# Breaking out. Striving to create new momentum





GlaxoSmithKline Pharmaceuticals Limited

Annual Report for the year ended 31st December 2009



## A word from the Managing Director



The continued focus on the strategy initiatives outlined for GSK India in 2007 has yielded results, with growth during the course of the year accelerating and a build up of momentum. Products launched in the last three years remain ahead of plan, apart from making a significant impact on the healthcare needs of the country. Rota-viral diarrhea vaccine ran ahead of plan in its first year and provided protection to a number of children from rotavirus diarrhea, one of the leading causes of infant mortality. With Tykerb, GSK India provided solutions for refractory breast cancer, again one of the leading causes of mortality among women. During the course of the year, GSK India also brought to market Cervarix, the first vaccine with a potential to prevent cervical cancer caused by certain strains of viruses. Building new capabilities remained a new focus area with entry into cardiovascular therapies, with Benitec making steady progress.

GSK India remains committed to strengthening and investing behind the resource base with further additions of 202 sales personnel in the current year.

Initiatives for fulfilling the requirements of multiple emerging customer segments such as rural, were continued to be progressed and rolled out. This will enable us to service the needs of the increasing number of patients.

GSK India's commitment to bring state of the art technology in the areas of manufacturing of products is being reinforced with upgradation of sites, commissioning of new lines and a slew of energy conservation and environment friendly measures.

Consistent with GSK India's philosophy of investing in the community in which it operates, the company has increased investments behind a number of projects in the area of Corporate Social Responsibility.

I am happy to share with you that the various initiatives that GSK India had undertaken in the last couple of years are now coming to fruition and a perusal of the following pages will indicate to you the momentum that is being built on the same.



The year gone by has seen GSK India step up the quest for faster growth and improved quality of performance.

Brushing aside fears of a global slow-down, we at GSK India took up the challenge of leading the way with innovative products and fresh marketing initiatives.

We enhanced our people strengths and have put in place several initiatives which will help us to explore new and promising opportunities in the growing Indian economy.

Our cover attempts to capture this management philosophy at GSK which will help to improve the quality of life by enabling people 'to do more, feel better and live longer'

## Adding energy to the synergy of growth

Many of our strategic Business Units have leveraged on their therapeutic domain knowledge and capabilities. This has helped to create a sustained growth in the impact which GSK India brands have made on the healthcare needs in the country, in the year gone by.

Consistent with our focus on preventive health, the vaccine franchise outperformed the market with the rota-viral diarrhea vaccine (Rotarix) recording significant acceptance among doctors. From public health standpoint, rota-viral diarrhea is one of the biggest causes of infant mortality in India and GSK India has successfully made an impact in this area.

The Dermatology products have similarly built on a strong foundation and continue to be leaders in providing therapeutic solutions in this area. Specifically, the solutions in the antifungal area have been accorded leadership by the dermatologist community through the highest number of prescriptions.

The steroid portfolio and GSK India's antiviral brand continue to be accepted as a leading solution in this area.

In the therapeutic area of cardiology, diabetes, hypertension, asthma and COPD, GSK India was able to strengthen its impact through strong education updates resulting in sustained acceptance of our newer solutions in these therapies.

The mass market segment with a maximum potential of impacting healthcare, and a traditional area of strength for GSK India, continues to grow on the significant trust that has been built up by GSK India in its brands over the years.

Your company also demonstrated an increase, ahead of the market in the year gone by.



## Developing innovative new product portfolios



Pursuant to the strategy of broad basing GSK India's capabilities across therapies, a number of products were launched in the last couple of years. These included Tykerb for refractory breast cancer, Cervarix for cervical cancer and Arixtra, an antithrombotic agent, among others. These new products have gained significant acceptance among the doctors and patients in this short time, testifying their efficacy and their ability to impact patient health.

Your company increased its investments in customer education and contact during the year. To enable the promotion of our products to a larger set of customers, GSK India added 202 new frontline sales personnel, in addition to the 70 already added in 2008.

The spend behind education to customers on the company's products was also substantially increased, given the number of new products in new therapeutic areas that were launched.

GSK India continued to help in mitigating the significant unmet need for healthcare in rural areas by continuing to increase contact with physicians in these geographies.



## **Board of Directors**

(As on 15.02.2010)

Chairman

D. S. Parekh

#### Vice-Chairman

V. Thyagarajan

#### **Managing Director**

Dr. H. B. Joshipura

#### **Directors**

P. Bains (upto 27.07.09)

R. R. Bajaaj

Dr. A. Banerjee

M. B. Kapadia

N. Kaviratne (CBE)

V. Narayanan

P. V. Nayak

A. M. Nimbalkar (w.e.f 27.07.09)

Dr. M. Reilly (upto 27.07.09)

R. C. Sequeira

D. Sundaram (w.e.f 27.07.09)

## General Manager - Administration & Company Secretary

A. A. Nadkarni

#### **Factories**

- 2<sup>nd</sup> Pokhran Road, Thane
- Ambad, Nashik

#### **Bankers**

Citibank N.A.

**HDFC Bank Limited** 

Hongkong and Shanghai Banking Corporation Limited

#### **Auditors**

Price Waterhouse & Co 252, Veer Savarkar Marg, Shivaji Park, Dadar (West), Mumbai 400 028

#### **Solicitors**

Crawford Bayley & Co.

Gagrat & Co.

#### **Registrars & Share Transfer Agents**

Karvy Computershare Private Limited

Unit: GlaxoSmithKline Pharmaceuticals Limited

Plot No. 17-24, Vittal Rao Nagar Madhapur, Hyderabad 500 081 Tel No. 040- 44655201/44655148 Email: satheesh@karvy.com

#### **Share Department**

Dr. Annie Besant Road,

Mumbai 400 030

Telephone: 022 - 24959415/434

Fax: 022 - 24981526

Email: ajay.a.nadkarni@gsk.com

## Management Team

#### **Managing Director**

Dr. H. B. Joshipura

#### Senior Executive Director

M. B. Kapadia

- Finance
- Corporate Communications, Secretarial & Administration

#### **Executive Directors**

Dr. A. Banerjee

Technical

R. C. Sequeira

Human Resources

#### **Executive Vice-Presidents**

Dr. S. Joglekar

Medical & Clinical Research

M. K. Vasanth Kumar

- Supply Chain

#### **Vice-Presidents**

- R. Bartaria
- Pharmaceuticals
- H. Buch
- Pharmaceuticals
- S. Khanna
- Finance
- S. Patel
- Legal & Corporate Affairs
- C. T. Renganathan
- Pharmaceuticals

#### **General Manager**

- S. Rajan
- Corporate Communications

#### **Registered Office**

Dr. Annie Besant Road

Mumbai 400 030

Telephone: 022 - 24959595 Fax: 022 - 24959494

rax. 022 - 24939494

Website: www.gsk-india.com

## Contents

Performance Summary & Charts	2
Directors' Report	3
Annexure to Directors' Report	9
Report on Corporate Governance	. 12
Auditors' Report	. 25
Financial Statements	. 28
Statement pursuant to Section 212	. 54
Biddle Sawyer Limited	. 55
Consolidated Financial Statements	61

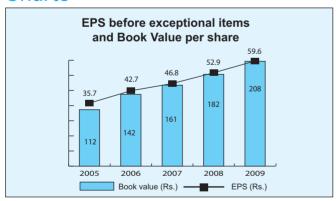
## Performance Summary

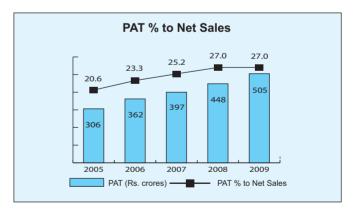
(Amounts in Rupees Lakhs)	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000
PROFIT AND LOSS ACCOUNT										
Sales	1912,77	1751,56	1712,84	1677,57	1575,89	1479,59	1191,69	1148,22	1097,37	934,62
Profit before tax	758,48	679,90	606,73	555,95	477,91	418,24	284,56	196,33	115,58	84,84
Tax	253,59	231,54	209,94	194,23	171,63	152,19	102,70	67,86	40,26	32,52
Profit after tax	504,89	448,36	396,79	361,72	306,28	266,05	181,86	128,47	75,32	52,32
Exceptional items (net of tax)	7,40	128,21	140,87	183,79	195,80	67,04	(9,63)	(30,41)	(31,34)	18,22
Net Profit	512,29	576,57	537,66	545,51	502,08	333,09	172,23	98,06	43,98	70,54
Dividends-equity	254,11	338,81	304,93	262,58	237,17	209,57	74,47	52,13	40,96	29,89
Tax on distributed profit	40,13	57,58	51,82	36,83	33,26	27,39	9,54	6,68	(5,16)	6,75
Retained Earnings	218,05	180,18	180,91	246,10	231,65	96,13	88,22	39,25	8,18	33,90
BALANCE SHEET										
Equity Capital	84,70	84,70	84,70	84,70	84,70	87,32	74,48	74,48	74,48	59,78
Reserves	1674,45	1456,39	1276,21	1110,01	863,91	836,94	593,01	504,80	486,10	334,67
Net Worth	1759,15	1541,09	1360,91	1194,71	948,61	924,26	667,49	579,28	560,58	394,45
Borrowings	5,42	5,65	5,77	5,54	4,85	3,85	2,86	1,98	9,71	34,85
Total Capital Employed	1764,57	1546,74	1366,68	1200,25	953,46	928,11	670,35	581,26	570,29	429,30
Net Fixed Assets	114,17	100,35	92,90	94,46	96,94	91,49	99,38	115,40	137,62	101,37
Investments	190,91	751,87	1333,32	1139,41	913,06	776,82	409,12	162,00	151,68	124,87
Net Current Assets	1459,49	694,52	(59,54)	(33,62)	(56,54)	59,80	161,85	303,86	280,99	203,06
OTHER KEY DATA										
Rupees per Rs.10/- Equity Share										
DIVIDENDS	30.00	22.00	18.00	17.00	14.00	13.00	10.00	7.00	5.50	5.00
SPECIAL ADDITIONAL DIVIDEND	-	18.00	18.00	14.00	14.00	11.00	-	-	-	-
TOTAL	30.00	40.00	36.00	31.00	28.00	24.00	10.00	7.00	5.50	5.00
EARNINGS before exceptional items	59.61	52.93	46.84	42.70	35.69	30.47	24.42	17.25	10.11	8.75
EARNINGS after exceptional items	60.48	68.07	63.48	64.40	58.51	38.15	23.13	13.17	5.90	11.80
BOOK VALUE	207.69	181.95	160.67	141.05	112.00	105.85	89.63	77.78	75.27	65.99
Number of employees	4006	3722	3620	3850	4016	4136	4271	4654	5338	4943

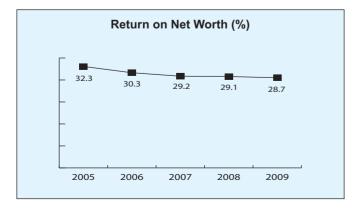
#### **NOTES**

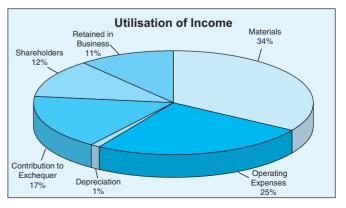
- 1. The Company has divested its Fine Chemicals business on 30th September, 2007 and its Animal Health business on 31st July, 2006.
- 2. The Company has bought back and extinguished 26,19,529 equity shares during 2005.
- 3. Burroughs Wellcome (India) Limited merged with the Company from 1.1.2004.
- 4. The Marketing Undertaking of Megdoot Chemicals Limited has demerged into, and Croydon Chemical Works Limited has amalgamated with the Company from 1.1.2002.
- 5. SmithKline Beecham Pharmaceuticals (India) Limited merged with the Company from 1.1.2001.
- 6. Figures have been adjusted/regrouped wherever necessary in line with the Accounts, to facilitate comparison.

## Charts











## Directors' Report

The Directors have pleasure in submitting their Report for the year ended 31st December 2009

#### 1. Results & Dividend for the year ended 31st December 2009

	Year ended 31 <sup>st</sup> December 2009 Rs. in Lakhs	Year ended 31 <sup>st</sup> December 2008 Rs. in Lakhs							
SALES (Gross)	1912,77.03	1751,56.06							
SALES (Gross)	1912,77.03								
Less: Excise duty on Sales	42,00.31	91,15.53							
NET SALES	1870,76.72	1660,40.53							
PROFIT BEFORE TAXATION AND EXCEPTIONAL ITEMS	758,48.20	679,89.76							
Less: Provision for Taxation	253,58.88	231,53.94							
PROFIT AFTER TAXATION AND BEFORE									
EXCEPTIONAL ITEMS	504,89.32	448,35.82							
Exceptional Items (Net of Tax)	7,39.77	128,21.08							
NET PROFIT AFTER TAX	512,29.09	576,56.90							
Add: Balance brought forward from the previous year	882,40.80	759,88.90							
Amount available for disposal	1394,69.89	1336,45.80							
APPROPRIATIONS:									
General Reserve	51,22.91	57,65.69							
Equity Dividend (including special additional Dividend									
in the previous year)	254,10.90	338,81.20							
Distribution Tax on Dividend	40,12.67	57,58.11							
Balance carried forward	1049,23.41	882,40.80							

The growth in Net Sales (net of Excise duty) was 12.7% and in Profit after Tax and before Exceptional Items was 12.6% for the year ended 31st December 2009. The growth in Gross Sales was impacted on account of lower selling prices as a result of the benefit of excise duty reduction being passed on to the consumer.

#### 2. Dividend

The Directors recommend a Dividend of Rs.30 per Equity Share for the year (previous year: Rs.22 per Equity Share and a special additional Dividend of Rs.18 per Equity Share). If approved by the Shareholders at the Annual General Meeting, the Dividend will absorb Rs.254 crores. The Dividend Distribution Tax borne by the Company will amount to Rs.40 crores.

#### 3. Management Discussion and Analysis

(a) Your Company maintained its leadership position in the Pharmaceuticals market with Net Sales registering a growth of 12.7%. Profit Before Tax and Exceptional Items grew by 11.6%. Sales performance in all of the Company's diversified business units i.e. in the mass market and mass specialty segments, dermatologicals, oncology, critical care and vaccines helped to support sales growth. Despite significant investments in sales promotion and field force expansion, Profit before investment income and tax was maintained at 35% of Net Sales.

Cash generation from operations was favourable, driven by the strong business performance and management of working capital. The Company's investment portfolio continues to remain deployed largely in Bank Deposits.

#### (b) Pharmaceuticals Business Performance, Opportunities and Outlook

Your Company continues to enjoy a leadership position in the categories in which its products are represented. The growth of your Company was marginally better than the growth of the Indian Pharmaceuticals market.

The Mass Markets activity comprising mainly of acute care products grew faster than the market in their represented segments: the rural marketing initiative has picked up momentum. Calpol, an anti-pyretic drug, is now the largest prescribed product in the industry (Source: CMarc - Dec'09) while other products such as Parit, Vozet, Cobadex CZS, Neosporin and Zentel have gained market share in their represented categories.

The Mass Specialty team continued to record good growth. Augmentin, currently the largest selling antibiotic brand in the industry, Arixtra, Zobactin, Supacef and Eltroxin are major growth drivers for this team. Arixtra is the 6th largest brand in the anti-thrombotic market. The focus on Hospital and Tender businesses will help further growth opportunities in these specialities.

The Company's chronic care portfolio includes the Dermatology, Oncology, Cardiovascular, Respiratory and Diabetes segments. Your Company is currently the leader in the Dermatology category with 14% market share and key products such as Betnovate, Zovirax, Zimig and Tenovate are consistently maintaining a leadership position in their respective categories. In Oncology, your Company has supported approximately 400 patients with the drug Tykerb. Lanoxin has consistently maintained a leadership position and launch of Benitec makes the Company's foray in cardiovascular therapy. In diabetes care, Windia is the leader in the Rosiglitazone segment. With the acquisition of distribution rights for the Stiefel (a global dermatologicals company) range of products in India, plans are in hand for market expansion in cosmetic dermatology therapies like acne, sun protection, emollients and moisturizers.

The Vaccines business continued to perform well in the current year. Rotarix, a vaccine for rotaviral diarrhoea is making significant strides. Cervarix, a vaccine for prevention of cervical cancer, was launched during the year. Your Company expects to introduce newer and sophisticated vaccines which will help increase market penetration.

New products launched during the year included Benitec A (Olmesatan in combination with Amilodipine) in Cardiology, Dermocalm (Calamine lotion) in Dermatology, Ventorlin CFC free inhaler (Salbutamol) in Respiratory and Esblanem (Meropenem) in Antibiotic segments.

Your Company continued the search for new Business Development opportunities in high growth therapeutic areas like Cardiology, Diabetes and Oncology and in therapeutic areas in which your Company has well established presence like Dermatology, Gynecology, Antibiotics and Gastroenterology. Going forward, your Company intends to enter into high growth segments such as CNS (Central Nervous System).

Exports recorded a sales turnover of Rs.71.50 crores comprising both Bulk Drugs and Formulations. Exports of bulk drugs were to major markets like Japan, Mexico, France, Indonesia, Jordan, U.K. and Germany.

#### (c) Risk, Concerns and Threats

As expected, India has been relatively insulated from the global recession, without any significant impact on the growth of the pharmaceutical industry. The industry growth is largely driven by chronic disease segments viz. cardiovascular, diabetes, asthma, cancer, and largely influenced by changing lifestyles. There are signs that health awareness has increased due to higher disposable incomes, urbanization and greater health insurance coverage, which could improve further with acceleration in Government spend on healthcare infrastructure. The adoption of intellectual property rights has encouraged innovation. The industry continues to remain under price control; the scope and coverage of the Government's new pharmaceuticals policy cannot be ascertained, since it is pending review by the Government and remains an area of uncertainity for the pharmaceutical industry. It is hoped that Government will consider several representations made by industry associations in framing the new policy. Data Exclusivity/Data Protection remain concern area for the industry.

#### (d) Research & Development and Regulatory Matters

GlaxoSmithKline continues to be committed to research and development of medicines that will improve the quality of life of people around the world and that truly make a difference to patients. The Clinical Operations group in India, which conducts clinical studies across a



number of disease areas ranging from Cancer, Coronary Heart Disease including acute coronary syndrome, Diabetes, Chronic Liver Disease and Hepatitis C, supports this effort.

Last year, your Company conducted 18 clinical trials, of which 7 were new studies initiated in 2009. In all, over 800 patients participated. The therapeutic area focus for 2009 has been Oncology and Cardiovascular diseases. Your Company has so far trained clinical trial investigators in over 131 hospitals / institutes across India. The quality of work continues to be of a very high order, evidenced by a number of successful internal compliance audits as well as US FDA inspections at two of our investigational sites.

During the year under review, in order to support the launch of new drugs that would benefit and improve the quality of life of Indian patients suffering from various diseases, your Company submitted 7 NDAs (New Drug Applications) for GlaxoSmithKline innovator and in-licensed products and 2 INDs (Investigations New Drug Applications) to the CDSCO (Central Drugs Standard Control Organization), Ministry of Health and Family Welfare, Government of India. Your Company has received approval for 3 NDAs and 1 IND from CDSCO which paves the way for speedy introduction of new drugs. Additionally, to support the R&D efforts of GlaxoSmithKline, your Company submitted 3 global Clinical Trial applications to CDSCO, and was granted approval to conduct these studies in the Indian population through the Clinical Operations group in India.

Efforts towards a speedy review and approval by regulatory authorities for some of these products, particularly a calcium supplement, micafungin, retapamulin and a new indication for Carzec help achieve early access to new and innovative therapeutic options to patients in the country. The Medical Affairs team is adequately resourced to play a pivotal role in communicating cutting edge scientific information to internal and external stakeholders.

#### (e) Internal Control Framework

Your Company conducts its business with integrity and high standards of ethical behavior, and in compliance with the laws and regulations that govern its business. Your Company has a well established framework of internal controls in operation, including suitable monitoring procedures and self-assessment exercises. In addition to external audit, the financial and operating controls of your Company at various locations are reviewed by the Internal Auditors, who report their findings to the Audit Committee of the Board. Compliance with laws and regulations is also monitored.

Your Company's Code of Conduct sets out the fundamental standards to be followed by employees in their everyday actions. In accordance with the Code of Conduct, and Standards associated with the Code of Conduct, employees are required to become familiar with the legal requirements, policies and procedures applicable to their areas of operation, avoid conflicts of interest and are tasked with upward reporting of all unethical and illegal conduct. All employees are committed to the principle of performance with integrity and ensuring that activities comply with all applicable laws.

Additionally, Managers are required to certify on an annual basis whether there have been any transactions which are fraudulent, illegal or violative of the Code of Conduct. Strong oversight and self monitoring policies and procedures demonstrate your Company's commitment to the highest standards of integrity.

#### (f) Human Resources

With the increasing importance of Human Resources, emphasis has been laid on capability building and towards enhancing the effectiveness of specialised teams. Structured Management Trainee schemes have been set up/revamped to support the different functions. Your Company's employees have played a key role in contributing to the growth and maintaining its status as one of the most reputed companies in India and more specifically in the pharmaceuticals industry.

In reaching out to its employees, the Company has also launched a Wellness and Well being Program, a recognition scheme called 'AAA award' (Acknowledge, Appreciate and Award) to recognize employees who have made good contributions as well as an Empowerment Program for employees to contribute their ideas through small group activities. Talent management continues to be an important area for your Company and key talent amongst the first line managers attended a three Module Leadership and Development program in collaboration with the SP Jain Institute of Management. Other employees were encouraged to avail of an educational assistance policy so as to encourage a learning culture.

Your Company has maintained an amicable relationship with its Unions. During the course of the year, long term settlements have been signed at the two manufacturing sites, Thane and Nashik. Long term settlements were also signed with the Unions representing the field sales force.

Sales training supports the delivering of quality communication to the medical fraternity. A 'Brand Calling Card' prompts Medical Representatives on differentiating their Brand communication to Doctors. This interactive detailing also has a bank of FAQs, Rebuttals, Clinical Papers and other Pathology-Product-Promotion literature for training. A new Development Navigator and Field Coaching Tool enables Performance Tracking and Continuous Improvement from the sales teams.

Your Company had staff strength of 4006 employees as on 31st December, 2009 compared to 3722 employees at the end of the previous year. The additional headcount is on account of new initiatives in the Field to extend our reach.

#### (g) Procurement

To meet the challenges in procurement which surfaced in 2008, strategic contracts helped in capitalizing on the opportunities in key raw material categories. This has ensured procurement efficiency and assurance of supply. Focus on risk based sourcing management received a thrust with the launch of advance procurement initiatives aimed at building capability of vendors. Supplier Quality Management, through a dedicated team launched this year, aims at ensuring best quality of all our ingredients by end to end quality management at vendors' sites. A vendor assessment tool specifically aimed at measuring capability and capacity of vendors was developed and deployed.

Sourcing strategies were developed for spend optimization in the area of marketing promotional support items, promotional printing, air travel and events management.

#### (h) Manufacturing

Your Company's Nashik site commenced manufacture and supply of Albendazole tablets to WHO for the Lymphatic Filriasis eradication programme. Thane site continued to supply Betamethasone and its derivatives to highly regulated markets. Upgradation at Nashik site has been undertaken resulting in significant increase in productivity. There was considerable focus on improving Environment, Health and Safety and a number of activities have been undertaken at both the Nashik and Thane sites during the year.

#### (i) Information Technology (IT) & Supply Chain

As a global initiative to bring down cost and reinvest for further improvements in technology, the IT function has been restructured globally to form IT demand (business facing) and IT supply (technology delivery) functions. The transition to the new model was well planned and executed, with no adverse impact on the business.

A mobile phone based Field activity reporting initiative was successfully piloted across two cities. Another major IT initiative, aimed at risk mitigation and control, was successfully completed during the year. IT enabled external facing web applications were reviewed and the identified risks were mitigated through a well coordinated plan.

In a goods and services tax regime, a Hub and Spoke initiative is being piloted in the distribution network. New ways of working were put in place for better networking of supply sites, both local and global, using global GSK systems and resources to ensure an uninterrupted supply.

#### (j) Corporate Social Responsibility

During the year, your Company undertook several community development projects by continuing to make a positive and significant contribution to the society.

Gramin Arogya Vikas Sanstha (GAVS), the Trust established and supported by the Company continues to operate in predominantly tribal and remote villages around Nashik. The Trust's Mobile Clinic operates in these remote regions covering a distance of over 160 kms each day, visiting around 35 clusters of villages in rotation. GAVS during the year has been successful in reaching out to over 40000 tribal people as direct and indirect beneficiaries, covering six blocks of Peth Taluka. Three Medical centres located in the pre-dominantly remote villages provide primary healthcare services to the tribals, who are socio-economically disadvantaged and marginalized group of people living in very difficult terrain, with very limited access to healthcare services. The project was executed in collaboration with Niramaya Health Foundation.