Indian solutions to global health problems via Globally Patented RECEPTOL, Lab & Virtual specialty Hospital on Chip driven by Artificial Intelligence based knowledge acquisition Tools (AIKAT)

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After years of research, we have successfully isolated Nano peptides from bovine colostrum and conducted global clinical studies on 25,301 subjects suffering from HIV, Swine flu & other communicable/immune disease via innovative oral spray drug delivery system that can provide solution to majority of health problems related to Poor Immunity.

What is NID/Receptol®

NID Active Pharmaceutical Ingredients (API) consist of Patented Nano - Informational Peptides extracted from mammalian/bovine colostrum via Ultra Nano filtration Technology having Radha 108 sequence id 1-8 & Proline Rich Poly Peptides

PRPs & NID are a class of nano informational peptide consisting of oligo-ribonucleotide attached to a peptide molecule that act as immunity drug via immune-modulation and anti-viral/bacterial activity.
Global Health Challenges – Millions suffer from

- Cancer
- Auto Immune: RA, Lupus, IBS
- HIV, TB

RECEPTOL helps high unmet needs for above diseases due to poor immunity

Source: IPSOS & Times studies
MILLIONS MORE SUFFER FROM IMMUNE SYSTEM RELATED ILLNESSES

SWINE FLU HIV/AIDS COMMON COLD HEPATITIS A, B & C HERPES SIMPLEX I&II ACUTE & CHRONIC VIRAL RESPIRATORY INFECTIONS DENGUE FEVER HUMAN PAPILLOMA VIRUS PHARYNGITIS (VIRAL) SARS RABIES ROTA VIRAL DIARRHEA ALLERGIES & ASTHMA TUBERCULOSIS ALZHEIMER BENIGN PROSTATE HYPERPLASIA HYPERTENSION LUPUS (DISCOID AND SYSTEMIC) ORAL THRUSH AUTISM PREMENSTRUAL SYNDROME RHEUMATOID & OSTEO ARTHRITIS SPINAL MUSCULAR ATROPHY
What if there was a way to treat all immunity disorders via RECEPTOL, The New Immunity drug that not only builds body’s own immune system but also prevents Recurrent infections in Cancer, Auto immune & AIDS patients.
Innovations at Biomix to provide health for all via

**Mission:**
Develop & manufacture affordable Nano-Biotech orphan drugs & diagnostics for prevention & treatment of life threatening disease globally

**Vision:**
Health for all

Indian solutions to global health problems via globally patented RECEPTOL, Lab & Virtual specialty Hospital on Chip driven by Artificial Intelligence based knowledge acquisition Tools
Creating Paradigm shift via innovations in Pharma, Healthcare & Diagnostics

Drug Discovery
Patents provide entry barrier for global Pharma MNCs in therapeutic areas of Oncology, Asthma, Auto immune: RA etc, Infectious disease, CNS & HIV Orphan drugs

Lab on Chip
Mass screening for Cancer, Auto Immune, Viral Pandemic, biological & nuclear warfare

Hospital on Chip
Taking health care to bottom of pyramid via telemedicine and tele diagnostic. Global hub for Pharma CRO & Drug discovery via AI based Virtual Hospital

Granted Global PATENTS
United States Patent

Saharan

(51) MANIMALIAN COLLOIDAL DERIVED NANOPARTICLES FOR BROADSPECTRUM VACAL AND RECURRENT INFECTIONS WITH A METHOD OF ISOLATION THEREOF

(21) Appl. No.: 13/845,377
(22) Filed: Mar. 18, 2013

(50) Prior Publication Data

(51) Related U.S. Application Data
Division of application No. 13/142,357, filed as application No. PCT/US2006/00744 on Dec. 29, 2005, now Pat. No. 8,514,644.

(51) Foreign Application Priority Data
Dec. 27, 2008 (DE) EP1338420B1

(24) Notice of Maintenance Fee Notice on the inside of the cover.

Michelle K. Lee
Director of the United States Patent and Trademark Office

(56) References Cited
U.S. PATENT DOCUMENTS

* cited by examiner

Primary Examiner -- KarlOtter R. Sieriewicz
Assistant Examiner -- Sevgi Collins
Attorney, Agent, or Firm -- Math, Goldberg & Meyers
Tanya E. Burke

(37) ABSTRACT
The present invention relates to nanopolymers isolated from mammalian colostrums with vaccine-like antiviral and immunomodulator activity via binding body’s own immune system and attachment inhibition on the cell surface receptors.

5 Claims, 10 Drawing Sheets
## Entry barrier via Global product patents

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<thead>
<tr>
<th>Jurisdiction</th>
<th>Application No./ Date</th>
<th>Title</th>
<th>Status</th>
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<tr>
<td>USA</td>
<td>13/142,327 DT. 27.06.2011</td>
<td>Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof</td>
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<td>USA</td>
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<td>Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof (For approved 58 indications for Radha 108)</td>
<td>GRANTED (Patent No. 9,249,188)</td>
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<td>An Apparatus and Method For Detecting Biological State in Sample by Using Bio Marker ERS</td>
<td>Granted (PARENT #:WO2011/158246A1)</td>
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</table>
Business Opportunity through breakthrough innovation

• RECEPTOL enables people to lead longer & healthier lives via building body’s own immune system naturally and saves billions from viral infections & Immune disorders.

• USP of RECEPTOL is its clinically proven Mode of Action via global studies.

• Granted product patent in North America, Europe and Asia PAC.

• Innovation led RECEPTOL has potential to be a blockbuster drug as illustrated by a series of globally accredited market research conducted by IPSOS US & IRMA/Indian Institute of Management indicating RECEPTOL as Doctors First Choice based on its USP, convenience of use with no side effects.

• Clinically proven indications of RECEPTOL include Cancer, Asthma, Allergy, HIV, Auto Immune disorder like RA, Lupus & other that accounts for expenditure of over $500 billion in US alone. (Source- www.cdc.gov).

• 21st Century Innovation- Creating a Paradigm shift in healthcare Life Sciences Drug Innovation.
Healthcare Challenges

The healthcare communication systems existing as of date are hindered by several drawbacks since medical information is not shared among professionals quickly enough to meet the need to provide rapid emergency care and universal development and distribution of medical knowledge.

Present medical knowledge databases rarely accumulate independent research work. Analysis of huge volume of data to produce medical treatment protocols requires laborious human work which tends to increase the cost and time of healthcare & clinical trial CRO systems. This is major “bottleneck” leading to ever increasing cost of medical care in modern, developed economies.

Hence, there is a need for an automated, integrated system, method and platform which helps in managing the total health care services with the inclusion of drug discovery and clinical trials in a cost effective and timely manner. The present invention, Virtual specialty hospit has the potential to be a blockbuster product providing a cost effective solution to medical healthcare, CRO & New Drug Discovery in a timely manner.
Virtual specialty Hospital on Chip driven by Artificial Intelligence based knowledge acquisition Tools (AIKAT)

- The Hospital on Chip invention relates to a web based integrated informatics system for healthcare services like Trauma Emergency care, TeleMedicine with a difference aiding clinical trials and new drug discovery.
- The system is configured to receive information sent by one or more specialty hospitals.
- The received information is then processed by AI based logic processor using the hospital patient databases.
- The processed request is integrated with relevant healthcare information or services and received by the specialty hospitals.
- Medical Informatics System is the intersection of computer science and healthcare which focuses on acquiring patient data, processes it and stores it in computers.
- Physicians and health administrators can efficiently retrieve this data as per their requirement and also use it for clinical research and new drug discovery.
- This can be applied to the areas for nursing, clinical care, dentistry, pharmacy, public health and bio medical research.
Hospital on chip information
Phases of discovery NID: RECEPTOL

16 years to put RECEPTOL in Market *

Phases and Time of drug discovery

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<th>Years</th>
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<tr>
<td>2</td>
<td>Laboratory and Animal Testing</td>
</tr>
<tr>
<td>4</td>
<td>Phase I 20-80 Healthy volunteers</td>
</tr>
<tr>
<td>6</td>
<td>Used to determine</td>
</tr>
<tr>
<td>10</td>
<td>Phase II 100-300 Patient volunteers</td>
</tr>
<tr>
<td>12</td>
<td>Used to look for efficacy</td>
</tr>
<tr>
<td>14</td>
<td>FDA Review/Aururo</td>
</tr>
<tr>
<td>16</td>
<td>Additional Post-marketing testing</td>
</tr>
</tbody>
</table>

Major functions of a CRO consist of:

- Drug discovery stage
- Pre-clinical stage
- Clinical stage

The various activities of a contract research organization includes:

- Clinical study design
- Project management
- Quality assurance auditing
- Medical safety monitoring
- Biostatistics
- Central laboratory services
- Clinical data management
- Regulatory submissions
- Scientific communication
RECEPTOL has completed Phase III trials per slide above and is in the Market*

Current global marketing channel : B2D

Approved by select regulatory agencies

Work in Progress for New Drug Approval by US FDA, EMA, TGA.

Key focus :

Oncology, Auto Immune, ID: AIDS, Immunology: Asthma
Medical confirmation of NID for globally patented 58 indications
(US Patent # 9,249,188 PCC# IN2009/000749 WO2010/079511)


Dengue fever, Shingles, Plantar Warts, Lymphoma, Herpes Simplex I & II, Parvo, Sarcoidosis, Celiac disease, Chronic Pancytopenia, Crohn’s disease, Diabetes type II, Fibromyalgia, Rheumatica, Mononucleosis, Multiple Sclerosis, Osteo Arthritis, Brown Recluse Spider Bite, Corneal Regeneration, Diarrhea, Guillain Barre Syndrome, Hemolytic Anemia, Idiopathic thrombocytopenia purpura, Myasthenia Gravis, Tuberculosis, Human Immunodeficiency Virus (HIV), Hepatitis A and C, Rabies in Dogs, Human Pappilloma Virus
Checkpoint inhibitors

Adoptive cell transfer

Monoclonal antibodies

Treatment vaccines

Bacillus Calmette-Guérin

Cytokines

RECEPTOL Acts when All fail

Act directly against the cancer

Enhance the body’s immune response to fight cancer

Builds bodies own immune system.
Stimulates
Tumor Necrosis Factors
NK cells
Interleukin-1 to IL-11,
Interferon-α, INF–γ.

Patent No – US 9,249,188 B2
“Cancer cells retain parts of healthy cells that can prevent damage by the immune system, resulting in a condition of immune gridlock. Cancer immunology zeroes in on this dynamic of competing signals and drives the immune response toward recognising cancer as dangerous.” Glenn Dranoff, Global Head of Immuno-oncology, at the Novartis Institutes for BioMedical Research

NID helps strengthen the Immune System to be able to perform and destroy tumour cells efficiently.

NID helps release Tumour Necrosis Factors and help build the immune system of the body thereby preventing recurrent infections.

It is a perfect fit for Immune Oncology as recommended by Oncologists world over including Dr Suresh Advani Medical Oncologist and Founder Tata Memorial Cancer Hospital, Mumbai and President Asian Cancer Society.
Current invention related to mammalian colostrum that provides answers to high unmet needs due to poor immunity in Cancer, AIDS, Swine Flu, Arthritis and other auto-immune disorders.

PRPs get absorbed in the blood through buccal mucosa and crosses BBB

- Radha108 (PRP) promotes differentiation of B cells, differentiation and maturation of macrophages and monocytes.
- Activates natural killer (NK) cells, cytotoxic cells of the innate immune system
- Mitigates cell fusion and docks on HIV glycoprotein like Gp120, 180,160 and 41 mimicking receptor on the cell surface closing entry of viruses.
- Stimulates production of cytokines IL-1 to IL-11, TNF-α, INF-γ.
- Stimulates the maturation of immature thymocytes into either helper or suppressor T cells
- Radha108 also functions as a molecular signaling device which works through receptors on target cell surfaces.
Mode of Action - Pharmacodynamics

- RECEPTOL get absorbed in the blood through buccal mucosa and crosses BBB.
- Stimulates maturation of immature thymocytes into either helper or suppressor T cells.
- Stimulates secretion of Tumor Necrosis Factor & cytokines IL-1 to IL-11, INF-α, INF-γ.
- Promotes differentiation of B cells, differentiation and maturation of macrophages and monocytes.
- Activates natural killer (NK) cells, cytotoxic cells of the innate immune system.
- Mitigates cell fusion and docks on HIV glycoprotein like Gp120, 180, 160 and 41 mimicking receptor on the cell surface closing spectrum entry of viruses.
- RECEPTOL also functions as a molecular signalling device which works through receptors on target cell surfaces.
Mode of action – 5 times increased Immuno Response by RECEPTOL

- **Antigen Presentation**
  - **Macrophage**
    - **Helper T-Cell**
      - **Active Cytotoxic T-Cell**
        - **Kills Infected & Cancer Cells**
      - **Memory T-Cell**
    - **Active B-Cell**
      - **Plasma Cell**
        - **Antibodies**
          - **Deactivates Antigens**
      - **Memory B-Cell**
Innovative, Affordable & Globally Patented

Builds bodies own immune system.

Stimulates Tumor Necrosis Factors NK cells, Interleukin-1 to IL-11,

Interferon-α, INF–γ.

Easy to administer

No side effects

Can be consumed by all.. has no age or sex barrier, drug , drug interaction
Manufacturing Facility, Tox Study & Product Range

FDA Approved Manufacturing facility

➢ **GMP Facility**
  • State of the art, nano biotech facility granted by TUV Nord Germany since 2012.
  • Extraction of API, PRP is done by Merck Millipore Molecular Exclusion Ultra filtration columns

**Toxicology study at FDA Approved National Institute of Nutrition (NIN), Hyderabad**
  • Acute (14 Days) Sub-chronic (60 Days-45 Days treatment 15 days recovery) repeated dose through oral route in sprague Dawley rats.

➢ **Acute Tox Study**
  • No pre-terminal deaths after administration of 50 times of intended therapeutic dose through oral route All rats were found to be active and with normal body weight. No Acute toxicity found.

➢ **Sub Acute Tox Report**
  • No significant difference in physical & neurological activity between control and test groups throughout the study period.
  • No significant abnormalities in hematology, clinical chemistry profile in blood/serum samples.
  • No gross lesions were found in any organ and no significant difference in histopathology of various organs. No sub chronic toxicity found.

**NID Product Range:**
Oral spray, Oral gargle, Capsules & Tablets & Powder
GMP Facility & Product Range

• Radha108 Nano Peptide manufacturing plant is state of the art, nano biotech facility granted by TUV Nord Germany since 2012. GSK Consumer healthcare group UK & India due diligence done on product & the manufacturing facility.

• Consistent raw material source: International quality from ISO/GMP certified, Amul, world’s largest 75 year old dairy with stringent QC/QA checks & balances, right at the origin of Colostrum.

• Extraction of API, PRP (Radha108, Type of PRPs of molecular weight from 1800 to 500kDA) is done by Merck Millipore Molecular Exclusion Ultra filtration columns of 100 to 10 kDA at cGMP facility shown below.
Product range

Oral spray

Oral liquid

Capsules & Tablets

Powder
## PHARMACEUTICAL DATA ON FORMULATION

### DOSAGE AND ADMINISTRATION

| 4 Sprays of 0.75ml metered dose (3ml), two each on each side of inner cheek 4 times daily |

### ROUTE OF ABSORPTION & DISTRIBUTION

- API (PRPs) absorbed through the buccal mucosa
- Crosses blood brain barrier due to low mol. wt below 2kDa.
- Distributed all over the body through the blood streams.

### INDICATIONS

- Treatment of HIV therapy & for associated recurrent infections.
- Immunity enhancer for immune disorders like Asthma, Rheumatoid Arthritis & others

### CONTRAINDICATIONS

- Proven to be safe in acute as well as chronic use.
- No incompatibility along with any other medication.
- No minor or serious contraindication reported.

### WARNINGS & PRECAUTIONS

None, Since its over dose does not harm anyone even neonates

### ADVERSE EFFECTS

No adverse effects observed.

### STORAGE

- Keep in cool & dry place.
- Keep under refrigeration once the bottle is opened and consume within 30 days after opening.
Market Analysis suggests 1 out of 3 Americans can be treated with NID: IMS US Data Poised to be $10+ billion block buster drug globally

* Unit sale 250 Million for Auto Immune, Asthma, Allergy & HIV Patients in US alone

* US alone accounts for $5 Billion

Rest of the world can account for additional $8 billion market

* Radha 108 dosage of 4 times/day @ 3ml/dose - 3 bottles/month/patient @$40 = $1440/patient per year

Source: www.cdc.gov
In US alone, more than **23M** people are affected by autoimmune diseases!

More than **$100Billion** is spent by sufferers on drugs every year!
Respiratory Disorder - Asthma

Asthma may affect as many as 334 million people.*

25MM alone in US

EXPECTED TO GROW BY MORE THAN 100MM BY 2025!

Global COPD and Asthma Devices Market

Global COPD and Asthma Devices Market is expected to reach $34.3 Billion by 2020.

Growing at a CAGR of 4.5% (2014-2020)

Global COPD and Asthma Devices Market By Product Type

- Inhalers
  - Drug powder inhalers (DPIs)
  - Metered Dose Inhalers (MDIs)
  - Soft Mist Inhalers (SMIs)
- Nebulizers
  - Compressor nebulizer
  - Ultrasonic nebulizer
  - Mesh nebulizer

Global COPD and Asthma Devices Market By Geography

Asia-Pacific, North America, LAMEA

Europe

Fastest Growing Segment at a CAGR 4.8% (2014-2020)

Allergies & Asthma

$25Billion is spent on Asthma drugs annually which has gone up by 50% since 2009!

30% adults and 40% of children worldwide are affected by allergies!

Infectious Diseases - HIV is a major threat affecting ~40m people worldwide and the sales for HIV drugs are expected to increase steadily.

1.2M only in US

The vast majority of people living with HIV are in low- to middle-income countries, particularly in Sub-Saharan Africa.

36.9 MILLION
people worldwide are currently living with HIV/AIDS.

2.6 MILLION CHILDREN
worldwide are living with HIV. Most of these children were infected by their HIV-positive mothers during pregnancy, childbirth or breastfeeding.

Forecast of HIV drug sales ($Billion)

Source: www.aids.gov
 IPSOS US Global Market Research

- Market Research conducted in India, UK, USA.
- Sample Size - 800 respondents.
- **Target population:** Households of SEC A in society consuming HFDs and FMCG products.
- **Product:** Radha 108 powder additive & Oral Spray in two concepts.
Concept P (50% lesser infection)

1. Concept P (50% lesser infection) - A trusted nourishment and dependable immune power of cow colostrum.

- Reduces common infections like those of stomach, nose and throat by up to 50% lesser infection using Radha 108 powder.

- ITP index 100 and ITP score 40%.

- ITP index (Concept Performance vs Success Norm)
- ITP score (Maximum trial potential in % within target)
2. **Concept Q (108 immunity superchargers)**: Packed with 108 immunity superchargers.

- Builds protection against all Pathogen types- Viruses, bacteria and fungi.

- ITP index 97 and ITP score 39%.
Respondents agreed that both the formulations of the product are much better than their existing products in use.
IPSOS studied Customer’s perceptions towards two concepts of the immune powder (as infection reducer & immunity super charger) and their willingness to buy HFDs (Health Food Drinks), and FMCG products with Radha 108 as an additive. Results were as follows:

The ITP index was around 97-100%, while the ITP score was around 39-40 in both the above mentioned concepts.

- Our product met mandate from 800 subjects who were willing to use our product as standalone / additive to various immunity building foods.

- 80% of the respondents surveyed were ready to pay a higher price for our product as compared to the all current brands.
RECEPTOL as Vaccine types and distribution

50% of the vaccines bought (volume wise) signify only 5% of value overall.

**Concerns:**
- Oligopoly, limited supply for DC and shortage risks
- Upstream factors: Technology transfer and IPRs, R&D for most needed vaccines, DCCM R&D capacity, etc.
- New vaccine costs and prices
- Financial sustainability? Govt responsibilities role
- Future of International initiatives
- Future of Emerging Manufacturers
- Impact of the financial crisis?

*Source: WHO*
Meta Analysis is a combined Statistical analysis of 25,000 subjects across HIV, Swine Flu, Allergy/Asthma, Rheumatoid Arthritis, Endometriosis & NCD: Chronic Fatigue Syndrome showing increase in weight gain as an Indication of overall wellness showing Safety & Efficacy of Radha108 Nano Peptide.

<table>
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<th>Sr.No.</th>
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<tr>
<td>1</td>
<td>Healthy people</td>
<td>10,000</td>
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<tr>
<td>2</td>
<td>HIV Patient in USA, Africa, India</td>
<td>5000</td>
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<tr>
<td>3</td>
<td>Swine Flu</td>
<td>5000</td>
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<tr>
<td>4</td>
<td>Other Indications like allergy, asthma, Rheumatoid Arthritis, Chronic Fatigue Syndrome, Endometriosis Study etc.</td>
<td>5000</td>
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</table>
Global Studies on Immunity Disorders

### Allergies
- Reporting Patients: 24
- Duration of Treatment: 6 months

More than half the respondents experienced complete resolution of symptoms!

### Rheumatoid Arthritis
- Reporting Patients: 63
- Duration of Treatment: 6 months

56% of patients found the product to be highly effective!
Chronic Fatigue Syndrome

- Reporting Patients: 108
- Duration of Treatment: 6 months

70% of patients received significant benefits!

Endometriosis

- Reporting Patients: 106
- Duration of Treatment: 6 months

Similarly for Endometriosis, complete resolution in most cases!
### CHANGES IN MEAN BODY WEIGHT AMONG STUDY CASES

<table>
<thead>
<tr>
<th>Duration (Weeks)</th>
<th>Mean weight (± SD) (N = 10000)</th>
<th>Mean Diff. (Baseline – Wk1) (P value)</th>
<th>Mean Diff. (Baseline – Wk2) (P value)</th>
<th>Mean Diff. (Baseline – Wk3) (P value)</th>
<th>Mean Diff. (Baseline – Wk4) (P value)</th>
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<tr>
<td>Baseline</td>
<td>50.30 ± 10.02</td>
<td>*0.35 ± 0.66 (0.001)</td>
<td>*0.71 ± 0.24 (0.001)</td>
<td>*0.17 ± 0.95 (0.001)</td>
<td>*0.70 ± 0.15 (0.001)</td>
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<td>2</td>
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<td>4</td>
<td>52.00 ± 09.96</td>
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By ANOVA, P<0.05, * Significant

- After 1 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 0.7% from baseline.
- After 2 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 1.4% from baseline. Same trend was observed till the end of 4 weeks.
### CHANGES IN MEAN WEIGHT AMONG STUDY CASES

<table>
<thead>
<tr>
<th>Duration (Months)</th>
<th>Mean weight (( \bar{X} \pm SD )) (N = 5000)</th>
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<tbody>
<tr>
<td>Baseline</td>
<td>50.38 ± 0.98</td>
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<tr>
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<td>50.72 ± 0.88</td>
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<tr>
<td>2</td>
<td>51.07 ± 0.82</td>
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<tr>
<td>3</td>
<td>51.51 ± 0.79</td>
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<tr>
<td>4</td>
<td>52.11 ± 0.75</td>
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<tr>
<td>5</td>
<td>52.54 ± 0.76</td>
</tr>
<tr>
<td>6</td>
<td>52.89 ± 0.77</td>
</tr>
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</table>

Mean Diff. (Baseline – 1 month) (P value): *0.34 ± 0.57 (0.001)

Mean Diff. (Baseline – 2 months) (P value): *0.69 ± 0.91 (0.001)

Mean Diff. (Baseline – 3 months) (P value): *0.13 ± 0.13 (0.001)

Mean Diff. (Baseline – 4 months) (P value): *0.73 ± 0.17 (0.001)

Mean Diff. (Baseline – 5 months) (P value): *0.16 ± 0.16 (0.001)

Mean Diff. (Baseline – 6 months) (P value): *0.51 ± 0.07 (0.001)

By ANOVA - Significant

- After 1 month of treatment, mean weight showed a significant rise of 0.7% from baseline.
- After 2 months of treatment, mean weight showed a significant rise of 1.4% from baseline, similar trend was observed till the end of 6 Months.
Efficacy & safety of NID on Swine flu

### CHANGES IN MEAN WEIGHT AMONG STUDY CASES

<table>
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<th>Duration (Weeks)</th>
<th>Mean weight ((\bar{x} \pm SD)) ((N = 5000))</th>
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<td>51.07 ± 9.82</td>
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<td>2</td>
<td>*51.51 ± 9.79</td>
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<tr>
<td>3</td>
<td>*52.11 ± 9.75</td>
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<tr>
<td>4</td>
<td>*52.53 ± 9.76</td>
</tr>
</tbody>
</table>

By ANOVA  \(P < 0.05\),  * Significant

- At the end of 2\(^{nd}\) week, mean weight showed significant change from baseline i.e. mean change of 1.44 kg.
- At the end of 4\(^{th}\) week mean weight increased significantly that is 1.46 kg from baseline.
Efficacy & safety of other indications like allergy, asthma, arthritis, diarrhea, fever, fatigue-malaise, anemia, endometriosis

<table>
<thead>
<tr>
<th>Duration (Weeks)</th>
<th>Mean weight ((\bar{X} \pm SD)) (N = 5000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>50.41 ± 10.03</td>
</tr>
<tr>
<td>1</td>
<td>50.76 ± 10.01</td>
</tr>
<tr>
<td>2</td>
<td>51.11 ± 09.94</td>
</tr>
<tr>
<td>3</td>
<td>51.60 ± 09.91</td>
</tr>
<tr>
<td>4</td>
<td>52.15 ± 09.91</td>
</tr>
</tbody>
</table>

Mean Diff. (Baseline – Wk1) (P value) 
*0.35 ± 0.57 (0.001)

Mean Diff. (Baseline – Wk2) (P value) 
*0.70 ± 01.05 (0.001)

Mean Diff. (Baseline – Wk3) (P value) 
*01.19 ± 01.77 (0.001)

Mean Diff. (Baseline – Wk4) (P value) 
*01.74 ± 01.95 (0.001)

By ANOVA * Significant

• After 1 week of treatment, mean weight showed a significant rise of 0.7% from baseline.
• After 2 week of treatment, mean weight showed a significant rise of 1.4% from baseline, similar trend was observed till the end of 4 weeks.
Safety & Efficacy Studies on 301 HIV+ Subjects

Safety and Efficacy Achieved by Global Trials:
Phase I : 12 cohort 30 days (completely safe) in Ohio, USA
Phase II : 30 cohort 90 days (highly effective with no side effects) in Nairobi - Kenya
Phase III : 60 cohort for 365 days (highly effective with no side effects) in Rwanda, Africa


- **Study I**: 50 HIV Positive Patients at Tertiary Care LTMG Hospital Sion, Mumbai
  (Clinical trial registry No. : CTRI-2012-08-002931)

- **Study II**: 51 HIV Positive Patients at Tertiary Care LTMG Hospital, Sion, Mumbai
  (Clinical Trial registry No. : CTRI-2012-09-002959)

*The study was fully controlled, conducted and sponsored, by Govt. of India with Indian Council of Medical Research proposed Protocols.*
Toxicology study at National institute of nutrition (NIN)

Pre-Clinical safety study has been undertaken as per schedule Y of DCGI guideline under the supervision of Dr. B. Dinesh Kumar, Asst. Director (Study director) at National Institute of Nutrition, Hyderabad.

Acute toxicity

RESULTS

No pre-terminal deaths after administration of 50 times of intended therapeutic dose through oral route

All rats were found to be active and with normal body weight.

No Acute toxicity found.
NIN Study: Sub acute data

No mortality was observed & product is safe

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>No. of Rats used</td>
<td>48</td>
</tr>
<tr>
<td>2.</td>
<td>Categories</td>
<td>Vehicle control (VC), Therapeutic dose (TD - 1.08ml), Average dose (AD - 5XTD), (five times of TD) and High Dose (HD - 10XTD), (ten times of TD)</td>
</tr>
<tr>
<td>3.</td>
<td>Days of trial</td>
<td>45</td>
</tr>
<tr>
<td>4.</td>
<td>Period of Observation</td>
<td>Biweekly for live phase, cage side, physical and neurological parameters. At 48hrs and 15th day hematology and biochemistry profile along with gross necropsy and histopathology of major organs were evaluated.</td>
</tr>
</tbody>
</table>

RESULTS

No significant difference in physical activity and neurological activity between control and test groups throughout the study period.

No significant abnormalities in hematology, clinical chemistry profile in blood/serum samples.

No gross lesions were found in any organ and no significant difference in histopathology of various organs.

No sub chronic toxicity found
Global Trial Results
Phase I - Ohio State University, USA

- 12 cohort, 30 days, moderate dose
- Patients may have previous exposure to AZT
- Balanced diet with vitamin-minerals provided
- 10 patients had weight gain and 7 patients had gained an average 6 lbs
- Highest weight gain was 12 lbs for a patient who was HIV positive for 10 years
- All 12 pt had improved symptom assessment score and average reduction approached 63 %

Free of side effects
Phase II - Nigeria, Africa

- Advanced HIV / AIDS, Limited access to conventional treatment
- 30 cohorts, 30 days Mono therapy
- No previous exposure to ART
- Some signs of detoxification, relieved by increase water intake
- Resolution or reduction in all Clinical symptoms
- Weight gain observed in all patients

Efficacious & Free of side effects
Phase III - Rawanda, Africa

- Safety and efficacy trial
- 60 AIDS patients - 365 days
- Patients were unaware of positive potential of drug
- Weight gain consistently observed
- After day 1 moderate level of relief of diarrhea and fever
- After 14 days, relief from skin lesion, mouth thrush, fever, diarrhea, tuberculosis symptoms
- After 90 days relief of all symptoms with increase in Absolute CD4 Counts & Reduction in Viral Load

No adverse effects observed over 12 months follow up with improved Quality of Life even after 5 years of therapy.

Highly Efficacious & Free of side effects
Summary of Mumbai, India phase III study on AIDS patients

- **Tertiary care, Sion Hospital, Mumbai 51 AIDS Patients Study**
  - Absolute CD4 cell count & HIV Viral Load - tested at IIH (ICMR)
  - Clinical & Physical symptoms study - at ART Center, Sion Hospital

- **Inclusion criteria** - absolute CD4 cell count greater than 100 cells/mm$^3$ and 100% Symptomatic patients at basal.

- **Exclusion criteria** - no pre-exposure to ART
  - Mean HIV log viral load has statistically significantly dropped ($p = 0.009$)
  - Statistically significant increase in CD4 cell count ($p = 0.042$)
  - Clinical symptoms disappeared in 3 weeks of treatment in All Patients ($p = 0.001$)
  - Statistically significant weekly weight gain in All Patients ($p = 0.001$).
Indian Study: STAND ALONE MONOTHERAPY

SION HOSPITAL MUMBAI

Weight gain after treatment

Statistically significant gain in weight $p<0.05$ in both the Study I and Study II

Study I:
- average weight gain of $4.73 \text{ kg}$ after 12 weeks of Radha108 therapy. statistically significant ($p < 0.05$)
- Mean weight was $50.48\text{ kg}$ at start of study.

Study II:
- average weight gain of $4.68 \pm 1.9 \text{ kg}$ after 12 weeks of Radha108 therapy. statistically significant ($p < 0.05$)
- Mean weight was $49.21\text{ kg}$ at start of study and $53.89\text{ kg}$ after 12 wks.
Statistically significant reduction in Fatigue / Malaise in both the Study I and Study II

Study I:
- 88% of the total study cases had fatigue at basal.
- After 6th week onwards only one or two patients had fatigue, statistically significant

Study II:
- 100% of the total study cases had a symptom of fatigue at basal. At the end of 2nd week proportion of symptoms of fatigue had a statistically significant fall from basal.
Data on fever & cough after Therapy

Statistically significant reduction in Fever and Cough in both the Study I and Study II

- **Study I**: Fever and cough was reported by 24% and 28% of total study cases at basal respectively. After treatment at the end of 4th week proportion of patients with symptom of fever and cough had a statistically significant fall.

- **Study II**: 100% of the total study cases had fever and cough. After treatment from 3rd week onwards all the patients had relief from fever and cough, statistically significant.
Data on Diarrhea after Therapy

Statistically significant reduction in Diarrhea in both the Study I and Study II

Study I: 18% of the total study cases had diarrhea at basal and after treatment from 5th week onwards all the patients had relief from diarrhea, statistically significant

Study II: 100% of the total study cases had diarrhea at basal and after treatment from 3rd week onwards all the patients had relief from diarrhea, statistically significant
**Study I:** The mean HIV log viral load has statistically significantly dropped from 4.63 to 4.18 after 12 weeks of treatment. (p = 0.03)

Metropolis Health Services (I) PVT. LTD. Laboratory, Mumbai (NABL & CAP accredited)

**Study II:** The mean HIV log viral load has statistically significantly dropped from 4.41 to 4.02 after 12 weeks of treatment. (p = 0.009)

Institute of Immuno Hematology (IIH), an ICMR Institute, KEM Hospital, Mumbai
Data on CD4 Cell Count after therapy

**Statistically significant increase in CD4 Cell Count**

<table>
<thead>
<tr>
<th>Study 1</th>
<th>CD4 baseline</th>
<th>CD4 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>370.63</td>
<td>390.65</td>
</tr>
<tr>
<td>Median</td>
<td>312.50</td>
<td>363.50</td>
</tr>
</tbody>
</table>

**Study I:** There was increase in CD4 count on the average by 51 (median CD4 cell counts from 312 to 363). This is of statistical significance ($p = 0.06$)

<table>
<thead>
<tr>
<th>Study 2</th>
<th>CD4 baseline</th>
<th>CD4 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>317.16</td>
<td>344.24</td>
</tr>
<tr>
<td>Median</td>
<td>276.00</td>
<td>305.00</td>
</tr>
</tbody>
</table>

**Study II:** There was increase in CD4 count on the average by 27 (median CD4 cell counts from 276 to 305). This is of statistical significance ($p = 0.042$)
<table>
<thead>
<tr>
<th>Clinical Symptoms</th>
<th>N</th>
<th>At Baseline</th>
<th>Responders At Week-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>51</td>
<td>51(100%)</td>
<td>12(23.53%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>51</td>
<td>51(100%)</td>
<td>3(5.9%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>51</td>
<td>51(100%)</td>
<td>17(33.3%)</td>
</tr>
<tr>
<td>Fever</td>
<td>51</td>
<td>51(100%)</td>
<td>13(25.5%)</td>
</tr>
<tr>
<td>Cough</td>
<td>51</td>
<td>51(100%)</td>
<td>13(25.5%)</td>
</tr>
<tr>
<td>Paraesthesia</td>
<td>51</td>
<td>51(100%)</td>
<td>16(31.4%)</td>
</tr>
<tr>
<td>Disturbed Sleep</td>
<td>51</td>
<td>51(100%)</td>
<td>0(100%)</td>
</tr>
<tr>
<td>Skin Rash</td>
<td>51</td>
<td>51(100%)</td>
<td>7(13.7%)</td>
</tr>
<tr>
<td>Fatigue/Malaise</td>
<td>51</td>
<td>51(100%)</td>
<td>0(100%)</td>
</tr>
<tr>
<td>Herpes Zoster</td>
<td>51</td>
<td>51(100%)</td>
<td>18(35.3%)</td>
</tr>
<tr>
<td>Hair Changes</td>
<td>51</td>
<td>51(100%)</td>
<td>16(31.4%)</td>
</tr>
<tr>
<td>Leukoplakia</td>
<td>51</td>
<td>51(100%)</td>
<td>0(100 %)</td>
</tr>
<tr>
<td>Oral Thrush</td>
<td>51</td>
<td>51(100%)</td>
<td>0(100 %)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline Mean ± SD</th>
<th>Week 12 Mean ± SD</th>
<th>Difference (Week 12 - Baseline) Mean ± SD</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 Counts (cells/ cmm)</td>
<td>317.16 ± 128.67</td>
<td>344.24 ± 165.79</td>
<td>+ 27.08 ± 92.47</td>
<td>0.042</td>
</tr>
<tr>
<td>CD8 Counts (cells / cmm)</td>
<td>1037.06 ± 285.02</td>
<td>1139.75 ± 386.76</td>
<td>+102.69 ± 267.44</td>
<td>0.008</td>
</tr>
<tr>
<td>KEY DIMENSIONS</td>
<td>PHASE I, II &amp; III INTERNATIONAL TRIALS</td>
<td>INDIA PHASE III STUDY 1</td>
<td>INDIA PHASE III STUDY 2</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------------</td>
<td>--------------------------</td>
<td>--------------------------</td>
<td></td>
</tr>
<tr>
<td>Phase</td>
<td>Phase I - HIV trial, US Phase II - HIV trial, Nairobi, Kenya Phase III - HIV trial, Rwanda</td>
<td>Phase III validation trial by GOI on HIV patients, Standalone monotherapy</td>
<td>Phase III validation trial by GOI on HIV patients, Standalone monotherapy</td>
<td></td>
</tr>
<tr>
<td>No. of patients</td>
<td>Phase I - 12 cohorts Phase II - 30 cohorts Phase III - 60 cohorts</td>
<td>50 HIV seropositive patients</td>
<td>51 HIV seropositive patients</td>
<td></td>
</tr>
<tr>
<td>Duration</td>
<td>30 to 365 days</td>
<td>180 days</td>
<td>180 days</td>
<td></td>
</tr>
<tr>
<td>Compliance</td>
<td>Very good</td>
<td>Very good</td>
<td>Very good</td>
<td></td>
</tr>
<tr>
<td>Side effect</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Weight gain</td>
<td>6 lbs average gain</td>
<td>4.73 kg per patient, p&lt;0.05</td>
<td>4.68 ± 1.9 kg per patient, p&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Clinical symptoms</td>
<td>90 days relief from symptoms</td>
<td>Improved within 3 weeks from starting of therapy</td>
<td>Improved within 3 weeks from starting of therapy</td>
<td></td>
</tr>
<tr>
<td>CD4 cell count</td>
<td>Phase II: Average by 31</td>
<td>Average by 51, median CD4 cell count from 312 to 363 (p = 0.06)</td>
<td>On an average by 27 (p = 0.042)</td>
<td></td>
</tr>
<tr>
<td>HIV Viral load</td>
<td>Phase II: Mean HIV log viral load from 4.6 to 2.5</td>
<td>Mean HIV log viral load from 4.63 to 4.18 (p = 0.001)</td>
<td>Mean HIV log viral load from 4.41 to 4.02 (p = 0.009)</td>
<td></td>
</tr>
</tbody>
</table>
67% Patients Viral load decreased as per controlled clinical trial data conducted by ICMR at Tertiary Care Sion Hospital, Mumbai

20% Virus free in 3 months time

8 year followup - Disease free survival
### Growth Funding: Details of Cost of the Project

<table>
<thead>
<tr>
<th>Heads of Expenditure</th>
<th>Estimated Funding requirement towards Expenditure for Global Business via New World Class Plants in Europe, America, Australia, India</th>
<th>Existing Business with Plant in India at Fortune 500 AMUL Dairy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plant &amp; Machinery</td>
<td>32 (USD Million)</td>
<td>4.5 (USD Million)</td>
</tr>
<tr>
<td>Laboratory Equipments</td>
<td>5.0 (USD Million)</td>
<td>1.2 (USD Million)</td>
</tr>
<tr>
<td>Building &amp; Other Civil Work</td>
<td>12 (USD Million)</td>
<td>1.5 (USD Million)</td>
</tr>
<tr>
<td>Miscellaneous Fixed Assets</td>
<td>2.0 (USD Million)</td>
<td>1.1 (USD Million)</td>
</tr>
<tr>
<td>Global Patents</td>
<td>5.0 (USD Million)</td>
<td>2.0 (USD Million)</td>
</tr>
<tr>
<td>Preliminary &amp; Pre-operative Expenses</td>
<td>2.0 (USD Million)</td>
<td>2.0 (USD Million)</td>
</tr>
<tr>
<td>Marketing Expenses</td>
<td>20 (USD Million)</td>
<td>2.0 (USD Million)</td>
</tr>
<tr>
<td>Global Clinical study</td>
<td>30 (USD Million)</td>
<td>2.5 (USD Million)</td>
</tr>
<tr>
<td><strong>TOTAL (USD Million)</strong></td>
<td><strong>108</strong> (USD Million)</td>
<td><strong>16.8</strong> (USD Million)</td>
</tr>
</tbody>
</table>
## Financial Snapshot

**(in USD Million)**

### I. Profit & Loss Statement

<table>
<thead>
<tr>
<th>Financial Year</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>60</td>
<td>125</td>
<td>300</td>
<td>420</td>
<td>546</td>
</tr>
<tr>
<td>y-o-y growth</td>
<td>108%</td>
<td>140%</td>
<td>40%</td>
<td>40%</td>
<td>30%</td>
</tr>
<tr>
<td>EBITDA</td>
<td>11.7</td>
<td>39.7</td>
<td>118.3</td>
<td>170.9</td>
<td>225.6</td>
</tr>
<tr>
<td>EBITDA %</td>
<td>20%</td>
<td>32%</td>
<td>39%</td>
<td>41%</td>
<td>41%</td>
</tr>
<tr>
<td>PAT</td>
<td>6.9</td>
<td>25.3</td>
<td>77.2</td>
<td>111.9</td>
<td>148.1</td>
</tr>
<tr>
<td>PAT %</td>
<td>12%</td>
<td>20%</td>
<td>26%</td>
<td>27%</td>
<td>27%</td>
</tr>
</tbody>
</table>

### II. Balance Sheet

<table>
<thead>
<tr>
<th>FY</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sources of Funds</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capital</td>
<td>14.50</td>
<td>14.50</td>
<td>14.50</td>
<td>14.50</td>
<td>14.50</td>
</tr>
<tr>
<td>Reserves</td>
<td>7.0</td>
<td>32.3</td>
<td>109.6</td>
<td>221.5</td>
<td>369.6</td>
</tr>
<tr>
<td>Term Loan - TDB</td>
<td>15.0</td>
<td>11.7</td>
<td>8.3</td>
<td>5.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Bank Loan</td>
<td>3.5</td>
<td>3.5</td>
<td>3.5</td>
<td>3.5</td>
<td>3.5</td>
</tr>
<tr>
<td>Total</td>
<td><strong>40.0</strong></td>
<td><strong>62.0</strong></td>
<td><strong>135.9</strong></td>
<td><strong>244.5</strong></td>
<td><strong>389.3</strong></td>
</tr>
<tr>
<td>Uses of Funds</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fixed Assets</td>
<td>17.8</td>
<td>16.9</td>
<td>16.0</td>
<td>15.1</td>
<td>14.3</td>
</tr>
<tr>
<td>Net Current Assets</td>
<td>16.5</td>
<td>40.8</td>
<td>117.0</td>
<td>228.0</td>
<td>375.0</td>
</tr>
<tr>
<td>Preliminary Expenses</td>
<td>5.6</td>
<td>4.2</td>
<td>2.8</td>
<td>1.4</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td><strong>40.0</strong></td>
<td><strong>62.0</strong></td>
<td><strong>135.9</strong></td>
<td><strong>244.5</strong></td>
<td><strong>389.3</strong></td>
</tr>
</tbody>
</table>

*Assumptions: P&L is based on real time market research by IRMA/IPSOS USA & tie-ups with Pharma/ Consumer Healthcare MNCs among with orders from Gov.
Financial Overview

Revenue Projections (In USD Million)

- CY2021: 0
- CY2022: 100
- CY2023: 200
- CY2024: 300
- CY2025: 400

Projected CAGR: 70%

EBITDA Projections (In USD Million)

- CY2021: 0
- CY2022: 10
- CY2023: 50
- CY2024: 100
- CY2025: 200

Projected CAGR: 110%

Profit Margin Projections (In USD Million)

- CY2021: 20
- CY2022: 50
- CY2023: 100
- CY2024: 150
- CY2025: 200

Projected CAGR: 115%
Team

Founder Directors: 2 times Nobel Prize Winner Prof George Wald, Harvard Medical Center
: Prof Joseph Weizenbaum, Founder Chair Robotics Comp science Dept. MIT

- Founder CEO
  - Dr. Pawan Saharan, MS, PhD (JNU, WVU)
    - AMP (ASCi in tie up with Harvard business school)
    - Best US graduate student award by AAAS with fellowship at Stanford University
    - Email id: biomix108@gmail.com / drpawan@biomix.in

- Research Director
  - Dr. C. R. Bhatia, Ph.D., Post Doc. (BNL, NY, US)
    - DBT Secretary Govt. of India & Director: BARC, Advisor: IAEC, Vienna
    - Email id: bhatia@gmail.com

- Project Director
  - Amitabh Thakore, B. Tech., MBA (IIM- Ahmadabad)
    - Email id: agthakore@yahoo.com

- Business Development Executive
  - Hemangi Saharan, Bachelor of Management, HR College of Commerce and Economics, Mumbai University
    - Email ID - hemangisaharan@gmail.com

- Medical Directors
  - Dr. S.H. Advani, MD, FICP, FNAMS
  - Oncologist & President - Asian Cancer Society
  - Padamvibhushan awardee by President of India
  - Email id: shadvani2000@yahoo.com

- Dr. Sushil Indoria, MD
  Medical Director Life care Hospital, Thane
  Email id: Sushilindoria@yahoo.in

- Dr. Sandhya Saharan, MD, DGO, Gynecologist and IVF specialist.
  Email id: drsandhyasaharan@hotmail.com

- Dr. Ali Irani - President API, Ortho & Sports Medicine
  Former Physiotherapist of Indian Cricket Team (12 years)
  Email Id: dralirani@gmail.com

Eminent scientists, engineers, doctors from World over with over 300 years of collective experience