
birac
Ignite Innovate Incubate
Creating
Positive Impact

FOREWORD

Prof. K. VijayRaghavan
Secretary, DBT, GoI & Chairman, BIRAC

Science and innovation play a key role in advancing humanity and bringing prosperity to society. Prosperous societies invest in science and nurture the entrepreneurial energies that can harness the fruits of science in form of innovative products. These products provide solutions to myriad challenges- from alleviating human disease conditions to helping clean the environment and bringing nutritive food on the dining table.

Product and technology development takes time, involves huge sums of capital and is riddled with risks. The role of the Government, as a catalyst, to reduce some part of this risk is a policy instrument that has been used across the world. BIRAC was established with the sole intention to imbibe a spirit of innovation in the Indian biotech sector, invest in R&D with translational goals, support startups and SMEs in biotechnology to develop products that are truly transformative- that combine affordability with high quality. India is the 'living laboratory' to experiment this paradigm. The products developed in India would impact not only communities in India but across the world.

Success in the biotech product development endeavour in India, as exemplified in the products showcased in this report, highlight the fact that given an optimal environment, the Indian biotech industry can deliver highly innovative technologies and products that not only have a national relevance but global relevance as well. BIRAC has launched and spearheaded many national programmes such as BIG, SBIRI, BIPP and SPARSH that spur the Indian biotech enterprise to drive innovative R&D for productisation from testing their ideas to POC as well as taking it further in the product development funnel- validation, scale and commercialisation.

It is indeed a pleasure to see the innovative products which have been facilitated by BIRAC support- all of them will create visible and tangible impact. Further they indicate a salient feature i.e Indian Biotechnology has the inherent strength to successfully deliver the goals of "Make in India"and "Start-up India". I wish the Innovators and their teams all success in future endeavours.

PREAMBLE

Dr. Renu Swarup
Senior Adviser/Scientist 'H',
DBT, GoI &
Managing Director, BIRAC

Transitioning India into a product development and manufacturing nation, especially a 'Biotech Product Nation' has been one of the primary aims of 'Make in India' and 'Startup India' programmes that were launched in 2014 and 2016, respectively.

The core philosophy of Biotechnology Industry Research Assistance Council (BIRAC) is "to stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly start-ups and SMEs, for creation of affordable products to address the needs of the largest sections of society". This perfectly aligns with the two national programmes mentioned above.

The basic premise behind establishment of BIRAC in 2012, by the Department of Biotechnology, Govt. of India was to catalyse the transformation of the Indian biotechnology ecosystem. BIRAC has initiated several pioneering national programmes in pursuit of its mandate that aim to facilitate product development by Indian biotech companies and entrepreneurial individuals.

Our early stage programme, the Biotechnology Ignition Grant (BIG), plays an important role in helping innovative ideas reach the important proof-of-concept stage. Further impetus for product development comes from our dual contribution (PPP mode) funding programmes such as the Small Business Industry Research Initiative (SBIRI) and Biotechnology Industry Partnership Program (BIPP). While SBIRI provides grants for early to late stage validation, BIPP is designed to provide matching grants to highly risky projects for scaleup.

In the last few years, BIRAC has initiated several other programmes such as Social Innovation Program for Products Affordable and Relevant to Societal Health, or SPARSH (for social innovations), and Industry Innovation Programme on Medical Electronics(in medical electronics) in partnership with Ministry of Electronics & Information Technology, Govt. of India. BIRAC aims to launch, in the near future, several more programs such as Secondary Agriculture, Precision Agriculture and a Mission Programme in Biopharma. We are confident that these new programmes will give additional fillip to innovative product development.

BIRAC's programmes have already started to show results, especially in product and technology development which this report seeks to showcase. One defining feature of all the products featured here is that they have successfully interwoven high quality with affordability and have a significant potential to deliver maximum societal impact- the true measure of success of any innovative product, service or process.

Integrating innovation culture into national scientific enterprise can indeed bear superlative results- BIRAC's experiments in triggering this culture is reflected in this report.

Each of the product has a passionate team behind it that has risen to the challenge of delivering a best in class product by India, in India, for India and the world. We congratulate them for their efforts and wish them even more success in the future.

ACIX 100

Point of Care **Diagnostics**

Point-of-care (PoC) diagnostic technologies are really important in countries like India where 65% of the population resides in rural areas where access to quality healthcare is difficult.

Need of the hour is for developing testing solutions that are small, automated, rapid, providing panel-based testing, and, as precise as central lab results.

ACHIRA

Breakthrough

- Developed ACIX 100, a microfluidics platform based on polymer sensors embedded into a microfluidic chip, with tests performed using an automated fluorescence detection system.
- ACIX 100 enables precise metering and panel-based testing while the miniaturized form factor ensures that both size and costs of expensive reagents are under control.
- Able to generate quantitative, confirmatory results for gynaecology, vitamin and thyroid panel in 30-45 minutes.

BIRAC's Support

BIRAC has supported the company under its BIPP scheme since it began development work in 2014. Subsequently supported in setting up of pilot scale plant, in year 2015, under its BIG program.

Key Highlights

* Established pilot manufacturing facility for microfluidic cartridges in 2015.
* Panels of endocrine and fertility-linked tests have been developed and validated using 1000+ clinical samples.
* Installed with several pilot customers across Bangalore and also undergoing field validation with NABL accredited labs.
* Vendor base developed with local and international partners to make micro-fluidic chips.
* National Award for Indigenous Product Commercialization 2016.

PCR KIT FOR AQUACULTURE INDUSTRY

Saving **Shrimps**

Shrimps have emerged as an important constituent of world's seafood production. Asian countries like Taiwan, Indonesia, Thailand and India are global leaders in shrimp production. Shrimp farming involves intensive application of fertilizers and chemicals to boost productivity.

However, shrimp aquaculture has been dramatically affected by viral diseases often leading to huge loss of productivity and revenue. Preventing/controlling viral diseases is high on priorities of the shrimp industry.

Breakthrough

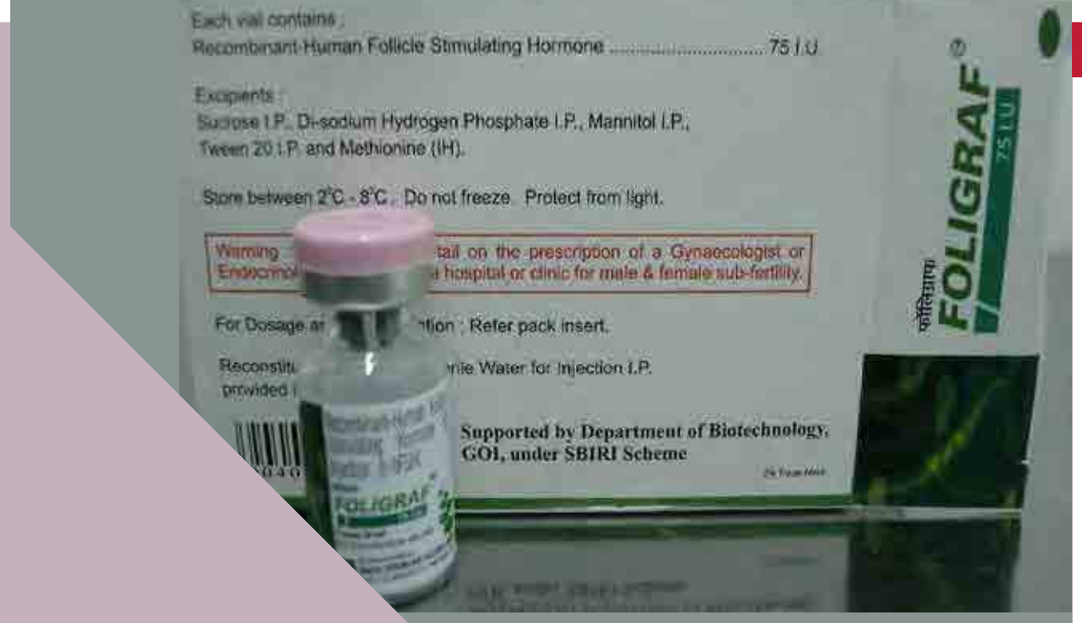
- Single tube nested PCR kits developed for four viruses infecting shrimps.
- Product well accepted by the customers.
- Kits successfully commercialised and rated better than imported products.
- Work underway to develop lateral flow and real time PCR based kits for WSSV.

BIRAC's Support

Support and mentoring under SBIRI scheme by BIRAC helped the company to grow in its initial days. The project has also nurtured many scientists.

Key Highlights

* Product commercialized in 2013.
* 51 Kits already sold to 10 users.
* 8000 reactions worth Rs. 23 lakhs in revenue already sold.
* Reduced dependence on costly imported kits.
* BIRAC Innovator Award in 2013.



Recombinant **FSH**

Infertility is an increasingly common medical problem. It is largely due to life style changes resulting in stress, obesity and medical disorders such as diabetes. In India, about 45 percent of couples face infertility problems. FSH (Follicle Stimulating Hormone) therapy is used to treat fertility disorders in women in India. Recombinant FSH has several inherent advantages over the urine derived product. Till recently, recombinant FSH was available to Indian patients only as an imported product. This made it unaffordable to many patients suffering from infertility.

FOLIGRAF

Bharat Serums & Vaccines Ltd.

Breakthrough

- First indigenous recombinant FSH developed with recombinant cell lines that mitigate the risks associated with urine derived products.
- Reduced costs by replacing high priced imported products.
- Launched under the brand name Foligraf® in September 2008, after DCGI approvals.
- Efforts on to improve delivery systems for the product to keep up with the current trends in improving patient compliance.

BIRAC's Support

Support under SBIRI helped to scale up the production of recombinant FSH derived from CHO Cell-line and to clinically prove the safety and efficacy of the indigenously developed recombinant FSH vis-à-vis the commercially available product.

Key Highlights

* First indigenous FSH developed and marketed in India.
* BSV's technology obviates the use of animal derived sera thus making the product safer.
* BSV has introduced delivery platforms and is now working on other devices to keep up with the market requirements and improve patient compliance.

Disease **Diagnosis**

Infectious diseases are a major health care challenge that continues to test the limits of modern science. Developing countries suffer disproportionately from infectious diseases due to environmental, socio-economic and demographic factors.

Low cost and widely available diagnostics are critical for achieving disease control in a country like India. However, currently available tests have very poor sensitivity and cannot detect infection at an early-stage. Sensitive molecular tests are a need of the hour.

PoC DIAGNOSTIC

bigtec Labs
Enabling better Medicine

Breakthrough

- A low-cost, battery-operated, portable, rugged, easy-to-use and affordable disease detection system developed for Malaria, Dengue and Typhoid.
- Platform can be used to detect a host of diseases at an early stage at the point of care.
- Aimed at bringing high-end disease diagnostics technology to the grass roots marking a paradigm shift in health care access.
- Developed for resource-limited settings like India, microPCR can test a sample in less than 60 minutes and at a fraction of normal costs.

BIRAC's Support

PoC diagnostics for Malaria, Dengue & Typhoid was developed with support under the BIPP initiative.

Key Highlights

* System is now commercially available.
* Significant reduction in cost and time gap in disease diagnosis.
* Tests launched for diagnosis of Tuberculosis, Drug Resistant TB, Hepatitis B, Malaria, Dengue, Chikungunya, H1N1 and Typhoid.
* Simplified sample processing with minimal user training.
* The system is now commercially available through Molbio Diagnostics, a JV between Bigtec and the Tulip Group – India's largest diagnostics company.

JEEV

Fighting **Encephalitis**

Japanese Encephalitis (JE) is most prevalent in Southern & Eastern Asia and the Pacific regions. Responsible for about 15,000 deaths annually, JE majorly affects children below the age of 10 years. JE is fatal for approximately 30% of those infected while leaving half of the survivors with permanent brain damage. There is no specific treatment currently available for JE. Vaccination is presently the most effective weapon against the disease.

Biological E. Limited
Celebrating Life Every Day

Breakthrough

- Developed JEEV, first indigenous, cost effective and second generation vaccine against JE.
- JEEV is inactivated JE vaccine based on SA 14-14-2 strain and produced on vero cells without any preservatives.
- Manufacturing commenced in Year 2011.
- JEEV was the first JE vaccine globally to receive WHO pre-qualification approval in 2013.
- Envisaging introduction of inactivated JE vaccines in the National Immunization Program.

BIRAC's Support

Phase III clinical study of JE vaccine has been funded under the BIPP program to the extent of INR 5.73 crores. This played a critical role in successful completion of the Phase III study and securing approvals from India NRA.

Key Highlights

* Launched in Year 2011 after obtaining all approvals under the trade name JEEV.
* cGMP facilities with a capacity of 10 million doses established.
* Launched in the Indian private market in 2012. Almost 5 Lac doses distributed.
* Secured WHO PQ approval. JEEV has already received marketing approval in 2 countries. Other registrations in process.
* Employment to ~250 professionals.

Monitoring **Arrhythmia**

Approximately 45 million individuals in India are considered at risk of a stroke. In fact, India has developed an epidemic rate of CVD, accounting for 60% of the world's cardiac disease burden. The predilection for heart ailments, coupled with low levels of good cholesterol and traditional cardiovascular risk factors such as obesity and hypertension has made urban India the capital of CVD. The need of the hour is a simple to use device that can monitor arrhythmia in real time without any dependency on internet and present the report to its users for planning appropriate action.

Breakthrough

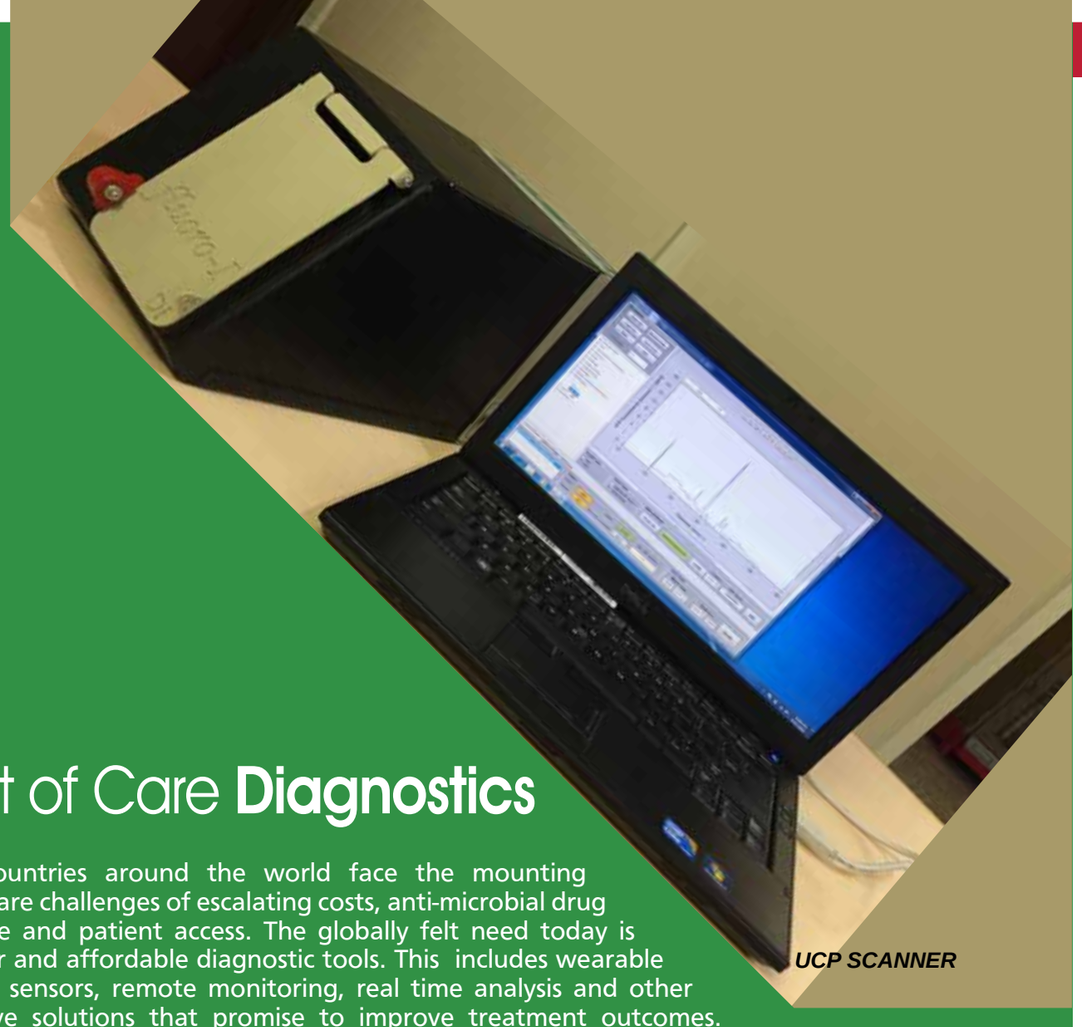
- Cardea Labs developed miRHYTHM - an ECG system which allows any Android phone to plot a medical grade high definition ECG even in the noisiest of environment.
- The algorithm classifies the ECG data into Normal and Arrhythmia in real time without any internet dependencies.
- The system is developed in collaboration with senior cardiologists from AIIMS, New Delhi.
- The system generates a file whenever an arrhythmia occurs.

BIRAC's Support

BIRAC supported development of the system through its SBIRI scheme contributing 80% of the funds required for its development.

Key Highlights

* It displays a real-time noise-free ECG signal and an instantaneous heart rate with a 'beep' sound for every peak.
* Performs a real time beat-to-beat arrhythmia detection and classification.
* Automated arrhythmia data saving and report generation.
* Works as a replacement to expensive "Event Recorders".



UCP SCANNER

Point of Care **Diagnostics**

Many countries around the world face the mounting healthecare challenges of escalating costs, anti-microbial drug resistance and patient access. The globally felt need today is for faster and affordable diagnostic tools. This includes wearable devices, sensors, remote monitoring, real time analysis and other innovative solutions that promise to improve treatment outcomes. Point-of-Care and rapid testing is cost effective indeed. However, healthcare systems need to adapt to take advantage of these possibilities and implement them whereever it makes sense.

DesignInnova
Innovation in design

Breakthrough

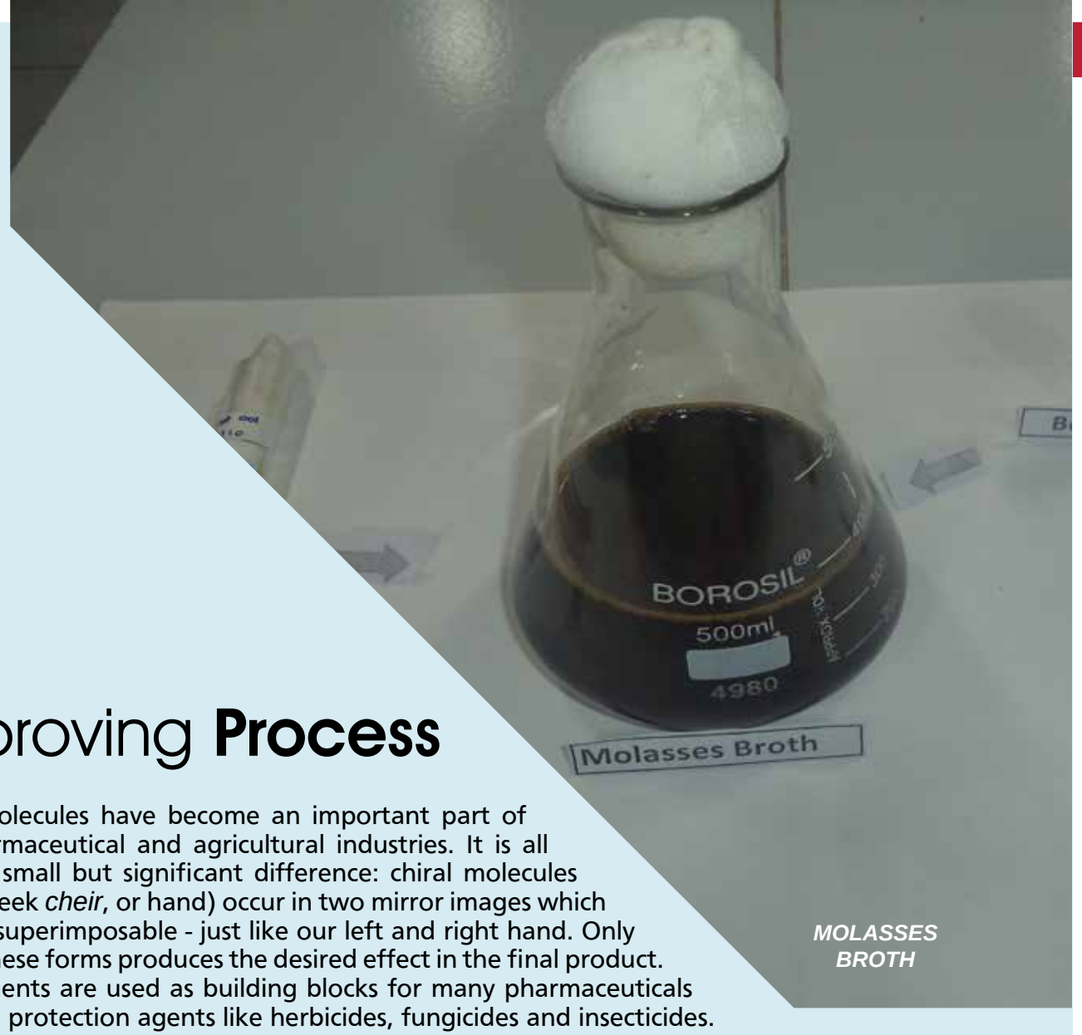
- DesignInnova in partnership with ICGEB, DBT and Turku (Finland) has developed an innovative, indigenous, affordable 'plug-and-play' point-of-care platforms capable of running tests from different developers.
- Robust solid-state design uses a novel up-converting phosphor technology technique as a detection system.
- Suitable for Point-of-Care diagnostics using standard lateral flow cassette format and adaptable to common diagnostic formats, ensuring an optimum design which is affordable & portable.
- Easy to handle, with features such as one minute scanning and easy readability.

BIRAC's Support

The project received funding through BIPP scheme under BIRAC which helped the company to steer ahead of the financial glitches.

Key Highlights

* Showcase of product at India-U.S. Startup Connect in the Silicon Valley San Jose, US on 27th September 2015.
* Holds a bright future towards PoC applications and reduction in cost of diagnosis.
* Product promises a great impact on a faster diagnostics of many diseases.



MOLASSES BROTH

Improving **Process**

Chiral molecules have become an important part of the pharmaceutical and agricultural industries. It is all about a small but significant difference: chiral molecules (from Greek *cheir*, or hand) occur in two mirror images which are non-superimposable - just like our left and right hand. Only one of these forms produces the desired effect in the final product. Chiral agents are used as building blocks for many pharmaceuticals and crop protection agents like herbicides, fungicides and insecticides.

Breakthrough

- The process improvement work evolved from making processes consistent, to making it more efficient.
- Technology adapted to commercial feedstock, bio-transformation optimized and scaled up.
- New process is greener, more efficient and has a modern technology at heart.
- The chiral intermediate goes into production of two major API's, used for preparation of cough and cold formulations, and into production of a chiral auxiliary for an anti-HIV API.

BIRAC's Support

BIRAC supported the project under its SBIRI scheme in a project titled "Demonstration of conversion of Benzaldehyde to Phenylacetylcarbinol (R-PAC) with improved efficiency on a scale of 4 KL".

Key Highlights

* New world beater technology developed nearly 40 years after the basic technology was first used in India.
* 28% improvement in throughput,~4% in biotransformation efficiency.
* 40% reduction in feedstock requirement, 25% drop in effluent volume.
* Project on road to commercialization after regulatory clearances.

Reinventing **BioGas**

Processing available organic feedstocks, such as urban organic waste, cow manure, poultry manure and agricultural residues for biogas can achieve twin objectives of solid waste management (SWM) as well as clean energy. Legacy technological gaps have not allowed biogas to achieve its full potential, especially in urban areas which continue to grapple with serious SWM challenges. Compact and reliable biogas plants can go a long way and also make a strong business sense.

Breakthrough

- Developed BioUrja, a state - of - the-art feedstock-agnostic anaerobic, zero water foot print digester.
- Expected to generate over 12 lakh kg of clean LPG equivalent and mitigate over 20,000 tons of GHGs by 2017.
- Generates 1.5-2x more energy (methane) than conventional plants with an uptime of >99%.
- Digestate converted into a proprietary liquid organic fertilizer (Organomagic).
- Cost competitive for bulk waste generators such as hotels, office complexes and educational institutions.

BIRAC's Support

The initial support for developing this technology was given by BIRAC through it's Biotechnology Ignition Grant (BIG).

Key Highlights

* Over 35 projects already functional in India, Bangladesh and the US with clients including leading corporates.
* Indigenous technology with 3 patents already, and 2 more expected.

Healing **Burns**

In India, more than 10 lakh people suffer moderately or severe burn injuries every year. The staggering mortality rate of more than 60% in body burn cases is often attributable to non-availability of proper dressings for burn wounds.

Silk protien, being "biocompatible" and "non-mammalian", offers a great potential for development of a breathable, non-toxic bilaminate (with hydrophobic and hydrophilic sides) wound dresssing material for burn cases to reduce patient trauma and hasten recovery processs.

FIBROHEAL

Breakthrough

- Developed "Fibroheal" a silk based dressing for burn wounds.
- Fibroheal utilizes the "Epidermal Growth Factor" kind of activity of silk protein to create a bio-modified active wound dressing environment. Ensures 40-45% faster healing than traditional method of dressing.
- Dressing comes in four standard sizes and can also be made to order. This is especially useful when treating burn victims, skin grafts, donor sites and caesarean sections.

BIRAC's Support

The project was supported by BIRAC in two phases under its SBIRI scheme. First for for proof-of- concept and later for scale up and validation studies.

Key Highlights

* Launched in 2014.
* About 4000 units sold.
* Targeted customers: Advanced wound care; Hospital with wound therapy and plastic surgery.
* Reduction in patient trauma and recovery time.
* Best Upcoming Innovator Award by FKCCI, Bengaluru in 2014.
* Employment to ~15 technical professionals.

Producing **Ethanol**

Ethanol is an alcohol-based, clean, affordable and low-carbon biofuel, emerged as a leading renewable fuel source.

Given the critical dependence on cane molasses as the main raw material for generating ethanol, and the need to free itself from the vagaries of the sugar cane industry leading to erratic availability of cane molasses, IGL took up the initiative to search for atechnology to produce cellulosic ethanol to ensure seamless availability of alcohol.

BIO-ETHANOL PLANT

INDIA GLYCOLS LIMITED

Breakthrough

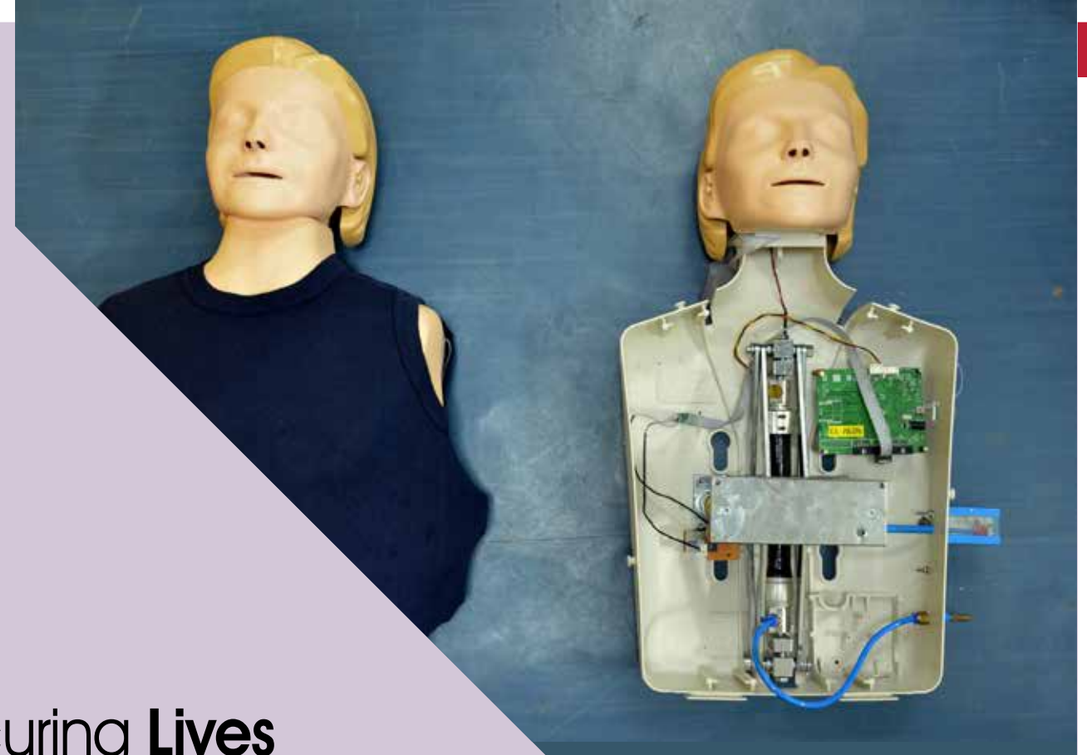
- India Glycols Ltd. (IGL) is one of the largest ethanol producer and consumer in the country.
- DBT-ICT Centre for Energy Biosciences, set up by DBT as country's first dedicated Centre of Excellence for development of biofuel technologies, developed a novel 2nd generation (2G) ethanol technology which converts any agricultural lignocellulosic waste into sugars and ethanol.
- IGL collaborated with the DBT-ICT Centre and launched an initiative for setting up a pilot and then a demo-plant.
- The pilot scale validation of the technology in 2012 at 1 ton/day scale was followed by the 10 ton/day demonstration plant (inaugurated in 2016) as India's first Second Generation (2G) Ethanol Plant.

BIRAC's Support

The pilot and the demo plant received support from BIRAC's BIPP scheme.

Key Highlights

* Largest ethanol producer and consumer in the country.
* 10 ton/day demonstration plant inaugurated on 22nd April 2016 by Dr. Harsh Vardhan, Minister of Science & Technology and Earth Sciences as India's first Second Generation (2G) Ethanol Plant.
* Emerged as the leading manufacturer of green technology based bulk, specialty and performance chemicals, natural gums, spirits, industrial gases, sugars and nutraceuticals.
* Example of successful translation of academic research into a commercially viable technology.



CPR MANNEQUIN

Securing **Lives**

Cardiovascular Disease (CVD) has acquired epidemic proportions in South Asia. Sudden heart attack with cardiac arrest is a common manifestation of untreated CVD. Eight minutes of untreated cardiac arrest can lead to irreversible brain damage. Victims of cardiac arrest require immediate Cardiopulmonary Resuscitation (CPR) to maintain blood supply to vital organs. Training of medical/paramedical staff and the general public in CPR techniques can greatly reduce morbidity and mortality from CVD.

Cardio Pulmonary Resuscitation (CPR) is a life-saving skill. However, it is not commonly taught to non-medical personnel in India.

MERKEL HAPTIC SYSTEMS

Technology of Touch
Committed to "Made in India"

Breakthrough

- Developed first ever Non-Linear CPR simulator in the world for use in training and periodic retraining to retain CPR skills.
- Full-body size, in adult clothing the mannequin simulates behavior of the real human chest.
- Available with interactive animation and in regional languages to enhance reach.
- Only commercially available mannequin to simulate human behavior.
- Multiple sets of non-linear technology give a feel for performing CPR on individuals with a wide variety of chest compliance and ventilation parameters.

BIRAC's Support

BIRAC has not only funded the project under its BIPP scheme but has also provided networking with the leading health-care providers in India for successfully commercialising the product.

Key Highlights

* First ever Non-Linear CPR Simulator in the world.
* First ever CPR Simulator designed in India.
* Hi-Fidelity (realistic) and affordable.
* Potential for export to the world market
* Mannequins customised for Indian populations.
* Great asset for training retraining of first responders in hazard/disaster/ conflict situations.
* Employment to ~20 technical professionals.

ONCOSCAN

Modernising **Pathology**

Radiology has gone digital at a phenomenal speed. Pathology needs to follow suit. Digital pathology is the process of converting glass slides into high resolution,whole-slide digital images that can be viewed, managed, analysed and interpreted by a pathologist with the aid of a computer (instead of a microscope) using a digital pathology work flow management system.

Breakthrough

- Developed OncoScan, an automated, affordable and compact whole slide scanner.
- A holistic digital pathology solution, OncoScan can revolutionize the process of pathology reporting.
- System scans glass slides to produce high resolution digital images with multiple game-changing benefits over the conventional microscope.
- Wide array of image analysis algorithms integrated with the system to facilitate mining and quantification of information from digital images.

BIRAC's Support

BIRAC supported the project under its BIPP scheme.

Key Highlights

* Automated and affordable digital whole slide scanner.
* Tele-pathology infrastructure to cater to needs of rural population.
* Enhanced accuracy and reduced subjectivity.
* System installed at various centers, including universities and laboratories abroad.

NITRIFYING BIOREACTOR

Clean **Aquaculture**

Aquaculture caters to over 60% of the world's demand for fish and is a rapidly growing sector. However, aquaculture is also associated with severe nutrient pollution. If not managed effectively, this can not only have a harmful impact on the environment but also seriously undermine fish quality.

Nitrifying bioreactors are self-sustaining systems that remove ammonia, nitrites and nitrates produced in aquaculture tanks and help to maintain optimal water conditions leading to reduced pollution, and a healthier catch.

Breakthrough

- Developed commercial models of nitrifying bioreactors (Stringed Bed Suspended Bioreactor-SBSBR and Packed Bed Bioreactor-PBBR) for establishment of Recirculating Aquaculture Systems (RAS).
- Systems developed based on patented technology from National Centre for Aquatic Animal Health, Cochin University of Science and Technology.
- Bioreactors are successfully functioning at various locations in the country.

BIRAC's Support

SBIRI funds by BIRAC helped to develop the Stringed Bed Suspended Bioreactor Packed Bed Bioreactor and to subsequently undertake field validation of these bioreactors at multiple sites. This enhanced the visibility of the company and helped to establish the business successfully.

Key Highlights

* Product launched in year 2015.
* More than 60 systems installed.
* Employment to ~ 6 professionals.
* Patented in India.

MAXIO

Tumor **Ablation**

Tumor ablation is an image guided minimally invasive procedure where Computed Tomography, Ultrasound or Magnetic Resonance Imaging is used to guide and position a needle probe into the tumor. then attached to a generator which “burns” or “freezes” the cancer.

Visualisation, planning and needle placement are key to successful tumor ablation.

Perfint

Breakthrough

- Developed MAXIO, an integrated planning, navigation and robotic targeting system for CT-guided tumour ablation.
- Combines tumour visualisation and procedure planning with robotic targeting to help clinicians achieve consistent procedure quality.
- Simplifies complex procedures while ensuring a high degree of accuracy.
- Will make it easy for large scale adoption of tumour ablation by reducing cost of oncologial ablation procedures.

BIRAC’s Support

MAXIO was developed through support under the BIPP scheme and meets the best-in-class standards globally.

Key Highlights

* Launched in year 2012 targeting teaching hospitals Oncology/Cancer focused Institutions.
* Over 9000 patients across the world benefited through diagnostic, therapeutic and pain management procedures.
* More than 30 units already sold.
* Exported to China, Vietnam, Turkey, Kuwait, Germany, Spain, Indonesia, Malaysia and Australia.
* Employment for 15 professional/ support staff.

Restoring **Vision**

Ability to see is a simple joy. More than 300 million individuals across the world suffer from visual impairments that, unless detected and treated early, could lead to permanent blindness.

Prohibitive cost and complexity of high quality imaging devices hinders early, decentralized and universal screening.

FUNDUS-ON-PHONE

remidio
simply innovate!

Breakthrough

- First high quality, smartphone based eye imaging device launched in 2014.
- World's first non-mydriatic (not requiring pupil dilation), high quality imaging device launched in 2015.
- World's first wide-angle retinal imaging system in support of Diabetic Retinopathy screening launched in 2016.
- Technologies developed have resulted in CE marked and FDA 510k registered products.
- Manufacturing at an ISO certified facility in Bangalore, India.
- Awarded "Affordable Healthcare in India Award" by the Wellcome Trust, UK.

BIRAC's Support

BIRAC supported Remidio's efforts in development of technology for large field of view retinal imaging under SBIRI program.

Key Highlights

* 300 systems already installed in India, 25 outside India.
* Nearly 750000 patients benefitted.
* Exports commenced to several countries such as Australia, Singapore and SE Asia.
* Employment to ~30 technical professionals.

Farm **Boost**

Agricultural biostimulants include diverse formulations of compounds, substances and micro-organisms that are applied to plants or soils to improve crop vigour, yields, quality and tolerance of abiotic stresses. Increased crop yield contributes to farmer's prosperity and national food security. Crop biostimulation is thus complementary to crop nutrition and crop protection.

Breakthrough

- Sea6 demonstrated technical feasibility of producing Biofuel from seaweed in year 2014.
- Developed and launched an agricultural biostimulant, Jingo in year 2015.
- Biostimulants are a new class of natural products (different from fertilizer or pesticides) which can stimulate plant growth and increase crop yields by as much as 20%.
- Two new products, Jingo-NXG and Agrogain launched in year 2016.

BIRAC's Support

Laboratory space and office space were made available with the help of supportive faculty of the DBT. This foundational help was very crucial for Sea6 in its early years. They received their first funding from BIRAC under the BIPP scheme and thereafter under the BIG scheme.

Key Highlights

* Jingo/ JingoNxg / Agrogain have helped more than 100,000 farmers to optimise crop yields.
* Rs. 2.0 crores revenue generated in year 2015-16.
* Employment to ~30 technical professionals.
* Assisting the nation to move towards improved farm prosperity and food security.
* Four patents applied.

Unique Polymer **Technology**

Medicines produce their effect in a patients' body by interacting with specific biomolecules which are described as 'drug-targets'. However, about 12% or more of marketed medicines produce their effect through unknown or unidentified 'drug-targets'. If these drug-targets could be identified it will significantly add to the understanding about the mechanism of action of these drugs. This in turn will directly help in discovering and developing new medicines.

TARGET IDENTIFICATION TECHNOLOGY

Shantani™

Breakthrough

- Developed a robust Drug-Target Identification Technology Platform.
- Unique Polymer Technology (UPT), which can reduce the drug-target identification efforts to a month from 3 to 6 months.
- Platform is being used for drug target identification, toxicity profiling of new lead-molecules and drug repurposing.
- Development of Type-2-diabetes drug discovery program.
- Poised for pre-clinical testing of a molecule for its anti-diabetic potential.

BIRAC's Support

Received SBIRI grant for technology substantiation and identification of a new drug target for treating Type-2-Diabetes.

Key Highlights

* Launched the technology in 2013.
* Wide client base spanning from India to global big bio-pharma, chemical and FMCG companies located in North America and Europe.
* Type-2 Diabetes drug discovery program at pre-IND stage with IND enabling studies planned.
* 3 international patents filed.

Restored **Hearing**

800,000 hearing impaired babies are born every year all over the world, of which 100,000 are in India and 90% in developing countries. It has been recommended by experts that hearing loss in infants be identified, and when possible treated, prior to attaining 6 months of age. Children identified with hearing loss within 6 months of birth have a better chance of developing skills equivalent to their peers by the time they enter the kindergarten.

SOHUM HEARING SCREENER

sohum
INNOVATION LAB

Breakthrough

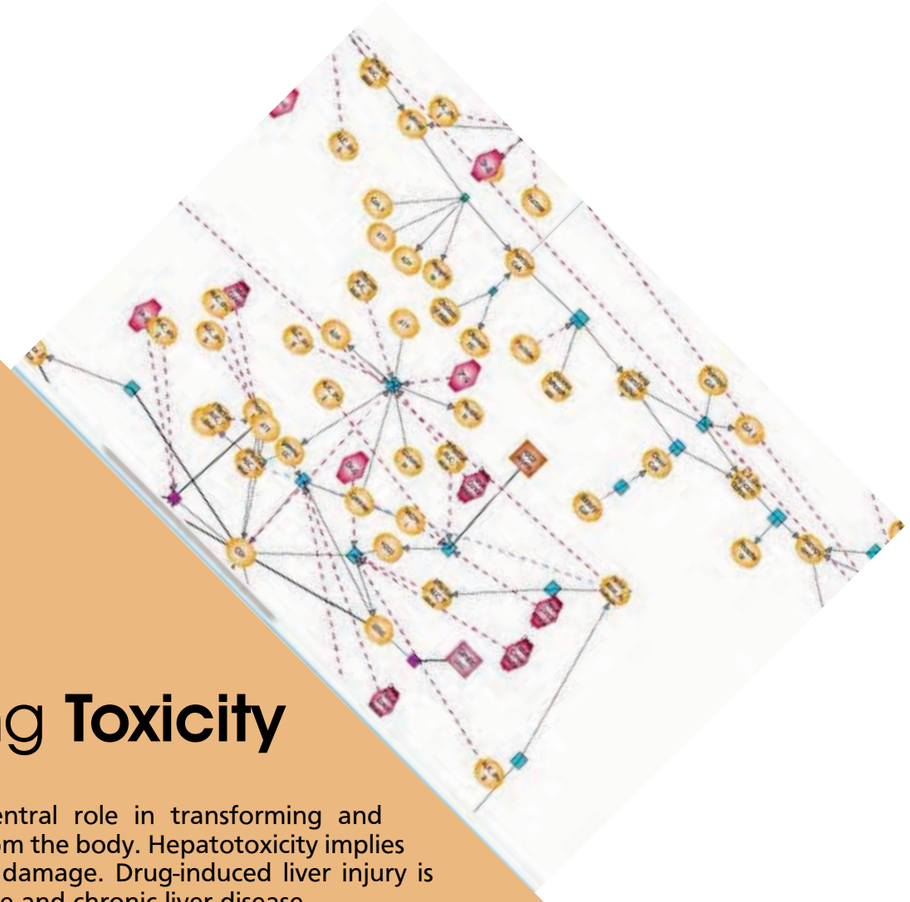
- Developed SOHUM, a highly proprietary, non-invasive, safe medical device to screen neonates for hearing impairment with high sensitivity and specificity.
- Specially designed for mass screening of newborns in resource constrained settings.
- SOHUM uses gold standard Brainstem Auditory Evoked Response (BAER) technology with an easy-to-use interface.
- SOHUM will serve a market of 20000 pediatricians, 17000 ENT specialists and about 40000 maternity and child care institutes.

BIRAC's Support

The project has been awarded funds by Department of Biotechnology, Govt. of India. it is also a recipient of support under BIRAC's BIG program.

Key Highlights

* Launched the product in 2016.
* 5 clinics in India and 2 clinics in Central America already using the Sohum device.
* Provides early screening, that leads to timely treatment and rehabilitation, as well as savings in healthcare expenses to the system.
* Reduced test duration ideal for mass screening.
* Employment to ~8 professionals.



HEPATOTOXICITY PREDICTION PLATFORM

Predicting **Toxicity**

The liver plays a central role in transforming and clearing chemicals from the body. Hepatotoxicity implies chemical-driven liver damage. Drug-induced liver injury is often a cause of acute and chronic liver disease.

There is a need for drug screening assays capable of detecting hepato-toxicity early in the drug development process.

Early and reliable prediction of hepatotoxicity of a drug can help late stage clinical failures or post-marketing withdrawal due to toxicity (mainly hepato-toxicity), saving huge resources in terms of time, and money.

strand

Breakthrough

- Developed a novel systems approach to model biological pathways in the liver.
- A detailed predictive platform capable of predicting Drug Induced Liver Injury.
- Approach helps in replacing/ reducing animal usage but also a major knowledge addition for toxicity prediction.
- Primarily designed to predict hepatotoxicity in the liver, platform can also be used for other organs such as the kidney and the heart.

BIRAC's Support

BIPP fund helped to set up a state-of-the-art laboratory and retaining a set of 5 scientists to work on the project. Under BIPP project, 50 compounds ran as a validation set through the predictive platform.

Key Highlights

* Technology Platform launched in 2014.
* Platform is already being used by several established multi-national pharmaceutical companies.
* Platform acquired by **Syngene International** for use in conjunction with other services they provide.
* Employment to ~20 professionals.
* 2 International patents.

AnMBR

Swatchh **Solution**

Treating domestic and industrial effluents to generate recyclable quality water is necessary to mitigate water scarcity and river pollution. High operational cost of conventional aeration technologies makes it difficult.

Anaerobic treatment systems have a good potential. However, their sensitivity to climatic changes frequently makes it difficult to achieve discharge norms. Anaerobic Membrane Bioreactor (AnMBR) offers a way out.

Breakthrough

- Developed Anaerobic Membrane Bioreactor technology at laboratory scale and bench scale operations for wastewater treatment.
- Results achieved comparable with aerobic membrane bioreactors with treated effluent meeting all discharge norms.
- Technology has the potential to be a sustainable and green solution for treatment of domestic and industrial effluent.

BIRAC's Support

The project was partially funded and also mentored/monitored under BIRAC's BIPP program.

Key Highlights

* Market targeted: Industrial Wastewater Treatment.
* This technology offers a sustainable and green solution for treatment of domestic and industrial effluents.
* Product will be launched soon.
* Best Innovator Award Winner - 2013 from BIRAC.
* Patent filed in year 2014.

Treating **Cancer**

Photodynamic Therapy (PDT) uses light and photosensitizing chemical, along with molecular oxygen to elicit cell death. It is used in treating acne and a wide range of other medical conditions, including several types of cancers.

PDT laser equipment till recently were imported at prohibitive costs. As India pursues aggressive health care goals, development of affordable medical equipment and machinery is a strategic and tactical imperative.

PHOTODYNAMIC THERAPY LASER SYSTEM

Breakthrough

- Developed an indigenous and affordable PDT laser system for cancer treatment.
- No compromise on quality as compared to imported alternatives.
- First PDT laser product meant for cancer treatment made by an Indian company.
- System lays great emphasis on quality and safety with reliable in built and external safety features.
- Ensures hospital database connectivity through WI-FI connection.

BIRAC's Support

BIRAC supported development of product under its BIPP scheme.

Key Highlights

* Launched product in year 2015.
* Reduced size, weight as well as the cost of the product.
* Two units already sold.
* Won Gold Medal in DST- Lockheed Martin IIGP-2013 and Udyog Bharti Award.
* Employment to 56 professional and support staff.

Treating **Hyperuricemia**

Patients undergoing anti-cancer therapy are at a higher risk of developing elevated plasma levels of uric acid. This can give rise to metabolic disorders and life threatening complications such as hyperuricemia.

The drugs to lower uric acid levels are highly indispensable. Urate Oxidase enzyme is considered as the most promising therapeutic candidate for reducing the uric acid levels.

RASBELON

virchow BIOTECH PRIVATE LIMITED

Breakthrough

- Developed RASBURICASE (Recombinant Urate oxidase) a biosimilar useful in treating conditions associated with initial management for plasma uric acid levels in pediatric and adult cancer patients.
- First biosimilar product approved in India.
- Cost effective agent for tumor lysis syndrome.

BIRAC's Support

Support from BIRAC helped in developing the technology for the Urate Oxidase production while also creating a platform to develop other biosimilar products. Due to BIRAC funding, the project also received positive response from the medical doctors during the Urate oxidase clinical trials.

Key Highlights

* Launched in India in year 2014.
* Reduced dependence on imports and lower treatment costs.
* More than 15000 units already sold.
* Employment to ~ 50 professionals/ support staff.

Affigenix Biosolutions

Monitor **Trypsin**

Trypsin is widely used in various biological processes such as Insulin manufacturing to cleave peptide linkers from pro-drug C peptide removal from Proinsulin and activation of vaccine viruses. Residual trypsin analysis is used during downstream processing.
Affigenix has developed anti-trypsin antibodies and immunoassay which will enable drug companies to monitor the clearance of trypsin used in the downstream processing of Biologics and Biosimilars. Received BIG funding.

Amar Immunodiagnostics

GMO **Testing**

Seed companies, as they develop GM seeds, need simple tests to identify plants or seeds that have been genetically modified.

Amar Immunodiagnostics has developed ELISA based test kits that detect newly introduced gene products using in-house monoclonal antibodies. Launched in year 2010, over 40 million tests have been sold till date. Kits are also being exported to many countries including USA, Belgium and South Africa. Received BIPP funding.

Alfa Corpuscles

Safety **Syringe**

Multiple, avoidable and unsafe injection practices can lead to large scale transmission of blood-borne viruses among patients, health-care providers and the community at large.

Alfa Corpuscles has developed a low cost indigenous single use safety syringe with passive spring actuated needle stick injury and reuse prevention mechanism. Received SBIRI funding.

Aumgene Biosciences

Lipase **Enzyme**

Aumgene Biosciences has focused on developing technologies for production of lipase enzymes for use by textile & leather industry. Having successfully increased the volumetric productivity and shelf life stability of lipase to come at par with imports, it is now in talks with prominent manufacturers of detergents and leather chemicals in India & other countries to encourage use of its lipase enzmye in their product formulations. Received SBIRI funding.

Bharat Biotech International

Rotavirus **Vaccine**

Rotavirus Vaccine, branded as ROTAVAC® was launched by Shri Narendra Modi, Hon'ble Prime Minister in March 2015. Priced for 'a dollar, a dose' for the Universal Immunization Programme (UIP) it is currently being supplied to Andhra Pradesh, Odisha, Haryana and Himachal Pradesh under the UIP. Other states will be supplied in a phased manner. The company has already filed patents in USPTO, European Patent Office, China and other countries, besides India. Received SBIRI & BIPP funding.

Cardea Labs

miBEAT

Cardea has developed "mBeat", an ICT based technology platform, in collaboration with faculty and staff from Harvard University, Stanford University, DSIR - Govt of India, DBT-Govt of India, IIT Delhi and AIIMS-New Delhi. miBEAT is an educational tool that enables engineering students to learn and implement necessary concepts required to design their own wireless, portable, high definition, medical-grade data acquisition system over smart phones and PCs. Received SBIRI funding.

Bhat Biotech India

Malaria **Detection**

Bhat Biotech has developed MALERISCAN®, an immunochromatographic based assay for the qualitative detection of Plasmodium lactate dehydrogenase (pLDH) specific to Malaria Pv & Pf antigens specific to Pf & Pv. in human whole blood. Received SBIRI funding.

Cellzyme Biotech

Immobilised **Enzymes**

Cellzyme Biotech has developed a green manufacturing process using an engineered enzyme. The product (enzyme) and the process can be used for the large-scale commercial manufacturing of cephalosporin antibiotics. The technology allows for manufacturing process to be executed at 26°C rather than -60°C and helps reduce cost and environmental impact. Recipient of various national and international awards, the product will be commercialized by year 2017. Received BIG funding.

Codon Biosciences

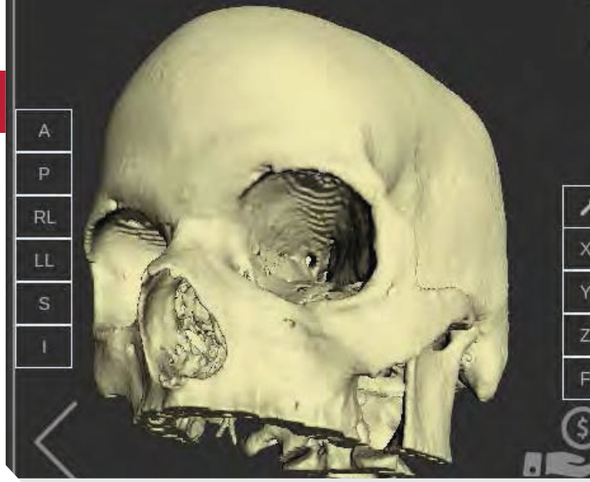
Mango **Wine**

Codon Biosciences has developed wine made from Alphonso mango and has set up a pilot production facility with a target of 5000 liters for the next six months. The company plans to focus on product branding and creating awareness about fruit wines in the state of Goa. The wine would be sold under the brand name *"Pomar de frutas"*, which means "Fruit Orchard" in Portuguese. The Alphonso mango wine would be available in Goa as an off-dry variant by December, 2016. Received BIG funding.

Df3D Creation

3D **Printing**

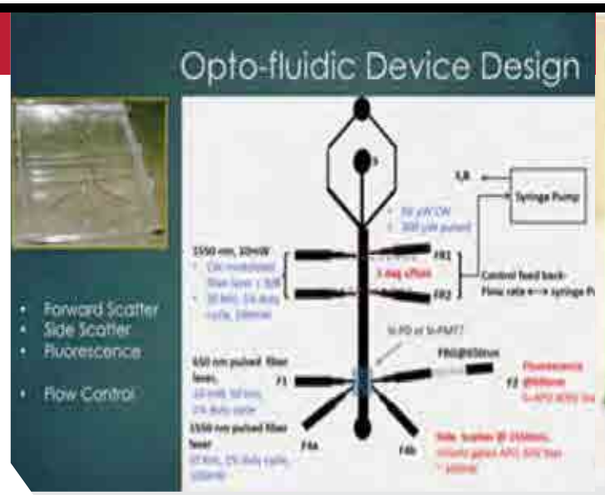
Oral cancer patients often require surgery for facial reconstruction which is not only expensive but can only be performed by very few specialists for the elaborate planning it requires. This limits access to care, and also affects prognosis. Df3D Creation is developing a cloud-based pre-surgical planning platform that leverages 3D printing technology for creation of patient-specific models and surgical guides for detailed pre-op planning & verification, precise resection of diseased tissue and contouring of donor tissue to defect. Received BIG funding.



C-CAMP

Microfluidic **Device**

There is a need for portable affordable immune health monitoring devices. Keeping this in mind C-Camp has developed a miniaturized instrument with increased functionality and accurate information using following techniques: Microfluidic device using 2D focusing, Flow monitoring and flow control, Coupled opto-electronic system, Embedded lens fiber, Gated avalanche photodiode for high-sensitivity detection & Gated data analysis. Received BIPP funding.



Genomix Molecular Diagnostics

Malaria **Diagnosis**

Malaria is a serious parasitic disease characterized by fever, chills and anemia that is transmitted from one human to another by the bite of infected Anopheles mosquito. Genomix Molecular Diagnostics has developed a kit for qualitative detection of malaria parasite (Pf & Pv) antigens in human whole blood. The kit is useful in differential diagnosis between Plasmodium *falciparum* and the other Plasmodium species. Received SBIRI funding.

Genrich Membranes

Oxygen **Therapy**

Oxygen therapy is a costly affair. In remote locations or in rural areas, cylinder transport logistics raises the cost even further. Genrich Membranes has developed a membrane based oxygen enrichment unit that provides cost-effective oxygen therapy to needy patients at site. The unit works at ambient temperature and oxygen enriched air it produces is of medical grade. This is expected to bring a disruptive change in the economics of oxygen therapy. Received BIG funding.

Jeevtronics

Lifesaving **Defibrillator**

Defibrillator is a device that is used to provide emergency care to patients undergoing a cardiac arrest. Jeevtronics has developed an affordable defibrillator with built in generator and audio ECG. The product is specially designed to work in rural areas where electricity supply can often be erratic. Received BIG funding.

Jeevtronics

Janacare Solutions

AINA **Device**

AINA device has been developed & commercialized to measure blood glucose, HbA1C, lipids (HDL, LDL, TrG), creatinine and haemoglobin. The device can be used in hospitals for in-patient management, for self-monitoring by patients at home and for general screening by health workers. Received BIPP funding.

JanaCare

K. N. Biosciences

Pest **Control**

Entomopathogenic nematodes (EPN) are a group of nematodes (thread worms) that cause death to insects and are useful in pest control in agriculture.
K.N. Biosciences has developed a innovative fermentation technology for production of EPN. The resultant product NEMA POWER- is an effective solution for management of white-grubs associated with areca nut, sugarcane, banana, cardamom, groundnut and potato. Received SBIRI funding.

KN BIO

Kwaklei & Khonggun Orchids

Hybrid **Orchids**

The company has produced novel hybrid orchids using different species available in north eastern region of India to enhance India's strengths to compete in the global market for orchids. Hybrids developed by the company have been tried by growers with significant increase in yields and earnings. An MoU has been signed with M/s Aten Biotech, Bangalore for transfer of starter cultures of some orchid hybrids for mass propagation and global marketing. Received BIG funding.

Nanosniff Technologies

Cardiac **Care**

Nanosniff Technologies has developed a device for rapid detection of acute myocardial infarction by sensing cardiac markers with high sensitivity and selectivity in less than 10 minutes.
The device can be used in rural primary healthcare centres or or even in a small ambulance. Received BIG funding.

Nagarjuna Fertilizers & Chemicals

Bio - **Hydrogen**

The company has developed a technology that uses agricultural wastes, constituting about 85% of agricultural output, as the starting material for production of hydrogen. The technology converts all the components of the biomass into sugars and then ferments all sugars into hydrogen. This opens up new avenues of income generation for farmers as tailored energy crops are profitable compared to most other agricultural crops. Received BIPP funding.

Navya Biologicals

Monoclonal **Antibodies**

BIRAC supported Navya Biologicals for the development of a novel intensified technology platform for production of low cost MAbs. The company is in the process of combining its mammalian expression/media platform with a continuous process platform which is under validation. The goal is to bring down the cost of production of MAbs by atleast 50% compared to existing benchmarks. Received BIPP funding.

Ozyn-D

Intraosseous **Device**

Establishing access to circulatory system is critical to resuscitate the patients in clinical emergencies. Even though peripheral intravenous (I/V) access is the standard of care, it is difficult to access these veins in many clinical situations. Intraosseous (IO) access through the long bones is a well proven alternative. 'Ozyn-D' is a novel IO device for emergency vascular access conceived under the Stanford-India Biodesign Program, the device has received accolades in the British Medical Journal India Awards as the best technology innovation in Healthcare Technology category.

Pandorum Technologies

Tissue **Engineering**

Pandorum Technologies has designed and manufactured functional human tissues for medical research and therapeutic applications. The 3D liver tissue/ organoid developed by Pandorum is intended towards use in a) in-vitro pre-clinical drug discovery and development process and disease modeling, and b) for clinical transplantation into human body. Liver tissues developed by the company are currently being evaluated. Pandorum is also working towards developing bio-artificial cornea. Human trials are planned by year 2017. Received BIG funding.

PathShodh Healthcare

Handling **Diabetes**

PathShodh has developed "anuPath", world's first multi-analyte point of care device. The device requires no antibodies and enzymes in sensing chemistry; completely dry chemistry with absolutely no reagents. After scale-up in hand held device and in-house manufacturing of test-strips, the product is likely to be launched in Indian market by end of year 2016 and in inter-national markets by year 2017. Initial offering is for medical practitioners, a new version is planned for home-diagnostics. Received BIG funding.

Pradin Technologies

Fetal **Monitor**

Pradin Technologies has developed a fetal electrocardiogram and uterine activity signal extraction from maternal electrocardiogram. This eliminates the need for conventional transducers. Transducer-less fetal monitor is a novel approach to promote continuous monitoring of high & medium risk pregnancies. It is an affordable, portable, non-invasive and easy to use solution for primary/ home care segment. Received BIG funding.

Rossari Biotech

Enzyme **Production**

The company has successfully developed two enzymes, cellulose and pectinase, by using agricultural waste and agricultural produce. It has also successfully scaled up cellulose enzyme fermentation by use of agri-waste. The two enzymes have great market potential. Received BIPP funding.

SanGeniX-Persistent Systems

Data **Analysis**

Next Generation Sequencing (NGS) technology has emerged as a transformative tool for DNA sequencing. Data obtained from NGS technology has outpaced computational capabilities with its becoming one of the biggest bottlenecks in sequencing projects. SanGeniX simplifies data analysis and interpretation and can be used by academic researchers with no background in informatics, diagnostics labs, clinicians and pharmaceutical biotech companies. SanGeniX is freely available helping researchers to get more insights into their data. Received BIPP funding.

Swasti Agro and Bioproducts

Plant **Vaccines**

Farmers can lose up to 90% of their crops because of various diseases, especially if the climate is bad. This is irrespective of using available treatment(s) - most of the times (80%) curative toxic chemicals. The company has developed "vaccines for plants". The products are being used for controlling bacterial blight of pomegranate since 2014. They are developing similar solutions for crop diseases caused by bacteria, fungi, viruses and nematodes. Received BIG funding.

Sahjanand Medical Technologies

Balloon **Catheters**

The company is a leading developer and manufacturer of minimally invasive coronary stent systems, with one of the broadest product portfolio in the industry. They have a strong international presence with global footprints in more than 40 countries. BIRAC supported the company in the development and building of indigenous capability for balloon catheter manufacturing. Received BIPP funding.

Span Diagnostics

Biomanufacturing **Facility**

Span Diagnostics has created a cGMP compliant Bioprocessing facility. A total area of 5721 sqft created for bulk production facility for monoclonal antibodies and antigens, contract manufacturing and process development services for academic researchers and startups/ SMEs and cGMP training center. The company has also developed differential rental model for usage which is available for academicians, researchers, SMEs and start-up companies for developing process and pilot scale production based on their proof of concept and initial laboratory work. Received BIPP funding.

Windmill

Neo **Breathe**

The company has developed “NeoBreathe”, an easy-to-use novel integrated resuscitation solution. Neobreathe is world’s first foot operated resuscitator. It enables frontline-health workers to resuscitate newborns effectively and help save hundreds of thousands of newborns from death and disability. Received BIG funding.

Span Diagnostics

Chemical **Analyser**

Span Diagnostics has developed a low cost clinical chemistry analyser that helps early diagnosis, reduces overall expenditure on healthcare. The product has a fault tolerant design, robust to withstand large power fluctuations which is important in rural settings. Received SBIRI funding.

Xcellence in Bio Innovations & Technologies

Right **Biotic**

The company has developed a Point-of-Care (POC) device for testing antibiotic sensitivity of pathogens found in human urine and leading to urinary tract infection (UTI). The standard UTI culture and sensitivity test takes between 48-72 hours. RightBiotic gives ready-to-use sensitivity report in less than 4 hours in prescribed conditions. Received SPARSH funding.

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Notes

BIRAC was incorporated on 20th March 2012 as a Section 8, Not for Profit Company. BIRAC is an industry-academia interface and implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and hand-holding schemes that help bring innovation excellence to the biotech firms and make them globally competitive. In four years of its existence, BIRAC has initiated several schemes, networks and platforms that help to bridge the existing gaps in the industry-academia innovation research and facilitate novel, high quality, affordable product development through cutting edge technologies. BIRAC has initiated partnerships with several national and global partners to collaborate and deliver the salient features of its mandate.

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