Summary

In a conservative investment climate, Stephen Saad saw opportunity, and in a reparative health policy environment, he saw need. The opportunity: to build a major pharmaceutical manufacturer capable of supplying the South African market with brand name, generic and over-the-counter medicines at affordable prices. The need: to supply South Africans with the essential medicines required for the treatment of life-threatening diseases such as HIV/AIDS, tuberculosis and malaria.

Through a series of well-planned deals and calculated risks, the greatest being the 2.4 billion rand (US $340 million) acquisition of SA Druggists, Saad turned Aspen Pharmacare into the largest producer of tablets and capsules in Africa. By building the largest manufacturing plant in the country, Saad put Aspen Pharmacare in a position to supply South Africa’s national anti-retroviral treatment programme with approximately 60 percent of its current requirements.

Five and half million South Africans are infected with HIV/AIDS, and more than 837,000 individuals urgently require access to life-prolonging antiretroviral medicines (ARVs). As is well known and according to the World Health Organization, the national government could be doing more: only an estimated 21 percent of people living with the human immunodeficiency virus (HIV), who require antiretroviral treatment (ART), have access to such treatment in public clinics and hospitals. Unless the roll out of the national ART programme expands significantly, 3.5 million South Africans will, according to current projections, die of AIDS-related infections by 2010.

The South African Government has started to move in the right direction. In 2004, it initiated a long-anticipated, free national ART programme for its HIV-infected population. However, delays in the implementation of the ART programme have been widespread. In March 2004, the South African Department of Health, pressed by the threat of legal action by national activist organizations, declared that they would need to purchase an emergency supply of ARVs as a stop-gap measure until the formal public sector tender process for drug procurement was concluded. In May 2004, despite the emergency supply, drug shortages continued to be well documented. Commentators observed that the South African Government was in the unenviable position of possessing “some generic medicines—sitting with the Medicines Control Council [South African equivalent of the US Federal Drug Administration] for more than a year awaiting registration” — while still being obliged “to purchase [ARVs] from brand name sources” at substantially higher prices.1

As the South African Department of Health has acknowledged, the solution to this dire situation—a free, sustainable, universal ART program—depends upon both lower drug prices and an uninterrupted local supply of ARVs. Companies such as Aspen Pharmacare have recognized that the Government’s best hope for meeting public health needs over the long-term rests on the State’s ability to nurture the country’s nascent generics industry (such an industry could also supply drugs to other African countries at affordable prices). While observing that the creation of such an industry posed an immense challenge for both government and big business, The Economist magazine noted that Aspen Pharmacare

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1 “Antiretroviral Sources of Supply May not be Able to Meet Popular Demand.” Available at http://www.redribbon.co.za.
provides a model for local generic firms and is currently “doing the most to supply the market with... generic drugs.”

**Positive Outcomes for the Poor**

- Aspen’s efforts provide increased access to affordable life-saving antiretroviral medicines (ARVs) for HIV-infected South Africans
- Aspen’s roll-out of ARVs and anti-TB treatments meets MDG Goals 6, 8 and Target 17 (Goal 6 is to combat HIV/AIDS; Goal 8 is to develop a Global Partnership for Development; and Target 17 is, in cooperation with pharmaceutical companies, to provide access to affordable drugs in developing countries)
- Aspen’s ability to assist the State with the roll-out of a national ART programme improves the health and quality of life for persons living with HIV/AIDS

**Challenges Faced**

- A viable generics industry depends, in part, upon continued tax relief, investment credits and other incentives—the South African government has been slow to construct and implement a stimulus package for the pharmaceuticals industry
- Aspen must scale-up production in order to satisfy demand for the full set of first and second line ARVs
- New competitors threaten Aspen’s market share
- Aspen must ensure that it secures ongoing access to the active pharmaceutical ingredients (APIs) necessary to produce ARVs
- Aspen must be able to negotiate the uncertainty surrounding the enforcement of international and domestic intellectual property regimes—Aspen has avoided confrontation with both governments and multinationals by securing voluntary licenses and tech transfers for the better part of its ARV product line

**Key Innovations**

- Aspen Pharmacare’s business plan demonstrates that generic pharmaceutical manufacturers can be part of the solution to the problem of providing affordable ARVs, as part of a sustainable national ART programme, in a developing country
- Aspen’s success was due, in part, to convincing the State to provide various forms of support for the expansion of Aspen’s manufacturing base
- Aspen’s ability to negotiate voluntary licenses with multinational drug companies allows drugs under patent to be distributed at significantly reduced prices and should enable the State to reach a larger number of individuals with HIV/AIDS
- Aspen’s positive relationships with multinational pharmaceutical companies enables it to negotiate voluntary licenses—these licenses allow Aspen, and the South African government, to avoid breaking patents, and the result is lower cost pharmaceuticals and a stable intellectual property regime
- Aspen’s joint ventures with Indian generic manufacturers provide greater assurance of an uninterrupted supply of the active pharmaceutical ingredients required for ARVs