11th Annual General Meeting and Conference of DCVMN
Hyderabad, India
September 15-16

(*Present name of the company is SCS Pharma Research and Development Private Ltd.*)
Vaccines for Disease Control and Elimination

- Prevent over 2 million deaths every year
- Comparable to providing safe drinking water in reducing mortality rates
- Vaccines have eradicated small pox, Polio in many parts of the world
- Vaccines are widely acknowledged as one of the most successful and cost–effective public health interventions.
Many Effective Vaccines Available

1796: Edward Jenner acted upon the observation that milkmaids who caught the cowpox virus did not catch smallpox

1901: 1st Nobel Prize (ever) to Emil von Behring for Diphteria serum therapy
Vaccines Offer Health and Economic Benefits

Diphtheria incidence in the US
Mortality 5/10,000 cases

Peak Incidence (1921): 206939
Incidence today: 1

Tetanus incidence in the US
Mortality 3/10 cases

Peak Incidence (1927): 1314
Incidence today: 40

H. Influenza type B incidence in the US
Mortality 2-3/100 cases

Peak Incidence (1984): 20000
Incidence today: 363

Childhood Immunization: Challenges ahead ...

34 million children are not fully immunized!

Source: WHO/UNICEF 2001
Vaccines have stabilized society, but....

**DW vaccine needs are unmet**
- Cost, financing, and systems

**DW needs are unique**
- Delivery, cold chain, and transportation
- Disease burden and epidemiologic features
- Role of NRA and WHO

**DCVMN have important role**
- Indigenous programs
- Partnerships with MNC, etc.
• Shared Vision: Create a sustainable, not-for-profit entity to turn innovative science into practical solutions for those in greatest need
• First time a research charity and a pharmaceutical company have partnered to form a separate joint venture with equally shared funding and decision-making rights
  • Merck and the Wellcome Trust to make equal initial investments totaling USD $145MM over 7 years (could be extended upon mutual approval of both parties)
  • Staff to include ~60 researchers and developers based in India
• Focus on producing affordable vaccines for low-income countries
  • Novel vaccines
  • Vaccines optimized for needs of low-income countries
• Leverages Merck’s expertise in vaccine development and the Wellcome Trust’s excellence in global biomedical research
  • Will seek partnerships with experts from academia, industry, NGOs and government
• Will be located in India to facilitate global partnerships

Launched September 17, 2009
Work of Hilleman Labs Through a Mixture of Funding

• Initial contribution by founding partners with the possibility of additional grants and investments when Hilleman Laboratories begins to yield promising innovations

• Sustained in later years through a range of potential business models
  • Core financial support from donors, governments, NGOs, etc.
  • Project-specific grant funding
  • Royalties and revenues received from intellectual property generated by the Hilleman Laboratories
  • Fees for services
  • Sale of vouchers
Shared Beliefs and Intent

• Many promising research concepts do not reach those who need them the most

• New models of public and private engagement are needed to meet the opportunities and challenges of product development for developing world populations

• India-based Hilleman Laboratories with support from Merck and the Wellcome Trust can help meet these needs

• Leverage Merck’s strengths in vaccine discovery and product development

• Leverage the Wellcome Trust’s strengths in understanding the needs of the developing world and supporting research of relevance to the DW

• Attract a broad range of potential partners

• Encourage innovation, transparency and sustainability for a long term impact
The Hilleman Laboratories: Working in India for Global Health Solutions

Why India--Science
- Strong academic infrastructure
- Centers of excellence in biomedical sciences
- Talented biomedical sciences and engineers investment

Why India--Industry
- Strong pharmaceutical and biotech sector
- Capacity for large scale manufacturing
- WHO approved vaccine development companies
- Experience in co-development of biological products
- Innovation in vaccine development
- Focus on new and improved vaccine development

Why India--Policy
- Strong regulatory environment by DCGI, MOH
- Focus on translational research by DBT, CSIR, and ICMR/DHR
- Attractive place for international collaborations

Located in the National Capital Region (Haryana)
Collaborate with academia, industry, government, NGOs, foundations, and international organizations
Hilleman Laboratories: Working for Developing Vaccines and Vaccine Technologies

Need for New Vaccines and Improved Vaccines
- Affordable vaccines against many diseases
- Advanced biotech sector capable of developing new and improved vaccines
- National Health Programs are expanding to include vaccines of public health relevance

Need for New Vaccine Technologies
- Technologies that reduce or eliminate use of cold temperature for storage and shipping
- Technologies that will make vaccines is easy-to-deliver for national health programs
- Technologies that would allow vaccines to be stored for longer period of time

Accomplishing Results Through Partnerships
- Link with academia and industry
- Listen to stakeholders and policy makers

Expected outcomes:
- Reduce disease burden, sickness, and deaths
- Better availability of vaccines for health programs
- Aligning our objectives with public health priorities
Models to Succeed: Developing Vaccines for Developing & Emerging Markets

Collaborate with scientists, clinicians and international funders (eg GAVI)

Apply innovations and skills from industry

Strong NGO / government relationships

What approach to choose?

Go it alone

- Expensive
- Time consuming
- Narrow viewpoint
- Concentrated risk

Partner

Focus Elsewhere

- Missed opportunity
- Health
- Business
- Learning
The Hilleman Labs Fills a Key Gap While Leveraging the Expertise of Others

- Leverages basic research innovations in academia, government, NGOs* and industry
- Leverages Merck’s skills and mentoring in vaccine bioprocess, formulation and analytics
- Leverages Wellcome’s excellence in biomedical research focused on making a tangible impact on global health
- Provides flexible approach to management of late development, manufacturing, and marketing / sales
- Establishes linkages among discovery, development and delivery experts

Vaccine Development Cycle

<table>
<thead>
<tr>
<th>Stage</th>
<th>Responsible</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Basic Research</td>
<td>External Scientists</td>
<td>Early Development</td>
<td>Merck and other Pharma Companies</td>
</tr>
<tr>
<td>Target -&gt; Lead Candidate</td>
<td></td>
<td>Lead -&gt; Phase I/II Clinical Trial</td>
<td>MSD Wellcome Trust Hilleman Laboratories</td>
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<tr>
<td></td>
<td></td>
<td>Late Development</td>
<td>Multi-National Pharmaceutical Manufacturers, Low Cost Manufacturers (LCM)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Phase III Clinical Trial -&gt; Registration</td>
<td></td>
</tr>
<tr>
<td>Large Scale Manufacturing</td>
<td></td>
<td>Marketing and Distribution</td>
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* NGO* = Non-Governmental Organization
The Key Competencies of the Hilleman Labs are Similar to that of a Biotech

- Translational Biology, Bioprocess, Formulation and Analytical Research
- Clinical Development through Phase I/II (Immune/Clinical Proof of Concept)
- Project Management
- Advocacy and Fund Raising
- Impact Assessment
- Communications / Public Affairs
- Licensing and Business Development

### Vaccine Development Cycle

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**Responsible**
- **External Scientists**
- **Merck and other Pharma Companies**
- **Hilleman Laboratories**
- **MSD Wellcome Trust**
- **Partner Outreach & Support**
There are Multiple Partnership Opportunities along the Product Development Cycle

- Global Academic Scientific Outreach
- Global Business Development Outreach
- Global Health Authorities and Major Donors
- Civic Society and Delivery Experts
- Recruitment and Training with Developing World Institutions
Evolving Towards a Commercial Continuum to Reach All Markets

A well-structured DW R & D effort will enable innovative products to be developed for the developing world, while also allowing use of those same innovations in commercially viable markets.
The Strategic Advisory Group will advise the CEO and Board of Directors of the Hilleman Laboratories regarding how they might best pursue its mission.

**Proposed Advisory Group**

**Strategic Advisory Group (SAG)**
Focus: Top line Strategic Issues

*In order to maintain alignment, members of the SAG will be asked to either participate in/review inputs from other boards.*

- Detailed medical input on chosen disease areas
- Detailed scientific and development input
- Business Excellence

Audience
- CEO
- BOD
- Executive Leadership - CSO, COO

Other advisory groups may be formed to guide executive leadership on specific issues.
The optimal SAG consists of a merger of expertise across a spectrum of disciplines

Membership Selection Criteria

Experience 1: Scientific Thought Leader in ID
Experience 2: Vaccine Development (Bioprocess & Clinical, Regulatory)
Experience 3: DW Disease Knowledge
Experience 4: DW Infrastructure/
Global/Public Health & Policy
Experience 5: Affiliation w/ Key International Organizations
Experience 6: Developing Country Research & Biomedical Ethics
Experience 7: Public-private Partnership Models
Experience 8: Healthcare Financing/ Business/ Economics
Experience 9: Entrepreneurship

Experience 1:

Scientific Thought Leader in ID

Experience 2:

Vaccine Development (Bioprocess & Clinical, Regulatory)

Experience 3:

DW Disease Knowledge

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Experience 7:

Public-private Partnership Models

Experience 8:

Healthcare Financing/ Business/ Economics

Experience 9:

Entrepreneurship
Chair: David L. Heymann

Chairman of Health Protection Agency, UK

- Former WHO: Assistant Director-General for Health Security and Environment and Representative of the Director-General for Polio Eradication (until March 09).
- Head, Chatham House Centre on Global Health Security
- Director of the WHO Programme on Emerging and other Communicable Diseases from October 1995 to July 1998.
- Prior extensive engagement with smallpox eradication efforts
Projects will be Selected by the Hilleman Labs, based on Medical, Technical, Commercial and Financial Factors

External input and counsel

Medical: Unique and valuable offering for unaddressed, prioritized need

Technical: Acceptable Probability of Success

Commercial: Viable path to large scale manufacturing and sales in accepted price range

Financial: Project’s estimated resource and timeline requirements fit within budget and sustainability plan
Criteria for Project Selection

• Desirability of vaccines and feasibility of production

• Clear line of sight through manufacturing and marketing

• Follow NRA and WHO guidelines

• Partnerships with DCVM

• Consultation with WHO and other individuals and organization in the vaccine development and delivery space
Candidate Vaccine: Thermostable Presentation of Existing Vaccine

Drivers:
- Potential elimination of the cold chain
- Potential footprint reduction of the final product
- Platform technology – applications to other similar products

Product Development Cycle:
- Stage 1: Definition
- Stage 2: Early pre-Clinical
- Stage 3: Pre-Clinical
- Stage 4: Phase I
- Stage 5: Phase II
- Stage 6: Phase III

Already Licensed Product

Candidate Gate Review
Stage I Gate Review
Stage II Gate Review
Stage III Gate Review
Stage IV Gate Review
Stage V Gate Review
Stage VI Gate Review

Hilleman Labs

MSD - Wellcome Trust
Hilleman Laboratories
Developing vaccines for global health
**Candidate Vaccine : Stage I, II & III**

<table>
<thead>
<tr>
<th>Stage I Deliverables</th>
<th>Stage II Deliverables</th>
<th>Stage III Deliverables</th>
</tr>
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<tbody>
<tr>
<td>Thermostable technology</td>
<td>Scaleable process</td>
<td>Clinical manufacturing</td>
</tr>
<tr>
<td>Vaccine antigen supply side agreement</td>
<td>Product delivery package development</td>
<td>Stability evaluation</td>
</tr>
<tr>
<td>Model for candidate vaccine testing</td>
<td>Pre-clinical manufacturing</td>
<td>Clinical plan for Phase I and IIa</td>
</tr>
<tr>
<td>Strategy for regulatory approvals</td>
<td>Stability evaluation</td>
<td>QC release of clinical material</td>
</tr>
<tr>
<td>Laboratory preparation and fit-out</td>
<td>Initiation of tox studies</td>
<td>DCGI release of clinical material</td>
</tr>
<tr>
<td>Expert Advisory Committee Setup (preclinical, clinical, delivery strategy)</td>
<td>GMP documents preparation – manufacturing and testing</td>
<td>Quality systems for lot release</td>
</tr>
</tbody>
</table>

**Go/No-Go Criteria**

**Go/No-Go Criteria**

**Go/No-Go Criteria**
Candidates Vaccine: New Vaccine

Drivers:
- Unmet medical need
- Candidate antigens exist in discovery stage
Drivers:
- More stable formulation
- Elimination of needle/syringe
- Combination vaccines
Initial Projects Being Contemplated

Novel vaccines
  • Recent summit on Group A Strep

Relevant platform technologies
  • Thermostability approaches / non-cold chain delivery
    • Technical feasibility of various biotechs’ approaches being explored

Product optimization
  • Discussion with firms to proceed: where is there need to reformulate for impact?

Other
  • JV engagement with academics, developing country firms, etc will yield other projects
Summary

• DCVMN have many success requirements common to MNCs, philanthropy and NGOs

• Joint Venture to advance vaccine development needs for DW needs

• Hilleman Laboratories will partner with scientists, governments and industry to develop novel and optimized vaccines

• This joint venture is an example of how partnership-oriented approaches can facilitate bringing new vaccines forward in an innovative and sustainable manner
Thank you for your attention

http://www.hillemanlaboratories.in
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