## **DiaGenic in India**

A market of opportunities

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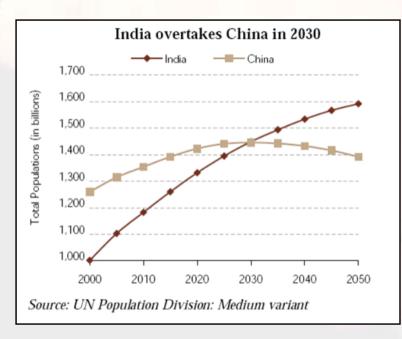
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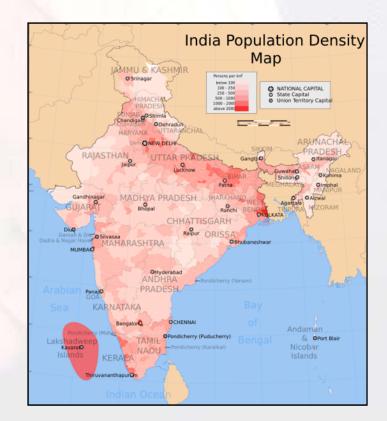
### • Why India?

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- DiaGenic India Business Structure
- Project Execution
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### Large population base

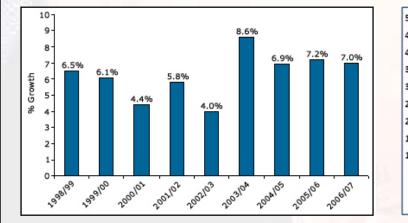
- Currently #2 in world in terms of population (>1.1 billion)
- Poised to become #1 within two decades; population will surpass China by 2030
- Population concentrated within regional pockets; excellent market access

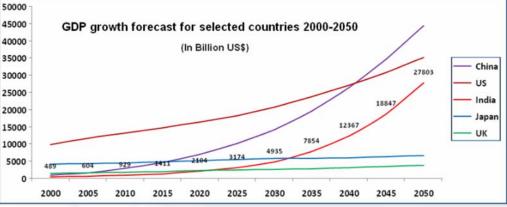




### Excellent economic growth

- Economic reforms begun in 1991 have led to excellent economic growth
- Real compound annual growth forecast at > 7% over next two decades
- Currently India is world's 12 largest economy; expected to be in the top 5 by 2025<sup>1</sup>





<sup>1</sup> Mckinsey Global Institute Report — Tracking the growth of India's middle class; 2007

### Expanding middle class

- Poverty has been cut by one-half in last 20 years; similar decrease over next 20 years
- Increased urbanization and economic growth has greatly expanded the middle class
- Middle class currently at 50 million; will grow by ten-fold to over 580 million by 2025<sup>1</sup>
- India's affluent population will grow to 24 million (more than the population of Australia)



<sup>1</sup> Mckinsey Global Institute Report — Tracking the growth of India's middle class; 2007

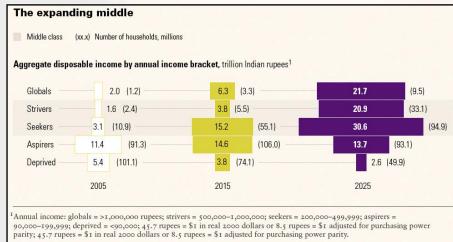


345.7 rupees = \$1 in real 2000 dollars or 8.5 rupees = \$1 adjusted for purchasing power parity.

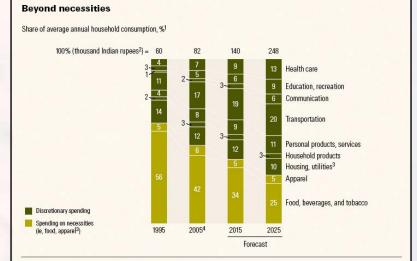
Source: McKinsey Global Institute analysis

### Increasing disposable income & purchasing power

- India will undergo a transition in the economic pyramid unlike any other country
- Economic growth will accompany similar growth in discretionary spending
- Increased spending on quality of life (health, education, lifestyle)
- Over 1.25 trillion USD in future purchases up for grabs by 2025
- 75% of India's consumer market in 2025 doesn't exist today!



Source: McKinsey Global Institute analysis



<sup>1</sup>Figures may not sum to 100%, because of rounding.

<sup>2</sup>Real 2000 rupees; 45.7 rupees = \$1 in real 2000 dollars or 8.5 rupees = \$1 adjusted for purchasing power parity. <sup>3</sup>McKinsey Global Institute's cross-country comparisons of necessary consumption exclude housing from the category of necessity because of significant variations in national housing market structures, regulations, and measurement methodologies. <sup>4</sup>Estimated.

Source: McKinsey Global Institute analysis

# Entry Strategies for Western Companies

### Setting up shop in India — the subsidiary approach

- All operational control under the umbrella of parent company
- Can capitalize on brand recognition to stimulate sales through local presence
- Huge expense in setting up operations
- Significant corporate resources (executive time and travel) needed

### The marriage option — the JV model

- Joint Venture with an Indian entity allows for faster entry into marketplace
- Indian partner to co-invest in setting up needed operations within India
- Tie-up often involves a long-term relationship, with steep penalties for divorce
- Out-licensing of technology often involved (IP transfer / ownership issues?)

### Being there without being there! — the Agency model

- Indian agent serves as operational arm of parent company; local presence not needed
- Greater operational control compared to JV model
- High consultancy fees
- Finding the right agent!

### PAC Med Biotech appointed as Indian agent for DiaGenic

#### Services to be provided by PAC Med — Phase I (Clinical trials)

- Set up clinical trials on behalf of DiaGenic
- Identify a research service partner to undertake laboratory work
- Negotiate all contracting with CRO and other parties; generate drafts of contracts
- Oversee all aspects of clinical trials and help in troubleshooting (when necessary)

#### Services to be provided by PAC Med — Phase II (Commercialization)

- Identify and recruit research firm to undertake formal market assessment
- Prepare short-list of commercial partners for review by DiaGenic
- Mediate all discussions (introduction to consummation)
- Prepare draft versions of business contract; serve as intermediary in negotiations
- Assist with commercial launch preparatory assistance, scheduling, CMEs, etc.

### DiaGenic – PAC Med collaboration (core understandings)

#### **Mutual promises**

- DiaGenic shall prioritize commercial entry into India as a key strategic objective
- DiaGenic shall provide all support functions necessary to service providers
- PAC Med shall work closely with and represent the best interests of DiaGenic
- PAC Med shall invest the time and effort needed to execute its mandate

#### **Financial considerations**

- PAC Med will not levy any charges for its services (waiver of consultancy fees)
- PAC Med will earn future revenue only if the test is commercialized in India
- Royalty recovery based on a percentage of DiaGenic's earnings in India

### Clinical trials – Appointment of Manipal AcuNova Ltd.

Manipal

#### Profile and characteristics

- MAL chosen after review of several top CROs in India
- Attributes fully accredited, excellent leadership, prior success, motivation
- Selected by Proximare as India's "Best Emerging CRO of 2005"

#### **Overview of functions**

- Identify clinical populations across India for study purposes
- Coordinate and oversee activities across all study sites; blood collection & transport

### Clinical trials – Appointment of LabIndia Instruments Ltd.



#### Purpose and requirements

- Study to be run on ABI 7900HT platform
- Few places in India have this instrument
- High capital investment (> 200k USD)
- Option: Find a service provider that has this instrument

#### Profile and overview of functions

- LabIndia is the Indian agent for Applied BioSystems Inc.
- Receive samples from Manipal AcuNova (CRO)
- Undertake all laboratory procedures and array scans





### **Clinical trials**

Q. Does the DiaGenic breast cancer test work in the Indian population?

Five study groups

- Group 1: early breast cancer
- Group 2: late breast cancer
- Group 3: genetic predisposition
- Group 4: radiographic concern (-ve cancer)
- Group 5: age-matched controls

#### Target

✓ No. of Subjects to be enrolled: 720

✓ Enrollment period: 12 months

✓ Sites: 9 sites in 4 different geographical locations in India

### **Clinical trials**

Geographic outline and operations flow



### **Clinical trials**

#### Timelines for various operational aspects of the study

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	Jan '07	Feb '07	Mar '07	Apr '07	May '07	Jun '07	Jul '07	Aug '07	Sep '07	Oct '07	Nov '07	Dec '07	Jan '08	Feb '08
Study documents										1				800 1
Sites selected for participation														
Final list of investigators						T								
EC submission & approvals				-			Ţ			1				
Sites initiated														
Subject enrollment														
Site monitoring														
DCFs resolution														

### **Clinical trials**

Q. Does the DiaGenic breast cancer test work in the Indian population?A. Yes.

- Indian data corroborates results of Scandinavian and U.S. cohort
- DiaGenic test is broadly applicable across diverge genetic pools
- DiaGenic test can be conducted successfully by alternate labs elsewhere
- scientific presentation of Indian data at 51st AICOG meeting in Delhi (Feb '08)
- international press release issued on Indian study outcome

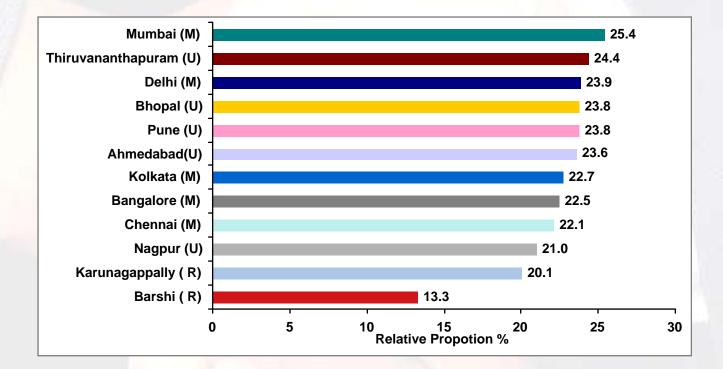


#### Market assessment

Indian study and future commercial prospects in India sets up need for assessing market conditions

- recruit a reputable market research firm
- examine urban population profiles in terms of incidence
- pattern of patient flow to identify key clinical domains
- KOL feedback

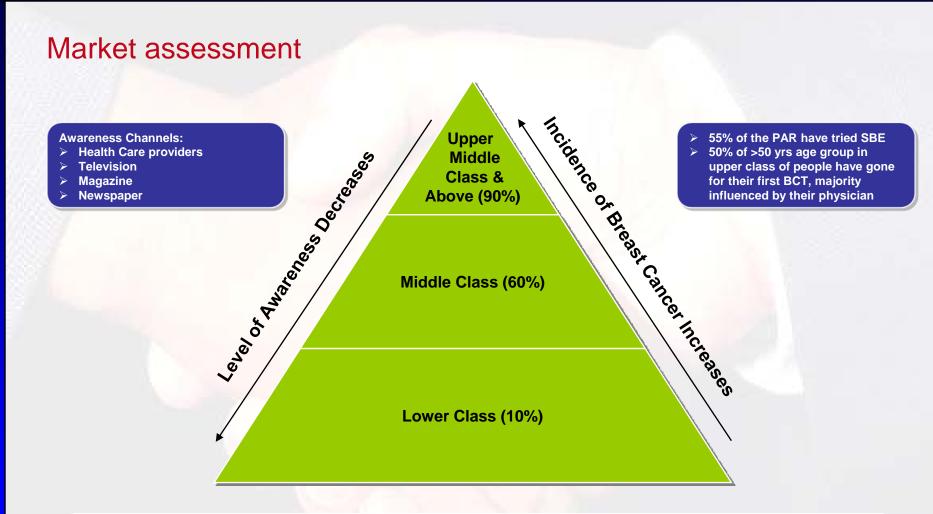
#### Market assessment



The Metro and Urban areas of India harbors significant PAR compared to the rural population
Western part of India has the incidence of maximum breast cancer cases

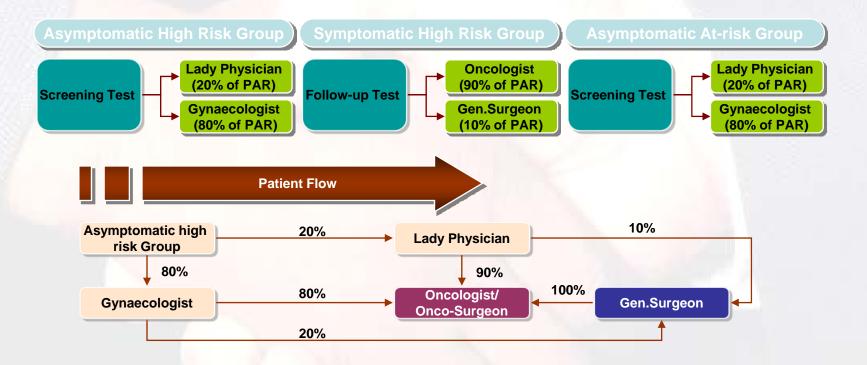
#### M=Metro, U=Urban, R=Rural

Note: Relative Proportion is in comparison with other types of cancer Source: http://www.canceratlasindia.org/map.htm



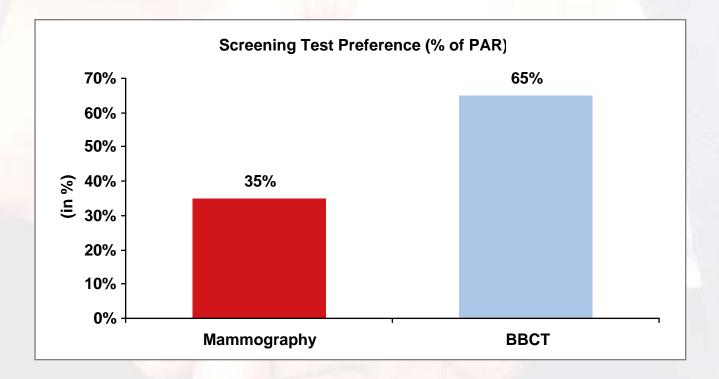
Opportunity exists for newer diagnostics for BC due to the high level of awareness and incidence of BC among the upper and middle class of women

### Market assessment



- > Gynaecologists & female physicians play a major role in screening asymptomatic high-risk patients
- All advanced cases are referred to oncologists by general surgeons, gynaecologists and physicians

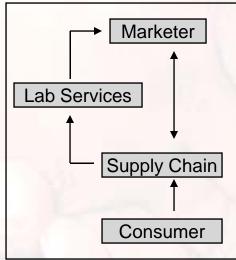
#### Market assessment



65% of PAR opted for DiaGenic BCT, due to its simple procedure

#### Partnership outline

Marketer – major laboratory chain Supply chain (blood collection & transport) — under management of marketer Lab services – LabIndia



#### Partnership arrangement

### Partnership outline

#### Characteristics of SRL Ranbaxy



- India's first and South/South-East Asia's largest clinical reference lab
- Over 750 collections centres in 375 cities throughout all parts of India; tie-up with Fortis
- > 5 m annual customers
- Extensive clinical contact network across multiple domains (especially OB/GN)
- Backing of major pharmaceutical company (Ranbaxy Ltd.)
- Strong R&D unit with extensive professional and test development experience
- Highly motivated and eager to partner with DiaGenic

### Partnership outline

#### SRL shall provide to DiaGenic ...

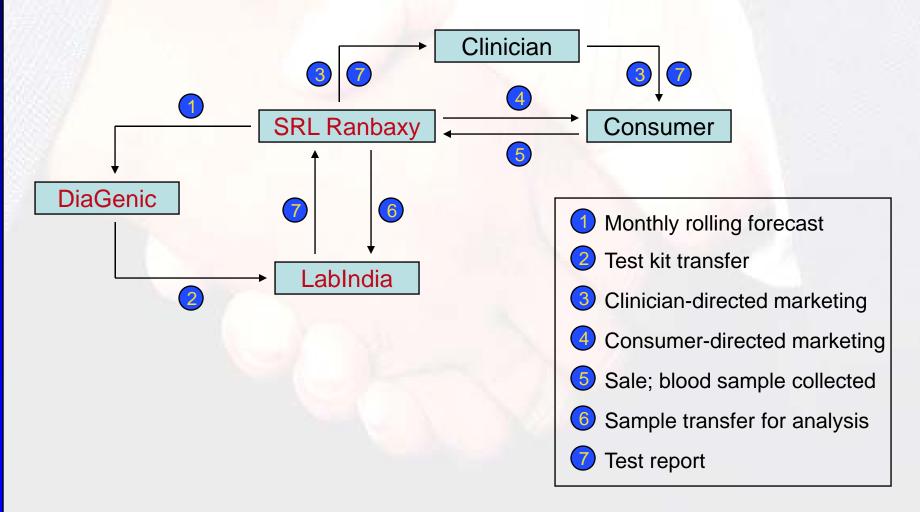
- Supply chain operations for blood collection throughout its network
- Marketing and promotional activities, including use of its national sales force
- Organize seminars and CMEs prior to test launch to inform clinical community
- Distribution of test reports to clinicians
- Substantial financial investment to ensure successful market penetration and uptake
- Fixed royalty per test

#### SRL shall receive from DiaGenic ...

- Marketing exclusivity of the breast cancer test in India
- Assistance with promotional materials in support of marketing
- Technical and logistical support during test launch
- Coordination assistance with LabIndia for analytical services

### **Operational details**

Process flow – materials transfer and marketing operations



## Synthesis

### Why India?

#### Time to market

Jul '06 – Partnership with PAC Med (MoU)

Oct '06 – Contract signed with MAL (CRO)

Jan '07 – Clinical study finalized and initiated

Aug '07 – Half study enrollment (Go-NoGo decision point) 22 months

Feb '08 - Presentation of interim data at AICOG (Delhi)

Mar '08 - Clinical study completed, with final report

May '08 - Contract with SRL Ranbaxy executed

Cost efficient and speedy entry into a lucrative market