K. Narasimha
- 4. Rajeev Kumar
- 5. R. Nalini
- 6. Sowmya Raghavan

### STRAND LIFE SCIENCES PVT. LTD.

### **Description of Innovation:**

Hepatotoxicity Prediction Platform. Large numbers of Liver failures are caused to drug exposure. Methods that have enabled reliable prediction of Hepatotoxicity are critical. Therefore, they have developed a novel system approach to model pathways in the Liver and combined it with invitro measurements that create a detailed predictive platform that is capable of providing insight into Drug Induced Liver Injury (DILI).

This unprecedented approach will help in replacing or reducing animal usage and increase efficiency of drug development by predicting Hepatotoxicity. It can be extended to organs such as the Kidney and Heart to predict Neprotoxicity, an effect of diet on Cardio Vascular diseases respectively.

### Collaborating Partners (if any):

None

### Higlights of the innovation:

- 1. Stage of Development: Extended Validation and Commercialization.
- 2. Innovative Elements: Combining in vitro assays along with a patented model of liver physiology to predict the effect of drugs on the liver to identify toxic side-effects.
- 3. Market Potential: Since toxicity is one of the major causes of drug failures in clinical trials as well as market-withdrawals, mechanistic toxicology testing is a key step in pharmaceutical drug development. The market of this was \$720M in 2011 and is expected grow at 15% per year.
- 4. Risk Factors: The product does not predict all the relevant aspects of hepatotoxicity.
- 5. National/ Social Relevance: Allows Indian Pharma organizations to assess toxicity cheaply, reduces animal usage in experimentation. Affordability of the test is also a positive factor.
- 6. Potential for IP Generation: The model is patent protected, assays developed also can be protected.
- 7. Progress Quatifiers: 3 out of 4 milestones completed, industrial participants for the 4th milestone already lined up.
- 8. Plans to take the innovation further: More molecules to be tested, assays to taken to high throughput platforms, customers to be approached.
- 9. Self-satisfaction: 8

### **Company Address:**

Strand Life Sciences Pvt. Ltd. 5th Floor Kirloskar Business Park Bellary Road, Hebbal, Bangalore - 560024





### **Team Members:** (including collaborators)

Team of molecular biology, cell engineering, process engineering, proteomics and biochemistry, analyticals, preclinical and clinical professionals.

#### **Company Address:**

**Sun Pharmaceutical Industries Ltd.** Tandalja, Sun Pharma Road, Vadodara - 390020, Gujarat

### SUN PHARMACEUTICAL INDUSTRIES LTD.

#### **Description of Innovation:**

Development of high expression platform for the production of affordable biosimilar drugs. Biosimilars sphere is now gaining momentum as the blockbuster drugs are getting off patent which is creating a promising space for Biosimilars.

The challenge lies with the development of an effective cell line producing product which is similar to the originator's product in terms of efficacy, immunogenicity and physio-chemical properties

#### Collaborating Partners (if any):

None

- 1. Stage of Development: Biosimilars sphere is now gaining momentum as the blockbuster drugs are getting off patent which is creating a promising space for Biosimilars. Engineering of high expression vector and development of cell lines for production of affordable biosimilars (recombinant proteins and monoclonal antibodies) has been developed.
- 2. Innovative Elements: Indigenization of Biosimilar Monoclonal Antibody-Bevacizumab. It will be developed employing their own Gene Expression Vector and Cell line.
- 3. Market Potential: Very high potential as large number of protein drugs are getting off patent between 2014 to 2020. The global sales of Bevacizumab was \$ 6 billion in 2010-11 fiscal year which would exponentially grow once the price falls under the affordable zone.
- 4. Risk Factors: Might show some different attributes than that of innovator's product in clinical studies and moreover, the production efficiency to ease the economy as well. In terms of efficacy, immunogenicity and physio-chemical properties also there can be difference with the original drug. These challenges are being addressed by engineering the expression vectors, cell lines screening and process engineering.
- 5. National/ Social Relevance: Presently, there is no Biosimilar Bevacizumab and the product planned is not affordable in developing countries like India. The indigenous new product planned will bring the drugs to the affordable zone and help the country to become self-sufficient.
- 6. Potential for IP Generation: Yes
- 7. Progress Quatifiers: 100 per cent
- 8. Plans to take the innovation further: Exploring for the production of Biosimilars.
- 9. Self-satisfaction: 9







### **Team Members:** (including collaborators)

- 1. Dr. M. Kuppusamy
- 2. Muthukrishnan
- 3. Ravindran
- 4. Kapil

### **Company Address:**

Tergene Biotech Pvt. Ltd. No.34, Tulsi Garden, J.J. Nagar PO, Yapral, Secunderabad - 500087 Andhra Pradesh

### TERGENE BIOTECH PRIVATE LIMITED

Description of Innovation: Development of an affordable, Asia specific 15 valent Pneumococcal Ploysaccharide - CRM 197 protein conjugate Vaccine. The proposed technology help generate better vaccines against Typhoid, Haemophilis Influenza Type B and Meningococcal diseases where the antigenic components are polysaccharides.

Collaborating Partners (if any): None

- 1. Stage of Development: Production of CRM carrier protein and Pneumococcal polysaccharides of 15 serotypes were optimized. Micro reactor based conjugation process established in prototype model. Purified conjugate is characterized, formulated and immunogenicity established in animal model.
- 2. Innovative Elements: Company is aiming at cost effective production of CRM and of polysaccharides. The conjugation protocol is expected to be highly efficient and India specific vaccine formulation will be affordable.
- 3. Market Potential: Historically, developing countries have waited 15 to 20 years to adopt vaccines after they have been introduced in industrialized countries. There are many explanations for this time lag - prices that are perceived as unaffordable, a lack of manufacturing capacity, perceived risk of limited demand in developing countries. Pneumococcal vaccine need is adjusted by the representative vaccine coverage rate such as DTP3 as the proxy, to establish the Potential Vaccine Market. By 2015, potential demand was forecasted at approximately 50 million doses, increasing to nearly 160 million doses by 2020, and peaking at just over 200 million doses by 2030.
- 4. Risk Factors: The life cycle of bacterial vaccines are very high, exceeding 50 years as proved in the existing bacterial vaccines. However, there are possibilities of Protein antigens being developed as alternate vaccine candidates.
- 5. National/ Social Relevance: Increasing incidence of streptococcal infection in the young and elderly and wide spread antimicrobial resistance (AMR) and diversity in the serotype distribution necessitate the need for the development of an Asia specific, indigenous and cost effective vaccine for S.Pneumoniae. According to WHO, Pneumonia is the leading cause of death in children worldwide. Pneumonia kills an estimated 1.6 million children every year worldwide, 25% in India alone - more than AIDS, malaria and tuberculosis combined. India is witnessing the highest number of pneumonia-related child deaths in the world. The infection is killing 16 lakh children under five every year, more than 3.7 lakh in India alone. Assuming pneumococcal vaccines prevent 7 deaths per 1000 children vaccinated, the demand forecast for 2005 projects that approximately 5.3 million deaths can be averted between 2010 and 2030. At present, there are no local manufacturing capabilities and the vaccine is imported.
- 6. Potential for IP Generation: Production technology of CRM and the conjugation protocol are unique and merits patenting.
- 7. Progress Quantifiers: The Company has achieved 100% target milestones well in advance of the set timelines.
- 8. Plans to take the innovation further: The company is looking at production of GMP grade polysaccharide and CRM. It is planning to formulate the final vaccine and conduct stability studies. It also has plans to conduct pre-clinical studies and Phase II & III clinical trials.
- 9. Self-satisfaction: 9







**Team Members:** (including collaborators) Dr Amitabha De

### **Company Address:**

Transasia Biomedicals Ltd. 405, Westend, Raheja Vihar Complex, Chandivali Studio Road, Andheri East, Mumbai - 400072, Maharashtra

### TRANSASIA BIO-MEDICALS LTD.

### **Description of Innovation:**

Development of Lanthanide – chelate reagents for high sensitivity detection assays using various platforms. The project is to develop novel 3rd Generation HIV (Antibody) & 4th generation (HIV Antigen and Antibody) immunoassay using flash type chemiluminiscence and magnetic particles as matrix. These techniques use automation to increase speed and miniaturization to reduce costs, but miniaturization requires high sensitivity to detect very small quantities of analytes. Fluorescence uses excitation by light, avoiding radioactivity as well as more cumbersome procedures of other methods. Thus fluorescence has become the cornerstone of high-throughput research. The company is to use this Luminescent based reagents on the following platforms.

#### Collaborating Partners (if any):

None

- 1. Stage of Development: (Discovery/ Proof of concept/ validation/ commercialization/ others) Proof-of-concept stage.
- **2. Innovative Elements:** The novelty of the project is to design a universal assay methodology amenable for automation and applicable to different detection platforms such as rapid tests and microwell-based tests. The inventive step is utilization of a universal, lanthanide-based reporter system on multiple platforms ranging from rapid tests to high throughput, automation-amenable systems such as magnetic beads. A single assay can also be used to detect multiple analytes at the same time in the same assay, allowing for reduction in time and cost.
- 3. Market Potential: Demand for fluorescent technology has continued to increase due to the enormous growth in high-throughput techniques for studying biomolecules. Immunochemistry market in India and worldwide with the distribution in china is potentially around US\$ 800 to 1000 million. The forecast for Indian market alone is US\$439 by 2017. Lanthanides are attractive alternative candidates for use as reagents because of their unique intrinsic luminescent properties. Lanthanide impregnated beads are now commercially available and can be used in various assay platforms.
- 4. Risk Factors: The uniformity of assay protocols may not be achieved in different assay formats. Universal reagents may not work in different assay formats. Issues with detection limits, magnetic particles uniformity for different analytes cannot be achieved in flash type chemiluminiscence. Non availability of analyte specific reagents, assay time objectives may not work leading to enhanced assay time defeating the high through put automated testing objective. Large lack of syncronicity might lead to slower throughput and larger turnaround times.
- 5. National/ Social Relevance: Lack of indigenous technology for high throughput automated immunoassays systems and reagent, dependence of the imported products make the diagnostic facility expensive for the masses. Development of an Immunoassay technique using magnetic beads and a chemiliuminscents reporter for the diagnosis/ detection of an analyte will allow developing and manufacturing automated reagent systems for chemiliuminscents platform for high throughput testing at lower cost indigenously.
- 6. Potential for IP Generation: No







### **Team Members:**

### (including collaborators)

- 1. Dr. Radha Rangarajan
- 2. Dr. Rajinder Kumar
- 3. B.V. Prabhakar
- 4. P. Chandrasekhar
- 5. P. Mallikarjuna
- 6. Ankita Banerjee

### **Company Address:**

### Vitas Pharma Research Pvt. Ltd.

Technology Business Incubator / IKP Knowledge Park, University of Hyderabad, Genome Valley Turkapally, Gachibowli, Hyderabad - 500046 Andhra Pradesh

### VITAS PHARMA RESEARCH PVT. LTD.

### **Description of Innovation:**

Novel Inhibitors of fatty acid biosynthesis for the treatment of drug resistant Staphylococcus aureus bacterial infections, the most commonly isolated Gram positive pathogen in infections acquired from hospitals. Staphylococcus aureus is the most common Gram positive pathogen isolated from healthcare associated infections.

Methicillin resistant S.aureus (MRSA), can account for 30-50 percent of isolates in hospitals in India and worldwide. Following a focused research backed strongly by Structure Guided Drug Design, the company has identified a novel scaffold with potent activity against drug resistant S.aureus.

### Collaborating Partners (if any):

None

### Higlights of the innovation:

- 1. **Stage of Development:** Currently, they are optimizing the lead series and establishing preclinial safety to establish proof of concept.
- 2. Innovative Elements: They have identified a novel scaffold targeting fatty acid biosynthesis with potent activity against drug resistant S. aureus. Their patented lead series is orally bioavailable with pharmacokinetic features suitable for IV/oral switchability and has demonstrated robust activity in vitro and in vivo. As their compounds target a novel mechanism, clinical candidates emerging from this work will be able to overcome existing patterns of resistance for multi drugs.
- 3. Market Potential: A drug emerging from this research has the potential to achieve peak sales of US\$ 100-200 million covering worldwide markets.
- **4. Risk Factors:** The Safety of the lead series both in terms of safety pharmacology and acute toxicity have not been evaluated to date. Nevertheless, a thorough review of the literature relating to chemical structures and their properties has not identified any overtly toxic features in the lead series.
- 5. National/ Social Relevance: The project addresses an issue of serious public health concern, namely the emergence of multidrug resistant S. aureus in India and other parts of the world, leading to considerable morbidity, mortality and economic burden. The goal of the project is to identify new drugs for treating MRSA infections, such as skin infections, pneumonia and bacteremias, that are highly resistant to multiple classes of antibiotics.

The project is relevant to improve health outcomes for the nation in the fight against infectious diseases. The incident of S. aureus resistance has been reported from different parts of the world leading to fewer therapeutic options for very sick patients. In fact, even the last line of defense has been reached with S. aureus resistant to Vancomycin and newer drugs such as Linezolid has now been reported worldwide.

- **6. Potential for IP Generation:** Yes
- 7. **Progress Quantifiers:** Currently, they are optimizing the lead series and establishing preclinical safety.
- 8. Plans to take the innovation further: (in case the same is nearing completion with the proposed two phases of human clinical trials): They intend to conduct early clinical studies to establish proof of concept in the target population and then out license.







### **Team Members:** (including collaborators)

- 1. Dr. Jayant Bhanushali
- 2. Mrs. G. Seeta

### AMAR IMMUNODIAGNOSTICS PVT. LTD.

### **Description of Innovation:**

Development of Diagnostic tools for GMO testing and Agriculture disease diagnostics. The project involves research and development of diagnostic kits for GMO detection for the first time in India using in house developed monoclonal antibodies.

### **Collaborating Partners (if any):**

None

### Higlights of the innovation:

- 1. Stage of Development: The project involves research and development of diagnostic kits for GMO detection for the first time in India using in house developed monoclonal antibodies. Several monoclonal antibodies have already been generated.
- 2. Innovative Elements: Development of monoclonal antibodies against different GMOS which are currently being commercialized in India. It is an integrated project involving research and development of diagnostic kits for GMO detection for the first time in India using in house developed monoclonal antibodies.
- 3. Market Potential: Market potential for these products is significant as India has approved commercialization of GMO cotton and many other crops such as corn, rice and soybean are likely to commercialize in near future. All these crops need to be tested for presence or absence of GMO using immunoassay based technology.
- 4. Risk Factors: If India does not approve GMOs for crops besides cotton, market size can be limited.
- 5. National /Societal Relevance: The project is of national importance as it replaces costly imported product. The project aims to make the country self-sufficient in terms of developing all kits which are needed to monitor and regulate GMO's in India.
- 6. Potential for IP Generation: Several monoclonal antibodies have been generated and patent is planned to be filed for the same.
- 7. Progress Quantifiers: The set targets have already been completed, with the products commercialized. They are currently being used by major seed companies of India.

### **Company Address:**

Amar Immunodiagnostics Pvt. Ltd. 242/1, Road No 18, Jubilee Hills Hyderabad - 33







### **Team Members:** (including collaborators)

- 1. Dr. A R Sharma
- 2. Dr Rajesh Sehgal
- 3. Mr Giteshwar Kalia

### AP ORGANICS PVT. LTD.

### **Description of Innovation:**

Project on value addition including potential nutraceuticals from derivatives of rice. The company is trying for two products: Oryzanol Concentrate for lipid management and Lysolecithin as animal feed supplement.

### Collaborating Partners (if any):

None

### **Higlights of the innovation:**

- 1. Stage of Development: Oryzanol Concentrate has been developed and the company's team is working on validations of batches. Lysolecthin as animal diet supplement is at the stage of validation.
- 2. Innovative Elements: Oryzanol rich concentrate has been developed and is being further developed into various oral dosage forms. These will be developed using novel drug delivery systems. Lysolecthin has been developed as animal diet supplement.
- 3. Market Potential: Oryzanol can be developed as a safe and effective nutraceutical to be used as an alternative or as an adjuvant treatment with statin drugs for Cholesterol Management. Although most statins drugs already have generic versions, Lipitor remains widely used especially among patients who don't respond to the generic formulations or require a higher dose than Lipitor's competitors offer. Lipitor was the best-selling drug in 2010 and it dominates the \$20 billion statin market. Oryzanol concentrate can be developed as food supplement with affordable price.

Rice bran lysolecithin: During refining of rice bran oil in the degumming process, large quantities of rice bran lysolecithin are produced as by product. Rice bran lysolecithin is a potent source of phospholipids and lecithins have emulsifying property that improves the digestibility of fats and fat-soluble vitamins.

- 4. Risk Factors: The company thinks that time to get various regulatory approvals is a risk. The risk of Lysolecthin as animal diet supplement is that the animal feed market is not fully developed in India and awareness among the stake holders is less. It will be a task to generate awareness amongst all the stake holders of animal feed industry, the company thinks.
- 5. National/Social Relevance: The Innovation of Oryzanol rich concentrate has a huge national significance as it is a value addition project on various derivative of rice, which can improve relisation to the paddy growers. Moreover, innovative product is of importance as it has health benefits without any side effects like typical allopathic drugs. Similarly, by-product of oil refining has a vast potential in the ruminant's diet to increase the energy density of their rations and to optimize the milk production.
- 6. Potential for IP Generation: IP will be generated once finished formulations are finalized.
- 7. **Progress Quatifiers:** The company has achieved 100 per cent of both the projects.
- 8. Plans to take the innovation further: The company is in talk with international clients for export of finished formulation for Oryzanol.
- **9. Self-satisfaction:** 9 for Oryzanol and 10 for Lysolecthin.

### **Company Address:**

AP Organics Pvt. Ltd. Saron Road, Village Mannwala, Dhuri, District Sangrur, Punjab - 148024







### **Team Members:** (including collaborators)

- 1. Mr. Sameer S. Agrawal
- Dr. Biswanath Mazumdar
- 3. Mr. Nandkumar Kunchge
- 4. D. Narendra Tutuja

### **BEJO SHEETAL SEEDS PVT. LTD.**

### **Description of Innovation:**

Development of 'Herbicide & Stress tolerant' transgenic Onion. Though hybrid seeds are available for onions, there is no variety or hybrid available for addressing drought tolerance. The weed management is big problem in seeded onion crop fields.

### Collaborating Partners (if any):

International for Genetic Engineering and Biotechnology.

### Higlights of the innovation:

- 1. Stage of Development: EPSPS gene is known for glyphosate tolerance and commercially being used. The gene source is new and validation of expression is studied in model plant. Helicase PDH 45 gene is identified for draught and salinity stress tolerance, while validation of gene is studied in Rice and Groundnut. Therefore functions are known but needs validation in crop of interest, i.e. Onion.
- 2. Innovative Elements: Use of plant helicase gene for drought stress tolerance and increased yield is additional benefit. The proposed transgenic plants will be developed using the genes of plant origin.
- 3. Market Potential: Hybrid onion seeds are available in the market with high yielding and quality characters. However there is no variety or hybrid available for addressing draught tolerance. The weed management is big problem in seeded onion crop fields and labor management is becoming tough day by day.
  - Mechanical tools are not available for weed management in Onion. Both the traits proposed by the company are of great importance to address the problem of weed management as well as for draught tolerance. To increase the productivity transgenic onion with these traits would be of great demand.
- **4. Risk Factors:** Acceptance of herbicide tolerance trait could be of social relevance.
- 5. National/ Social Relevance: Seventy per cent of the Indian population depend on agriculture and onion is one of the important vegetable crop for Indian farmers. Also 90% of the vegetable export is contributed by onion crop.
  - Presently onion productivity in India is too low (15.1 tonnes/ha) as compared to USA or global productivity (56 tonnes/ha). As deployment of transgenic cotton for insect resistance has brought revolution in cotton there are great chances of onion production and economic revolution if transgenic onion is deployed with herbicide and draught stress tolerance.
- 6. Potential for IP Generation: It is expected to generate IP on role of new plant helicase gene in onion stress management.
- 7. Progress Quatifiers: In terms of time lines, target and mile stone the progress of achievement is 100%
- 8. Self-satisfaction: 7

#### **Company Address:**

Bejo Sheetal Seeds Pvt. Ltd. P.O. Box - 77, Bejo Sheetal Corner, Mantha Road, Jalna - 431203 Maharashtra







### **Team Members:** (including collaborators)

- 1. V. Subbulakshmi
- 2. Kiran V. Hegde

### **CHROMOUS BIOTECH PVT. LTD.**

### **Description of Innovation:**

Development of fast molecular protocols for pathogen detection. Rapid nucleic acid isolation protocols offer a convenient method towards fast diagnosis of several potato viruses important in Indian agriculture, including tissue culture industry.

The proposal aims at development and standardization of a uniform extraction protocol for potato viral genome (DNS/RNA) from potato. The company is also developing virus specific primers based on most conserved region of the genome for the amplification and detection.

### Collaborating Partners (if any):

None

### Higlights of the innovation:

- 1. Stage of Development: Proof of concept for fast detection of pathogens is established, validation is on and commercialization strategies are being explored.
- 2. Innovative Elements: Possibilities of detecting pathogens within 30 min using inhouse, patent-pending PCR enzyme FasTaq polymerase. It can be inexpensive and can be practiced on-site.
- 3. Market Potential: The company expects the potential is huge, current market size is estimated at Rs 3,400 crores using inferior technologies. Fast PCR-based technology offers convenient, sensitive and specific detection of potato viruses to aid growers, nursery men, agronomist, horticulturist, breeders and plant-health professionals. Currently, no indigenous diagnostic kits are commercially available for detection of potato viruses in India.
- 4. Risk Factors: The company thinks that lack of investments and shortage of trained man-power required to perform the tests could be a challenge.
- 5. National/Social Relevance: Once implemented, it would provide diagnostics for the mass / poor and once diagnosed, rampant prescription of broad-spectrum antibiotics can be avoided.

Fast PCR-based technology offers convenient, sensitive and specific detection of potato viruses to aid growers, nursery men, agronomist, horticulturist, breeders and plant-health professionals. Currently, no indigenous diagnostic kits are commercially available for detection of potato viruses in India. Chromous Biotech's product enables up to 96 potato samples examined for diseases and viruses in less than 90 minutes.

- **6. Potential for IP Generation:** The potential exists and is being considered.
- 7. Self-satisfaction: 8

#### **Company Address:**

Chromous Biotech Pvt. Ltd., A/603, Sterling Park, Sanjeevini Nagar, Bangalore - 560092







### Team Members: (including collaborators)

- 1. Dr Vivek
- 2. Dr Muralidhar Rao

### Geo Biotechnologies India Pvt. Ltd.

### **Description of Innovation:**

Association mapping and whole genome marker assisted recurrent selection for development of abiotic stress resilient maize. Company wants to develop successful trait specific inbred development by use of whole genome Marker Assisted Recurrent Selection (MARS). It also aims to fast track development of inbred lines using whole Genome MARS approach.

### **Collaborating Partners (if any):**

CYMMIT, International Maize and Wheat Improvement Center

### Higlights of the innovation:

- 1. Innovative Elements: Identification of trait specific candidate gene markers for targeted traits (drought, downy mildew, heat, PFSR (Post flowering Stalk Rot) using Association mapping. The approach involves utilizing large and diverse population. Another innovation is the precision phenotyping by multi location targeted environment evaluation.
- 2. Market Potential: Maize is cultivated as rain-fed crop in about 6 million hectors as against nearly 2 million ha under irrigated condition. Developing drought tolerant maize through this project would enhance the yields and reduce crop failure. Large part of maize production is also affected by downy mildew, resulting into no harvests from the severally affected fields. Thus development of downy mildew resistant varieties would prevent yield losses, also prevent environmental pollution to large extent by using use of fungicide.
- 3. Risk Factors: Complete tolerance for drought may not be achieved due to complexity of the trait. Weather conditions may not allow precision phenotyping for drought screening. It is also likely that screening of downy mildew may not be precise due non-congenial weather condition for disease development. Change in race pattern of downy mildew pathogen may also affect selected resistant types.
- 4. National/ Social Relevance: Majority (80%) of maize area in India is under rain-fed cultivation and is vulnerable to severe yield losses due to erratic rainfall. Development of drought tolerant maize would help large number of small and marginal farmers to protect them from vagaries of nature and changing rainfall patterns. The company's product will also help as 20 % of maize area in India is vulnerable to downy mildew with 80-100% losses in the affected fields. Overall it would contribute to national food security.

### **Company Address:**

GEO Biotechnologies India Pvt. Ltd. Sri Krishna Mansion, 131, 6th 'C' Main, 2nd Floor, 4th Block, Jayanagar, Bangalore - 560 011





### **Team Members:** (including collaborators)

- 1. Dr. Debashis Rana Project head
- 2. Mithun Chakraborty Scientist
- 3. Ghulam Mustafa Molecular Biologist
- Rajeshwar Rao Gopala Entomologist
- 5. Maninder Singh Rice Breeder

### **Company Address:**

JK Agri Genetics Ltd., 1-10-177, 4th Floor, Varun Towers, Begumpet, Hyderabad-500 016

### JK AGRI GENETICS LTD.

### **Description of Innovation:**

Development of BT-Rice with two cry genes. The objective is to identify transgenic events that stably exhibit desired insect resistant phenotype in field condition and show stability of gene expression. Yellow stem borer attacks rice plants in vegetative as well as in reproductive state and are present throughout the rice growing regions of the country. Rice leaf folders are also a major pest of rice especially in the coastal rice growing regions. The purpose of developing transgenic rice with Bt genes is to impart resistance against yellow stem borer and leaf folder. The cultivation of Bt-rice is expected to lower application of insecticides and stabilize yields, bringing more profits to rice farmers.

#### Collaborating Partners (if any):

None

- 1. Innovative Elements: Keeping in mind the debate over introduction of GMOs in the food chain, two strategies were adopted. One was to remove the selectable marker, kanamycin from the transgenic plants. The second was to have little or no expression of Bt proteins in the rice grains by using a promoter which expresses only in the green tissues. Both these approaches are expected to make Bt-rice acceptable to critics of GMOs as well as to consumers.
- 2. Market Potential: Currently, only 2 per cent of rice area is under hybrid rice cultivation with it anticipated to go up in the foreseeable future. Hybrid rice varieties containing Bt genes is expected to provide additional benefits to farmers by stabilizing the yield with less input cost.
- 3. Risk Factors: There is the risk of the insect developing resistance to the Bt-proteins. However, the rice transgenics comes with two different sets of Bt genes, cry1Ac and cry2Ax. Once required safety study is completed, the two genes are to be stacked in a single plant as the chance of developing insect resistance to both the genes is extremely small. Given the history of safety of Bt proteins, it is anticipated that the protein will be safe for human consumption and pass other associated environmental risks.
- 4. National/Societal Relevance: Our national food security depends on adequate production of rice. Several biotic and abiotic stresses constrain productivity of rice in Indian agriculture. Given the increasing population and shrinking land under cultivation, there is urgent need to address major abiotic and biotic stresses to secure the food supply in the country. Yellow stem borer is a major pest of rice occurring throughout India, causing about 10-15 per cent of yield loss in rice. Rice leaf folders are also a major pest of rice especially in coastal rice growing regions. Chemical control of rice leaf folders is less successful since the insects live inside leaf cases where insecticides cannot reach. The purpose of developing transgenic rice with Bt genes is to impart resistance against yellow stem borer and leaf folder. Cultivation of Bt-rice is expected to lower application of insecticides, stabilize yields and bring profits to rice farmers.
- **5. Progress Quantifiers:** The project is on track with the stated milestones.
- 6. Self-satisfaction level (On a scale of 1 to 10): 8



### birac Ignite Innovate Incubate

### **AGRICULTURE**



### Team Members: (including collaborators)

- 1. Dr N.P. Sarma
- 2. P. Santosh
- 3. Dr D. Prasad
- 4. Dr N.P. Sarma
- 5. Dr B.S. Dahiya
- 6. Dr G. Srinivas
- 7. Ch. Bheemaiah

### **Company Address:**

**Kaveri Seed Company Ltd,** #513-B, 5th Floor, Minarva Complex, S. D. Road, Secunderabad – 500003 Andhra Pradesh

### **KAVERI SEED COMPANY LTD.**

### **Description of Innovation:**

Development of Biotic stress resistant rice through conjunct use of Bio and hybrid technologies. This involves development of hybrid rice through biotechnology intervention by incorporation of genetic resistance in the hybrid. As biotechnology steers the breeding process, through conjunct use of DNA marker technology and hybrid technology it should be feasible to generate value added new generation.

### Collaborating Partners (if any):

None

- 1. Innovative Elements: Hybrids outperform varieties due to inherent phenomenon called heterosis. Hybridity imparts greater buffering capacity to withstand abiotic stress. Incorporation of genetic resistance to major pests in hybrids is the other advantage making it economical and attractive for the farmer. Fast track breeding for parental line improvement using modern tools of biotechnology holds the key for developing biotic resistant new generation rice hybrids.
- **2. Market Potential:** Rice being a high volume crop, the potential for hybrid rice seed demand is high. One of the major reasons for slow adoption of this technology is the non-availability of adequate quantities of quality hybrid seed.
- **3. Risk Factors:** Failure to develop competitive hybrids could adversely affect seed business.
- **4. National/Societal Relevance:** Investment in agriculture is the most effective way of ensuring food security and economic growth and seed is the main player in accomplishing this increase in productivity. The need is for quality hybrid seeds that are high yielding as well as resilient to less inputs and biotic and abiotic environments. Ministry of Agriculture plans to replicate the Chinese model of hybrid rice production by promoting hybrid rice and encourage private sector participation in the development and spread of hybrids.
- **5. Potential for IP Generation:** The hybrid developed will be registered with PPV & FR for proprietary factor of the company.
- **6. Progress Quantifiers:** Improved cms line carrying genetic resistance to Bacterial blight and blast were conferred by Xa21, Xa13 and Pi54 genes which can be used as parent for several hybrids. Improved restorer (R) line with brown plant hopper resistance was conferred by Bph18 gene. Over the last 16 months since the project was commissioned, the progress is as per time lines envisaged.
- 7. Plans to take up innovation further: This would be in the area of genetically fortified rice hybrid with resistance to BB, Blast and BHP. Another area to be addressed is locating an alternate gene source in lieu of recessive xa13 gene to fortify genetic resistance of hybrid.
- 8. Self-satisfaction level: 7







### **Team Members:** (including collaborators)

- 1. Dr. Anup Karwa Director Life Sciences -Coordinator
- 2. Dr. Brijvir Singh Principal Scientist, Pulses Dr. M.S. Kuruvinashetti, VP (Biotech) ICRISAT, Hyderabad
- 2. Dr. Rajeev Varshney Theme Leader, Comparative **Genomics and Applied** Genomics (CAG)
- Dr. Kul Bhushan Saxena **Principal Scientist**
- 4. Dr. Dr. Rachit Saxena **Visiting Scientist**

#### **Company Address:**

Krishidhan Bhavan, D3 to D6, Addln MIDC, Aurangabad Road, Jalna 431 203

### KRISHIDHAN SEEDS PVT. LTD.

### **Description of Innovation:**

Genomics assisted accelerated product development of high yielding pigeonpea hybrid. The project envisages deploying cutting edge molecular assisted breeding strategies to embark on accelerated product development of high yielding pigeonpea hybrids.

### Collaborating Partners (if any):

International Crops Research Institute for Semi-Arid Tropics (ICRISAT), Patancheru, Hyderabad, India.

- **1. Stage of Development:** It is at the stage of validation.
- 2. Innovative Elements: The genomic sequence data obtained by sequencing parents will be aligned to discover large number of genomewide SNPs. They will be used to find genomic blocks that might contribute to heterosis based on information on the parents and their hybrids. Predicting heterotic patterns and heterotic combinations based on sequence data of parents will be explored. The same SNPs will be used to tag the genes for fertility restoration in A4 cytoplasm based male sterility.
- 3. Market Potential: Presently, the share of hybrids is very meager, about 1-5 per cent based on different estimates. Assuming that 1 mha of pigeon pea area is brought under hybrids in the near future, the hybrid seed market itself will be of the order of over Rs. 100 crores. The benefits to the society however will be much larger. Assuming an incremental yield of about 250Kg/ ha it turns out to be Rs. 1000 crores.
- 4. Risk Factors: There are very few risk factors in this effort, except where the genes and genome segments responsible for heterosis are distributed entirely randomly in the population. This is very unlikely.
- 5. National /Societal Relevance: Pigeonpea grown in 3.6 mha is poor man's source of protein in India, especially for the large vegetarian population. Increase in per capita income seen in recent years, is going to generate higher demand for protein foods. In that context increase in pigeonpea yields through F1 heterosis is necessary.
- **6. Potential for IP Generation:** PPV-FR for high yielding hybrids could be registered.
- 7. Progress Quantifiers: Have assembled a diverse panel of parental genotypes available with partners.
- 8. Plans to take up innovation further: Plans to employ the genomics assisted breeding to develop superior high yielding pigeon pea hybrids with other improved agronomic traits.
- 9. Self-satisfaction level: (On a scale of 1 to 10): 8





### **Team Members:** (including collaborators)

- 1. Dr Usha Zehr
- Dr Bharat Char
- 3. Dr Leela Alamalakala

### MAHARASHTRA HYBRID SEEDS COMPANY LTD.

#### **Description of Innovation:**

Development of Sucking Pest Tolerant Cotton and Rice. The company will focus on developing genes for conferring sucking pest tolerance in cotton and rice. The proposal will use genetic engineering approach to generate transgenic rice and cotton lines with enhanced tolerance to sap-sucking insect herbivores. At present such technology is not available for this group of agricultural pests.

### Collaborating Partners (if any):

### Higlights of the innovation:

- 1. Stage of Development: Currently, genes for conferring sucking pest tolerance are being validated in cotton and rice. These genes have proof-of-concept data available in some cases, and the project is aimed at obtaining sufficient numbers of lines to proceed with field evaluation in both crops.
- 2. Innovative Elements: The commercial level rice events for sucking pest tolerance would serve as the major contribution under this proposal. The innovative step would be the identification, functional validation and deployment of novel crop protection genes with a broad spectrum of insect tolerance. Currently no sucking pest tolerant GM product is sold in the world.
- 3. Market Potential: Sucking pests are both a constraint to productivity as well as a cause of significant economic input for the farmer in terms of control measures. Given the prevailing 60 to 80 per cent losses in these crops because of sucking pests, the impact of cotton and rice having tolerance to these pests will be of major significance for farmers and consumers. A solution in this area will have a significant market potential.
- 4. Risk Factors: Genes expressed need to have a broad spectrum of action especially in cotton. Besides, the results obtained in controlled conditions may not always translate on to the field.
- 5. National /Societal Relevance: Sucking pests are a constraint to productivity and a cause of significant economic input for the farmer in terms of control measures. Yield losses caused by sucking pests are estimated between 10 to 70 per cent in rice by brown planthopper and 50 to 80 per cent by whiteflies in cotton. Hence the impact of cotton and rice having tolerance to these pests will have a major significance for farmers and consumers.
- 6. Potential for IP Generation: The lead events will be protected with event ID patents.
- 7. **Progress Quantifiers:** The project is currently on track. Amongst the genes tested, the milestones have been met in terms of generating events for greenhouse testing.
- 8. Plans to take up innovation further: The project is about 50 per cent complete and the next step would be field evaluation, which is planned. The company also plans to develop elite varieties or hybrids tolerant to plant pathogens transmitted by sucking pests. Another area of innovation planned is validation of techniques to study the probing and feeding behavior of sucking pests on susceptible and tolerant varieties.
- 9. Self-satisfaction level: (On a scale of 1 to 10): 7

### **Company Address:**

### **Maharashtra Hybrid Seeds Company Limited**

Mahyco Research Centre, PO Box 76, Jalna-Aurangabad Road, PO Dawalwadi, Tq. Badnapur, Jalna - 431203





### **Team Members:** (including collaborators)

- 1. Dr Usha Zehr
- Dr Bharat Char
- 3. Dr Pankaj Bihani

### MAHARASHTRA HYBRID SEEDS COMPANY LTD.

#### **Description of Innovation:**

Stress Tolerant Rice. The company will focus on the development of genes for conferring drought and stress tolerance in rice. Currently such novel rice and wheat lines with stacked genes conferring tolerance to multiple abiotic stresses are not available.

#### Collaborating Partners (if any):

### Higlights of the innovation:

- 1. Stage of Development: Genes for conferring drought and stress tolerance are currently being validated in rice by the company. These genes have proof-of-concept data available and the project is aimed at obtaining sufficient numbers of lines to proceed with field evaluation.
- 2. Innovative Elements: The innovative element involves the novel combination of genes that are effective against multiple stresses. Development of commercial level rice events for drought and salinity tolerance would be the other major contribution. The production of abiotic stress tolerant rice and wheat lines is a valuable addition to the seed industry in India.
- 3. Market Potential: Drought and salinity increasingly affect significant portions of the over 40 million hectares under rice cultivation in the country. Currently at least 25 to 30 per cent of the area under cultivation is affected by drought or salinity every growing season. The impact on productivity of drought or salinity tolerant rice will be significant in economic terms for farmers and consumers. This hence spells a huge market for the same.
- 4. Risk Factors: Yield differences may however not be significant under all environmental conditions. Besides, over expression of stress tolerant genes may induce pleiotropic effects which may negatively impact yield and plant phenotype.
- 5. National /Societal Relevance: Given that drought and salinity significantly affect large portions of the over 40 million hectares under rice cultivation in the country, the impact on productivity of introducing drought or salinity tolerant rice will be significant in economic terms for farmers and consumers.
- 6. Potential for IP Generation: The lead events will be protected with event ID patents.
- 7. Progress Quantifiers: For the genes being tested, the majority of the milestones have been met in terms of extensive greenhouse testing and in one case, field evaluation.
- 8. Plans to take up innovation further: At present, the project ends at greenhouse evaluation. The next step would be field evaluation which is planned. The company also plans to take up development of elite varieties or hybrids in various breeding programs.
- 9. Self-satisfaction level: (On a scale of 1 to 10) 7.5

### **Company Address:**

### **Maharashtra Hybrid Seeds Company Limited**

Mahyco Research Centre, PO Box 76, Jalna-Aurangabad Road, PO Dawalwadi, Tq. Badnapur, Jalna - 431203



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**AGRICULTURE** 



### Team Members: (including collaborators)

- 1. S.Mukundan
- S Shivakumar
- 3. B P Ravikumar
- 4. M J Vasudeva Rao
- 5. Gautham Nadig
- 6. Prashant Mohale
- 7. Suresha P
- 8. S Sarala
- 9. Kiran
- 10. Jayant Pawar
- 11. Kapil Kumar
- 12. B Lokesh
- 13. Ravikiran
- 14. L. Sampath

#### **Company Address:**

**Metahelix Life Sciences Pvt. Ltd.** Plot No 3, KIADB, 4th Phase, Bommasandra, Bangalore – 560099, Karnataka

### METAHELIX LIFE SCIENCES LTD.

**Description of Innovation:** A proposal for funding of deregulation trials Phase I of transgenic rice events expressing Metahelix synthetic Cry1C, Cry1Ac and Cry1Ab genes for tolerance to rice yellow stem borer, Scirpophaga incertulas. The three genes under study are synthetic, internally designed, codon optimized, owned and developed by Metahelix offering high degree of resistance to rice yellow stem borer.

Collaborating Partners (if any): None

- 1. Stage of Development: The company has generated large number of events carrying Cry1AcOs, Cry1AbOs and Cry1COs. It has successfully conducted event selection trial for a total of 566 events carrying Cry1AcOs and Cry1AbOs during summer 2011. It has also conducted in-house experiments like protein expression, bio-efficacy tests, stabilization of events, line conversion of elite events, bio-equivalence and inheritance pattern studies besides bio-informatics and preliminary bio-safety studies.
- 2. Innovative Elements: The three genes under study are synthetic, internally designed, codon optimized, owned and developed by Metahelix offering a high degree of resistance to rice yellow stem borer. The genes are driven by a patented novel chimeric promoter which results in high level of expression in leaf and other parts of rice plants but no expression in the endosperm, which is the edible part of the seed.
- **3. Market Potential:** Rice is grown on approximately 42 m ha in India and yellow stem borer occurrence is very widespread and prevalent in most of the rice growing regions causing 38-80 per cent loss to yield, especially in late sown crops. Rice hybrids or varieties tolerant to YSB will be preferred by farmers as they will bring in yield benefits and reduce usage of pesticides.
- **4. Risk Factors:** Regulatory trials of GM crops, have been virtually halted in the country due to reasons beyond technology. This situation poses a high level of uncertainty regarding time and costs required for obtaining commercialization approvals.
- 5. National/Societal Relevance: Rice crop is the major consumer of pesticides next only to cotton. Rice yellow stem borer, among other insect pests of rice, is a devastating pest of rice, causing huge losses. Conventional genetic improvements supported by pesticide usage have only resulted in limited control levels of rice yellow stem borer. This transgenic crop tolerant to yellow stem borer results in reduction in pesticide use and a consequent increase in yield due to prevention of loss caused by the insect.
- **6. Potential for IP Generation:** The 3 genes are driven by Metahelix's proprietary promoter covered under the PCT, Indian Patents and European Patents. There are no FTO issues with respect to technology in this proposal as it is developed in-house.
- 7. **Progress Quantifiers:** Some of the key quantifiers include conversion to transgenic A lines, expected to be completed in 18 months. The seed increases of the transgenic plants and lines, to be completed in 18 months.
- **8. Plans to take up innovation further:** Testing events have already been generated through deregulatory trials at BRL-I stage with the long term objective of achieving environmental release of transgenic events, eventually leading to their commercialization.
- **9. Self-satisfaction level:** (**On a scale of 1 to 10**) Research output and product development: 8. Regulatory trials and product commercialization: **2**









### **Team Members:** (including collaborators)

- 1. Dr. Jaysing Rajput (Director Research) Nirmal Seeds Pvt. Ltd.
- 2. Mr. Gaurav Dhande (Biotechnologist) Nirmal Seeds
- 3. Mr. Irappa Halkude (Research Manager) Nirmal Seeds Pvt. Ltd.
- 4. Dr. Shashi Bhushan Tripathi (Fellow) (The Energy and Resources Institute, New Delhi)
- 5. Dr. Nutan Kaushik (senior fellow) (The Energy and Resources Institute, New Delhi)

### **Company Address:**

Nirmal Seeds Pvt. Ltd., Bhadgaon-Pachora Road, Pachora, Jalgaon - 424201 Maharashtra

### NIRMAL SEEDS PVT. LTD.

Description of Innovation: Development of nutritionally improved mustard (Brassica juncea) varieties/hybrids having low erucic acid and low glucosinolate content using marker assisted selection. The innovation involves improving nutritional quality of oil and oilcake by developing double low varieties and hybrids. This is proposed to be achieved by using genotypic and phenotypic selection complementarily in a relatively shorter time frame.

Collaborating Partners (if any): The Energy and Resources Institute, New Delhi

- 1. Stage of Development: The project is currently under middle phase of completion. Introgression of DL traits in Nirmal's Brassica genotype has been completed up to BC1 generation. The validation of DL traits has been done at The Energy And resources Institute, New Delhi using markers specific to DL traits.
- 2. Innovative Elements: The seed yield and oil content are essentially major targets for genetic improvement in Indian mustard. The project addresses the improvement of nutritional quality of oil and oilcake by developing double low varieties and hybrids (low erucic acid and low glucosinolate content). This is proposed to be achieved by using genotypic and phenotypic selection complementarily in a relatively shorter time frame (3-4 years using marker assisted selection as compared to 5-6 years in case of only phenotype based selection).
- 3. Market Potential: Rapeseed-mustard, one of the most commonly used edible oilseeds in India, contributes nearly 30 per cent of the total oilseed production. Rajasthan, UP, Haryana, MP and Gujarat cover more than 80 percent of the total acreage under mustard and India is the third largest rapeseed-mustard producer in the world. This crop accounts for nearly 1/3rd of the oil produced in the country. Since cultivation of canola varieties accounts for less than 1 per cent of the total area under rape-seed and mustard in India, raising its share is important for increasing the quality of edible oil available to consumers.
- 4. Risk Factors: The selection of low erucic acid and low glucosinolates is difficult due to complicated genetic factors associated with these traits. The biggest challenge is combining the double low characteristics with good yielding capability, as some of the loci associated with low glucosinolate content are negatively associated with yield.
- 5. National/Societal Relevance: B. juncea is the most widely cultivated Brassica species in India. Mustard oil is preferred in most Northern states due to its characteristic pungency. However, the oil has high amounts of erucic acid which is anti-nutritional. The oil cake also has high levels of glucosinolates making it unfit as cattle feed. There are no double low variety and hybrids of B. juncea released so far. Hence, a double low variety would have wider acceptance and increased utility both as edible oil and cattle feed, benefitting Indian farmers.
- 6. Potential for IP Generation: It has developed high yielding mustard varieties tolerant to abiotic and biotic stresses which have the potential for IP generation.
- 7. Progress Quantifiers: The project evaluated 90 mustard lines for eurucic acid and glucosinolate content and selected the parental lines. Also successfully completed was the cross between recipient and donor parent and harvesting of F1 seed.
- 8. Plans to take up innovation further: The Company plans to take up crossing of developed Brassica population (BC1) with recipient parental line (NML-100) along with validation of DL traits using molecular markers.
- 9. Self-satisfaction level (On a scale of 1 to 10): 10







#### **Team Members:** (including collaborators)

- 1. Dr. K. R. K. Reddy Chairman & Managing Director, SRI BIOTECH
- 2. Dr M. V. Rajam Professor, University of Delhi-**South Campus**
- 3. Dr. K.R.N. Reddy Scientist In-Charge, SRI **BIOTECH**

#### **Company Address:**

Sri Biotech Laboratories Pvt. Ltd. Plot No. 21, Street No. 2, Sagar Society, Road No. 2, Banjara Hills, Hyderabad - 500034 Andhra Pradesh

### SRI BIOTECH LABORATORIES INDIA

### **Description of Innovation:**

Control of shoot and fruit borer insect pest (Leucinodes orbonalis L) in Brinjal through RNA interference. Company plans isolation and cloning of vital genes from L. orbonalis and development of RNAi constructs for three genes and later transformation to Brinjal through agrobacterium mediated transformation. The purpose is to develop insect resistant brinjal transgenics.

#### Collaborating Partners (if any):

University of Delhi- South Campus, New Delhi

- 1. Stage of Development: Isolation and cloning of vital genes from L. orbonalis was completed and RNAi constructs for these three genes were developed and transformed to Brinjal through Agrobacterium mediated transformation. Since the company is in the testing of putative transgenic brinjal plants to target insect resistance, the innovation is in discovery stage.
- 2. Innovative Elements: Cloning of vital genes of the target insect pest of brinjal and development of transgenic brinjal plants for resistance to shoot and fruit borer insect pest.
- 3. Market Potential: The developed insect resistant brinjal without fruit damage would be of great demand in the market and the farmers can reduce the pesticide sprays by 50 per cent.
- **4. Risk Factors:** The company does not foresee any risk factors. However, the campaign against BT Brinjal could be a discouraging factor.
- 5. National /Societal Relevance: The damaged brinjal fruits are unfit for human consumption. Therefore, the developed insect resistant brinjal transgenics without fruit damage would be preferred for human consumption. In addition, the farmer's community would benefit economically because of increased fruit yield and quality. Pesticide residues on the harvest will be reduced heavily.
- **6. Potential for IP Generation:** The innovation will have scope of both isolation and cloning of vital genes of specific insect and product patents.
- 7. Progress Quantifiers: Isolation and cloning of cDNA of Chitin synthase (CHS), Cathepsin L (CTSL) and Acetylcholineesterase (AChE) genes from L. orbonalis was completed and RNAi constructs for these three genes were developed and transformed to brinjal plants through Agrobacterium mediated transformations.
  - Testing of putative transgenic brinjal plants for resistance to target insect pest is under progress. Further studies on isolation of partial cDNA of Ornithine decarboxylase (ODC), Chitinase (CHI) and Juvenile Hormone Acid O-Methyltransferase (JHAMT) and design of siRNAs specific to the cloned genes of brinjal fruit borer and screening of these siRNAs for their effect on the larval growth and development is under progress.
- 8. Plans to take up innovation further: This innovation further will take up development of insect resistant brinjal and commercialization.
- 9. Self-satisfaction level (On a scale of 1 to 10): 10





### **Team Members:** (including collaborators)

- 1. Dr. K. R. K. Reddy Chairman & Managing Director, SRI BIOTECH
- 2. Dr Hari Sudini Groundnut Pathologist, **ICRISAT**
- 3. Dr. K.R.N. Reddy Scientist In-Charge, **SRI BIOTECH**

#### **Company Address:**

Sri Biotech Laboratories Pvt. Ltd. Plot No. 21, Street No. 2, Sagar Society, Road No. 2, Banjara Hills, Hyderabad – 500034 Andhra Pradesh

### RI BIOTECH LABORATORIES II

**Description of Innovation:** Development of Actinomycetes based Metabolites as delivery systems for Soil Health Management in Groundnut (Arachis hypogaea L). Actinomycetes (out of 112 strains) strain from Groundnut rhizosphere has antagonistic activity against soil-borne pathogen of Groundnut and the secondary metabolites extracted from this strain are effective even at lower concentrations. This development of eco-friendly product will enhance soil health by reducing the load of harmful organisms in the groundnut rhizosphere.

Collaborating Partners (if any): International Crops Research Institute for the Semi- Arid Tropics (ICRISAT), Hyderabad

- 1. Stage of Development: Identified a potential Actinomycetes (out of 112 strains) strain from Groundnut rhizosphere which is having antagonistic activity against soil-borne pathogen of Groundnut and the secondary metabolites extracted from this strain is found effective even at lower concentrations. Since the stage of development is in the characterization of secondary metabolites, development of metabolite formulations, the innovation is in Discovery stage.
- 2. Innovative Elements: Secondary metabolites derived from potential antifungal actinomycetes will be identified, quantified and effective delivery systems will be made out of this project.
- 3. Market Potential: The environmentally safe soil health improving product quality and productivity will have good market potential.
- 4. Risk Factors: The company does not see any potential risk as this product is made out of common soil inhabitants.
- 5. National/Societal Relevance: Though large number of improved groundnut cultivars available today, yield potential is not fully explored due to soil borne pathogens. Therefore, development of eco-friendly product which enhances soil health by reducing the load of harmful organisms in the groundnut rhizosphere is more important to benefit the ground nut farmers in general and rain-fed in particular.
- **6. Potential for IP Generation:** The innovation will have scope of both product patents in the form of novel strains of actinomycetes, secondary metabolites and process patents for mass multiplication and formulation strategies.
- 7. Progress Quantifiers: A total of 112 strains of Actinomycetes were isolated from Groundnut rhizospheres of Anantapur District, Andhra Pradesh, India and screened for their efficacy on soil-borne pathogen (S. rolfsii) of Groundnut. Out of 112 strains, six strains showed highest efficacy and these strains were evaluated for production of secondary metabolites. The metabolites extracted from a strain (SBTA 23), effectively controlled the pathogen even at lower concentration. Further studies on characterization of secondary metabolites, optimization of fermentation conditions for mass production of metabolites and development of formulations are under progress.
- 8. Plans to take up innovation further: This innovation further will take up to development of product and commercialization.
- 9. Self-satisfaction level (On a scale of 1 to 10): 10



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### **AGRICULTURE**



### Team Members: (including collaborators)

- 1. Anand Gole (coordinator)
- Naveen Kalra
- 3. Subhendu Bhadraray
- 4. B. B. Singh
- 5. K. V. Satyanarayana

### TATA CHEMICALS LTD.

### **Description of Innovation:**

Inorganic and polymer nano-composites for micronutrient & pesticide delivery for boosting crop health and yield. The project is based on nano technology based delivery vehicle to supply micronutriants, pesticides and growth factors for crops.

### Collaborating Partners (if any):

None

### Higlights of the innovation:

- 1. Stage of Development: Proof-of-Concept, Scale up activity and pot trials
- 2. Innovative Elements: The project is centered on using nanotechnology based delivery vehicles to supply micro-nutrients & pesticides for crops so as to boost crop health, quality and yield. It will also address the region and crop specific micro-nutrient requirements, reduce/control the amount of pesticides, and have a overall positive impact on the soil and plant. For this the company has developed three different particle systems: a) Nano-silica based delivery vehicles; b) Inorganic complex based delivery systems (slow release) and c) Polymer based slow release system.
- 3. Market Potential: Controlled delivery of nutrients and pesticides with growth factors together clubbed as a customized region and crop specific plant essentials would be a significant value addition to the Indian agricultural community. The improved yield, health, and quality would be a major benefit to the farmers and may be ready to pay a premium. Since Tata Chemicals has a strong relationship with farmers through its franchise network in rural areas, it would be able to realize the true market potential. Micronutrient market in India: Rs 1000 crore, Microbooster: 280 crore and for pesticide the market is huge.
- **4. Risk Factors:** The small and marginal farmers, which account for a large segment of the farming community are price sensitive and lack risk taking appetite. Our efforts of providing a cost effective solution should meet the expectation of the farmers.
- 5. National/ Social Relevance: Nanotechnology being an enabling technology would help to significantly enhance productivity and protect the environment by addressing issues such as: a) Increasing productivity to meet the ever increasing food demand b) Addressing issues such as deteriorated soil health, unbalanced use of fertilizers, use of organic chemicals, toxic pesticides, ground & drinking water contamination c) Low use efficiency.
- **6. Potential for IP Generation:** The new formulations could be patented.
- **7. Progress Quatifiers:** 1st milestone achieved. (Nanoparticle synthesis & Soil mapping).
- **8. Plans to take the innovation further:** Scale-up, field trials, regulatory process.
- 9. Self satisfaction: 8

### **Company Address:**

**Tata Chemicals Limited**Bombay House
24 Homi Mody Street
Fort, Mumbai 400 001







### **Team Members:** (including collaborators)

### **Project Coordinator:**

1. Mr. S.R Soni

#### **Company Team Members:**

- 1. Mr. Alok Singhal (Jt. GM Tech)
- 2. Mr. Prashant Yadav (Assistant Mgr. - Tech)
- 3. Mr. Umesh Joshi (Jt. Mgr. QC)

#### **Collaborators Team Members:**

- 1. Dr. Arvind Mallinath Lali (Professor of Chemical Engineering)
- 2. Dr. Annamma Anil Odaneth (Assistant Professor in Biochemistry)
- 3. Dr. Abhishek Mule (Research Scientist)

#### **Company Address:**

#### India Glycols Limited,

A-1 Industrial Area, Bazpur Road, Kashipur, U.S. Nagar, Uttarakhand - 244713

### INDIA GLYCOLS LTD.

### **Description of Innovation:**

Setting up 10 ton Lignocellulosic biomass/day processing plant to produce about 3000 Litre ethanol/ day. Development of a new technology that facilitates manufacture of cellulosic ethanol at less than Rs 20 per litre. The technology incorporates aspects like viability, sustainability, waste management, integrated bio refinery approach.

#### Collaborating Partners (if any):

DBT-ICT Centre for Energy Biosciences, N.P Marg, Matunga, Mumbai 400019

- 1. Stage of Development: The technology to be used has been conceptually proved & working for Phase - II, to run the plant in an integrated continuous mode. Each segment of the pilot plant has been independently tested and the process validated to provide required data for the scaled up plant. Hence Phase - II is planned to operate the entire plant in integrated continuous mode.
- 2. Innovative Elements: Alkaline fractionation to achieve 90 per cent de lignified biomass with 90 per cent sugar recovery followed by enzymatic hydrolysis with reuse of enzymes, are the main pioneering elements in this innovation/ technology. This technology has several aspects like viability, sustainability, waste management, integrated bio refinery approach with value added side products. Hence it provides passage for scale up of many factors.
- 3. Market Potential: This innovation has the possibility of great market potential as there is an acute shortage of ethanol for chemical processing industries and ethanol produced from biomass may serve as feedstock for these industries. In addition, blending of ethanol with Gasoline also provides a huge scope.
- 4. Risk Factors: There is an associated risk that one or the other component of the technology may not work out to be viable.
- 5. National /Societal Relevance: India imports 70 per cent of its transport fuel energy which is set to go up to 90 per cent by 2020. Self-dependency in transport fuel is a necessity. With huge potential of cellulosic ethanol existing, the national importance of the emergence of a new technology that facilitates manufacture of cellulosic ethanol at less than Rs 20 per litre is obvious.
- 6. Potential for IP Generation: Several innovations are made in the course of pilot plant operation and optimization which will constitute new IP generation on the pilot plant.
- 7. Progress Quantifiers: In terms of timelines, Targets & milestone accomplishment, progress quantifiers are near 100 per cent.
- 8. Plans to take up innovation further: Making the technology available for implementation across the country at a scale ranging from 10 ton/day to 1000 ton/ day.
- 9. Self-satisfaction level: (On a scale of 1 to 10): 9







#### Team Members: (including collaborators)

### **Project Coordinator:**

1. Dr Banibrata Pandey

### **Team members:**

- 1. Dr Samir Kumar Roy
- 2. Dr Sarvana Kumar Iyappan
- 3. Dr Sibnath Ray
- 4. Dr Cherish Babu

### **Company Address:**

Nagarjuna Fertilizers & Chemicals Ltd.
Nagarjan Hills

Nagarjan Hills, Panjagutta, Hyderabad Andhra Pradesh - 500082

# NAGARJUNA FERTILIZERS & CHEMICAL LTD.

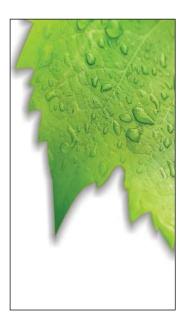
**Description of Innovation:** Transformational Technology Platform Development for Biological Hydrogen. Development of core technology starting from renewable raw material to final Biohydrogen production. Use of cellulosic route where the raw material usage from various biomass sources is maximal as opposed to current raw material which is sugar. Company is also developing dedicated energy crops in-house to source cheap and economical raw material through the year. The purpose is to address high cost and lack of continuous availability of raw materials.

Collaborating Partners (if any): None

- 1. Stage of Development: Developed core technology starting from renewable raw material to final Biohydrogen production which is ready and tested for proof of concept (POC) at lab level. The technology is already protected in the form of IP and now ready to enter the Proof of Value (POV) stage.
- 2. Innovative Elements: Bringing in economic process by using hydrogen as raw material for various applications. Carbon di oxide resulting from the process will be back end integrated for urea production. The customized raw material platform gives scope to use any biomass. The pre-treatment module uses water as reactant, saccharification employs the use of Solid Acid Catalyst and low enzyme, upstream and downstream processes is through freeze concentration and liquid separation respectively, resulting in the process being green.
- **3. Market Potential:** Hydrogen being the backbone of chemical and energy sector, there is no limitation of its demand. Hydrogen could be used as raw material in chemical industry replacing chemicals that are currently exclusively dependent on Hydrocarbon as raw material.
- **4. Risk Factors:** Complete end to end integrated technology not available. To mitigate this, all areas in existing technology are looked into, with gaps identified and competencies developed to address gaps. Technology prototype offering a complete picture for up scaling and commercializing is not available. Continuous availability and high cost of raw materials is also a problem.
- 5. National/Societal Relevance: Hydrogen whether used for energy or as raw material is currently produced from petrochemical route in India. India imports 85 per cent of its petrochemicals. Hence biological hydrogen production will reduce import of petrochemicals. Biomass based hydrogen production offers several opportunities in agriculture sector. Biohydrogen also plays vital role in chemical industries by replacing petroleum feedstock.
- **6. Potential for IP Generation:** In each of the areas, necessary IP is protected through 10 International patents in the following countries viz India, Australia, Canada, China, Europe, Japan, Korea, USA, New Zealand, Brazil, South Africa, Mexico and Nigeria.
- 7. Progress Quantifiers: Trial runs for individual technology modules to be completed by mid-September 2012 and process parameters optimization to be completed by December 2012. Front End Engineering Design (FEED) is under progress with basic engineering work to be completed by mid- November.
- **8. Plans to take up innovation further:** Commercial production of Ammonia at 200 to 250 MT/day is to start from 2017-18. First commercial plant proposed to be set up in Nizamabad followed by Kakinada in Andhra Pradesh. Further plants to set up in Punjab, UP, Haryana and Maharashtra.
- 9. Self-satisfaction level: (On a scale of 1 to 10): 7







### RICHCORE LIFESCIENCES PVT. LTD.

### **Description of Innovation:**

Viable Enhancement of ethanol yield from molasses fermentation by adding a specific enzyme to convert an unfermentable sugar to a fermentable sugar.

### Collaborating Partners (if any):

None

### Higlights of the innovation:

- 1. Stage of Development: Laboratory studies to demonstrate increase in alcohol yield from molasses fermentation upon addition of enzymes have been completed. Validation at large scale plant scale trials and commercialization are in the pipeline.
- 2. Innovative Elements: The innovative element in this study is the improvement in ethanol yield from molasses fermentation by the addition of a specific enzyme to convert the unfermented pentose sugar, present in large amount in molasses (upto 5%) to its more readily fermentable isomer by a reaction analogous to the isomerization of glucose to fructose. This results in increase in alcohol.
- 3. Market Potential: The market potential for this innovation is estimated to be Rs 875 Cr annually worldwide.
- 4. Risk Factors: Change in product performance with the amount of unfermentable sugar in molasses from different sources is a possible risk factor that may affect the economic output.
- 5. National/Social Relevance: The solution directly increases ethanol productivity from molasses by about 5% without any additional capital expenditures by the industry. As ethanol production from molasses will be increased by 5000 million liters worldwide, the impact of this proposal in India alone will be Rs 147 Cr annually.
- **6. Potential for IP Generation:** 2 Patents have been filed at the Indian patent Office and PCT.
- 7. Progress Quatifiers: Targets and milestones listed in the project proposal have been successfully completed within the timeline.
- 8. Plans to take the innovation further: They plan to conduct large scale plant trials and proceed to commercialization.
- 9. Self-satisfaction: 9

#### **Team Members:**

#### (including collaborators)

- 1. Dr. Dhinakar S. Kompala (Project Director)
- 2. Mr. Subramani R (CMD, Richcore Lifesciences)
- 3. Dr. Swati S. Dash (Project Coordinator)
- 4. Ms. Nethra V
- 5. Ms. Deepa Kumar (Research Associates)

### **Company Address:**

#### Richcore Lifesciences Pvt. Ltd

Plot No. 204 and 237, Bommasandra - Jigani Link Road, K.I.A.D.B Industrial Area, Bangalore - 560105 Karnataka







### **SEA6 ENERGY PVT. LTD.**

### **Description of Innovation:**

Sea6 Energy is developing Seaweed Biofuel, through a cost-effective offshore biomass production and bio-conversion to fuel. Sea6 Energy is developing the bio-engineering to grow seaweed biomass offshore at large scales economically into ethanol biofuel. It is also simultaneously exploring emerging technology options to convert the novel seaweed biomass to a gaseous fuel like methane

#### Collaborating Partners (if any):

None

### Higlights of the innovation:

- **1. Stage of Development:** They have currently developed proof of concept and are currently validating it.
- 2. Innovative Elements: They are developing systems to cultivate macroalgae in rough ocean conditions at large scales and lowered costs and subsequently convert the biomass into ethanol completely in a salt water environment through enzymatic hydrolysis and fermentation, thereby eliminating the need for fresh water. Taken together this allows the development of a biofuel technology which is not limited by the availability of land and fresh water, two resources extremely crucial for food production.
- **3. Market Potential:** Alternate energy is the need of the hour, the market potential is huge as this project can help save our foreign exchange.
- **4. Risk Factors:** Potential risks involve market fluctuations in crude oil prices, but the fact that the cultivated seaweed itself is a valuable commodity today insures us against this.
- 5. National/ Social Relevance: India Imports more 85% of its liquid fuel requirement. Country does not have oil reserves to cater to the current demand and it is growing every day. The project has the possibility to bring about energy independence for the nation while potentially creating a whole new source of livelihood for the various coastal communities.
- **6. Potential for IP Generation:** Yes. Patents are applied for their technology both on our seaweed cultivation system and the seawater based bioconversion technology.
- 7. **Progress Quatifiers:** They have completed their first two milestones on time and are working towards the third milestone.

### Team Members: (including collaborators)

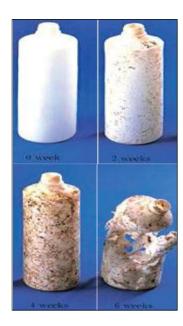
- 1. Sailaja Nori
- 2 Sawan Kumar
- 3. Sowmya Balendran
- 4. Nelson Vadassery
- 5. Shrikumar Suryanarayan

### **Company Address:**

Sea6 Energy Pvt. Ltd. Flat A13 Block 2 IISCON Homes, 4th Street Parameshwari Nagar, Adyar, Chennai – 6000020







### **Team Members:**

(including collaborators)

- 1. M.S.Shankara Prasad
- 2. Dr Sateesh Kumar
- 3. Dr Ashwin Madia

### **Company Address:**

**SPC Biotech Private Ltd.** AG-8, Metropalm Grove, Somajiguda, Hyderabad Andhra Pradesh - 500082

### SPC BIOTECH PVT. LTD.

### **Description of Innovation:**

Bioconversion of Agri waste of mango kernel to Polylactic acid a Bioplastic. Involves preparation of poly lactic acid (PLA) from mango kernel. Addresses development of cost effective, low energy intensive process for manufacturing biodegradable polymer (Poly-lactic acid), using locally available agricultural waste.

### Collaborating Partners (if any):

Dr Mahanwar, ICT Mumbai

- 1. Stage of Development: Process of preparation of poly lactic acid (PLA) from mango kernel has been patented. Designing of process equipment for the process of lactic acid preparation and single step clarification to obtain fermentable clarified sugars from acid Hydrolysate for lactic acid preparation is under patenting stage. Proof of concept and pilot scale demonstration completed with respect to production of lactic acid from mango kernel. Pilot scale demonstration of synthesis of PLA from lactic acid derived from Mango kernel is near completion stage.
- 2. Innovative Elements: Development of low cost, time and energy intensive biotechnological processes for development of green products utilizing local agricultural waste as raw material. Company's R&D team has developed cost effective, low energy intensive process for manufacturing biodegradable polymer (Poly-lactic acid), using locally available agricultural waste. The Biodegradable plastics developed from agricultural waste will degrade into soil under compost condition, enriching soil fertility.
- 3. Market Potential: The biodegradable polymers are used in multiple industries. World Demand for it is expected to expand nearly 16 per cent per year to 1500 million pounds in 2012, valued at \$1650 million. Of the current market size of US 300 billion for finished plastic goods, biodegradable plastics market share potential is \$ 30 billion. Single use Electronics items, Packaging, Healthcare, Consumer Durables are potential growth areas for bio-plastic consumption.
- 4. Risk Factors: Inability to scale up production as planned, unavailability of raw materials in the required amounts, price fluctuations of both finished products and raw materials, are the concerns.
- 5. National /Societal Relevance: Utilization of agricultural waste in developing high value biodegradable green products will result in generating additional income to the farming community, enrich soil fertility, reduce ground water contamination besides addressing global warming. Being alternatives to petrochemical products, valuable foreign exchange is saved while decreasing carbon foot print. Reuse of disposable syringes is responsible for 25-30 per cent of HIV-AIDS cases in India (WHO report). Use of cheaper biodegradable syringe effectively reduces reuse.
- **6. Potential for IP Generation:** The application being novel, should result in generation of new IP.
- 7. Plans to take up innovation further: The company has undertaken a process for isolation of sugar source from agricultural waste on commercial scale. It is also working on a conversion of liquefied sugar fermented under special conditions.
- 8. Self-satisfaction level: 10



### birac Ignite Innovate Incubate

### **ENERGY**



### Team Members:

(including collaborators)

- 1. Dr. R. R. Sonde
- 2. Dr. V. Kalyan Raman
- 3. Dr. U S Adhyapak
- 4. Mr. Janardhan Bornare

### THERMAX LTD.

### **Description of Innovation:**

Development of Anaerobic Membrane Bioreactor (AnMBR) for Waste to Energy Solution. This involves the integration of membrane separation process with anaerobic bioreactors for wastewater treatment with an objective to generate energy and recyclable quality water.

The proposed system has great potential for energy recovery from low and medium strength wastewater. Methane can be generated from wastewater while the water can be simultaneously treated to be used as recycled water.

### **Collaborating Partners (if any):**

None

### Higlights of the innovation:

- **1. Stage of Development:** The proof of concept is established and the project validation is undergoing through pilot scale studies.
- 2. Innovative Elements: Anaerobic treatment for low to medium strength wastewater suffers operational difficulties due to retaining biomass in the bioreactor. The integration of membrane separation process with anaerobic bioreactors to retain effective microbial population is an innovative step for wastewater treatment, with better solids separation and higher quality effluent.
- 3. Market Potential: The global market for membrane bioreactor technology is growing at an annual growth rate of 10.5 per cent and should reach \$488 million in 2013 showing big potential for the development of Anaerobic Membrane Bioreactors. The municipal and domestic waste water treatment is expected to generate \$ 249 million by 2013.
- **4. Risk Factors:** The major challenges are to generate biogas from low to medium strength wastewater and integrate quality membrane to keep sufficient flux by reducing fouling on membrane surface.
- 5. National /Societal Relevance: The anaerobic process significantly reduces energy costs. This technology can create major impact in developing countries like India by simultaneously tackling energy demand and waste management issues.
- **6. Progress Quantifiers:** The project has achieved 100 per cent targeted deliverables as per the timelines/milestone of the project.
- 7. Plans to take up innovation further: The Company plans to take up optimisation of design and operational parameter in laboratory scale experimentation. A pilot scale treatment system is also envisaged for low and medium strength wastewater using anaerobic process coupled with membrane filtration.
- 8. Self-satisfaction level (On a scale of 1 to 10): 9

### **Company Address:**

Thermax Ltd.
D-13, MIDC Industrial Area,
R.D. Aga Road, Chichwad,
Pune – 411019
Maharashtra





### **BIO-INFORMATICS**



### **PERSISTENT SYSTEMS**

### **Description of Innovation:**

SanGeniX: A comprehensive Next Generation Sequence (NGS) data analysis solution. SanGeniX will be a Java technology based solution with rich graphical user interface using Java Swing and will enable the user to do primary, secondary and tertiary analysis of NGS data in a seamless fashion.

#### **Collaborating Partners (if any):**

Dr. Sanjeev Galande, Dr. Farhat Habib (Indian Institute of Science Education and Research, Pune) Dr. Srinivas Aluru, Dr. Abhiram Ranade (IIT-Bombay) Dr. Ramesh Kumar Vijh (National Bureau of Animal Genetic Resources)

### **Higlights of the innovation:**

- 1. Stage of Development: The SanGeniX project is currently in the development stage. The project has made significant progress in developing an architecture that will enable development of a user friendly and highly customizable product. The Company is also actively working on optimizing de novo genome assembly algorithm such that large genomes can be assembled on commodity hardware.
- 2. Innovative Elements: The project involves the development of easy to use comprehensive NSG data analysis solution for seamless data flow and management. Further, it involves the development and optimisation of genome assembly tools and algorithms, integration of analysis software with sequencing instruments for seamless data input.
- 3. Market Potential: A few commercial tools are currently available, but most of them support only some aspects of the analysis and are exorbitantly priced. As a result, there is great demand for analysis suites that provide predefined, easy to use workflows and support de novo genome assembly on commodity hardware. SanGeniX is being developed to address these market requirements.
- 4. Risk Factors: Management, analysis and interpretation of NGS data is very challenging and requires a highly skilled workforce.
- 5. National /Societal Relevance: Globally and in India, major research institutions and Biopharmaceutical companies are rapidly adopting NGS technology for human, animal and plant research. In India, multiple CSIR and DBT research institutions and some universities have already invested in NGS technologies. Additionally, ICAR is funding large scale genome sequencing projects for medicinally important plants.
- 6. Plans to take up innovation further: The Company plans to work with researchers in national institutes like IGIB, ICGEB, IISC, NCBS, NBAGR, for data analysis services where a huge market is envisaged in the near future. It also plans to regularly conduct NSG data analysis workshops to educate and sensitise the Indian scientific community about latest advances in NGS and promote SanGeniX.

### **Company Address:**

Persistent Labs,

Pingala - Aryabhata, 12A/12, Karve Road, Erandwane, Pune - 411004, Maharashtra





### **INDUSTRIAL**



## ROSSARI BIOTECH LTD.

### **Description of Innovation:**

It is Microbial Biotechnology based innovation, utilizing agro waste and produce as substrate to manufacture widely applicable heath care and nutritional products, enzymes with innovative processes. It results in viable enzymes production using Agro waste/ produce as raw material of industrial/ feed and health care use with large viable market demand.

#### Collaborating Partners (if any):

None

### Higlights of the innovation:

- Stage of Development: Presently working on two enzymes Cellulase and Pectinase. Cellulase enzyme- lab studies (shake flask), lab fermenter studies are completed. Scales up batches have been taken and studies are underway. Pectinase enzyme-shake flask studies are completed. Lab fermenter studies are underway.
- **2. Innovative Elements:** The major media composition comprises of agricultural waste as raw material in fermentation process. Work is also on with non-conventional substrates for production of enzymes.
- **3. Market Potential:** Cellulase and pectinase enzymes finds applications in various industry like textiles, brewery, food, animal feed etc. There is a huge market potential available for feed supplement Mix-2000 tonnes a month in India whereas cellulase and desize enzyme having 5000 tonnes a month demand for textile processing.
- **4. Risk Factors:** At present there is no risk in the project except for variation in activities if there are changes in the quality and source of material.
- 5. National/ Social Relevance: Their technology is based on using in-house developed technology and low cost raw material to produce enzymes at affordable prices for applications. This will open up new market in India and substantial export market. Creation of employment opportunities in biotechnology sector, environmental protection, value addition to Agri products and waste among others.
- 6. Progress Quatifiers: Achieved 70-80 % activities of the proposed project.
- **7. Plans to take the innovation further:** They have planned to take the enzymes produced in 30KL fermenters.
- 8. Self-satisfaction: 9

#### **Team Members:**

#### (including collaborators)

- 1. Dr. Vadiraj Jahgirdar
- 2. Dr. Amey Damle
- 3. Mr. Suresh Shinde
- 4. Ms. Smita Mahajan
- 5. Ms. Bhakti Manohar
- 6. Mr. Devidas Choudhari
- 7. Mrs. Manjiri Paranjape
- 8. Mr. Ayan Dhar
- 9. Mrs. Aarti Gavande
- 10. Mr. Bhavesh Jain

### **Company Address:**

#### Rossari Biotech Ltd.,

201, A & B Ackruti Corporate Park, LBS Marg, Near to GE Gardens, Kanjurmarg, Mumbai – 400078 Maharashtra







# BIRAC Funded Research Programs Impact Assessment Report





# Improving Quality and Outcomes

Funders, social investors, non-profits, and social enterprises are united by a common goal: social change. To reach this goal, we have funded companies that identified what approaches work, and why. We have received a lot of positive feedback about the usefulness of the funded research programs aimed at advancing the quality of social life. All programs address the imperative: lowering costs, improving quality and outcomes. The key actions focus on clear and specific goals in many areas of science. All programs are intended solely to enhance scientific knowledge, which will lead to improved results related to efficiency, effectiveness, value, and behavior in the production and consumption of technologies, products, and health.

**Methodology for qualitative assesment**: In this section we deep dive into critical assessments of projects by classification, stage of development, innovative elements, commercial potential, risk factors, progress, IP potential, national / social relevance, and self-satisfaction score. The objective involves assessment of technologies developed through funding through BIPP and to identify sectors which have shown relatively higher progress in comparison to other areas.

Impact assessments are driven by responses provided by the funded companies (53) to prepare comparative scores. These scores are correlated with initial project plan, milestone descriptions and proposed innovative elements to determine the impact of funding in different areas.

A total of 93 programs are approved for funding in different areas of science covering an entire spectrum of research areas.









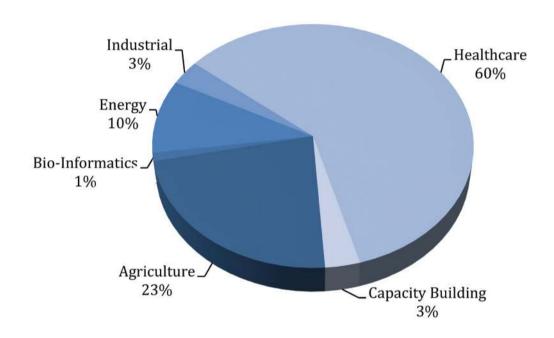




# **Program Highlights**

About 60% of the funded programs were in Healthcare, followed by 23% in Agriculture, and 10% in Energy.

### **Industry-wise Funded Programs**





Global R&D activities are focused on areas of high unmet medical need. The same trend follows in India as most of the funding was for programs focused on healthcare. Some of the factors driving this funding include rising population, growing lifestyle-related health issues, rising costs for medical treatment, government initiatives and focus on Public Private Partnership (PPP) models.

The government too has given top priority to healthcare by significantly increasing expenditure on health care in the 12 th Five Year Plan. Given the development scenario in Indian agriculture, 23% of the programs are funded in Agriculture while 10% of the programs are funded in Energy.

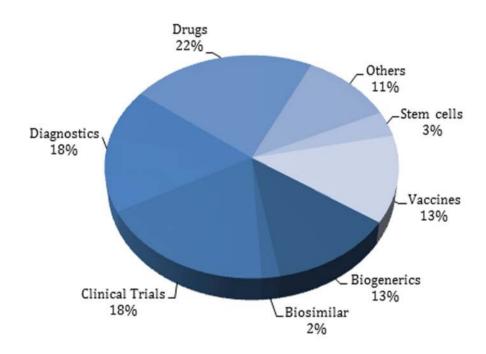




## Programs in Healthcare

Several programs that aim to develop cancer drugs have been funded which is reflective of BIPP's strong commitment towards prevention and management of cancer in India.

### Funded Programs in Healthcare Sector



A diverse range of programs covering various healthcare segments are funded. It includes therapeutic development, clinical trials, diagnostics, stem cells, vaccines, biogenerics, and biosimilars. The promise and the excitement about the potential of stem cells, is greater than ever. Vaccines are among the most successful and cost-effective public health tools for preventing disease, disability, and death. Building point-of-care detection devices and technologies is also of focus, as point-of-care diagnostics—either for home use or for a "near-patient" environment such as the general practitioner's surgery presents a huge opportunity for growth for the healthcare industry. Of equal importance are biosimilars and biogenerics which offer a cost advantage up to 25%.



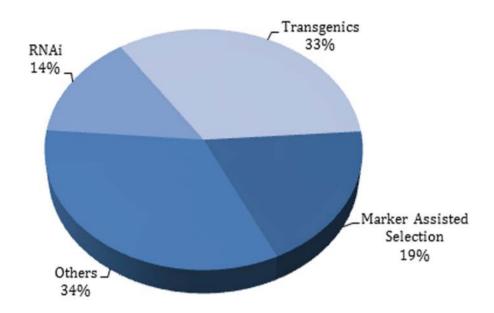




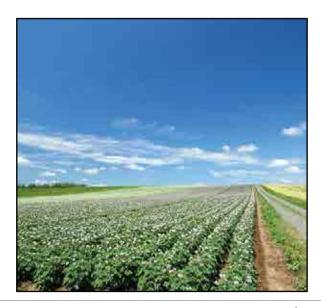
# Programs in Agriculture

The quality of agricultural produce has been improved utilizing the modern RNAi technique in many ways. About 14% of the funded programs in Agriculture focus on RNAi.

### **Funded Programs in Agriculture Sector**



A complete range of programs covering various segments in agriculture are funded. It includes programs based on RNAi, transgenics technologies and marker assisted selection. It is likely that the novelty of some of the products of genetically modified crops will present new challenges and perhaps opportunities to manage particular crops in creative ways. It includes developing stress resistant crops and pest tolerant rice. Similarly, RNAi is proved to be a tool for plant researchers to produce improved crop varieties. By working with a plant's own naturally-occurring processes, there exists a potential to create products that are very precise. Tools such as marker assisted selection are of great focus which helps in quicker selection of plant traits. Programs on bio-pesticide, soil health management, and Nano-pesticide are also funded.



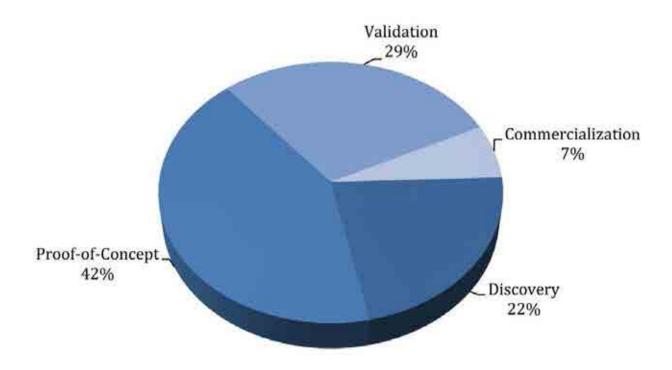




# Stages of Development

Funded programs are spread through early and late stage development of technologies and products.

### Funded Programs according to Stage of Development



Stage of development indicates current status of the programs across four stages: proof-of-concept, discovery, validation, and commercialization. Programs in proof-of-concept stage (42%) involve conducting enough research to prove that the idea is feasible and productive.

Most of these programs have identified a social or community need, and a potential business opportunity which is scalable. Programs in validation stage (29%) or development stage are focused on testing products before the launch. Programs on hepatotoxicity prediction platform, biomass production, and bioconversion are in the commercialization stage.



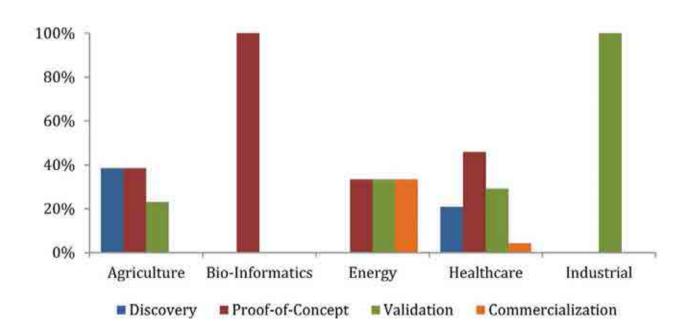




# Stage of Development by Industry sectors

Programs in energy, agriculture, and healthcare are almost equally distributed by stages.

### Industry by Stage of Development



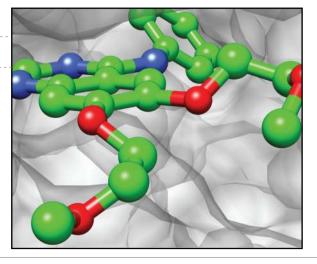
Most of the healthcare programs are in the proof-of-concept stage.

Stage

**Key Healthcare Programs** 

**Proof of Concept** 

Prodution of Nanoparticles, Ketoreductases, 15 valent Pneumococcal Polysaccharide, 13 Valent pneumococcal conjugate vaccine, HPV Vaccine, microPCR, Intraarterial (Hepatic) Ex-vivo cultured adult allogenic stemcells, Percutaneous Aortic Valve Technology, flash type chemiluminiscence, Flow analyzer, Percutaneous Aortic Valve Technology, Intraarterial (Hepatic) and Cell-based therapy in cardiovascular disease.



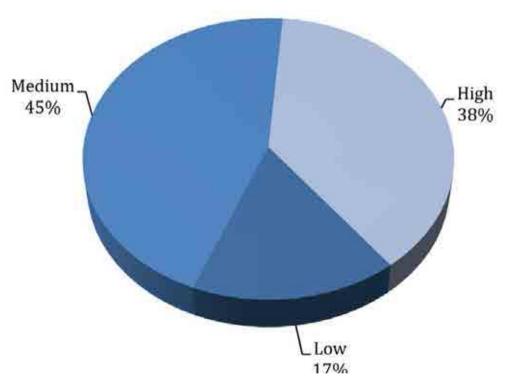




### **Innovative Elements**

>80% of the funded programs have a strong commitment to innovation which is expected to create the maximum social impact.

#### **Innovative Elements in Funded Programs**



Innovation requires collaboration, ideation, implementation and value creation. All the funded programs actively engaged in innovation illustrated each of these elements. They shared replicable concepts and initiatives that are showing real results. In the world of community development, technology and innovation are the fundamental underpinnings of our programs. The purpose of innovation is to create holistic value. All the funded programs' value is defined as incremental improvement to existing products, the creation of entirely new products and services, or reducing cost, which will result in long-lasting social impact. All funded programs seek to create value because their survival, growth and ability to compete in a rapidly changing market depend on whether they innovate effectively. Innovative elements are calibrated on a scale of high, medium and low. The calibration is purely relative as there is no absolute way to award score or point in this category.



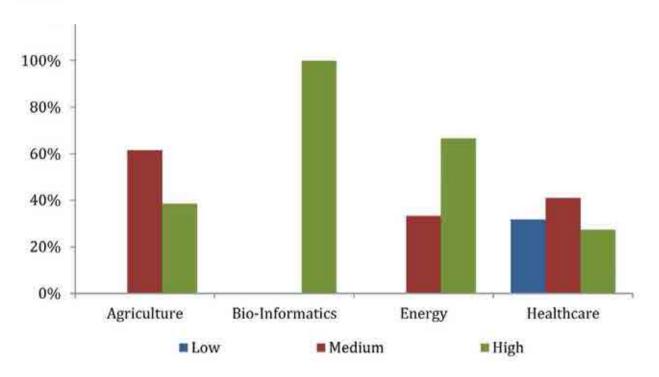




### Industry-wise Innovative Elements

Agriculture and Bioinformatics stand out among other Industries as most of the programs have an innovation element of medium to high.

### Innovative Elements according to Industry Sectors



Agricultural innovation has the key elements of physical and economic access to food for all the citizens, balanced diet with necessary macro- and micronutrients, and environmental security, i.e. without compromising sustainability of natural resources & environment. These innovations address critical issues such as global food crisis with rapid increase in food prices and slowdown of agricultural growth in India. Birac funded programs in energy has high innovative element and they focus on biological hydrogen production. Bioenergy is a promising renewable energy source which could contribute significantly to future gas, power, transport fuel and heat demands. Its relative use across these energy markets is subject to significant innovation. A series of assessments to outline the innovations in technology are performed to ensure bioenergy can play a role in an affordable, secure and sustainable energy system of the future and to improve the efficiency of heating and energy use.



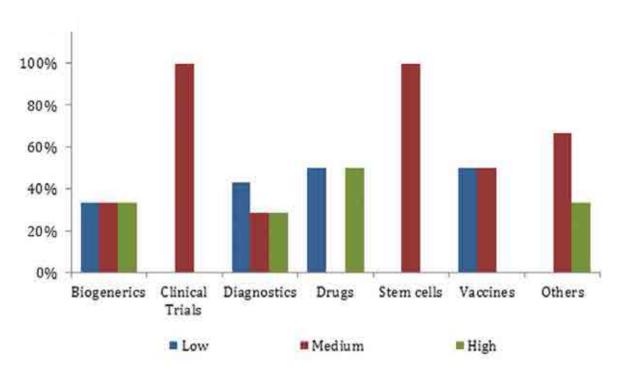




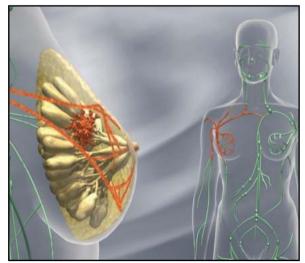
# Innovative Elements in Healthcare Programs

Healthcare programs focused on drugs, biogenerics, and diagnostics have the highest innovation element.

**Healthcare Programs: Innovative Elements** 



Innovation in all the funded healthcare programs aim at achieving a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of economic or social condition. Innovation elements possessed by the programs funded in healthcare are intended to accomplish this. Some of the innovation element in the programs are development of a novel polymer- drug, stem cell technologies for the treatment of liver cirrhosis, indigenization of a biosimilar monoclonal antibody, cost effective production of polysaccharides, drug development for controlling the prandial glycemic surges in diabetic patients, and production of ranibizumab for the treatment of age-related wet macular degeneration.



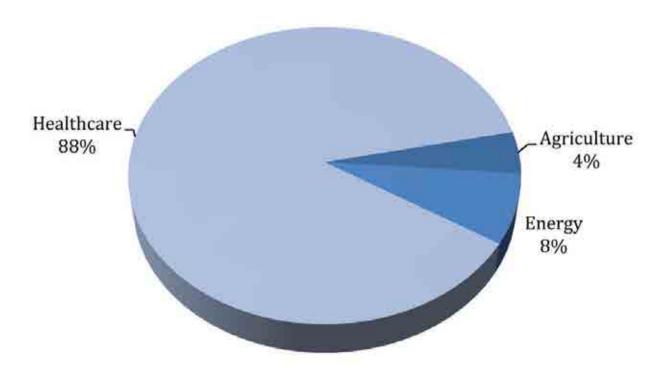




### Market Potential

### All the funded programs have begun with end in the mind, targeting promising markets and creating social impact

### Market Potential according to Industry Segments



The definitive success of funded programs depends on whether or not enough potential customers in a chosen market have a need for the product or service. All funded programs have been initiated based on whether there is such a need, whether there are enough potential customers in the marketplace that have the need and can afford to buy the product or service, and which competitors are currently meeting the need. Market potential analysis reveals the potential demand for products and services in a market. Most of the responses have qualifiers, while, some responses have provided quantifiable numbers.

Most of the products or technologies' being developed has a market potential between US\$100 million and US\$1 billion.



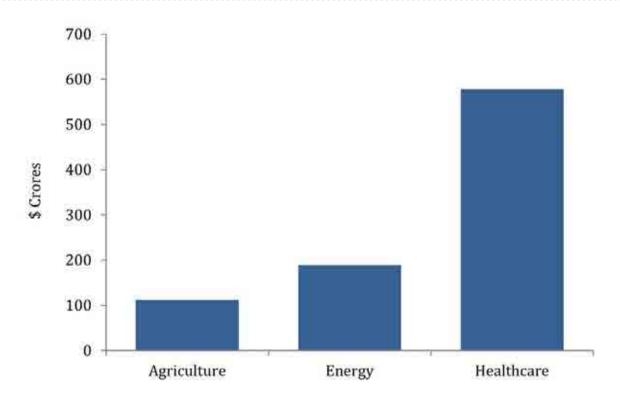




### Industry-wise Market Potential

Healthcare will remain as the focus area of growth for investments owing to high market potential and unmet needs.

#### Market Potential (Value) by Industry



The Indian healthcare sector is expected to reach US\$ 100 billion by 2015 from the current US\$ 65 billion, growing at around 20% a year. Prime Minister, Dr. Manmohan Singh also emphasized the need for increased outlay to health sector during the Twelfth Five Year Plan. Government initiatives in the public health sector have recorded some noteworthy successes over time with focus on investments related to better medical infrastructure, rural health facilities etc.

The government's concern is reflected in significant increase in allocation for The National Rural Health Mission (NHRM) scheme.



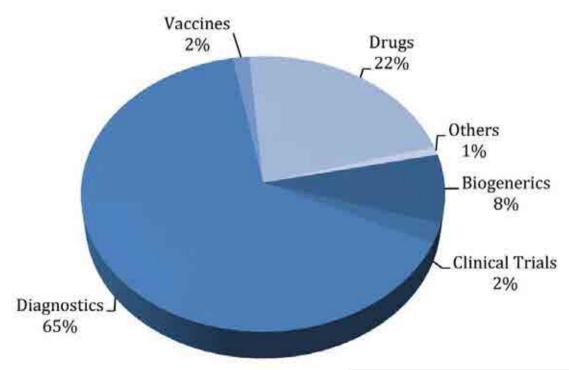




### Healthcare Programs - Market **Potential**

Drugs and Diagnostics segment put together has the maximum market potential compared to other segments in healthcare.

#### Market Potential for Healthcare Programs



The diagnostics market in India is witnessing a 20% growth which is the faster than any country in the world (the growth in the U.S. is 1%-2%). Also, the growth rate for the domestic Indian pharmaceutical market is set to rise over medium-term.

The growth is expected due to factors like new product launches, focus on improving effectiveness of field force additions and favorable pricing environment. Likewise, India's vaccine production sector is likely to expand dramatically by 2016. These facts support the growing need for diagnostics, vaccines, biogenerics, and therapeutic drugs in the Indian market.



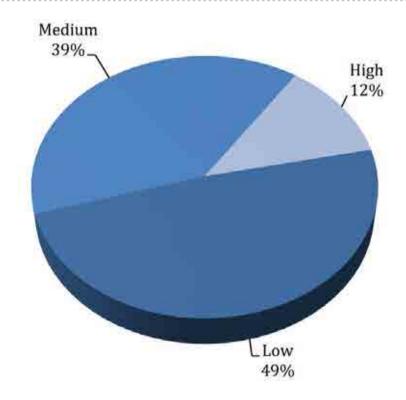




### Risk Factors

About 88% of the programs are identified to be between low and medium risks.

### **Risk Factors in Programs**



It is important to gather enough evidence to prove that development risk is proportionally low. It was recognized that a thorough and specialized process of due diligence was necessary to decrease the risk of funding low-potential, high-risk programs. Qualitative responses are collected for risks.

Some examples are viability of component technologies, competition, and availability of raw materials. These risk elements are categorized and then divided on the scale of severity of high, medium, and low.



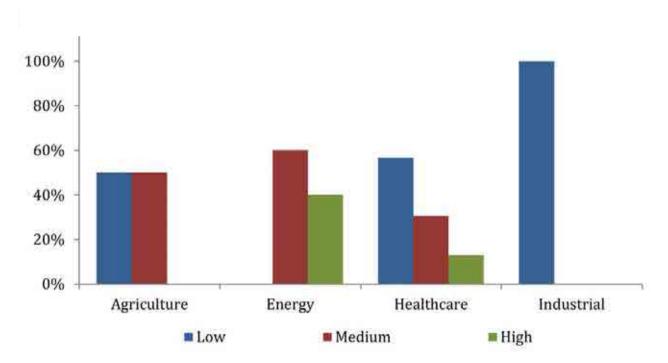




### Industry-wise Risk Factors in **Programs**

Identification and evaluation of the risk factors involved in a project is important. Moreover Biotech R&D is a particularly highrisk undertaking because of the substantial start-up costs, lengthy experimentation period, and possibility of the technology not being viable.

#### Risk Factors in Industry Programs



About 50% of agriculture projects pose medium risk and this can be attributed to the development stage of projects as many of the projects are still in proof-of-concept stage. The lengthy experimentation period and stringent regulatory affairs pose high risk for energy projects to be commercialized, which results in 40% of the energy projects being at high risk. The risk factors for the healthcare programs are almost equally distributed between low and high as there is a wide split in the sub-type of the healthcare projects. All of the industrial projects are low risk projects.



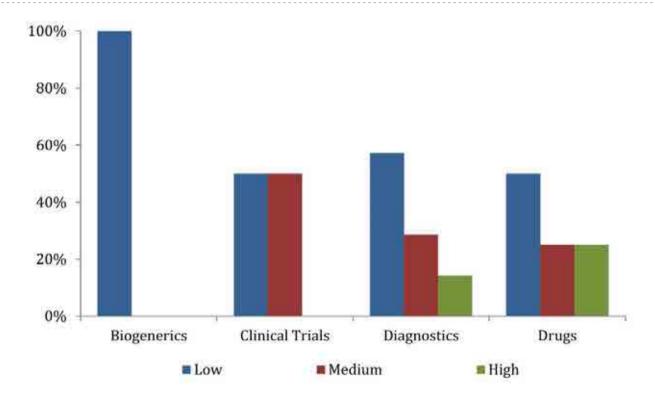




### Risk Factors in Healthcare

Risk management in the healthcare industry involves following all the right processes and protocols for successful outcomes; stem cells research programs involve high risk while biogenerics research is a low risk category.

#### Risk Factors in Healthcare Programs



Owing to the increased success in biogenerics research programs globally, the entire research category has a low risk. However, the success depends on the production process, purification, and formulation. Any minimal changes can significantly affect the safety and efficacy parameters of biogenerics. Clinical research programs have an equal medium/low risk split. The ethical appropriateness determines the degree of risk involved in clinical trials research. Majority of diagnostics research has medium/low risk involvement while drug related research is equally split in high/medium/low risk category. Stem cells research is a high risk area as it might threaten human life. 70% of the vaccines-related research involves low risk while other healthcare research has medium/high risk.



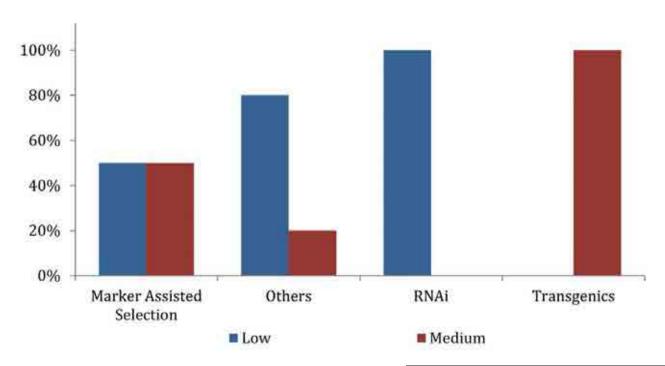




### Risk Factors in Agriculture **Programs**

Marker assisted selection research, RNAi and others possess a low risk profile while transgenics research funded programs have a significant risk attached to them.

### **Risk Factors in Agriculture Programs**



Marker assisted selection research programs have equal medium/ low risk involvement due to high capital requirements, technology constraints, and large scale plant capacity requirements. Also, the programs include the risk of being replicated by competitors. Environmental risks associated with transgenics research in the agriculture industry results in the entire category falling in the medium risk domain.

The entire RNAi research and other agriculture related research programs fall under the low risk category.



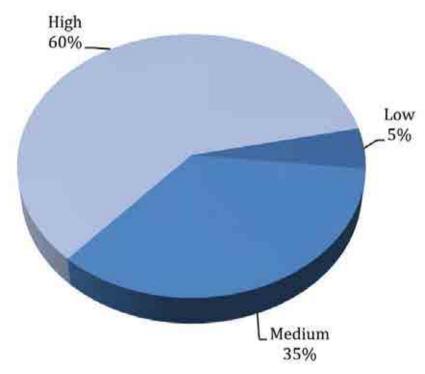




### National / Social Relevance

Majority of the funded research programs have high national/ social relevance owing to their increased importance in improving the quality of life; in turn, economic development of a country.

### National / Social Relevance according to Programs



High dependence of the society on knowledge creation to yield innovations that offer economic and social benefits influences the publically funded research program. Thus, about 60% of the funded research programs have high national/social relevance while 35% have medium relevance.

Moreover, the focused and high quality nature of such programs also results in the R&D development and economic growth of the country. Funded research programs across sectors, primarily healthcare, agriculture and energy, hold significance to enable a country become self-sufficient to enhance the quality of life of its people. Due to cost and technology constraints, about 5% programs hold low national/social relevance.



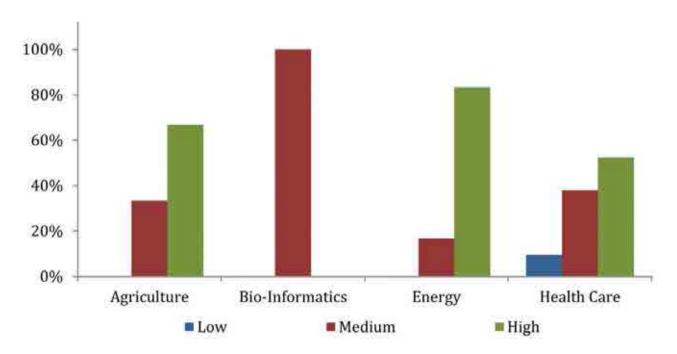




## National / Social Relevance by Industry

Advancement in technology, customization, scalability and improvement in process costs are some of the key benefits of funded research programs; about 90% of the funded research programs in the energy sector have high national/social relevance.

### National / Social Relevance by Industry



Investment in agriculture is the key to ensure food security and economic growth. Thus, 70% of the funded research programs in the agriculture industry have high relevance. The bio-informatics programs hold medium relevance driven by the economic benefits for farmers to increase the quality of yield. The need for self-sufficiency and development of new technology has high importance for the energy sector with 90% of the programs falling under high relevance. In the healthcare sector, 50% programs have high importance to cater to the high unmet needs and leverage India's cost advantage to provide affordable treatment to patients globally.

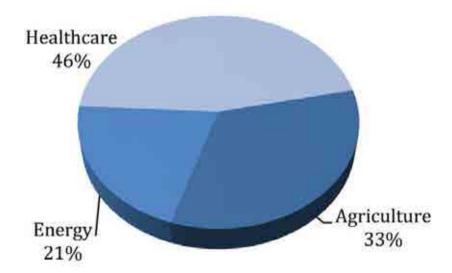






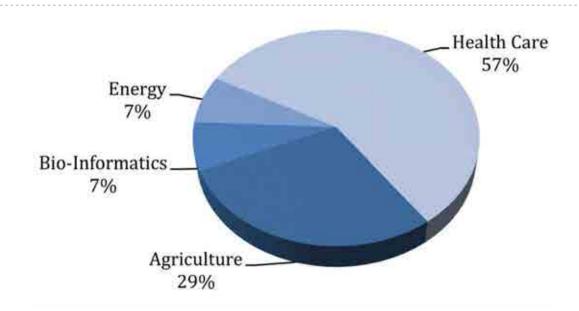
# Amongst the funded programs with high national / social relevance, healthcare programs accounted to 46%.

### Programs with High National / Social Relevance



Amongst the funded programs with medium national / social relevance, healthcare programs accounted to 57%.

### Programs with Medium National / Social Relevance



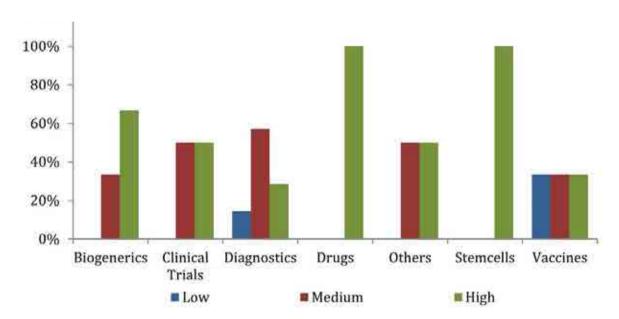




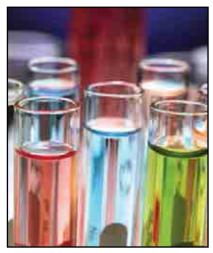
## National / Social Relevance of Healthcare Programs

The entire drug and stem cells related funded research programs in the healthcare domain have high national/social relevance; clinical trials and other healthcare research funded programs have equal high/medium relevance

#### Healthcare Programs -National / Social Relevance



Development of new drug treatment options provides high/medium relevance to biogenerics-related research programs. The entire drug related research programs have high importance to enable reduced therapy cost of chronic diseases like diabetes in India. It will also enable the country to develop as a destination to manufacture low cost drugs to provide affordable care globally. Clinical trials research programs are equally distributed in high/medium relevance category to develop them as a key research tool for advancing medical knowledge and patient care in the country. About 60% of the diagnostics research has medium importance to ensure effective patient management and control of infectious diseases. Stem cell research, an emerging area of human biology, holds medium social relevance while other healthcare research programs have equal high/ medium importance. Vaccines research against infectious diseases of public health importance is equally distributed in high/medium/low category.



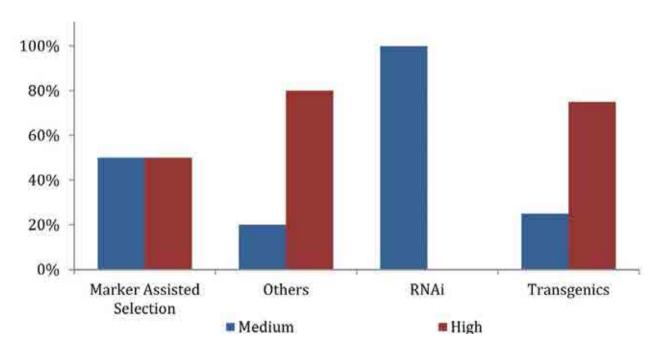




# National / Social Relevance of Agriculture Programs

Increased investment in agriculture research has made it as one of the largest publicly funded programs in the country.

National / Social Relevance of Agriculture Programs



The funded marker assisted selection research programs have equal high/medium national/social relevance owing to their development as a tool for genetic improvement of crops, in developing countries like India to achieve national food security. About 80% of other agricultural research programs, such as conservation, hybrids, extension and irrigation, have high social importance (primarily benefit the Indian farmers). The entire RNAi research programs are of medium relevance, and offer ways to control pests and diseases introduce novel plant traits and increase crop yield. In addition, RNAi research also leads to development of novel crops such as nicotine-free tobacco and decaffeinated coffee. About 80% of transgenics have high importance to enhance plant productivity.



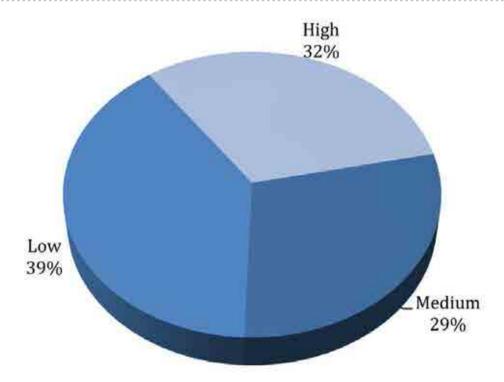




### **IP Potential**

About 61% of the funded programs have greater potential to generate IP.

### IP Potential in Programs



Intellectual Property (IP) can often represent a significant portion, even a majority, of a company's assets. Whether it is patents, the design for a new product, or blueprints for a new technology, medicine, or industrial process, intellectual property can be critical to a company's ability to compete in its industry.

'IP Potential' for the funded programs is quantified based on the number of patentable technologies into high, medium and low potential. From the responses, quantifying economic, social and environmental value of IP was not possible, and therefore it was difficult to perform comparisons on IP value generation.



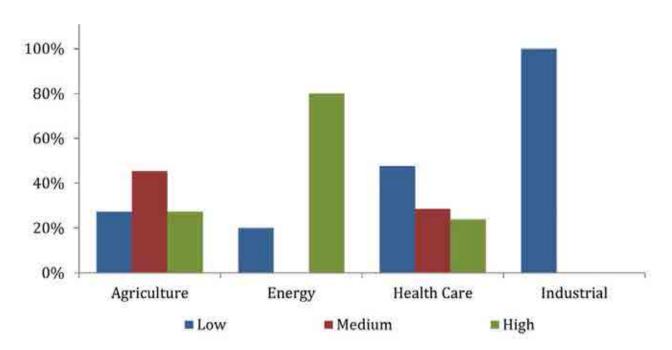




### Industry-wise IP Potential

Healthcare Programs accounted for 42% of the programs with high potential for IP generation.

#### **IP Potential in Industries**



The healthcare programs are enabled for medical innovation through Intellectual Property, from diagnosis to therapy. New technologies undoubtedly bring new challenges to society and this is especially true of technologies concerned with human health. The government wants to get the balance right.

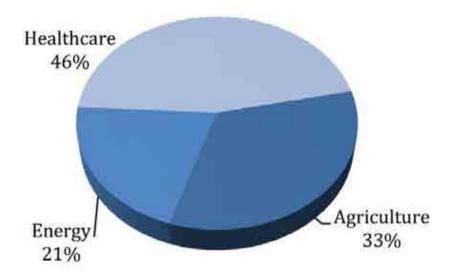
The biotechnology industry also rightly seeks the support of government to make sure it remains competitive. Partnership is the key to realizing the IP potential in the field of healthcare. It is these partnerships between commercial bodies, Government organizations and academia that drive innovation – for the benefit of all.





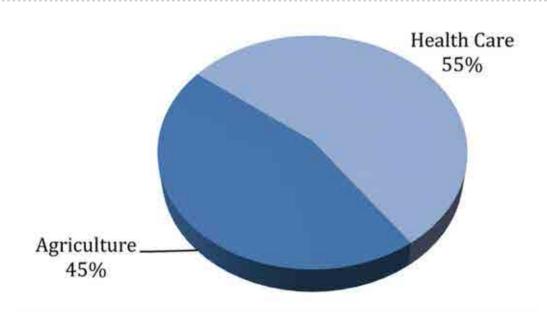


### Sectors with High IP Potential



# Amongst the funded programs with medium IP potential, Agriculture programs accounted to 55%.

### **Programs with Medium IP Potential**



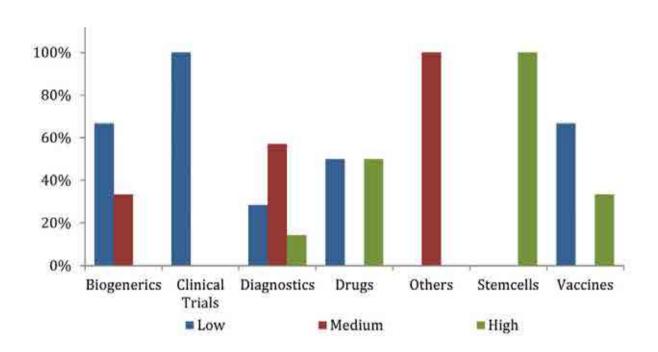




# IP Potential in Healthcare Programs

Healthcare Programs focused on drugs, stem cells, vaccines, and diagnostics are better prospects for IP generation.

#### Healthcare Programs-IP Potential



Patenting of inventions used in genetic testing and stem cells is challenging and important. The development of drugs is costly for companies, and without intellectual property law protection, the formula for the drugs can be easily duplicated and the drugs can be synthesized at a cheaper cost.

Thus, intellectual properties laws often allow companies to monopolize the synthesis and sales of drugs. Healthcare programs focused on drugs, vaccines, and stem cells have greater chance to be IP protected. One patent application has already been filed for Rural Primary Care Diagnostic Device and a few more patents are expected to be filed.



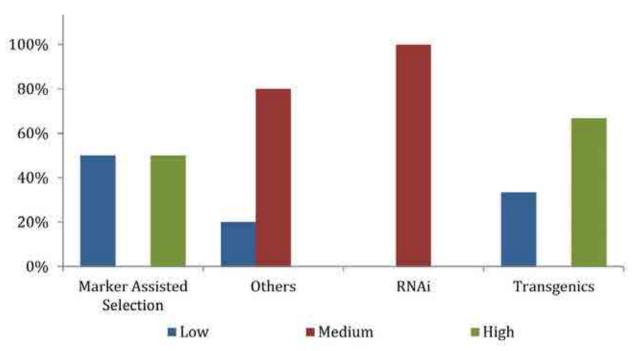




## IP Potential in Agriculture **Programs**

Agriculture Programs focused on Transgenics and Market Assisted Selection are the better prospects for IP generation.

#### Agriculture Programs -IP Potential



The law of Intellectual property might be seen as complex in Agriculture, but it is vital that it is accessible and understood by the public and private sector to compete in the global economy. Though some of the transgenic products have been accepted, there were major objections to them from some quarters. Efforts are being made from biotechnology for consumers to benefit in the form of a nutritional improvement. These techniques also allow improvements to be introduced in crop yields and farming tasks to be reduced, among other benefits. These aspects will all make future products increasingly competitive. Projects such as high yielding mustard varieties tolerant to abiotic and biotic stresses have the potential for IP generation.



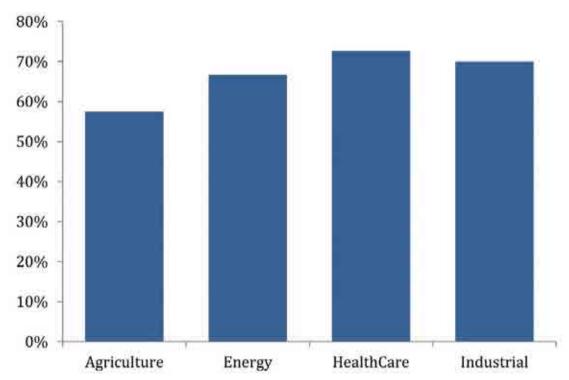




## **Progress of Projects**

Funded Programs across the Industries have achieved >50% completion, demonstrating a noteworthy progress.

### Percentage Project Completion by Industry



Project progress reported is compared with milestones committed during funding application to assess the percentage of completion. Measurable milestones are mandatory to ensure accountability and reassurances.

Accountability focus on the goal enable to measure whether the programs are headed in the right direction and help determine the progress to reach the milestones. Also, when navigating the chaos and uncertainty, well-laid plans, metrics and measurements can provide encouragement that programs are going the right way



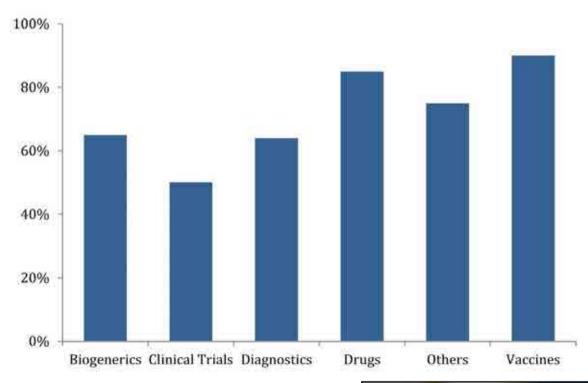




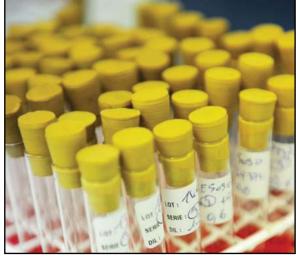
## Healthcare-Progress of Project

All segments under healthcare achieved completion of >40%, while programs focused on developing drugs were 85% completed.

#### Percentage Project Completion by Healthcare Programs



Healthcare Programs that have achieved >70% completion include projects on production of Nanoparticles, c-Met kinase inhibitors, Platinum Nano Particles, Ketoreductases, 15 valent Pneumococcal Polysaccharide, HPV Vaccine, microPCR, Software platform DXPhone, and Hepatotoxicity prediction platform.



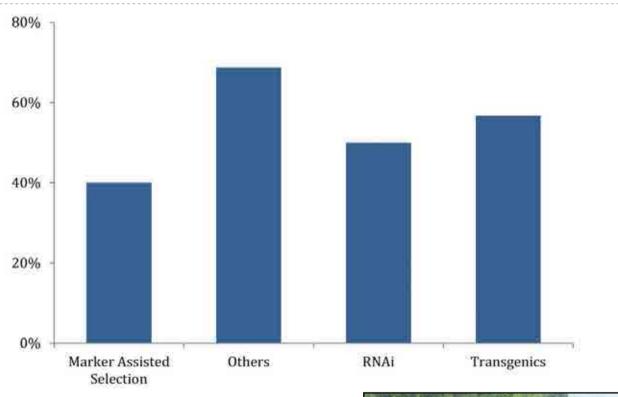




## Agriculture-Progress of Project

Funded Programs in RNAi, Marker Assisted Selection, and Transgenics, together achieved an average completion of 49%.

### Percentage Completion according to Agriculture Programs



Agriculture Programs that have achieved >70% completion include projects on stress tolerant rice, 'Herbicide & Stress tolerant' transgenic onion, and value addition including potential neutraceuticals



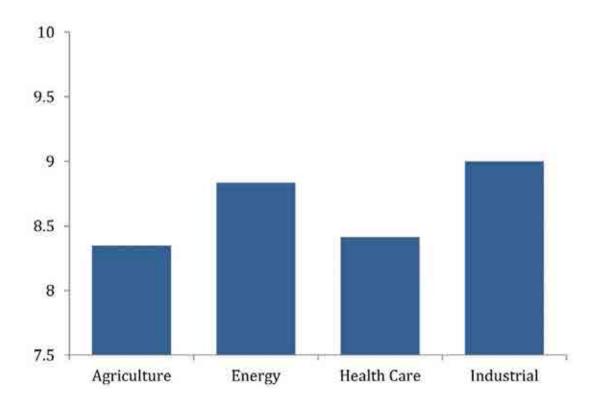




### Project Team-Self-Satisfaction

Funded programs across the industries have achieved an average self-satisfaction score of greater than 8/10.

### Industry-wise Average Self-Satisfaction Score



A team's drive to pass milepost, reach goals, and tally results are vital. This is particularly valuable where supervision is minimal, but results relative to time are important. Once a project is started, completion is a strong objective.

Self-satisfaction score is tied directly to completed achievements. It is quantified based on the response provided by the team from the funded companies.

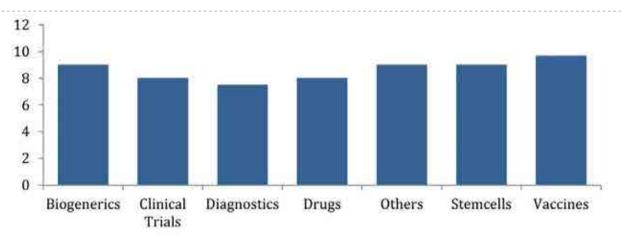




# Self-Satisfaction Score of Healthcare and Agriculture Programs

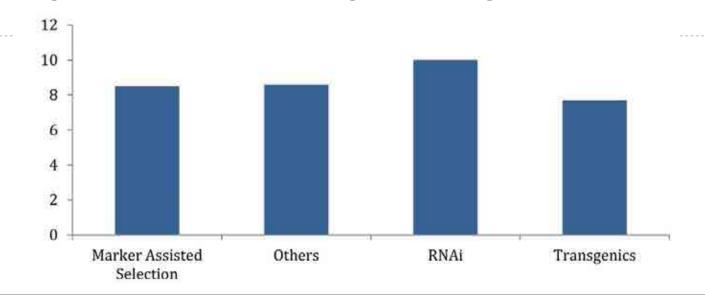
Average self-satisfaction score for all the segments of Healthcare excluding diagnostics was greater than 8/10.

Average Self-Satisfaction Score in Healthcare Programs



Average self-satisfaction score for all the segments of Agriculture excluding Transgenics was greater than 8/10.

Average Self-Satisfaction Score in Agriculture Programs



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