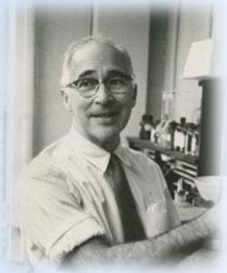
Indian solutions to global health problems via Globally Patented RECEPTOL, Lab & Virtual specialty Hospital on Chip driven by Artificial Intelligence based knowledge acquisition Tools (AIKAT)

Dr. Pawan Saharan MS Ph.D.(USA) drpawan@biomix.in, www.biomix.in, Cell # +91-8291084108



2 Nobel Prize Winner
Prof George Wald

Joseph Weizenbaum

Dr. Pawan Saharan

Receptol® Immunity shield

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

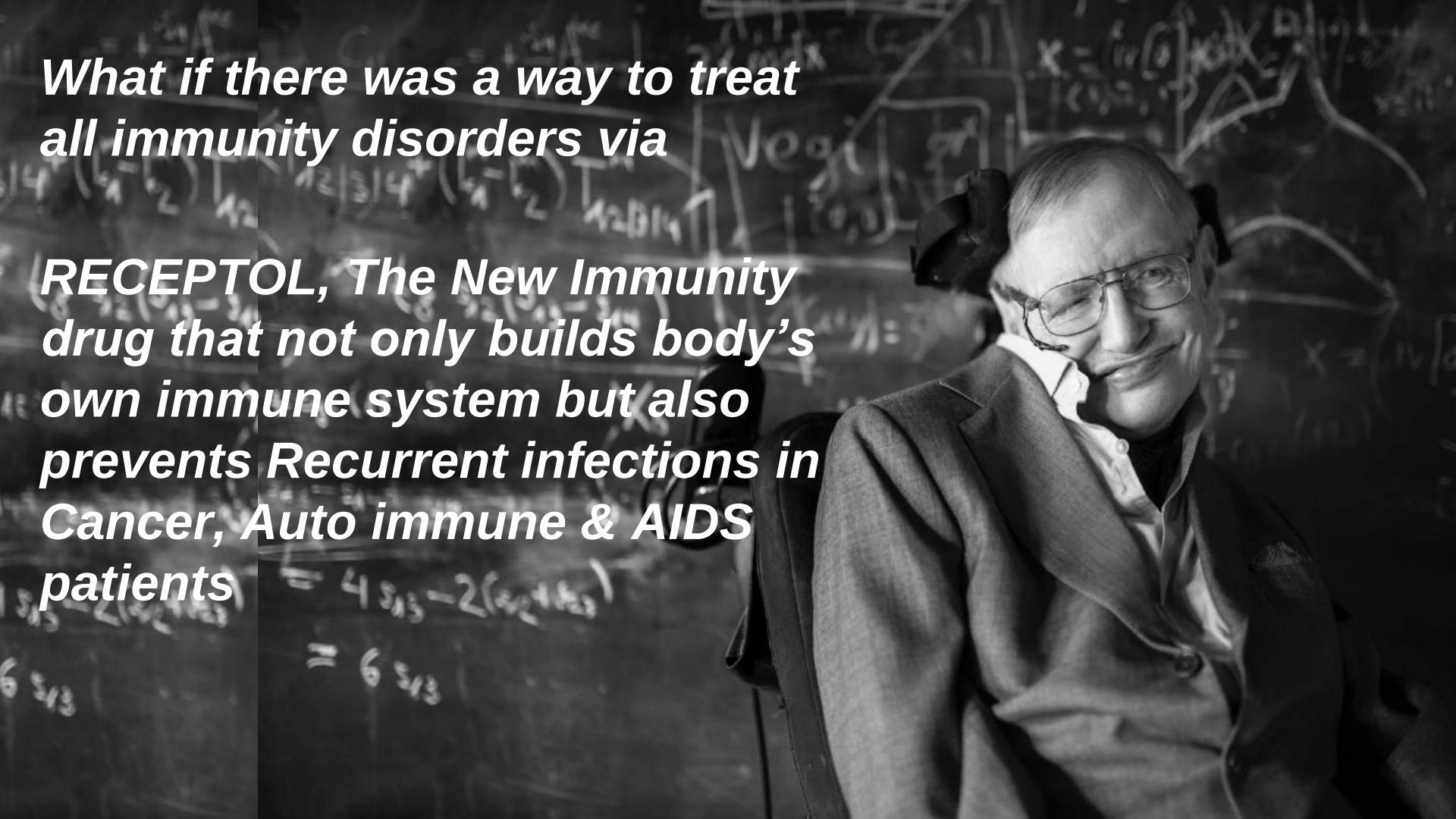
RECEPTOL helps high unmet needs for above disease due to poor immunity

Source :IPSOS & Times studies

MILLIONS MORE

SWINE FL & C HERPES SIMPLEX I&II ACUTE &
CHRONIC S DENGUE FEVER HUMAN PAPILLOMA
VIRUS AL DIARRHEA ALLERGIES & ASTHMA
TUBERCUI ASIA HEPATIC CELLULAR CARCINOMA
HYPERTEN THRUSH AUTISM PREMENSTRUAL
SYNDROM RTHRITIS SPINAL MUSCULAR ATROPHY

SUFFER FROM IMMUNE SYSTEM RELATED ILLNESSES


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 heath 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, Ashtma, 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 Hospitl

Granted Global PATENTS

United States Patent

Patent No :-USA,249,188B2

Date of Patent :-Feb,02,2016

The United States of America

The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America, and if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States of America, or importing into the United States of America, products made by that process, for the term set forth in 35 U.S.C. 154(a)(2) or (c)(1), subject to the payment of maintenance fees as provided by 35 U.S.C. 41(b). See the Maintenance Fee Notice on the inside of the cover.

Michelle K. Lee

Director of the United States Patent and Trademark Office

US009249188B2

(12) **United States Patent**
Saharan

(10) **Patent No.: US 9,249,188 B2**
(45) **Date of Patent: Feb. 2, 2016**

(54) **MAMMALIAN COLOSTRUM DERIVED NANOPEPTIDES FOR BROADSPECTRUM VIRAL AND RECURRENT INFECTIONS WITH A METHOD OF ISOLATION THEREOF**

(71) Applicant: **Pawan Saharan**, Maharashtra (IN)

(72) Inventor: **Pawan Saharan**, Maharashtra (IN)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 75 days.

(21) Appl. No.: **13/845,577**

(22) Filed: **Mar. 18, 2013**

(65) **Prior Publication Data**

US 2013/0274177 A1 Oct. 17, 2013

Related U.S. Application Data

(62) Division of application No. 13/142,327, filed as application No. PCT/IN2009/000749 on Dec. 29, 2009, now Pat. No. 8,518,454.

(30) **Foreign Application Priority Data**

Dec. 27, 2008 (IN) 1353/MUM/2008

(51) **Int. Cl.**

A61K 38/00	(2006.01)
A01N 37/18	(2006.01)
A61P 31/18	(2006.01)
A61K 38/10	(2006.01)
A61K 38/08	(2006.01)
C07K 7/08	(2006.01)
A61K 35/20	(2006.01)
C07K 7/06	(2006.01)

(52) **U.S. Cl.**

CPC . ***C07K 7/08*** (2013.01); ***A61K 35/20*** (2013.01); ***A61K 38/08*** (2013.01); ***A61K 38/10*** (2013.01); ***C07K 7/06*** (2013.01)

(58) **Field of Classification Search**

CPC C07K 7/08; C07K 7/06

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,683,878	A	11/1997	Ellmeier et al.	
2002/0127279	A1	9/2002	Matthews	
2003/0103968	A1 *	6/2003	Amelsberg et al.	424/138.1
2005/0175597	A1	8/2005	Rawlin et al.	
2007/0212367	A1 *	9/2007	Keech	424/185.1

FOREIGN PATENT DOCUMENTS

KR	20020024902	A	4/2002
WO	01/55199	A1	8/2001
WO	01/62785	A2	8/2001
WO	2005/081628	A2	9/2005

OTHER PUBLICATIONS

Blake, Bovine Colostrum, The Forgotten Miracle, Journal of the American Holistic Veterinary Medical Association Jul. 1999, vol. 18, No. 2, pp. 39-40.*

Fonterra Co-operative Group Ltd, Colostrum and Stolle Sales Get a Boost from SARS, 2003.*

Veracity, Colostrum is a proven, effective immune system booster, Natural News, 2005.*

Hong, S.Y. and Qin, Z.B.; "Inhibitor of Binding 3" XP002586928, Aug. 2, 2005, retrieved from EBI Database accession No. Q4JQP9.

Struff W.G. et al.; "Bovine colostrum as a biologic in clinical medicine: a review—Part II: clinical studies"; Int. Journal of Clinical Pharmacology and Therapeutics, vol. 46, No. 5, pp. 211-225, May 1, 2008; XP009150270, ISSN: 0946-1965.

Bocci V., Von Bremen K., Corradeschi F., Luzzi E., Paulesu L.; "Colostrum stimulates the lymphoid tissue providing benefits in aged or immunodeficient people"; Journal Biology Regul Homeost Agents, Oct.-Dec.; 5(4):121-4; 1991; abstract only, full-text unavailable.

Oda, S. et al.; "Insulin-like growth factor-I, GH, insulin and glucagon concentrations in bovine colostrum and in plasma of dairy cows and neonatal calves around parturition"; Comp. Biochem. Physiol.; vol. 94A, No. 4, pp. 805-808, 1989.

Bhora, F.Y. et al. "Effect of growth factors on cell proliferation and epithelialization in human skin", Journal of surgical Research; vol. 59, pp. 236-244, 1995.

Examination report of corresponding European patent application 09827010.1, issued on Mar. 20, 2013.

* cited by examiner

Primary Examiner — Karlheinz R. Skowronek
Assistant Examiner — Sergio Coffa
(74) *Attorney, Agent, or Firm* — Nath, Goldberg & Meyer; Tanya E. Harkins

(57) **ABSTRACT**

The present Invention relates to nanopeptides isolated from mammalian colostrums with vaccine like antiviral and immunodulator activity via building body's own immune system and attachment inhibition on the cell surface receptors.

9 Claims, 10 Drawing Sheets

Entry barrier via Global product patents

Jurisdiction	Application No./ Date	Title	Status
USA	13/142,327 DT. 27.06.2011	Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED (PATENT# US8518454)
USA	U.S. Patent Application No. 13/845,577	Mammalian Colostrum Derived Nanopeptides For Broad spectrum Viral And Recurrent Infections With A Method Of Isolation Thereof **(For approved 58 indications for Radha 108)**	GRANTED (Patent No. 9,249,188)
SOUTH AFRICA	2011/4687 DT. 24.06.2011	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED (PATENT # 2011/04687)
SINGAPORE	201104717.2 DT. 29.12.2009	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED (PATENT # 172793)
INDIA	1353/MUM/08 DT. 27/06/2008	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED
EUROPE	EP 09827010.1 DT. 30.06.2011	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED
CANADA	2478449 DT. 29.12.2009	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED
PCT	PCT/IN09/749 DT. 29.12.2009	Mammalian Colostrum Derived Nanopeptides For Broadspectrum Viral And Recurrent Infections With A Method Of Isolation Thereof	GRANTED
Hospital on chip	PCT/IN2011/000522 09.08.2011	An Automated Integrated System, Method and Plate form For Healthcare Services	Granted(PATENT #:WO2012/020429)
Lab on chip	PCT/IN2010/000424 DT. 18.06.2010	An Apparatus and Method For Detecting Biological State in Sample by Using Bio Marker ERS	Granted (PARENT #:WO2011/158246A1)

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 & othersthat 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

PCT/IN2011/000522 09.08.2011
Granted(PATENT #:WO2012/020429)

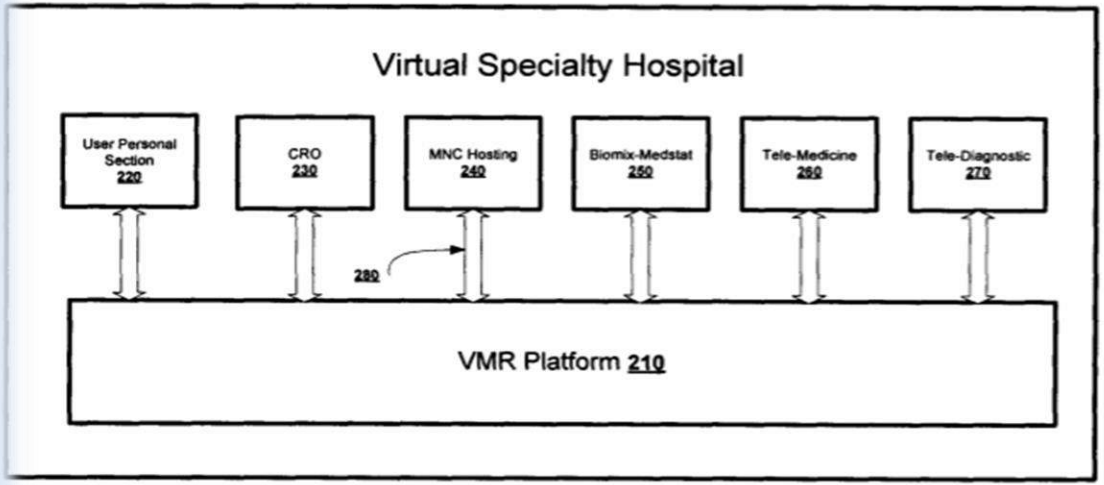


FIGURE 2

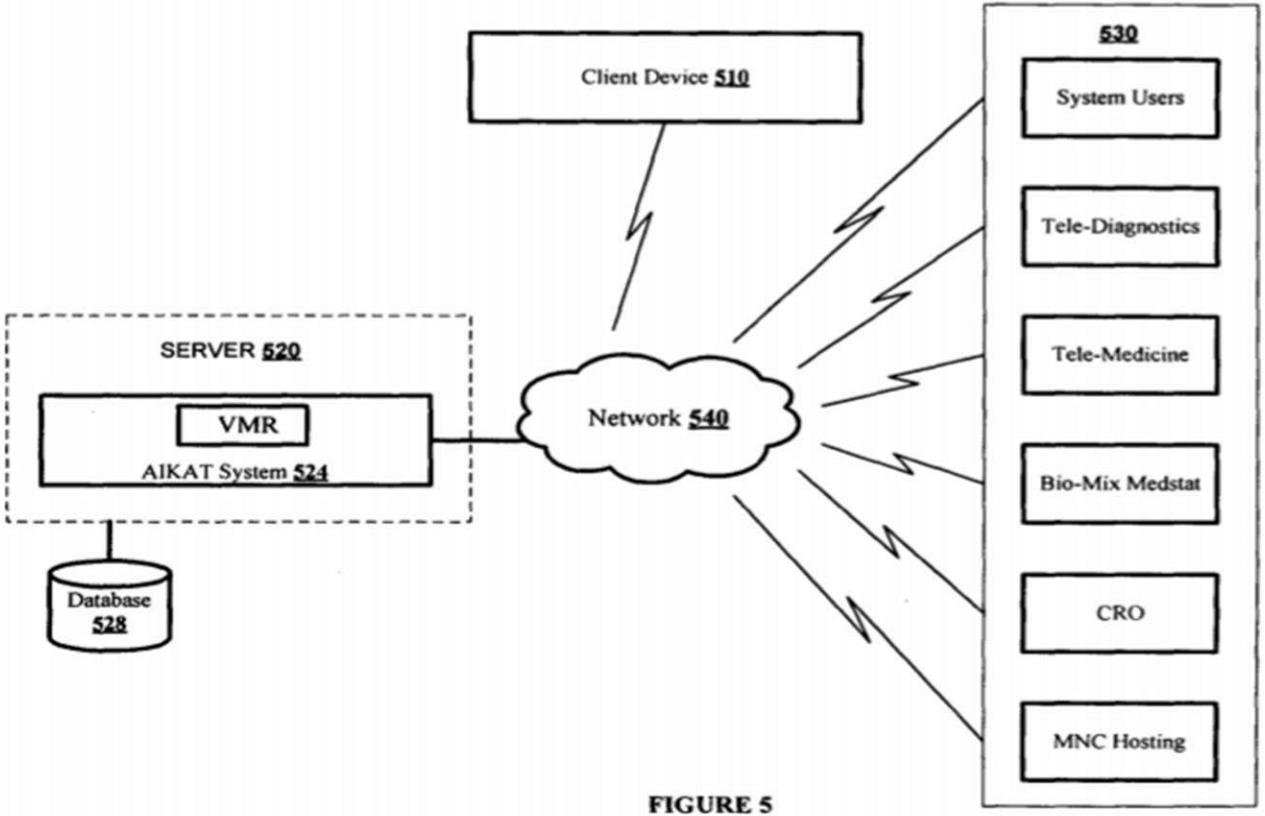
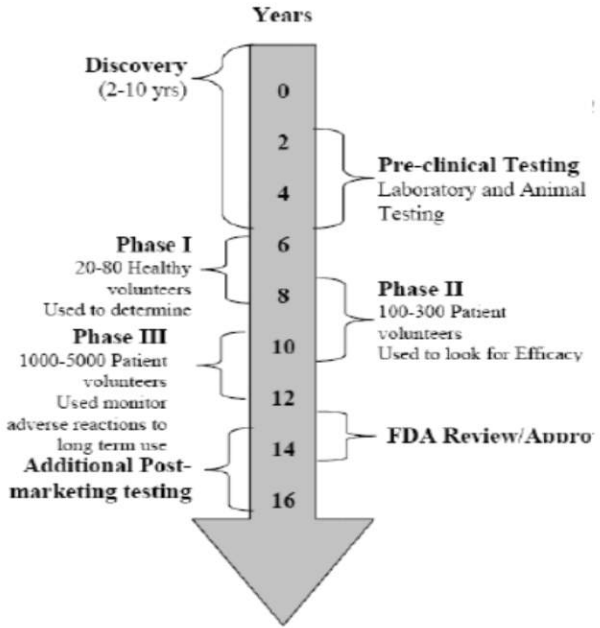

Client Device 510
530
System Users
Tele-Diagnostics
Tele-Medicine
Bio-Mix Medstat
CRO
MNC Hosting
SERVER 520
VMR
AIKAT System 524
Network 540
Database
528

FIGURE 5

Phases of discovery NID: RECEPTOL
16 years to put RECEPTOL in Market *

Phases and Time of drug discovery



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

Current Position

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)

Allergies , Asthma, HIV, Autoimmune Disorders, Viral Respiratory Infection, Rheumatoid Arthritis, Endometriosis , Cancer, Lupus , Severe Acute Respiratory Syndrome (SARS), Cold & Flu, Benign Prostatic Hyperplasia , Premenstrual syndrome, & Alzheimer's, Hypertension, Thrush,Austism, Perthes disease, Prion disease, Psoriasis, Sjogren's syndrome, Spinal Muscular Atrophy,

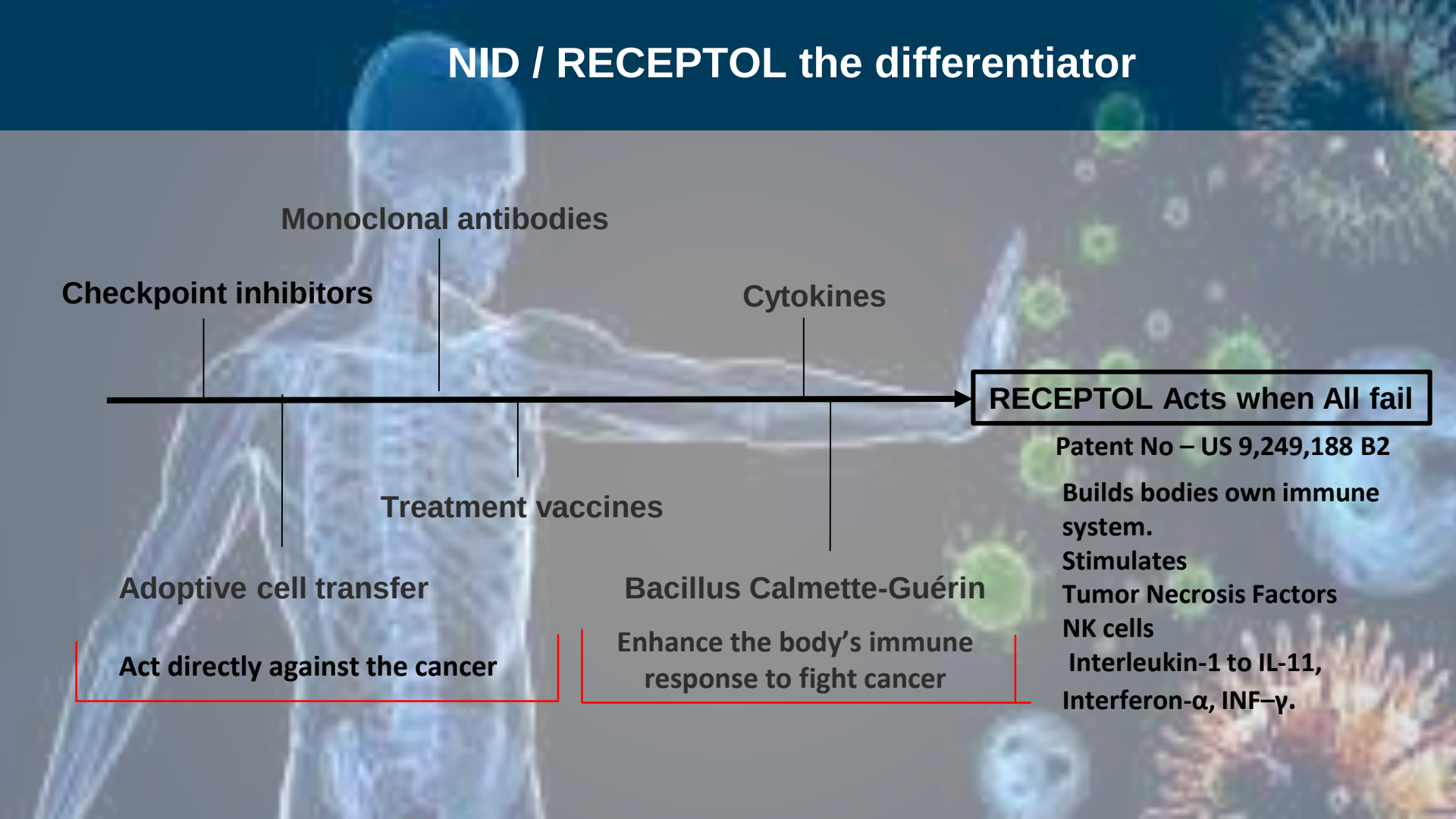
Thrombocytopenia, Burns, Infection, Insect bites, Daiper rash, Herpetic lesions, Pharangitis, Porphyria, Raynaud's phenomenon, Acute Viral Infection.

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

NID / RECEPTOL the differentiator



Immuno-oncology and NID

"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.

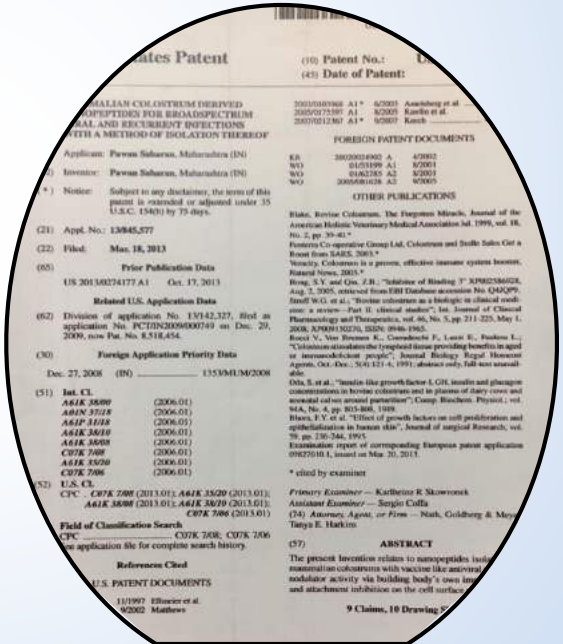
It is a perfect fit for Immune Oncology as recommended by Oncologists world over including Dr Suresh Advani Medical Oncologist and Founder Tata Memorial Cancer Hospital, Mumbai and President Asian Cancer Society.

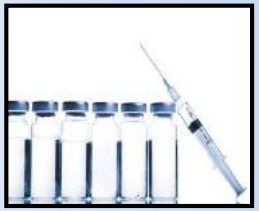
Patents for Preventive Therapy

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.

Abstract : US Patent **US 9,249,188 B2**

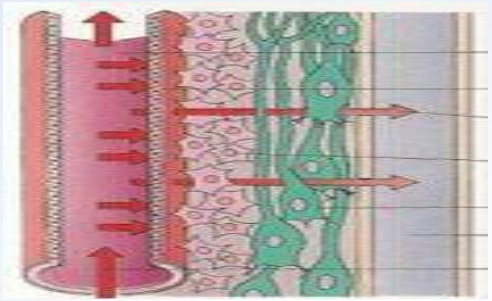
The present Invention relates to nanopeptides isolated from mammalian colostrums with vaccine like antiviral and immunodulator activity via building body's own immune system and attachment inhibition on the cell surface receptors.

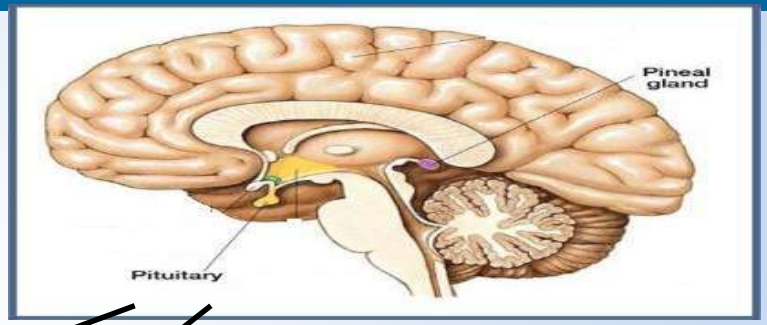




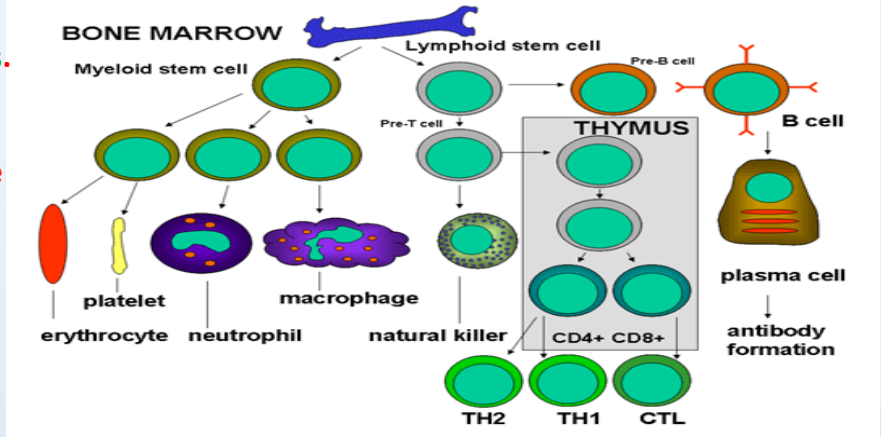
Mode of action: Science behind MoA

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.

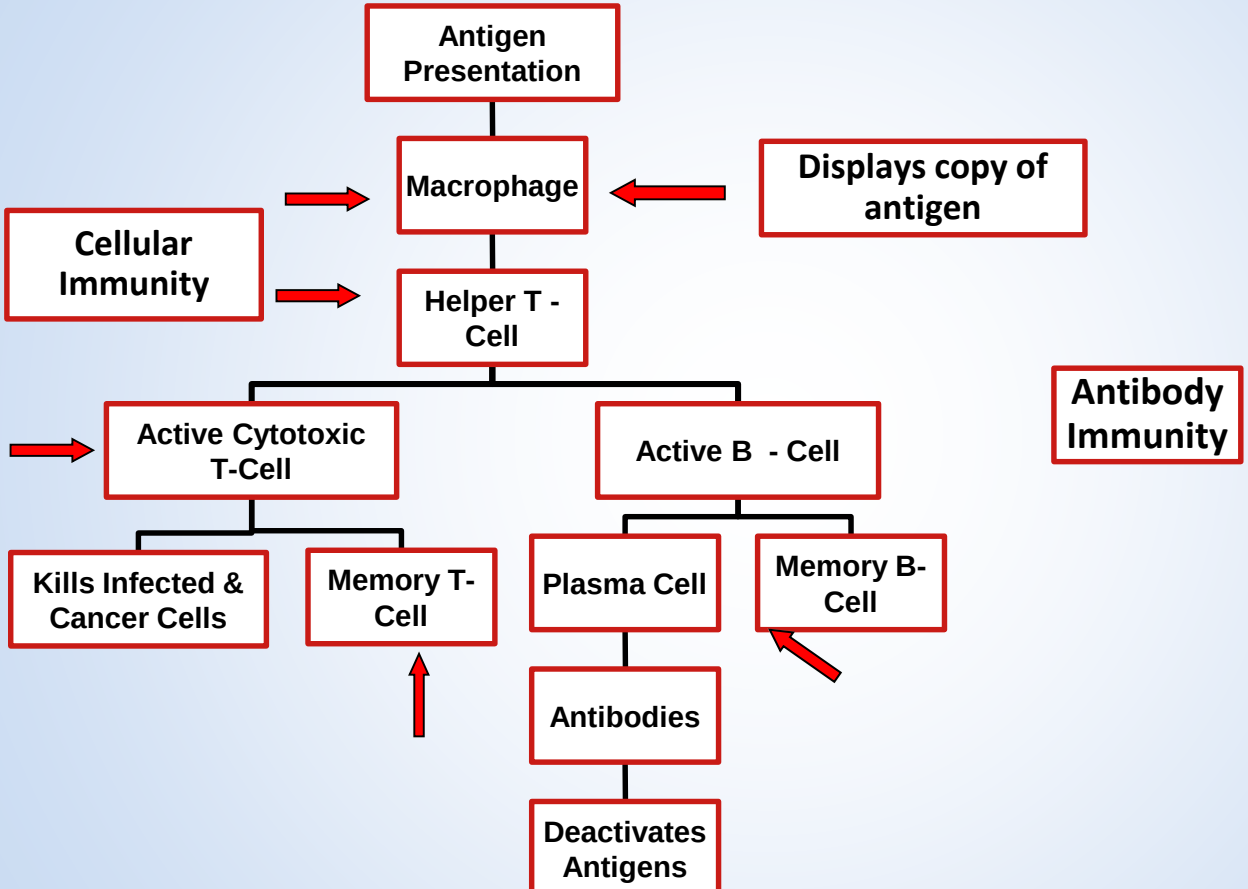


- Stimulates production of cytokines IL-1 to IL-11, TNF-α, INF–γ.
- Stimulates the maturation of immature thymocytes into either helper or suppressor T cells
- Radha108 also functions as a molecular signaling device which works through receptors on target cell surfaces

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 (→)



USP

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:

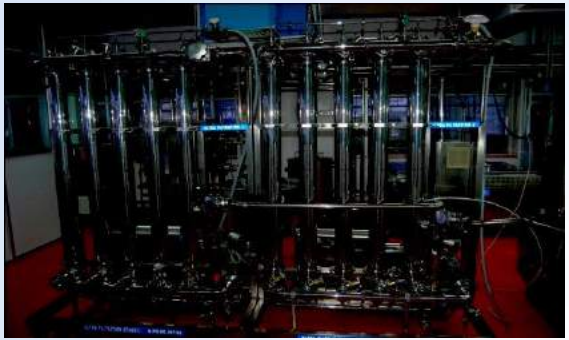
Oral spray, Oral gargle, Capsules & Tablets & Powder

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.



X

Product range

Oral spray

Oral liquid

Capsules & Tablets

Powder

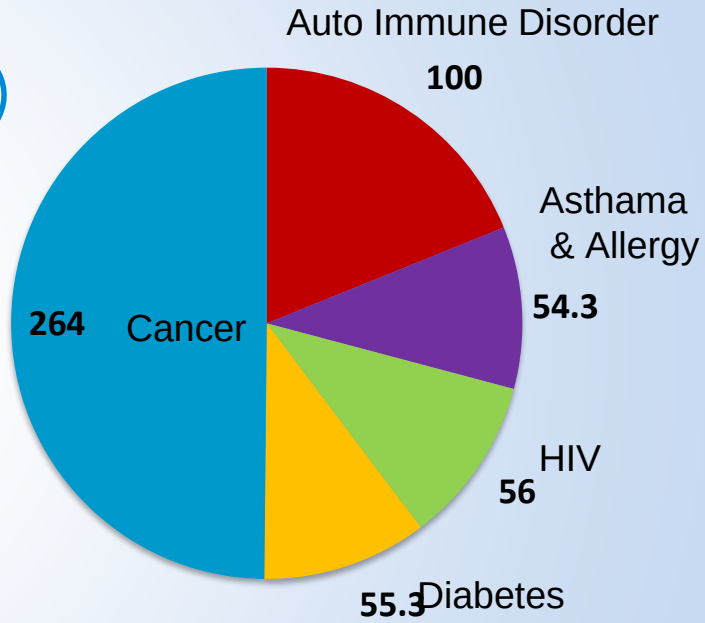
PHARMACEUTICAL DATA ON FORMULATION

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

*US alone accounts for **$5 Billion**

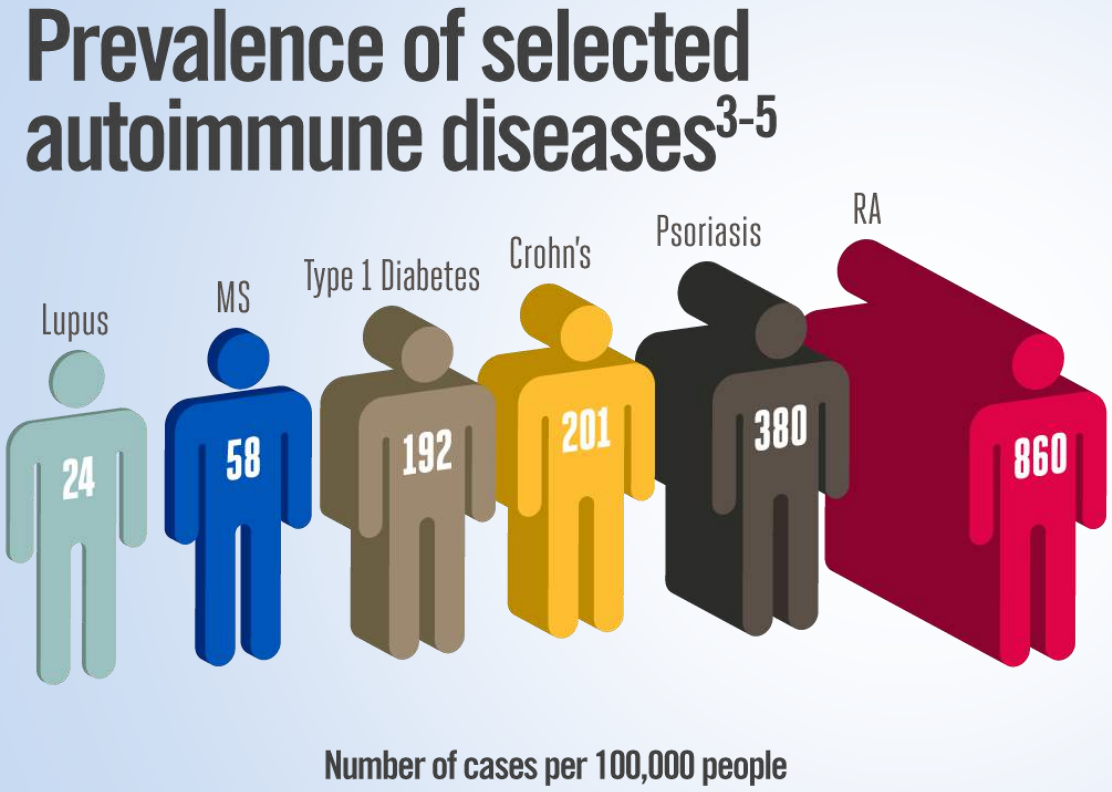


Rest of the world can account for additional $8 billion market

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

Source: www.cdc.gov

Auto immune disorders



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

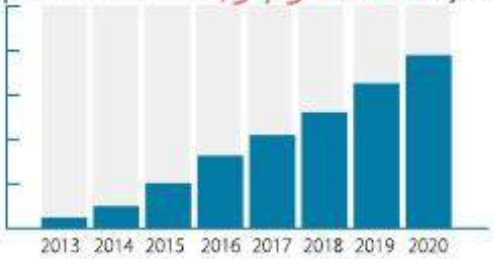
25MM alone in US

Asthma may affect as many as 334 million people.*

EXPECTED TO GROW BY MORE THAN 100MM BY 2025!

Global COPD and Asthma Devices Market

Global COPD and Asthma DevicesMarket 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)

***Source**: www.GlobalaAthmaReport.gov

Allergies & Asthma

Adults

Children

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

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

***Source**: www.GlobalaAthmaReport.gov

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

36.9 MILLION

people worldwide are currently living with HIV/AIDS.

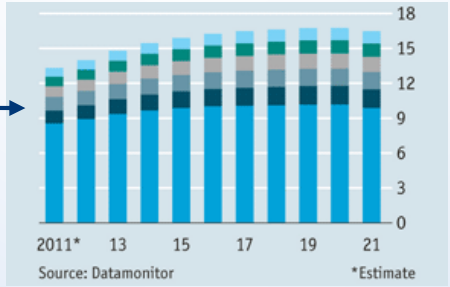
The vast majority of people living with HIV are in low- to middle-income countries, particularly in Sub-Saharan Africa.

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.

Source: www.aids.gov

Forecast of HIV drug sales ($Billion)



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)

X

Concept Q (108 Immunity superchargers)

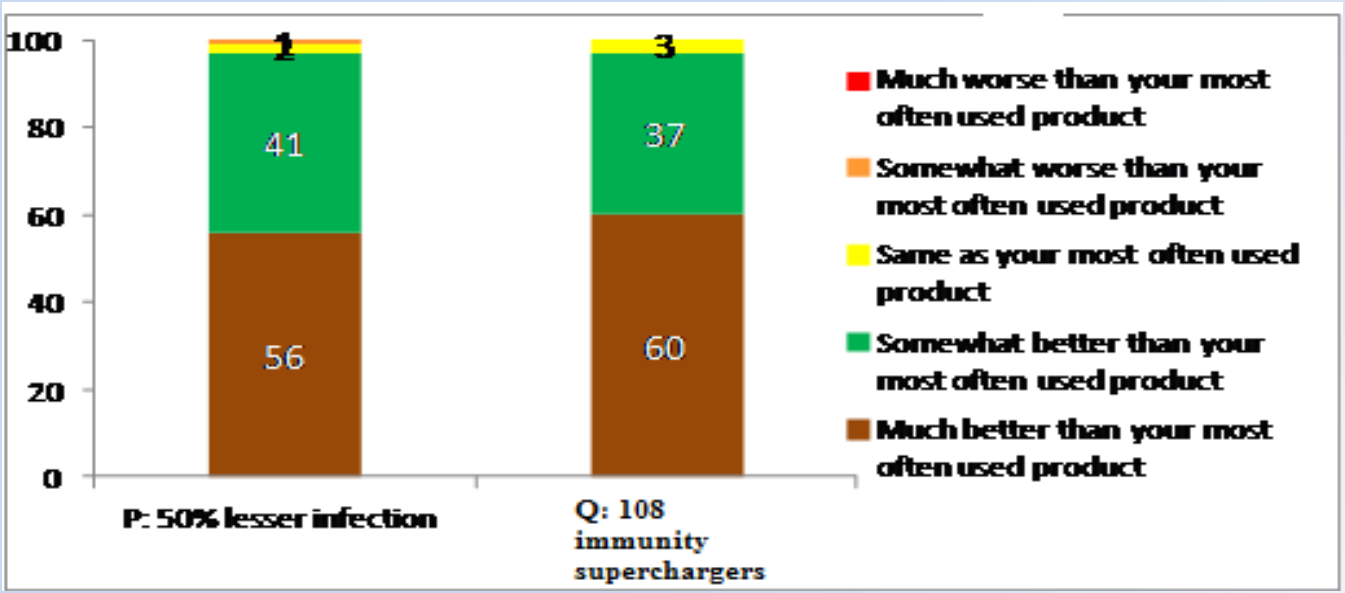
2. **Concept Q (108 immunity superchargers) : Packed with 108 immunity superchargers.**

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

- **ITP index 97 and ITP score 39%.**

Product perception & Intended purchase pattern

Respondents agreed that both the formulations of the product are much better than their existing products in use.



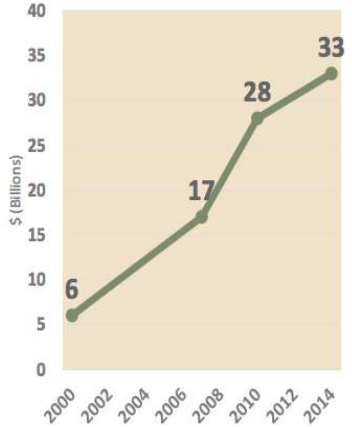
Commercial Market Advantage

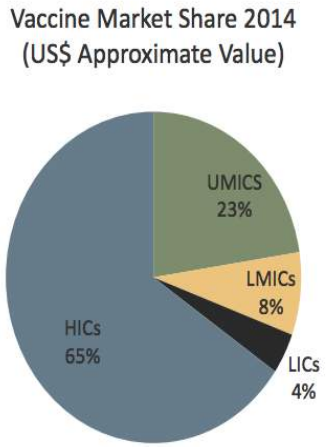
IPSOS studied Customer's perceptions towards two concepts of the immune powder (as infection reducer & immunity super charger) and their willingness to buy HFDs (Health Food Drinks), and FMCG products with Radha 108 as an additive.Results were as follows:

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



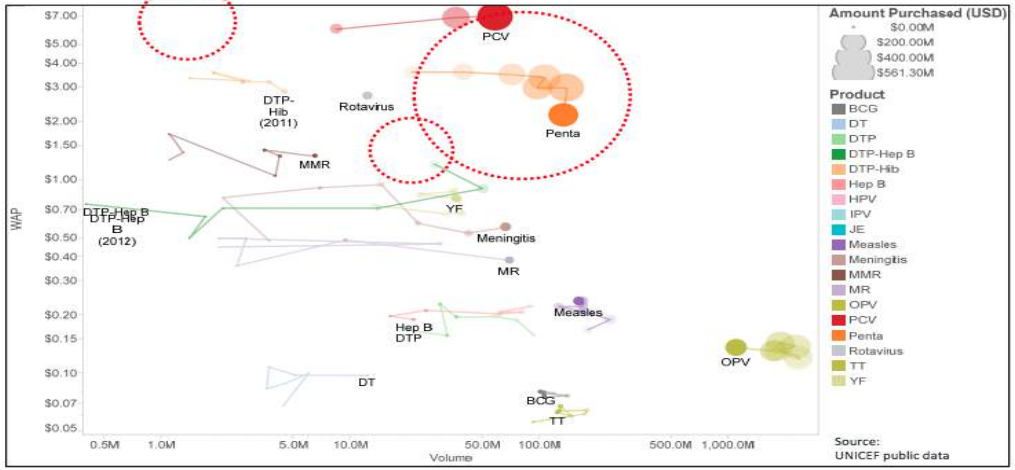


Source: Global Vaccine Market Model preliminary routine immunization market value analysis, March 2016

- **Positive trends**
  - Immunizations: on the top of the agenda: DOV ands GVAP
  - Promising vaccine pipeline, R&D
  - Growing support: GAVI partners + Gov funding
  - Multiple initiatives, PDPs and PPPs
  - New players on supply and funding
  - More WHO PQ vaccines leading to competition, price decrease
  - Strategic role of UNICEF SD and PAHO and increasing role of funders

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

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

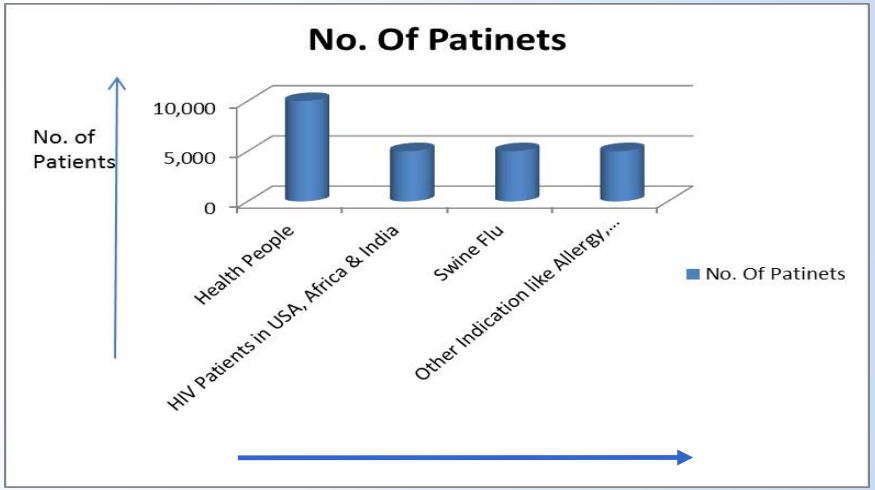


*Source: WHO

Meta Analysis on 25000 Patients

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.

Sr.No.	Stand Alone Receptol Therapy in Global clinical studies	No. of Patients
1	Healthy people	10,000
2	HIV Patient in USA, Africa, India	5000
3	Swine Flu	5000
4	Other Indications like allergy, asthma, Rheumatoid Arthritis, Chronic Fatigue Syndrome, Endometriosis Study etc.	5000

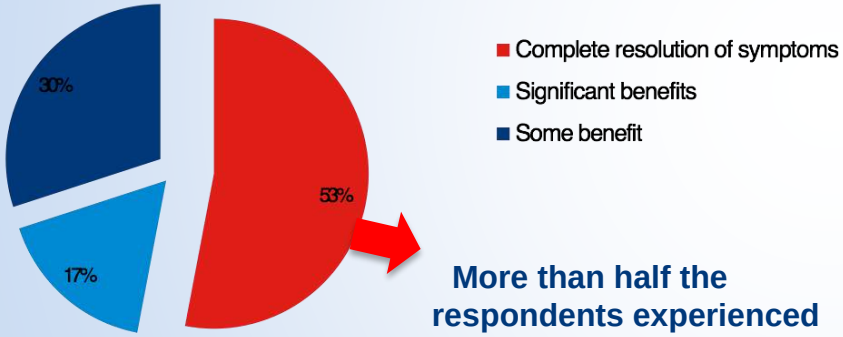


Stand Alone Radha 108 Therapy in Global Clinical Studies

Global Studies on Immunity Disorders

Allergies

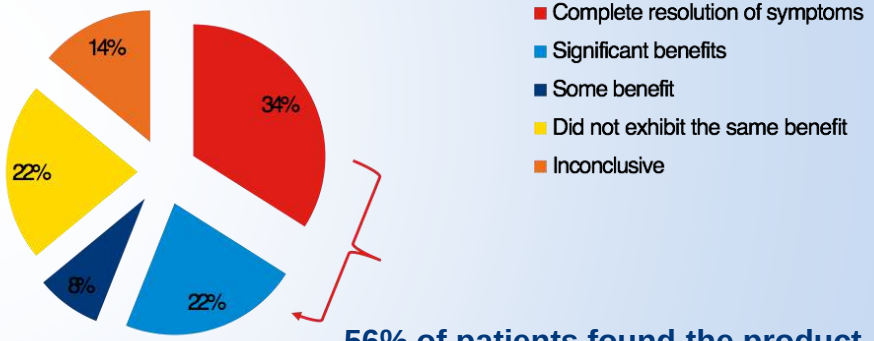
Reporting Patients	:	24
Duration of Treatment	:	6 months



More than half the respondents experienced complete resolution of symptoms!

Rheumetoid Arthritis

Reporting Patients	:	63
Duration of Treatment	:	6 months

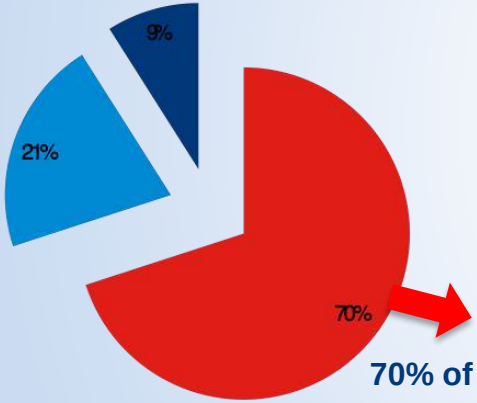


56% of patients found the product to be highly effective!

Global Studies on Immunity Disorders

Chronic Fatigue Syndrome

Reporting Patients	: 108
Duration of Treatment	: 6 months

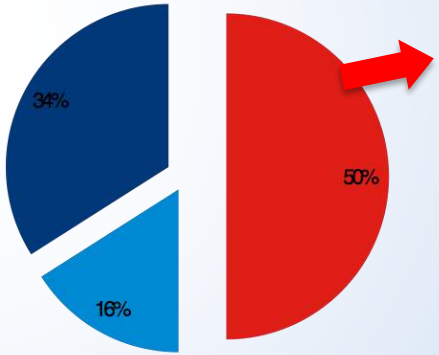


- Significant benefit
- Some Benefit
- Did not exibit the same benefit

70% of patients received significant benefits!

Endometriosis

Reporting Patients	: 106
Duration of Treatment	: 6 months



Similarly for Endometriosis, complete resolution in most cases!

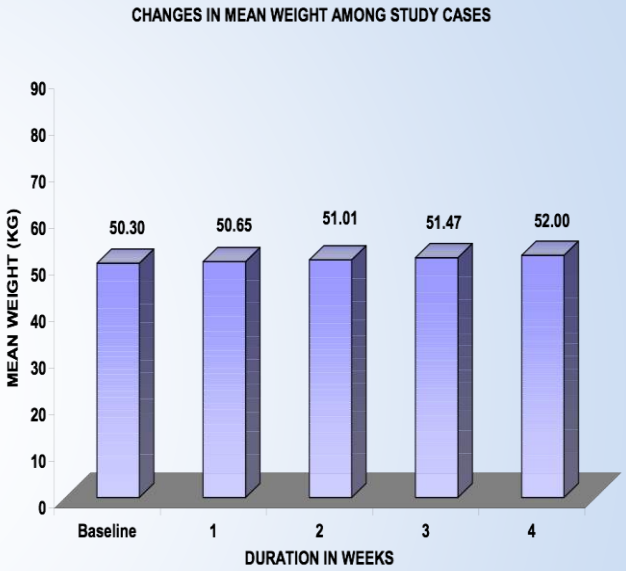
- Complete resolution of symptoms
- Some benefit
- Inconclusive

Efficacy & safety of on Healthy Population

CHANGES IN MEAN BODY WEIGHT AMONG STUDY CASES

Duration (Weeks)	Mean weight $\bar{X}$ ($\pm$ SD) (N = 10000)
Baseline	50.30 ± 10.02
1	50.65 ± 10.01
2	51.01 ± 09.96
3	51.47 ± 09.94
4	52.00 ± 09.96
Mean Diff. (Baseline – Wk1) (P value)	*00.35 ± 00.66 (0.001)
Mean Diff. (Baseline – Wk2) (P value)	*00.71 ± 01.24 (0.001)
Mean Diff. (Baseline – Wk3) (P value)	*01.17 ± 01.95 (0.001)
Mean Diff. (Baseline – Wk4) (P value)	*01.70 ± 02.15 (0.001)

By ANOVA P<0.05, * Significant

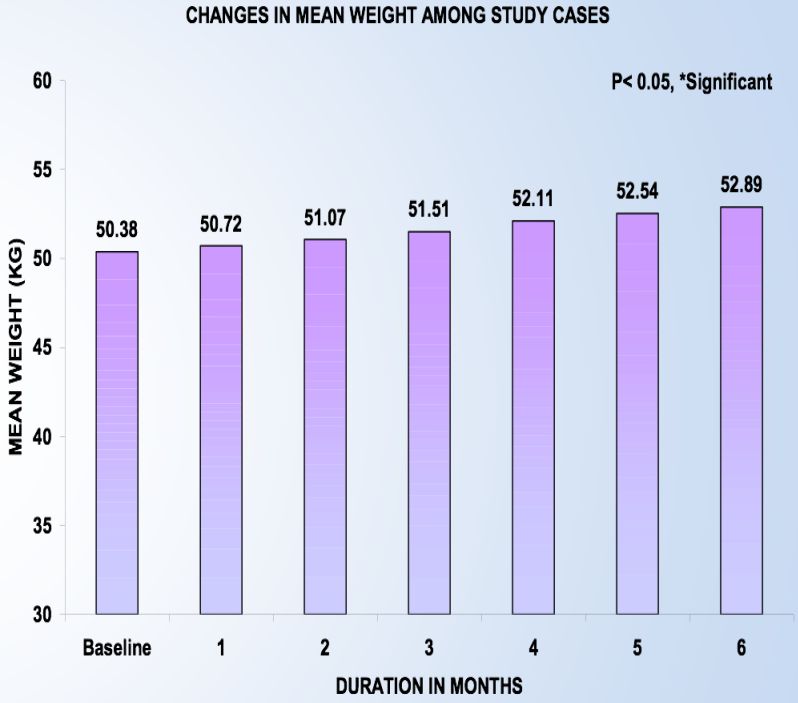


- After 1 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 0.7% from baseline.
- After 2 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 1.4% from baseline. Same trend was observed till the end of 4 weeks

Efficacy & safety of on HIV+ patients in USA, India

CHANGES IN MEAN WEIGHT AMONG STUDY CASES

Duration (Months)	Mean weight ($\bar{X} \pm$ SD) (N = 5000)
Baseline	50.38 ± 09.89
1	50.72 ± 09.88
2	51.07 ± 09.82
3	51.51 ± 09.79
4	52.11 ± 09.75
5	52.54 ± 09.76
6	52.89 ± 09.77
Mean Diff. (Baseline – 1 month) (P value)	*00.34 ± 00.57 (0.001)
Mean Diff. (Baseline – 2 months) (P value)	*00.69 ± 00.91 (0.001)
Mean Diff. (Baseline – 3 months) (P value)	*01.13 ± 01.39 (0.001)
Mean Diff. (Baseline – 4 months) (P value)	*01.73 ± 01.71 (0.001)
Mean Diff. (Baseline – 5 months) (P value)	*02.16 ± 01.76 (0.001)
Mean Diff. (Baseline – 6 months) (P value)	*02.51 ± 02.07 (0.001)



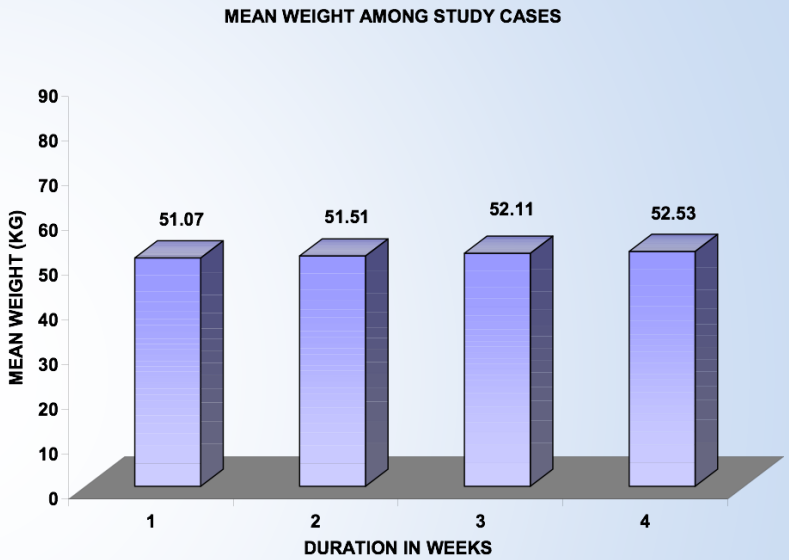
By ANOVA - Significant

- 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

Duration (Weeks)	Mean weight ($\bar{X} \pm$ SD) (N = 5000)
1	51.07 ± 9.82
2	*51.51 ± 9.79
3	*52.11 ± 9.75
4	*52.53 ± 9.76

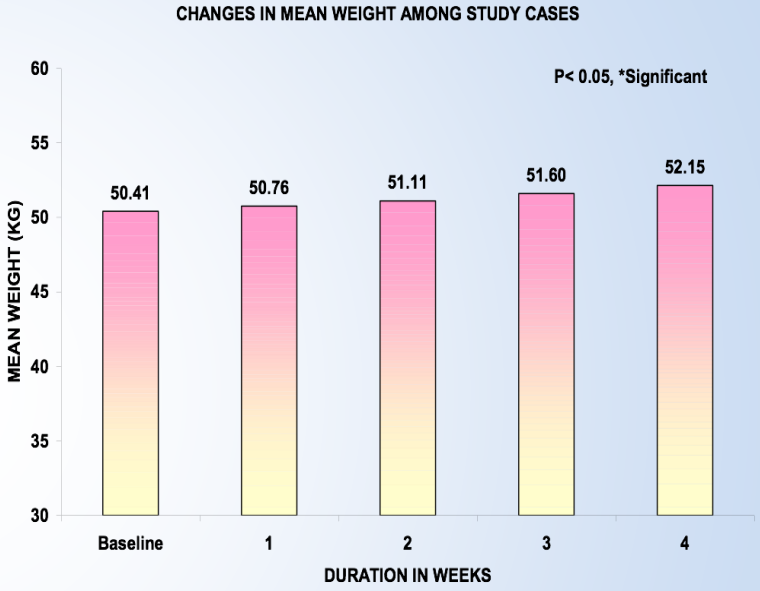


By ANOVA $P < 0.05$, * Significant

- At the end of 2nd week, mean weight showed significant change from baseline i.e. mean change of 1.44 kg.
- At the end of 4th 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

Duration (Weeks)	Mean weight ($\bar{X} \pm$ SD) (N = 5000)
Baseline	50.41 ± 10.03
1	50.76 ± 10.01
2	51.11 ± 09.94
3	51.60 ± 09.91
4	52.15 ± 09.91
Mean Diff. (Baseline – Wk1) (P value)	*00.35 ± 00.57 (0.001)
Mean Diff. (Baseline – Wk2) (P value)	*00.70 ± 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

Phase III Indian Safety & Efficacy Mono Therapy Clinical Trials- with Radha 108 Nano Peptide by Government of India, Ministry of Health/National AIDS Control and Monitored by Indian Council of Medical Research/NARI* by US PATH accredited org.

- **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

1.	No. of Rats used	48
2.	Categories	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)
3.	Days of trial	45
4.	Period of Observation	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.

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 ($p = 0.001$).

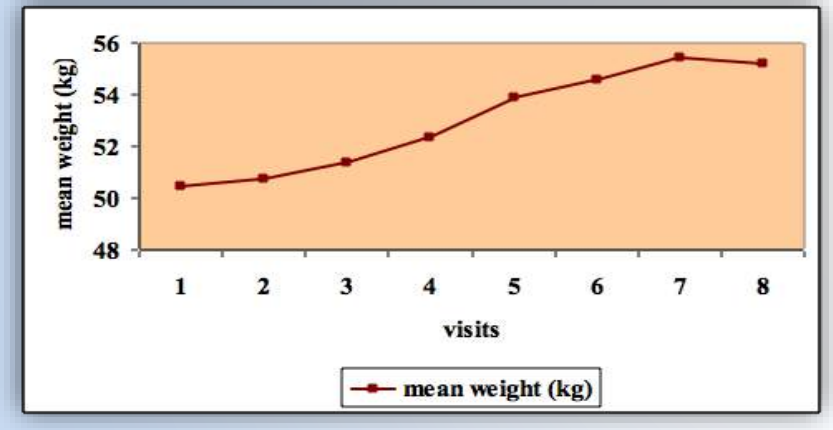
Indian Study : STAND ALONE MONOTHERAPY

SION HOSPITAL MUMBAI

Weight gain after treatment

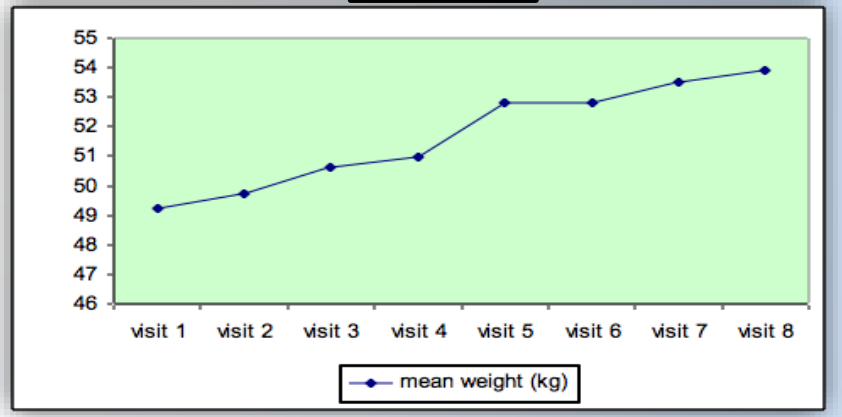
Statistically significant gain in weight p<0.05 in both the Study I and Study II

Study 1



Study I : average weight gain of **4.73 kg** after 12 weeks of Radha 108 therapy. statistically significant ($p < 0.05$)
Mean weight was **50.48 kg** at start of study.

Study 2

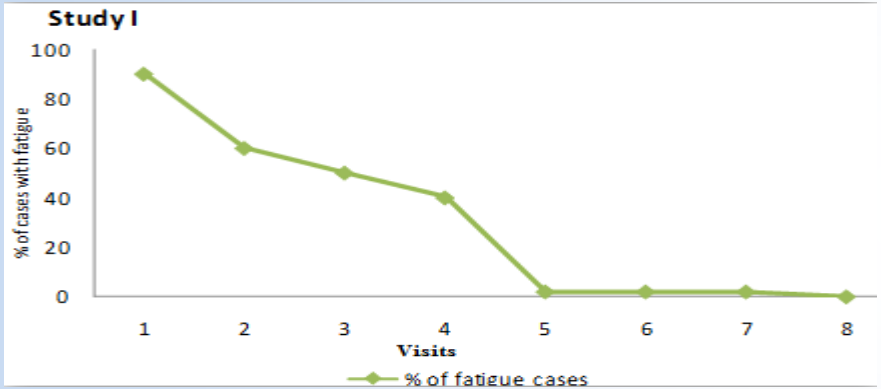


Study II : average weight gain of **4.68 ± 1.9** kg after 12 weeks of Radha108 therapy. statistically significant ($p < 0.05$)
Mean weight was **49.21kg** at start of study and **53.89 kg** after 12 wks.

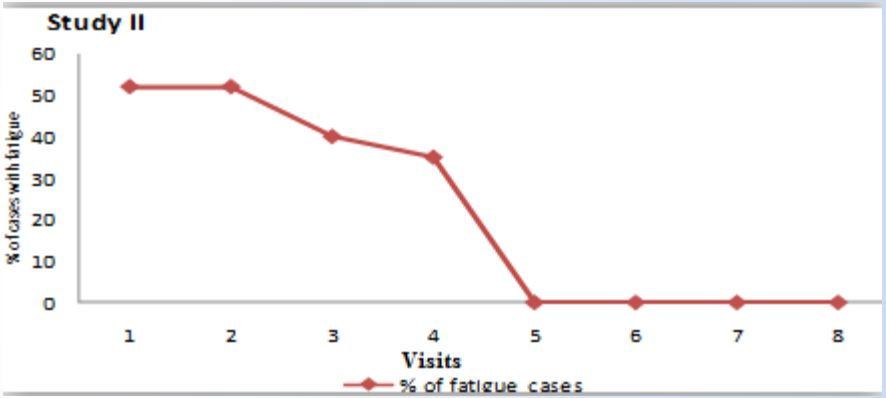
Data on chronic fatigue syndrome after therapy

Statistically significant reduction in Fatigue / Malaise in both the Study I and Study II

Study 1



Study 2



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

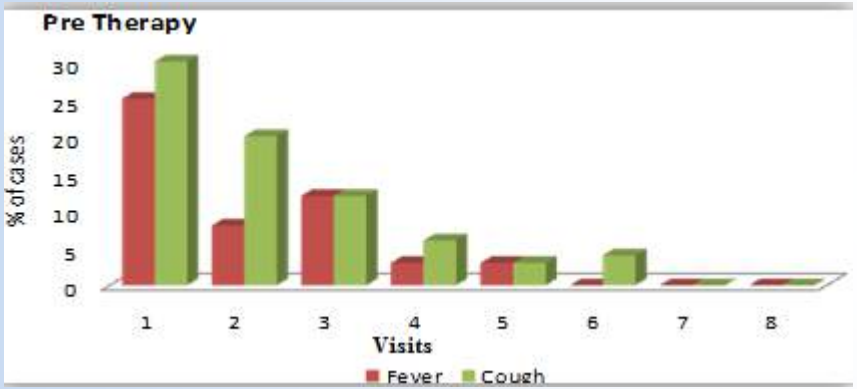
Study II:

- 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.

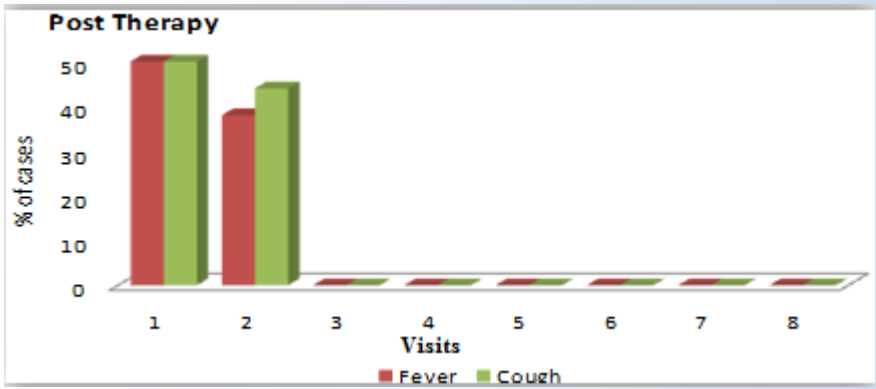
Data on fever & cough after Therapy

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

Study 1



Study 2



- 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

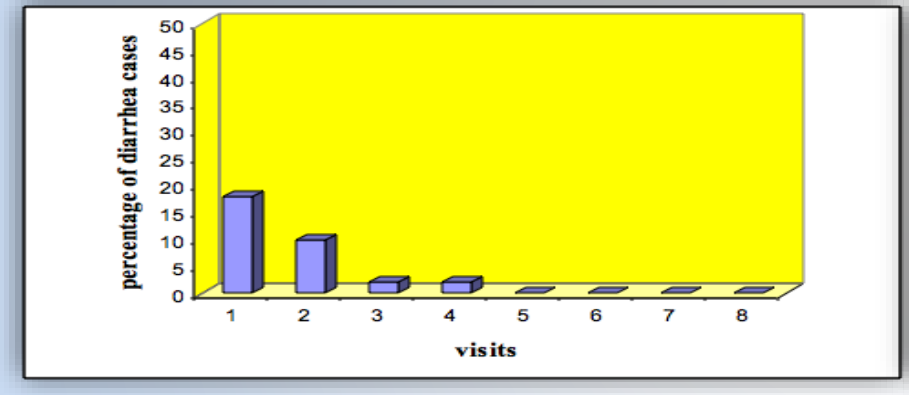
Study II: 100 % of the total study cases had fever and cough.

after treatment from 3rd week onwards all the patients had relief from fever and cough, statistically significant

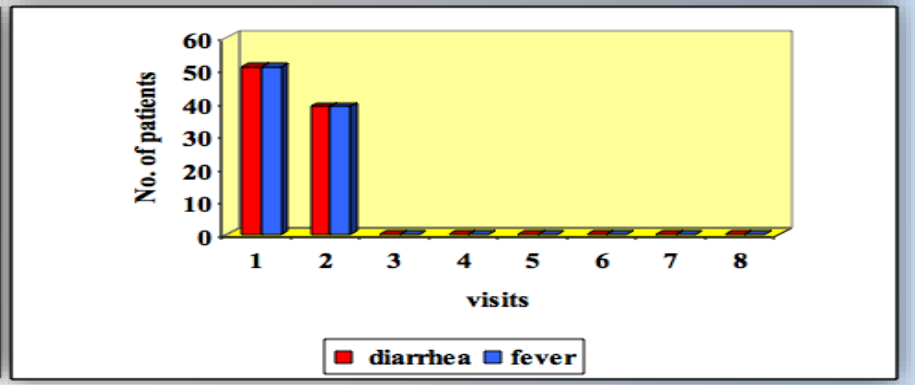
Data on Diarrhea after Therapy

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

Study 1



Study 2



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

Data on HIV viral load after Therapy

Statistically significant reduction in HIV Viral Load

Study 1

	Viral Load baseline	Viral Load 3 months
Mean	335278.23	141053.42
Median	92457.50	25332.50

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 2

	Viral Load baseline	Viral Load 3 months
Mean	119243.49	38814.33
Median	38108.00	14073.00

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

Study 1

	CD4 baseline	CD4 3 months
Mean	370.63	390.65
Median	312.50	363.50

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)

Study 2

	CD4 baseline	CD4 3 months
Mean	317.16	344.24
Median	276.00	305.00

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)

Summary of Mumbai, India phase III study on AIDS patients

Clinical Symptoms	N	At Baseline	Responders At Week-2
Diarrhea	51	51(100%)	12(23.53%)
Nausea	51	51(100%)	3(5.9%)
Vomiting	51	51(100%)	17(33.3%)
Fever	51	51(100%)	13(25.5%)
Cough	51	51(100%)	13(25.5%)
Paraesthesia	51	51(100%)	16(31.4%)
Disturbed Sleep	51	51(100%)	0(100%)
Skin Rash	51	51(100%)	7(13.7%)
Fatigue/Malaise	51	51(100%)	0(100%)
Herpes Zoster	51	51(100%)	18(35.3%)
Hair Changes	51	51(100%)	16(31.4%)
Leukoplakia	51	51(100%)	0(100 %)
Oral Thrush	51	51(100%)	0(100 %)

Parameter	Baseline Mean ± SD	Week 12 Mean ± SD	Difference (Week 12- Baseline) Mean ± SD	P-value
CD4 Counts (cells/ cmm)	317.16 ± 128.67	344.24 ± 165.79	+ 27.08 ± 92.47	0.042
CD8 Counts (cells / cmm)	1037.06 ± 285.02	1139.75 ± 386.76	+102.69 ± 267.44	0.008

SUMMARY - GLOBAL SAFETY & EFFICACY STUDY DATA ON AIDS SUBJECTS

KEY DIMENSIONS	PHASE I, II & III INTERNATIONAL TRIALS	INDIA PHASE III STUDY 1	INDIA PHASE III STUDY 2
Phase	Phase I - HIV trial, US Phase II - HIV trial, Nairobi, Kenya Phase III - HIV trial, Rwanda	Phase III validation trial by GOI on HIV patients, Standalone monotherapy	Phase III validation trial by GOI on HIV patients, Standalone monotherapy
No. of patients	Phase I - 12 cohorts Phase II - 30 cohorts Phase III - 60 cohorts	50 HIV seropositive patients	51 HIV seropositive patients
Duration	30 to 365 days	180 days	180 days
Compliance	Very good	Very good	Very good
Side effect	None	None	None
Weight gain	6 lbs average gain	4.73 kg per patient, $p<0.05$	$4.68 \pm 1,9$ kg per patient, $p<0.001$
Clinical symptoms	90 days relief from symptoms	Improved within 3 weeks from starting of therapy	Improved within 3 weeks from starting of therapy
CD4 cell count	Phase II: Average by 31	Average by 51, median CD4 cell count from 312 to 363 ($p = 0.06$)	On an average by 27 ($p = 0.042$)
HIV Viral load	Phase II: Mean HIV log viral load from 4.6 to 2.5	Mean HIV log viral load from 4.63 to 4.18 ($p = 0.001$)	Mean HIV log viral load from 4.41 to 4.02 ($p = 0.009$)

Treatment of HIV with Biomix NID per Global Clinical Trial Results

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

(USD Million)

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

Financial Snapshot

(in USD Million)

I. Profit & Loss Statement

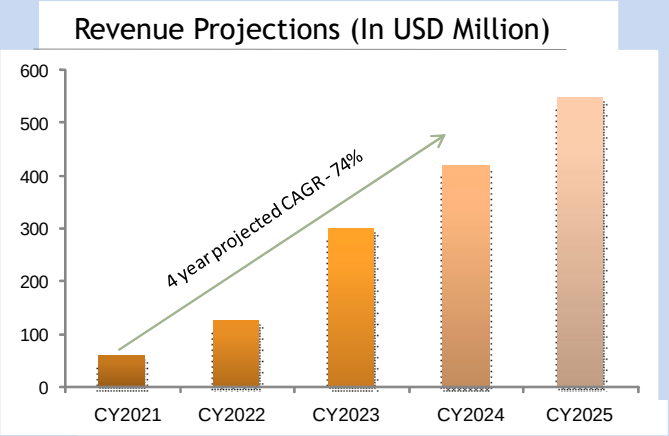
Financial Year	2020	2021	2022	2023	2024
Revenue	60	125	300	420	546
y-o-y growth		108%	140%	40%	30%
EBITDA	11.7	39.7	118.3	170.9	225.6
EBITDA %	20%	32%	39%	41%	41%
PAT	6.9	25.3	77.2	111.9	148.1
PAT %	12%	20%	26%	27%	27%

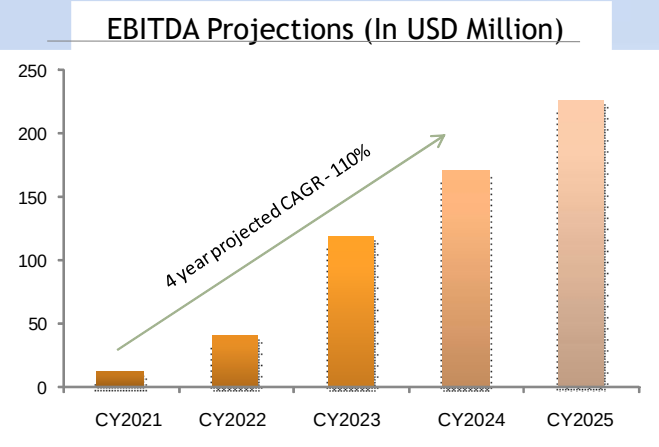
II. Balance Sheet

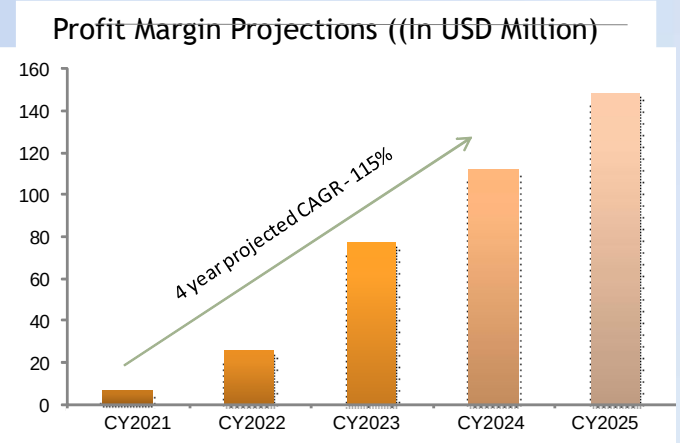
FY	2020	2021	2022	2023	2024
Sources of Funds					
Capital	14.50	14.50	14.50	14.50	14.50
Reserves	7.0	32.3	109.6	221.5	369.6
Term Loan - TDB	15.0	11.7	8.3	5.0	1.7
Bank Loan	3.5	3.5	3.5	3.5	3.5
	40.0	**62.0**	**135.9**	**244.5**	**389.3**
Uses of Funds					
Fixed Assets	17.8	16.9	16.0	15.1	14.3
Net Current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

*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 GoI

Financial Overview







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
  - Padamvibhusan 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

X