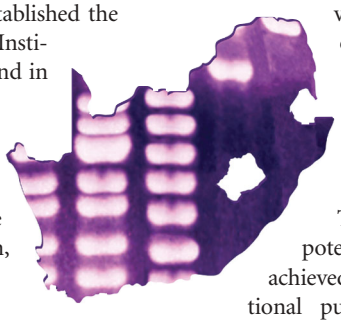
South Africa—blazing a trail for African biotechnology

Marion Motari, Uyen Quach, Halla Thorsteinsdóttir, Douglas K Martin, Abdallah S Daar & Peter A Singer

UNDER the apartheid regime, South Africa was isolated from the global community. Consequently, it developed its own scientific and technological capacity by focusing on the development of the arms, textile and mining industries. The successes in mining and arms created among South African scientists a certain degree of confidence, which spilled over to other areas, such as veterinary sciences. This cultivated a culture for research oriented to local needs. Data from 28 interviews with experts in South Africa indicate that this strong scientific base, developed to support the apartheid regime, is now being used to develop biotechnology in the country.

South Africa has made huge strides in the development of agricultural biotechnology[1] and is beginning to move into health biotechnology. Today, post-apartheid South Africa is one of the leading sub-Saharan African countries in developing the capacity and capability for R&D in health biotechnology, especially through the New Partnership for African Development (NEPAD), a framework designed by African leaders to accelerate sustainable development in African countries. According to most respondents, South Africa hopes to use this and other regional initiatives to start exporting health biotechnology products to neighboring countries. With its leadership role, the country is strategically positioning itself institutionally and politically to harness health biotechnology innovations to address public health problems faced by the whole region. For instance, it established the South African Bioinformatics Institutes in 2001, the first of their kind in the region. South Africa is also taking a leading role in the development of vaccines, most notably for HIV-AIDS through the South African AIDS Vaccine Initiative (SAAVI, Cape Town, South Africa).



The success of South Africa's health biotechnology sector

HIV-AIDS affects a substantial portion of the population in South Africa[2]. Key players in the country's health biotechnology sector are beginning to lead the way toward addressing this urgent public health problem, which is connected with the problem of underdevelopment. According to the SAAVI (http://www.saavi.org.za/index.htm.), six potential novel candidate vaccines are currently under evaluation at the University of Cape Town and the University of Stellenbosch. In 2003, two phase I trials were launched, making South Africa the first African country to execute multiple HIV-AIDS vaccine trials. Even more important, South Africa is the first country in the world involved in a trial on a preventative vaccine against the HIV-1 C subtype[3]. In the Americas, Western Europe, Australia and New Zealand, the HIV-1 subtype B is the dominant strain, so this has been the target for HIV-AIDS vaccine development. In other areas of the world, such as Africa and Asia, however, where the HIV infection rate is higher, the subtype C strain is most prevalent.

The development of the potential vaccines has been achieved through an international public-private partnership (PPP). The South African partners are SAAVI, the University of Cape Town, the University of Stellenbosch, the National Institute for Communicable Diseases (Sandringham, South Africa) and the Medical Research Council (MRC, Tygerberg, South Africa). The international partners include AlphaVax (Durham, NC, USA), the University of North Carolina in Chapel Hill, the Division of AIDS at the National Institute of Allergy and Infectious Diseases (Bethesda, MD, USA), the HIV Vaccine Trial Network (Seattle, WA, USA) and the International AIDS Vaccine Initiative (IAVI, New York, NY, USA).

Another noteworthy project has focused on exploiting indigenous knowledge to develop biotechnology medicines. For years, traditional healers have made use of South Africa's rich biodiversity. The government and the MRC have initiated programs since 1997 for the development of medicines and remedies based

Illustration by Erin Boyle

Marion Motari is a PhD Candidate, UNU-INTECH-MERIT Programme, United Nations University, Institute for New Technologies, Keizer Karelplein 19, 6211 TC Maastricht, The Netherlands; Uyen Quach is Research Assistant, Canadian Program on Genomics and Global Health, University of Toronto Joint Centre for Bioethics, 88 College Street, Toronto, Ontario M5G 1L4, Canada; Halla Thorsteinsdóttir is Assistant Professor, Canadian Program on Genomics and Global Health, University of Toronto Joint Centre for Bioethics and Department of Public Health Sciences, 88 College Street, Toronto, Ontario M5G 1L4, Canada; Douglas K. Martin is Assistant Professor, Department of Health Policy, Management and Evaluation, and the University of Toronto Joint Centre for Bioethics, 88 College Street, Toronto, Ontario M5G 1L4, Canada; Abdallah S. Daar is Director of Ethics and Policy, McLaughlin Centre for Molecular Medicine; Professor of Public Health Sciences and of Surgery, University of Toronto; and Co-director Canadian Program on Genomics and Global Health, University of Toronto Joint Centre for Bioethics, 88 College Street, Toronto, Ontario M5G 1L4, Canada; and Peter A. Singer is Sun Life Financial Chair and Director, University of Toronto Joint Centre for Bioethics; Professor of Medicine, University of Toronto; and Co-director Canadian Program on Genomics and Global Health, 88 College Street, Toronto, Ontario M5G 1L4 Canada.
e-mail: halla.thorsteinsdottir@utoronto.ca

on this knowledge. One South African expert interviewed for this study predicted that "…for the purpose of developing our economy in biotechnology, I see the indigenous knowledge dominating as opposed to the pure science route." The case study described in **Box 1** illustrates the successful use of this knowledge by local actors.

South Africa possesses excellent researchers and facilitites, a strong base in biomedical research, good infrastructure and a sound regulatory system. Looking at a sample of South African health biotechnology products and services, it is clear that what now exists represents a promising future for the country (see **Table 1**).

Comparing South Africa's health biotechnology publications in international peer-reviewed journals and patents granted in the United States Patent and Trademark Office (USPTO, Washington, DC, USA) between 1991 and 2002 provides another indicator of the country's innovation level in terms of scientific output and commercial potential in the field (see **Fig. 1**). Data derived from ScienceMetrix[4] show South Africa's overall scientific output in health biotechnology is increasing slowly. According to an analysis of USPTO database carried out in July 2004 (http://www.uspto.gov/), the country's patent activity (based on inventors' addresses in USPTO-granted patents in health biotechnology) is weak, with only a few patents granted during this period.

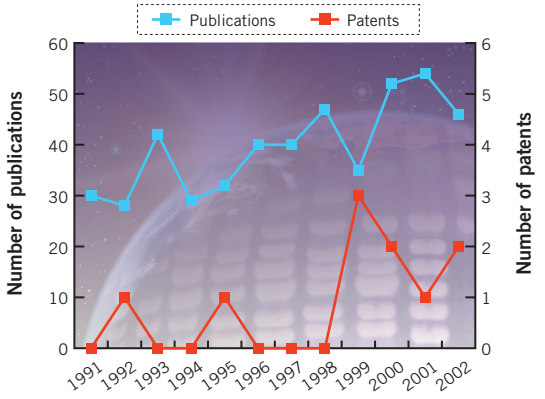


Figure 1 South African publications and USPTO patents in health biotechnology (1991–2002). Source: Publication data are from ref. 4. Patent data are from the USPTO.

Main features of the South African sector

Since adopting a national strategy for biotechnology 3 years ago, the South African government has established several regional innovation centers and put in place initiatives to encourage international partnerships that can spur internal development of life science ventures. This strategy seeks to capitalize on the high quality of research carried out in public research institutions and universities, but is hampered somewhat by the lack of entrepreneurial culture among South African researchers. Although private sector development is still relatively embryonic, startups are spinning out of universities and pre-existing companies that make generic products. Diagnostic testing and clinical trials are growing as services for multinational companies. Although the majority of the public has a poor grasp of health biotechnologies, recent controversy over national policy for the management of the country's HIV-AIDS sufferers has raised awareness and interest in recombinant vaccine trials.

Government. Government support of health biotechnology has been growing, and in 2000 it began focusing its research support to biotechnology. This led to the adoption of the 2001 National Biotechnology Strategy, a policy framework to create incentives for the biotechnology sector. Within this framework, biotechnology is identified as potentially contributing to national priorities of access and affordability of health care, food security, job creation and environmental protection. The Department of Science and Technology (DST, Pretoria) is responsible for administering this strategy. Besides addressing human resource development, funding, and regulatory and legal issues, the strategy identifies a gap between research endeavors in academic and other public research institutions and the market. Two mechanisms have been encouraged to bridge this gap. The first is cultivating PPPs between domestic and international actors. Although PPPs are clearly not a replacement for developing a system of innovation in health biotechnology for the country, they serve as a means toward that process. Work on HIV-AIDS, tuberculosis and malaria, diseases of particular relevance to the South African population, dominates these PPPs.

Second, the government is supporting the creation of three biotechnology regional innovation centers "to act as nuclei for the development of biotechnology platforms, from which a range of businesses offering new products and services can be developed."[5] This initiative involves strategically developing 'bioclusters' rather than encouraging clusters to grow under their own impetus. South Africa has formed three innovation centers, with the Cape Biotechnology Initiative in Cape Town and the East Coast Biotechnology Consortium (EcoBio) specifically targeting health biotechnology R&D. The third innovation center is Biopad in Johannesburg, which mainly focuses on agricultural biotechnology.

The government-run Innovation Fund (Pretoria), National Research Foundation (NRF, Pretoria), Technology and Human Resource for Industry Programme (THRIP, Pretoria) and Godisa Trust (Pretoria, http://www.godisa.net/) are all active in funding R&D, research capacity building and technology transfer. For example, Godisa is a South African initiative with a series of activities and programs jointly funded by the European

Box 1 Indigenous knowledge and benefit sharing

South Africa is home to the cactus *Hoodia gordonii*. The San people, who live in the semi-deserts of South Africa, have traditionally chewed the plant when going on long hunting trips to control hunger and thirst. In 1996, scientists from CSIR isolated the hunger-suppressing steroidal glycoside, known as P57AS3 (P57) and patented it. CSIR later licensed the molecule to Phytopharm (Godmanchester, UK) to develop further and commercialize the P57 component. Phytopharm then licensed Pfizer (New York, NY, USA) to develop and commercialize P57 as an antiobesity pill. If it performs well in clinical trials, it could potentially become a blockbuster drug. In the United States alone, the obesity drug market is worth approximately $3 billion annually.

Although it will be some years until there may be a drug on the market from P57, in March 2003, the CSIR and the South African San Council announced it had reached an agreement to ensure benefit sharing from the expected commercial success of P57 (refs 12,13). The terms of the agreement will involve the CSIR paying the San 8% of all the milestone payments it receives from the licensees and 6% of all royalties once P57 becomes a commercial product. These payments will be put into a trust established by the two groups for the San people. With South Africa's rich indigenous knowledge from its biodiversity, this example is a promising precedent of how local actors can bring together indigenous knowledge with modern science and benefit from it in an equitable manner.

Illustration by R. Henretta

Table 1 Examples of South African health biotechnology products

Sector	Type	Application	Producer
Therapeutics	Recombinant human erythropoietin α	Anemia	Bioclones (Johannesburg, South Africa)
	Mouse monoclonal peroxidase antiperoxidase (PAP)	Immunohistology	Bioclones
	Cyclodextrin drug delivery	Analgesic	Shimoda Biotech
Diagnostics	Rhesus antigen typing test kit (immunoblot)	Blood testing/typing	National Bioproducts Institute (Pinetown, South Africa)
Services	Testing and laboratory services	HIV clinical trials and genomic testing	Ampath Clinical Trials (Pretoria)/Genepath (Pretoria)
	Diagnostic, predictive and carrier testing	Genetic testing	Genecare Molecular Genetics (Cape Town, South Africa)
	Diagnostic pathology services	Various diseases	Lancet Laboratories (Durban, South Africa)
	Contract R&D	Human molecular genetics	DNAbiotec (Pretoria)
Other	Single-stranded RNA polymers	Used to produce double-stranded RNA	Ribotech (Cape Town, South Africa)
	Expressed sequence tag, mRNA analysis software	Bioinformatics	Electric Genetics

Union (Brussels) and DST to facilitate technology transfer and incubation in small, medium and micro-enterprises. The Medicines Control Council (Pretoria) and the Companies and Intellectual Property Registration Office (Pretoria), oversee the regulatory and intellectual property (IP) system. According to several respondents, the biotechnology strategy has created awareness in government departments and agencies of the role of biotechnology in meeting health and socioeconomic needs.

Public research institutes and universities. Public research institutes, laboratories and universities are key players in South Africa's health biotechnology development. The government has two main research institutions doing health biotechnology R&D, the Council for Scientific and Industrial Research (CSIR, Pretoria) and the MRC, the latter of which is of particular interest because it specifically targets health research.

The MRC is a statutory council charged with conducting health research that plays an influential role in shaping health biotechnology, because it identifies niche areas for development, focuses research efforts and provides funding. Most government funding for health research is through the MRC. Three of its research nodes, SAAVI, the South African National Bioinformatics Institute (SANBI, Bellville, South Africa) and the Indigenous Knowledge Systems for Health (IKSH, Tygerberg, South Africa), represent niche areas through which strategic research is targeting specific needs. In terms of knowledge production in health biotechnology, public research institutes in general have a lower rate of health biotechnology publications in internationally peer-reviewed journals than their university counterparts[4].

Universities play several roles in the innovation system, including education and training, research and the provision of infrastructure and facilities for projects carried out by research institutes. Many universities house MRC research units and work in a wide range of fields, including immunology and infectious diseases, oncology, hereditary diseases and HIV-AIDS. In terms of productivity of health biotechnology papers, the University of Cape Town has led the country, publishing 20.4% of the total country output between 1991 and 2002 (ref. 4). The University of Stellenbosch followed with 19.7%. The most active universities are also involved in robust, often collaborative domestic R&D. For example, the University of Pretoria's national collaboration rates in health biotechnology for 1991–2002 was 52.5%. The second highest national collaboration rate in health biotechnology for that same period was the University of the Western Cape (Bellville, South Africa) with 50% (ref. 4).

Although the country has contributed only a relatively few publications to internationally peer-reviewed journals, those publications are found in some of the most highly cited international journals and have a high 'average relative impact factor' (ARIF) compared with other developing countries[4]. This is clearly indicative of the quality of South African health biotechnology research. However, despite the high value of knowledge production in the universities, some of the respondents did note that, in general, academics did not see themselves as entrepreneurs, partly explaining the gap between high-quality, high-impact research and commercialization.

Industry. South Africa's entry into the modern health biotechnology industry is recent and, therefore, most of the companies have a short list of novel bioproducts for health biotechnology. Their portfolios generally consist of biogenerics, licensed products from foreign companies or products still in the pipeline. As one respondent discussing health biotechnology products in South Africa remarked, there has "been a lot of research in the labs, but very little converted into products or commercialized." However, good infrastructure, high-quality medical schools and laboratories, and a sound regulatory environment have made clinical trials and diagnostic testing services a strong sector in South Africa, sometimes attracting multinational corporations.

According to the National Biotech Survey 2003 (ref. 6) of South Africa's biotechnology industry, there are about 106 biotechnology firms, including 47 identified as 'core' biotechnology companies—that is, the majority of their activities involved biotechnology. Of the core companies, 37% were spinoffs from another enterprise, 34% were startups and 29% were spinoffs from a research group[6]. A good example of a university spinoff company in South Africa is Electric Genetics, a bioinformatics company based at the University of Western Cape. Electric Genetics makes software for processing and analyzing mRNA and expressed sequence tag data, and this platform has already been exploited, for example, in drug target discovery in trypanosomes.

South Africa also has a strong presence of multinational corporations, particularly in the manufacturing and distribution sectors, including GlaxoSmithkline SA (Bryanstone, South Africa), Pfizer Laboratories SA (Sandton, South Africa), Merck SA (Modderfontein, South Africa) and Novartis SA (Johannesburg, South Africa). The respondents noted that

Box 2 Securing access to cheap antiretroviral drugs

In 1997, Section 15 of South Africa's Medicines and Related Substances Control Act was passed, allowing parallel importing and compulsory licensing of medicines in times of national public health emergencies. This was a way to get cheaper antiretroviral drugs for a population suffering from HIV-AIDS. However, in 1998, the Pharmaceutical Manufacturers Association of South Africa (Pretoria) and 39 international pharmaceutical corporations sued the South African government over its law, alleging violation of the World Trade Organisation (Geneva, Switzerland) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which provides exclusive rights to patent holders. By 2001, the lawsuit was dropped after concerted international pressure, a result of a campaign spearheaded by a South African activist group, The Treatment Access Campaign and Doctors Without Borders.

As a result, several Western pharmaceutical companies are reducing the cost and donating or offering voluntary licensing of their antiretroviral treatments. One big South African pharmaceutical manufacturing firm, Aspen Pharmacare (Durban, South Africa), now has licensing agreements with GlaxoSmithKline (Brentford, UK) for its Combivir (lamivudine/zidovudine), AZT (3′-azido 3′-deoxythymidine; Retrovir) and 3TC (2′-deoxy-3′-thiacytidine; Epivir) drugs, Boehringer Ingelheim (Ingelheim, Germany) for Viramune (nevirapine) and access to the generics for Bristol Meyer Squibb's (Princeton, NJ, USA) Zerit (stavudine, 2′,3′-didehydro-, 3′-deoxy-thymidine) and Videx (didanosine, 2′,3′-dideoxyinosine). (For more information, see refs 14,15.)

most of the multinationals do not contribute heavily to the development of the local health biotechnology sector but take advantage of South Africa's manufacturing base and clinical trials strength. In the late 1990s, the Pharmaceutical Manufacturers Association of South Africa (Pretoria) and 39 pharmaceutical multinational corporations brought a lawsuit against the country's new law allowing parallel importing and compulsory licensing of medicines in times of national health emergencies. However, with strong international pressures, this lawsuit was dropped and South Africa is currently securing access to cheap antiretroviral drugs for its population with cooperation from many of these multinational companies (see **Box 2**).

The general public. In general, the respondents felt that because of the low levels of education among the majority of the people, there was little knowledge of biotechnology and its potential risks and benefits. Biotechnology was often seen as being synonymous with genetically modified organisms. These misperceptions were seen as being perpetuated by popular media and by some foreign influences. Respondents also felt that health biotechnologies, or health-related solutions, will not be met with as much resistance as agricultural biotechnology.

Moreover, statements and attitudes of high-level government officials have played a major role in influencing public perception toward biotechnology. Some of the respondents said that there has been confusion and damage to the image of biotechnology caused by public confrontations between scientists and government officials over HIV-AIDS. President Thabo Mbeki has questioned the link between HIV and AIDS, and he has doubted the efficacy of some AIDS drugs. This has instigated clashes with HIV-AIDS researchers and civil society organizations. One scientist believed that this dispute "is likely to cause problems when the technology is eventually introduced." The respondents stressed the need for the government to improve the way it presents some of the issues to the public. Despite initiatives by the DST, MRC and Department of Health to promote awareness, there is still insufficient information provided to the population about the benefits of biotechnology. On a positive note, however, these public confrontations about HIV-AIDS have created a certain level of awareness (whether appropriate or inappropriate), and there is now a great interest in what is happening in the development of the HIV vaccine by SAAVI.

Main challenges for development

The legacy of apartheid has had a broad-reaching, systemic effect on the development of South Africa's health biotechnology innovation system that is reflected in the challenges described in the following paragraphs.

Lack of human resources. The most recent national R&D survey shows that there are 1.88 full-time equivalent researchers per 1,000 employed South Africans, with 7.7 full-time equivalent R&D personnel per 1,000 in the labor force[7]. The situation of a relatively low number of researchers and R&D personnel is aggravated by the migration of professionals and skilled personnel out of the country and an education system historically skewed by disparities along racial lines. The people interviewed in this study asserted that racial discrimination in academia is a serious problem for the development of health biotechnology.

The poor educational infrastructure and lack of resources in rural schools, especially those in black neighborhoods, mean many children get less opportunity than those in urban schools, which had been internationally competitive and were formerly reserved for white children. The country is now restructuring its education system with the aim of providing equitable access for all children[8]. Another problem is the difficulty in attracting bright students to science-based university programs. At universities in South Africa, the lack of human resources entails that they are generally understaffed and many professors complain they have heavy teaching and mentoring roles. Furthermore, heavy teaching loads and a culture that encourages academics to do research and not to be engaged in business is not a conducive environment for academics to venture into more entrepreneurial pursuits. Most universities do not have commercialization departments, which further discourages entrepreneurialism, and the majority of universities are just beginning to put in place a system for dealing with IP within the university.

Low levels of venture capital. There is a relatively low level of venture capital investment both for early- and late-stage R&D in health biotechnology. South Africa only has one venture capital firm, Bioventures (Northlands, South Africa), dedicated to funding local biotechnology companies. It has committed 12 million rand (about US $1.9 million) to Shimoda Biotech (Port Elisabeth, South Africa) and, along with the CSIR, has helped in the formation of startup Mbuyu Biotech (Lynwood Ridge, South Africa), with an initial investment of 2 million rand (about US $328,000)[9].

Although other South African venture capital firms are beginning to show interest and to invest in biotechnology, the capital available continues to be minimal. This combination of inadequate levels of public funding and low levels of private investment creates a serious barrier for bridging the gap between research ideas and commercialization. The study revealed that there was a lack of angel investors willing to invest in health biotechnology R&D, probably due to the uncertainties involved in the process of developing new technologies or because the culture of making such

investments has not yet taken root in South Africa for this particular industry.

IP and indigenous knowledge. IP protection of indigenous knowledge remains a very problematic area. Indigenous knowledge and medicinal plants are not fully covered under existing legal frameworks, meaning that there is still a need for a suitable model for protection. The government is now restructuring its entire IP system with the aim of adequately protecting the existing IP in the country. Other challenges exist in developing mutually beneficial contractual agreements between local communities (holders of indigenous knowledge), research scientists and private firms.

Conclusions

The South African biotechnology strategy has lessons to offer other developing countries in how it has articulated the relationship between health needs and biotechnology. The government has articulated the importance of addressing its biotechnology sector to unmet medical needs specific to the country. Because treatments and prophylactics for these diseases will require considerable investment in R&D innovation and development, further prioritization of goals and indications will probably be required. For historical reasons, the country's scientific excellence provides a strong basis for innovation and for transforming traditional knowledge into health care biotechnology products.

Focus on public health needs. The National Biotechnology Strategy identifies objectives for issues in institutional arrangements, human resource development, policy and legislative reforms and ways of meeting goals[5]. One of the objectives is to create a biotechnology industry "in sectors that are well aligned with national imperatives, market demand and regional expertise"[5].

Because one of South Africa's national imperatives involves improving its public health, its first intervention for this objective is to address its most urgent public health need, HIV-AIDS. One goal is the development of a safe and efficient HIV-AIDS vaccine by the SAAVI—something that has so far eluded vaccine developers in both developed and developing countries. Focus on other health needs also suggested in the National Strategy includes the development of cheap diagnostics, and drug and vaccine development for other diseases prevalent in the country, such as hypertension, cancer, malaria and tuberculosis. However, it is vital that these action steps be prioritized and followed through.

Exploit indigenous knowledge and science-based innovation. Numerous actors within South Africa are recognizing the opportunities in exploiting the local and traditional knowledge to find solutions for the country's health needs. This innovative approach takes into account indigenous knowledge and seeks to add value by complementing it with scientific knowledge. Indigenous knowledge can be useful in developing countries[10], but, because of its tacit and oral nature, it is easily lost if not well protected. South Africa recognizes the need to address IP protection for indigenous knowledge and to regulate its exploitation.

At the time of this study, the government was formulating a national policy on indigenous knowledge and had two draft pieces of legislation: the Bill on Recognition, Promotion, Development and Protection of Indigenous Knowledge Systems, and the National Biodiversity Bill. There are national efforts to create incentives for innovation based on indigenous knowledge and to encourage knowledge diffusion into the system. Establishing IP frameworks for protecting indigenous knowledge is an attempt to capture and codify tacit knowledge and to use it for economic gain and to deliver better health[11].

Other developing countries with rich biodiversity and indigenous knowledge can learn from South Africa by adopting a broad concept of innovation systems. They would make use of traditional knowledge systems as complements to a science-based innovation system, as illustrated in the case of the San people and the *Hoodia* cactus (**Box 1**).

Develop local R&D infrastructure for self-reliance. The isolation of South Africa from the international community caused it to look inward and to develop its own research capacity. The research infrastructure developed during that time is now being exploited for the development of biotechnology. Developing countries need to examine their own research infrastructure with specific research targets.

In the case of health biotechnology, a good starting point would be to identify a problematic disease prevalent in the community and a technology that can be applied to address the problem and then develop an infrastructure to support R&D in the area. This would be useful for addressing urgent local needs and for expanding the local science base in a way that leads to economic development.

Because of its strong scientific and technological infrastructure, South Africa is poised to take the lead in developing health care biotechnology in the sub-Sahara African region. Its progress augurs well not only for the country but also for the region.

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