



CASE STUDY

Giving Millions of Children a Healthy Start in Life

BioE: Providing Quality Immunizations at Low Cost
in Over 80 Countries

MARCH 2019

ABOUT IFC

IFC—a sister organization of the World Bank and member of the World Bank Group—is the largest global development institution focused on the private sector in emerging markets. We work with more than 2,000 businesses worldwide, using our capital, expertise, and influence to create markets and opportunities in the toughest areas of the world. In FY18, we delivered more than \$23 billion in long-term financing for developing countries, leveraging the power of the private sector to help end poverty and boost shared prosperity.

ABOUT THE CASE STUDY

Expanding access to quality and affordable healthcare is a central element to eliminating extreme poverty and promoting shared prosperity. The World Bank Group has a goal to end preventable deaths and disability through Universal Health Coverage (UHC). In many developing countries, governments do not have the capacity to serve the entire population and private healthcare providers often play a critical role in meeting societal needs. IFC is developing case studies that demonstrate the ability of the private sector toward achieving global and national healthcare goals. Through a focus on efficiency and innovation, certain business models can provide better outcomes at a lower overall cost to society.

WRITTEN BY

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Photo © GAVI/Adrian Brooks

Nearly one-third of deaths of children under five years old can be prevented with vaccines.

GIVING PEACE OF MIND TO PARENTS

Baby Ibrahim's mother sleeps better at night knowing that her son is now protected against five deadly childhood diseases. Ibrahim was the first child in Nigeria to be immunized with Biological E. Limited's (BioE's) new Pentavalent, five-in-one vaccine. Pentavalent safely combines five antigens that will prevent catastrophic illness, disability, and death from Diphtheria, Tetanus, Pertussis, Hepatitis B, and Haemophilus influenzae type B (Hib), which causes meningitis and pneumonia.

Today, Pentavalent is one of the most used vaccines in the world, in part, because it is effective and offers greater convenience. By reducing the number of shots needed from nine to three, children like Ibrahim are more likely to receive the entire regimen and be fully protected over their lifetime. Fewer doses also helps governments to reduce the overall cost of vaccination, which includes the purchase price of the vaccines, cold chain logistics, as well as transportation and wages for health workers who administer the vaccines.

In June 2012, the government of Nigeria introduced the Pentavalent vaccine into the routine immunization schedule of the most populous nation in Africa. This was an important step for a country that accounted for half of global childhood deaths at that time.

Nearly one-third of deaths of children under five years old can be prevented with vaccines. But for decades, millions of children across the world did not have access because vaccination costs were high. Further, there was often a 10 to 15-year lag between the release of a new vaccine in rich countries and the time it took to reach low- and middle-income countries.

These circumstances led the Bill and Melinda Gates Foundation (BMGF), to pioneer a partnership that included the Global Alliance for Vaccines and Immunization (GAVI), UNICEF, the World Health Organization (WHO), the World Bank, several development organizations and vaccine manufacturers. By consolidating country demand and channeling procurement through UNICEF and the Pan American Health Organization (PAHO), they created a large and sustainable market. The result was a surge in demand for vaccines. BioE was just entering the international market but it was able to respond with large volume capacity.

Ms. Mahima Datla, Managing Director of BioE explains, "We were able to produce large-scale quantities and provide affordable vaccine at prices close to one dollar a dose. When BioE entered the market with Pentavalent, our price was about 30 percent less than the competition. This meant that life-saving vaccines can reach the most underprivileged children in the world."

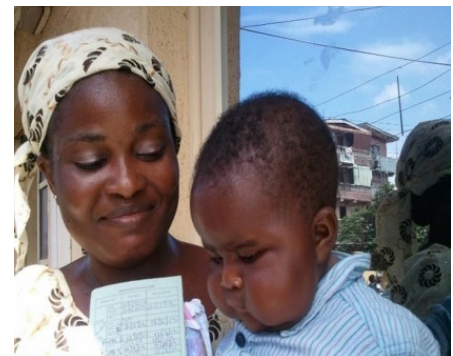


Photo © BioE

In September 2012, Ibrahim was the first child in Nigeria to be immunized by BioE's Pentavalent vaccine.

But price is not the only factor to consider for vaccination—quality is important. To get its vaccine to the international market, BioE had to pass the World Health Organizations (WHO’s) rigorous inspections which certify that its vaccines meet global standards for quality, safety and efficacy. BioE’s Pentavalent vaccine earned the “WHO pre-qualification,” which enabled it to supply to UNICEF, the world’s largest purchaser of vaccines.

Between 2012 and 2017, BioE supplied more than 2 billion doses of different vaccines. Its low-cost vaccines are reaching children in over 80 countries across the world. In Sierra Leone, villagers who survived the ravages of the Ebola outbreak immunized their babies with Pentavalent to protect them from another serious and preventable health crisis. In South Sudan, a mother whose four oldest children contracted measles, eagerly sought out the Pentavalent vaccine to protect her youngest son. From fragile countries to middle-income countries such as India, BioE’s immunizations are giving millions of children a healthy start in life.



Photo © BioE

“When BioE entered the market with Pentavalent, our price was about 30 percent less than the competition. This meant that life-saving vaccines can reach the most underprivileged children in the world.”

Mahima Datla
Managing Director

BioE is a privately held vaccine and pharmaceutical manufacturing company. Founded in 1953, BioE was the first private-sector biological products company in India. It later diversified into what is now its core business – producing high-quality, low-cost, generic vaccines. Today, BioE is a leading global supplier of the Liquid Pentavalent Vaccine (LPV), and it produces more than one million vaccine doses a day. It is the second largest vaccine manufacturer in India.

Since 2008, BioE has invested over \$100 million in Research and Development (R&D) to successfully develop and commercialize six vaccines. BioE has eight vaccines that are WHO pre-qualified, and it is constantly undergoing WHO approval processes for new products in its R&D pipeline.¹ It ranks as one of the most reliable suppliers amongst the six companies that have WHO pre-qualification for Pentavalent vaccine and it is one of just two companies that are pre-qualified to supply the Japanese Encephalitis (JE) vaccine. For two years, it was the exclusive supplier of LPV and JE in India. For its newest vaccine, Measles and Rubella (MR), it has taken pre-orders and will begin distribution in India beginning in 2019.

In terms of products in the R&D pipeline, BioE is currently developing Hexavalent, a next generation vaccine, which adds protection against polio to the Pentavalent vaccine. It is also preparing Pneumococcal Conjugate Vaccine (PCV), Typhoid Conjugate Vaccine and Inactivated Polio Vaccine (IPV).

BioE is headed by Ms. Mahima Datla, the Managing Director and is one of the few women corporate leaders in the industry. In 2018, the company had about 4,500 employees and contract workers, of which about 30 percent were women. BioE has R&D facilities in India and France, and it has five manufacturing facilities in India. It is among the largest pure-play vaccine manufacturers in emerging markets, with about 80 percent of revenues coming from vaccines.

¹ The eight vaccines that are WHO Prequalified are the Pentavalent vaccine (DtwP-rHeb-Hib) in both liquid and lyophilized (freeze-dried powder) forms and in single dose and 30 dose vials; Tetanus Toxoid (TT); Tetanus and Diphtheria (Td); Japanese Encephalitis (JE); and Measles and Rubella (MR).

Narender Mantena, Director, explains, “Part of BioE’s success is that we are fully backward integrated for all the vaccines currently in production. This means we produce our own antigens, and combined with our capacity to manufacture high volumes, we can maximize efficiency and generate cost savings that we pass down to our clients through lower prices.” Notwithstanding lower prices, for the 2017-2018 fiscal year, BioE had about \$155 million in gross revenues and it is constantly reinvesting proceeds to fund R&D and future expansion.

In 2017, IFC approved a \$60 million loan to BioE to fund diversification of its product range and increase its production capacity. It needed funds for R&D to develop new vaccines and to scale up its manufacturing facilities for new products such as MR and PCV. It also needed to be able to install and enhance new capacity in its facilities so that once it received WHO pre-qualification for its newest vaccines, it could immediately begin large-scale production.



Photo © GAVI/Mike Pflanz

Two days after the pentavalent vaccine was introduced in South Sudan, Jackline Juan cradles her daughter, Keji Francis, after the baby's first dose. July 2014.



Photo © GAVI/Adrian Brooks

A partnership led by the Bill and Melinda Gates Foundation developed ways to overcome structural obstacles to market development, so that more vaccine producers could enter the market with more affordable products.

BECOMING A LEADING GLOBAL VACCINE MANUFACTURER

In 1953, Mahima Datla's grandfather, Dr. Datla Venkata Krishnam Raju, founded Biological Products Private Ltd. He was succeeded by her father, Dr. Vijay Kumar Datla. For the first ten years, the company manufactured, for the Indian market, generic biological products, such as heparin injections, an anticoagulant that prevents blood clots. In 1963, the company entered into an equity partnership with Evans Medical, a UK-based pharmaceutical and vaccine manufacturer, and the company changed its name to Biological Evans Ltd. It later became Biological E. Limited.

Between 1972 and 1979, BioE added new technology and know-how, and the company began manufacturing Tetanus Toxoid (TT) and Diphtheria, Tetanus and whole cell Pertussis (DTwP) vaccines for sale in India. At that time, vaccinations were not a well-funded public health priority neither in India, nor in most of the developing world. Thus, demand was minor and consequently, the vaccines segment of the business was relatively small.

This continued until 1990, when the Children's Vaccine Initiative (CVI), was founded with the mission to immunize all children; to promote research to determine the feasibility of a single-dose multivalent vaccine; and to introduce new vaccines for infectious diseases. At that time, 30 million children living in poor countries were not fully immunized because it was too expensive for health systems to afford. A partnership led by the Bill and Melinda Gates Foundation (BMGF) began developing ways to overcome structural obstacles to market development, so that more vaccine producers could enter the market and they could scale up production and make their products more affordable.

Considering the seismic shift occurring in the industry, BioE recognized that Pentavalent was the product of the future. It already had most of the antigens required for production, but to have a pathway for the Pentavalent vaccine, it needed to develop a method to safely and effectively combine Hepatitis B and Hib with its DTwP vaccine. This kind of discovery is a labor-intensive effort that takes years of research to properly develop. It also had to find a way to finance several years' worth of research and development costs with reasonable certainty that one day it would recover its investment. Narender explains, "One of the key challenges of the vaccine industry is that we have large fixed costs spread out over many years. We invested nearly ten percent of our revenues annually in R&D until revenues from Pentavalent began to flow, and then we continued to invest at the same levels in new R&D." In 2011, BioE successfully licensed the Liquid Pentavalent Vaccine (LPV) in India and in 2012 it received WHO prequalification. This milestone catapulted the company into a new era of growth.

Another element critical to growth was the guarantee provided by the BMGF. Narender reflects, "The BMGF played a critical role by providing a backstop to help us introduce the product in the market. This was an extremely important element, because this guarantee provided us with capacity utilization visibility for 230 million doses to be supplied over five years." The guarantee contract, and other factors, allowed BioE to gain 20 percent market share in the first year, and this increased to about 45 percent by 2017. Since 2012, BioE has supplied over 400 million doses of LPV to children in more than 80 countries, with good quality and 99 percent reliability.



Photo © BioE

"We invested nearly ten percent of our revenues annually in R&D until revenues from Pentavalent began to flow, and then we continued to invest at the same levels in new R&D."

Narender Mantena
Director



Photo © GAVI / Doune Porter

“All of our community knows how important it is to vaccinate our children,” says Sauda Sarum, “that is why there are so many people here.”

CREATING SCALE TO DRIVE PRICES DOWN: BIOE's BUSINESS MODEL

ESTABLISHING A SUSTAINABLE VACCINE MARKET

Prior to 2000, vaccine procurement was largely done at the national level by individual governments. The market was highly fragmented, and demand was low, in part because prices for Pentavalent were \$3.50 a dose. This meant that it would cost \$10.50 to fully immunize one child with only one vaccine. Thus, a full course of immunizations quickly became unaffordable for many countries and children were not immunized.

The Gates Foundation saw an opportunity to address these structural issues and brought in partners to consolidate the fragmented demand. GAVI would help 73 of the lowest-income countries pay for immunization through cost-sharing. UNICEF would conduct a consolidated procurement on behalf of all the GAVI countries, as well as some middle-income countries. PAHO facilitated purchases on behalf of countries in Latin America. By consolidating the purchasing power of multiple countries, it created a larger marketplace under the umbrella of large global purchasers. This gave manufacturers greater predictability of prospective volumes and the potential for increased demand.

Having addressed the demand side, the group tackled the supply side. In 2001, GlaxoSmithKline (GSK) was the single supplier of the Pentavalent vaccine, and the Gates Foundation wanted to promote greater competition. To attract new entrants to the market, it had to offer tools for reducing the risks. Because manufacturers incur significant costs that are spread out over multiple years, they needed more certainty that they could recover the costs and generate a return that could be reinvested back for the development of future vaccines. In response, the Gates Foundation created a mechanism that would guarantee the purchase of a fixed quantity, if UNICEF did not procure a manufacturer's supply.



Photo © GAVI /Johan Halgins

Through a partnership, the purchasing power of multiple countries was consolidated to create a significantly larger marketplace under the umbrella of large global purchasers.

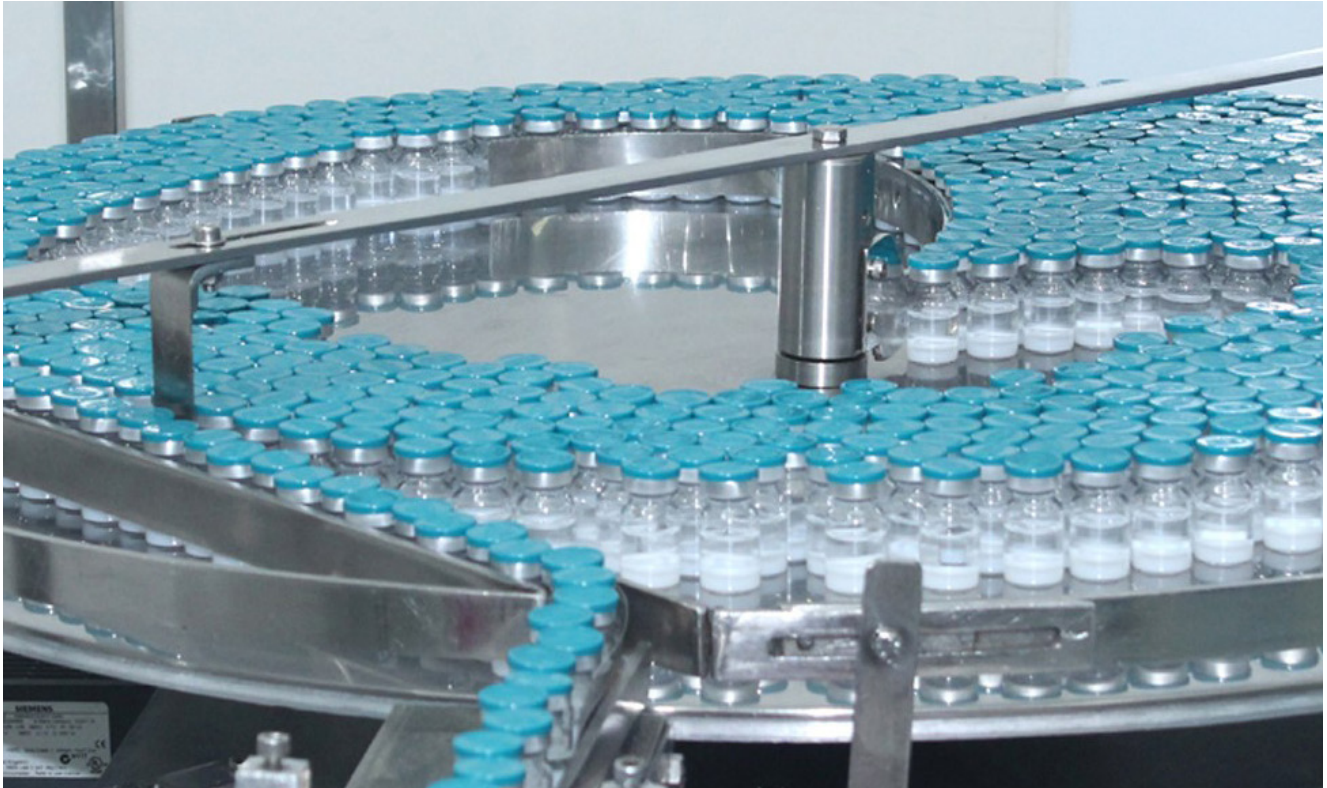


Photo © BioE

A massive surge in demand helped vaccine suppliers confidently make investments in scaling up operations to supply large volumes.

To be eligible to sell to UNICEF and be eligible for the Gates Foundation guarantee, vaccines would need to be WHO prequalified. This step proved that the vaccine formulation was safe and effective after having undergone a rigorous scientific review and clinical trials by the world’s leading health body.

Overall, the effort to consolidate the market has worked well. It took five years but in 2006, a second manufacturer entered the market and Pentavalent supply increased to an average of about 16 million doses per year. In September 2012, BioE helped increase the global supply substantially when it began selling Pentavalent, starting in Nigeria. By 2016, more manufacturers had obtained WHO prequalification and UNICEF had procured about 226 million doses. Also, that year, India graduated from GAVI and combined with other middle-income countries—they had procured an additional 15 million doses. Between 2017 and 2019, UNICEF expected its demand to reach about 450 million doses. This massive surge in demand has helped vaccine suppliers confidently make investments in scaling up its operations to supply large volumes.

KEY CLIENTS

The revolutionized market was a game changer for new entrants like BioE, which entered the Pentavalent international market in 2012. In only five years, BioE had supplied more than 2 billion doses of multiple vaccines to children across the globe, and the company has emerged as a leading global supplier. In 2018, BioE estimates that about 40 percent of revenues were derived from the international donor market.

In 2016, India transitioned out of GAVI and it began procuring Pentavalent independently. BioE had sold vaccines to the Indian government for decades but Pentavalent catapulted the company to a new level. Between 2016 and 2018, BioE was the sole supplier to the Indian government for about 180 million doses. Narender reflects, “This opportunity demonstrated BioE’s ability to reliably deliver massive quantities.” In 2018, about 40 percent of revenues are estimated to have originated in India.

In addition to UNICEF, PAHO and the government of India, BioE sells directly to middle-income countries. Several of these countries, such as Algeria, Egypt, Philippines, Sri Lanka, and Vietnam have graduated from GAVI. Middle-income countries and the private market (mostly pediatricians in India) contribute about 20 percent of revenues. As more countries graduate from GAVI, and BioE continues to diversify its client mix, this proportion is expected to increase.

REACH IN AFRICA

BioE reaches nearly all countries in Africa through UNICEF. Further, middle-income African countries purchase directly from BioE through local agents or distributors. The average order is for between two to three million doses of Pentavalent.

TENDERS

UNICEF evaluates proposals on a variety of criteria including WHO pre-qualification, reliability and consistency of quality supply over several years, competitiveness of price, and volume capacity. These factors are designed to ensure a diverse supply base and to reduce reliance on a single producer in the event of interruptions in supply. UNICEF tries to ensure that all participants have enough demand to remain a sustainable provider.



Photo © GAVI /Adrian Brooks

Between 2012 and 2017, BioE supplied more than 2 billion doses of multiple vaccines to children across the globe, and the company has emerged as a leading global supplier.



Photo © GAVI/ German A. Miranda

“These products are for children and we take quality very seriously. BioE’s philosophy is, ‘Quality or Nothing.’” Mahima Datla.

QUALITY

In 2012, when BioE’s pentavalent product was entering the market, two companies had quality problems and left the market. In the vaccine industry, quality problems have immediate and devastating financial implications for the manufacturer from which can take several years to recover, if the company can recover at all. Manufacturers need cash flows to pay back years of investments in product development. BioE recognizes that without quality, it cannot be a sustainable supplier with a secure business future.

BioE’s philosophy is “Quality or Nothing.” Mahima explains, “These products are for children and we take quality very seriously. We would rather stop manufacturing and tell our customers that we cannot supply, rather than put out products that do not meet our high-quality standards.”

Narender adds, “We have built a team with international expertise. We have implemented quality guidelines that follow WHO standards. There is an independent quality assurance department that systematically audits products and reports directly to the board of directors.” The result is that BioE has been able to deliver quality vaccines with 99 percent reliability, and this has positioned the company for continued growth in orders.

Since 2010, BioE has won many tenders from its key clients, including eight from UNICEF, seven from PAHO and about 50 from the government of India. It has also won about 25 bids from other governments and public organizations. Due to its high-volume capacity for multiple products, its economies of scale, and continuous improvements, BioE is able to offer competitive prices.

PRICING

Donor organizations have designed the bidding system to ensure that vaccines are affordable. UNICEF has held several rounds of bidding for large, three-year contracts (the current round covers 2017 to 2019) and UNICEF introduced a transparent bidding process that brought the Weighted Average Price (WAP) per dose down from \$1.65 (2016) to \$0.84 (2017-2019) a dose. Since 2001, the cost to fully immunize one child with Pentavalent dropped from \$10.50 to about \$2.50. By cutting prices by about 75 percent of the original cost, UNICEF was able to purchase 523 million doses of Pentavalent to vaccinate children in 83 countries.^{2 3} The lower prices have saved UNICEF and GAVI about \$500 million over 5 years.

RISK MANAGEMENT

While lower prices are important to increase widespread immunization, one of the greatest risks BioE faces is price erosion. Since 2018, a few suppliers left the market because they did not have the volumes to absorb the low prices. BioE's large capacity allows it to deliver high volumes and this has helped the company to adapt, even as prices have continuously dropped.

Narender explains, "We are focused on technology as well as the right capacity solution at the lowest cost possible without compromising quality. When we design a product, we also design the facility cost effectively." He adds, "We ensure that we have an efficient Cost of Goods (COGS), and we are backwardly integrated, ensuring price control over all inputs."

Chirag Mehta, the Chief Financial Officer (CFO), elaborates further, "BioE needs at least 30 to 40 percent capacity utilization to be cost effective, but any supplier that has between 20 and 30 percent market share should be able to sustain lower prices. However, if a supplier does not have that kind of significant capacity, it would need a diversified portfolio so that one product can take a hit while other products sustain the top line."

BioE is in the process of diversifying its portfolio of products and has four new vaccine products in the pipeline. In addition, it is diversifying the range of products on the pharmaceutical side with high-complexity injectables used in hospitals. To start with, it is targeting the U.S. market for pharmaceutical products from its U.S. FDA-approved greenfield facility in Hyderabad, India.

GROWTH

BioE's growth has been purely organic. Until about five years ago, BioE had vaccine manufacturing capabilities in five different areas (bacterial, microbial, yeast based, cell culture based, and conjugate) but it needed virus capabilities to be able to manufacture all six types. In 2013, BioE acquired a facility and the viral vaccines expertise in Nantes, France. This gave it the final key capacity it needed for R&D and pipeline development. This was important for the development of its MR and IPV projects. In terms of distribution, the contracts with UNICEF catapulted its reach from largely serving the Indian population to having a global footprint. The map below shows the global reach of BioE's vaccines.

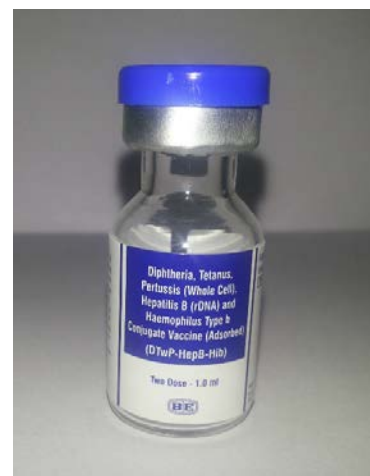


Photo © BioE

Since 2001, the cost to fully immunize one child with Pentavalent dropped from \$10.50 to about \$2.50.

² Pentavalent Vaccine (DtwP-hepB-Hib): Market Supply and Update, UNICEF Supply Division, May 2017, pg 1.

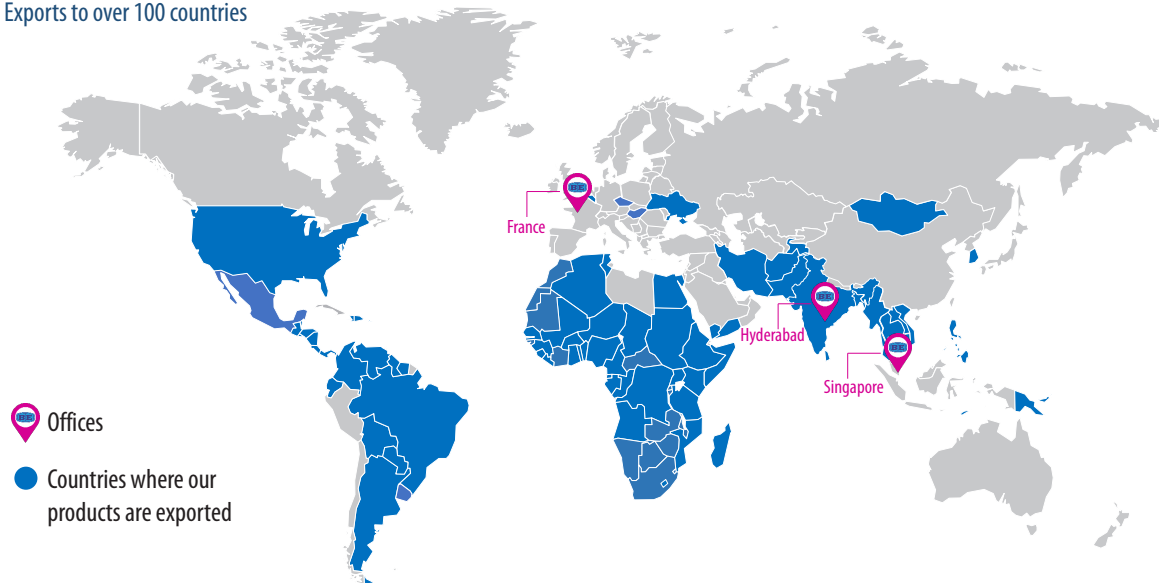
³ "Pleased to Introduce You to the Pentavalent Vaccine! The Story of How Pentavalent Became one of the Most Used Vaccines in the World." UNICEF, Published in Medium. 28 June 2017.

BioE's Global Footprint

GLOBAL PRESENCE

Ensures Uninterrupted Supply

Exports to over 100 countries



R&D

BioE develops vaccines in generic form. When a vaccine comes off-patent, the formula becomes publicly available; however, the details on how to safely and effectively develop and manufacture the vaccine is not disclosed due to the proprietary nature. As a result, BioE still needs to invest heavily to create its own formulations, and it needs to develop the product in a manner that is cost effective. As a result, the average timetable to develop a vaccine is five to seven years, including time for domestic and WHO quality approvals.

Vaccines have a lifespan of about seven or eight years and for the business to remain viable, manufacturers need to continuously reinvest to introduce new products. Srividya Jagannathan, IFC's Global Lead for Life Sciences explains, "In an environment with heavy price erosion, companies cannot depend on a single product and rest on their laurels. Manufacturers need to keep the innovation going and continuously reinvest in R&D. While there have not been many companies that have successfully maintained cost-effective vaccines in the market while working to launch new products, BioE has made R&D a priority."

In the last five years, BioE has reinvested 10 to 15 percent of revenues in new product development that it believes will be aligned with demand generated by the Gates Foundation. In 2019, BioE's latest vaccine, Measles Rubella (MR) will arrive in health facilities across India. Hexavalent, Inactivated Polio Vaccine (IPV), Pneumococcal Conjugate Vaccine (PCV), and Hepatitis A (Hep A) are all in clinical trials and BioE hopes to bring them to market in the next two to four years. To further diversify its customer base, it is increasing the R&D budgets for the development of novel vaccines for the U.S., E.U. and other emerging markets.

BioE is currently developing Hexavalent, a next generation vaccine, which adds protection against polio to the Pentavalent vaccine.



Photo © RIBI



Photo © DFID/Pippa Ranger



Photo © BioE

BioE’s technological strength has allowed it to partner with large multinational companies such as GlaxoSmithKline (GSK) for the development of Hexavalent.

PARTNERSHIPS

BioE’s technological strength has allowed it to partner with large multinational companies such as GlaxoSmithKline (GSK) for the development of Hexavalent and Novartis for Typhoid Conjugate Vaccine. For both sides, partnerships offer an opportunity to share scientific knowledge, which can reduce the time needed for new product development. For BioE, these partnerships have provided important learning opportunities. For multinationals who may have other competing priorities, such as developing the next blockbuster drug, BioE brings speed to developing the next generation vaccine for emerging markets. BioE’s technical depth, its agility, and skills in project management can help get a product to market quickly– it just delivered MR in a record time of four years – and that capability is attractive to the multinationals.

TALENT

BioE’s competitive edge is found in its pool of talented people. BioE has attracted talent from large multinational pharmaceutical companies such as Wyatt, Pfizer and GSK. It has invested in its people, and it highly values the cadre of talent it has built up as a resource. It has cultivated a culture where different business units “synchronize well together as a team.” As a result, Chirag believes that “our people are better project managers and that allows us to get things done faster, enabling the company to bring down project costs significantly.”

COST OF GOODS (COGS) COMPETITIVENESS

When BioE started developing LPV, it decided that it would be backwardly integrated from day one. In other words, BioE would control all steps in the manufacturing process, which is essential for BioE to control costs and quality, and to maintain a steady supply of the key ingredient- the antigens. BioE is backwardly integrated for almost all its existing portfolio of vaccines. For MR, while it does not yet make the measles

antigen in-house, it has started to implement its strategy to backward integrate that component as well. By not depending on third party suppliers for full or partial inputs, the company has brought down costs and reduced the timeline for development.

In some areas, BioE's costs are still at U.S. and E.U. prices. Scientists and other key talent are compensated at international wage levels and equipment is purchased from western countries in U.S. dollars and Euros. Labor arbitrage works to a certain extent, but disciplined project management helps keep costs to a reasonable level. In an environment of systematic price erosion, companies that cannot maintain competitive cost of goods will not survive.

ECONOMIES OF SCALE

Vaccine development requires very large facilities and production sometimes takes place in different buildings. Given these significant infrastructure requirements, BioE decided that it needed to position itself as a big player. Chirag explains, "If the facility is only going to make a few million doses, we will never have the margins to recover past investments and simultaneously reinvest in the next generation product. Thus, we needed to build for large capacities for our future pipeline." He added, "We need to prepare to service at least 50 percent of the market."

REVENUES

BioE's participation in the international donor market changed the company's growth trajectory. Narender explains, "In the earlier part of this decade we were about a \$55 million company. For the 2017-18 fiscal year, (which ended in March 2018), we became a \$155 million company." The vaccines business is the most significant driver of company revenues bringing in about 80 percent, while pharma and sera accounted for about 20 percent. In 2018, the EBITDA margin was about 20 percent, taking into consideration that it reinvested about 10 percent of revenues and channeled it into R&D.

In terms of products, about 60 percent of revenues is from Pentavalent. The second most important revenue driver was from pre-orders for MR. BioE's has about 15 key clients but the top three are UNICEF, PAHO, and the government of India. About 40 percent of sales is from international donors, and another 40 percent is from the government of India. About 20 percent of revenues are from direct sales to middle income countries and others.

BioE's growth in the last five years has been exceptional. After India transitioned out of GAVI three years ago and it began procuring vaccines on its own, BioE's sales to India increased markedly, to the point that it is now on par with that of international donors. In the last three years, BioE grew by about 30 percent at a CAGR of about 14 percent. Chirag reflects, "That's as fast as any pharmaceutical company I've seen can grow. The WHO prequalification was extremely important and has given us a quality stamp that's going to sustain our business going forward."



Photo © BioE

"If the facility is only going to make a few million doses, we will never have the margins to recover past investments and simultaneously reinvest in the next generation product. We need to prepare to service at least 50 percent of the market."

Chirag Mehta,
Chief Financial Officer



Photo © GAVI /Adrian Brooks

“Companies, especially those with long-gestation R&D, like working with IFC because we are a patient capital provider and we value the partnership over the long run.”

THE ROLE OF IFC

In 2017, BioE began exploratory discussions with IFC. Chirag had known Srividya for many years from his prior work. BioE wanted to have access to debt on top of retained earnings and sought out IFC because there were good synergies in its development mission and BioE’s clients. Chirag explains, “We felt that IFC would be a strategic partner because the development missions of both organizations were aligned to do something good for the world. Further, the name IFC carries a lot of weight and brings goodwill from across the world, especially in the donor community, and that was important to us.”

IFC was interested in working with BioE because IFC values the core business of the company in providing affordable vaccines to children in emerging markets. Further, BioE’s work directly supports the achievement of the Sustainable Development Goals (SDGs) by supporting the research and development of vaccines that address communicable diseases and that reduce mortality for children under the age of five.

In 2017, IFC approved a \$60 million long-term loan for BioE’s capital expenditure and expansion of its vaccines business.⁴ Srividya said, “Companies, especially those with long-gestation R&D, like working with IFC because we are a patient capital provider and we value the partnership over the long run.”

Narender adds, “IFC teams are always talking to us about new business plans and future opportunities and the option to do follow-on transactions.” Srividya explains, “BioE appreciated having a partner that brings an international perspective, who can provide them with contacts and help them navigate the business climate if they want to reach out to countries in other regions that are not currently in their portfolio. IFC could help them, if required.”

⁴ IFC’s funds were not for BioE’s growth in the pharmaceutical segment since that targets the US market.



Photo © GAVI /Christ Stowers

BioE’s work directly supports the SDGs by supporting the research and development of vaccines that address communicable diseases and that reduce mortality for children under the age of five.



Photo © GAVI /Adrian Brooks

BioE has played an important role in bringing affordable access to vaccines to children around the world.

CONCLUSION

Across the globe, more children are surviving beyond their fifth birthday. The Sustainable Development Goals Report 2018 found that between 2000 and 2016, the mortality rate for children under age five was nearly halved, dropping from 9.9 million to 5.6 million. Even in the region facing the greatest health challenges, such as Sub-Saharan Africa, “progress has been impressive.”⁵ Immunizations have played a role in protecting children from devastating diseases. According to UNICEF, immunizations have saved between two to three million lives, making vaccines one of the most cost-effective health interventions globally.

BioE has played an important role in bringing affordable access to vaccines to children around the world. It is helping to equalize access between children living in developed countries and those born into fragile environments. The Gates Foundation and its partners created a sustainable marketplace that has made the price of vaccines much more affordable. BioE’s quality and ability to service large-scale orders has sparked greater competition that has helped drive prices down globally. As BioE continues to introduce new vaccines, more children than ever have received life-saving immunizations that protect them from devastating diseases. BioE’s vaccines help children to lead healthy lives and to celebrate life.

⁵ The Sustainable Development Goals Report 2018, United Nations, pg 5, 2018.



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BioE’s vaccines help children to lead healthy lives and to celebrate life.

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