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The path to product and profitability for stem cell players is fraught with challenges

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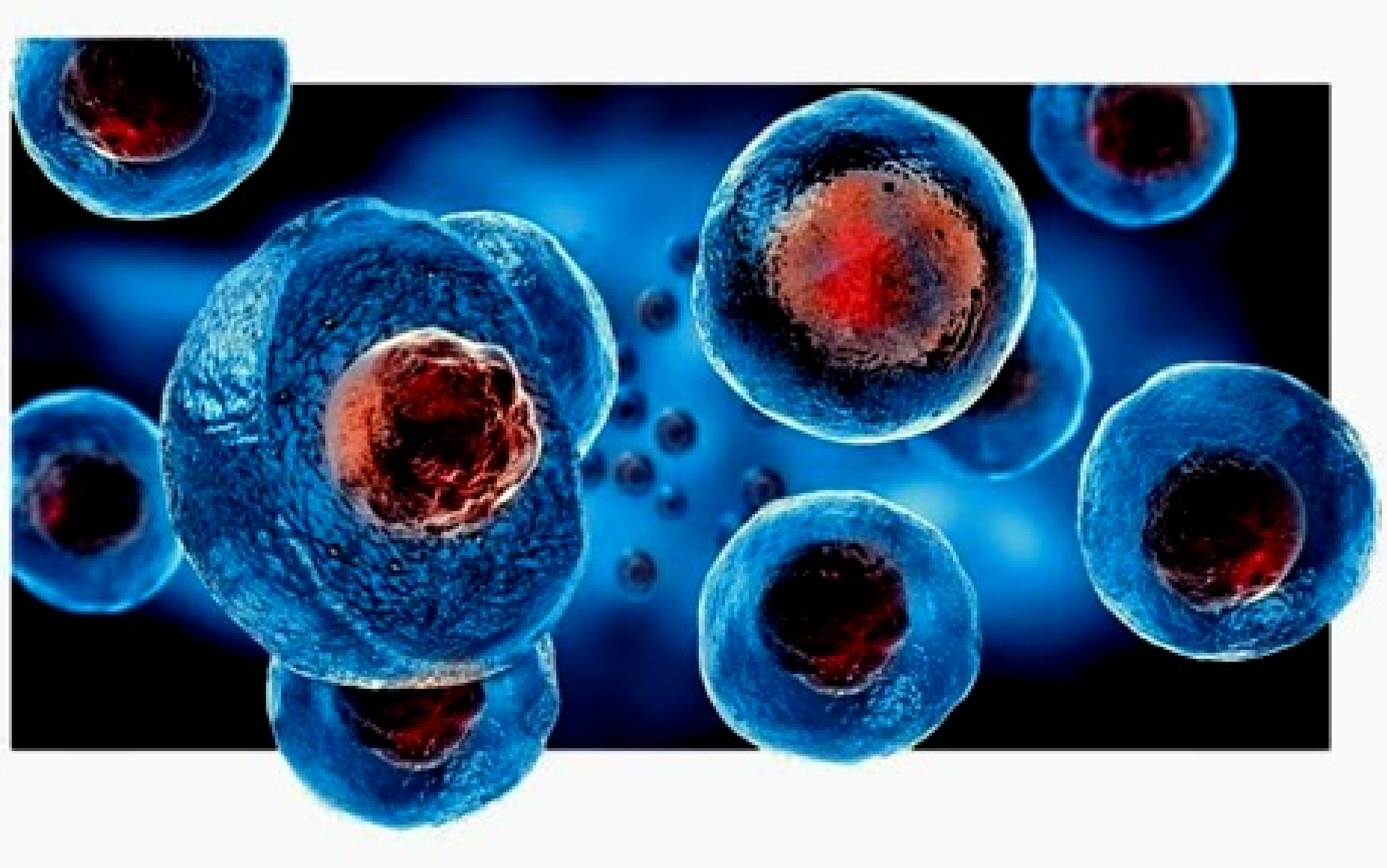
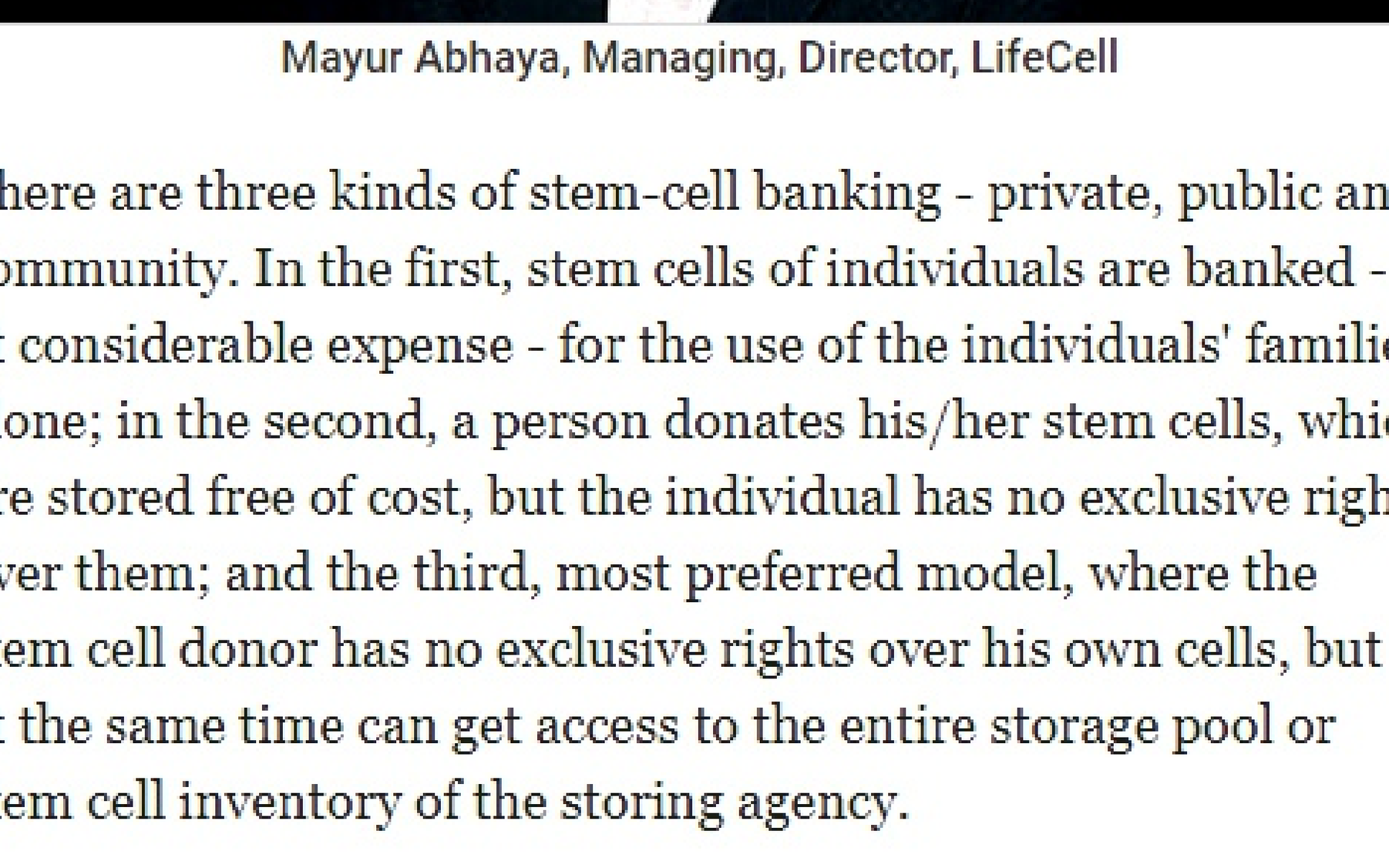


Miracle cures promised by regenerative medicine using stem cells have been heard about for years. Stem cells are the ones from which all other body cells of specific kinds - blood cells, bone cells, brain cells and more - are generated, and thus have the capacity to regrow or repair damaged cells. They are found in large numbers in embryos and umbilical cords, and in smaller numbers in adult adipose tissue and bone marrow, and have to be extracted from these. Their therapeutic possibilities are staggering, with the likelihood of healing many currently near-incurable conditions - diabetic foot ulcers, burn injuries, incapacitation following a stroke, Parkinson's and Alzheimer's disease, among others.

But in practice so far, relatively few stem cell-related therapies have been developed, and only about a couple of them locally. Both took many years to clear regulatory norms and reach the market. What is holding them back in terms of wide usage is the price and the scale of production. Most of these therapies are quite expensive, costing around Rs 1 lakh per dose. Domestic companies that offer these, however, point out that their therapy costs are barely 1/15th of their counterparts in the US, and that the total cost of disease management over its lifecycle might well be lower using regenerative rather than conventional therapies, as the former tackle the problem at its root and do not require any other accompanying medication.

Stem Cell Banking

Companies in this segment are of two kinds - those which bank stem cells in the form of blood or tissue, and those working on therapies using such cells. "Stem cell banking is a Rs 300-crore market in India," says Mayur Abhaya, Managing Director, LifeCell, a leading player, set up in 2004 and headquartered out of Chennai. It claims about 50 per cent market share, with about a dozen significant players, including others majors like Cryoviva and Cordlife. Scale is apparently crucial to viability in stem-cell banking. "Subscale operations are difficult to sustain in this space and that is one reason some units shut down," says Abhaya.



Mayur Abhaya, Managing, Director, LifeCell

There are three kinds of stem-cell banking - private, public and community. In the first, stem cells of individuals are banked - at considerable expense - for the use of the individuals' families alone; in the second, a person donates his/her stem cells, which are stored free of cost, but the individual has no exclusive right over them; and the third, most preferred model, where the stem cell donor has no exclusive rights over his own cells, but at the same time can get access to the entire storage pool or stem cell inventory of the storing agency.

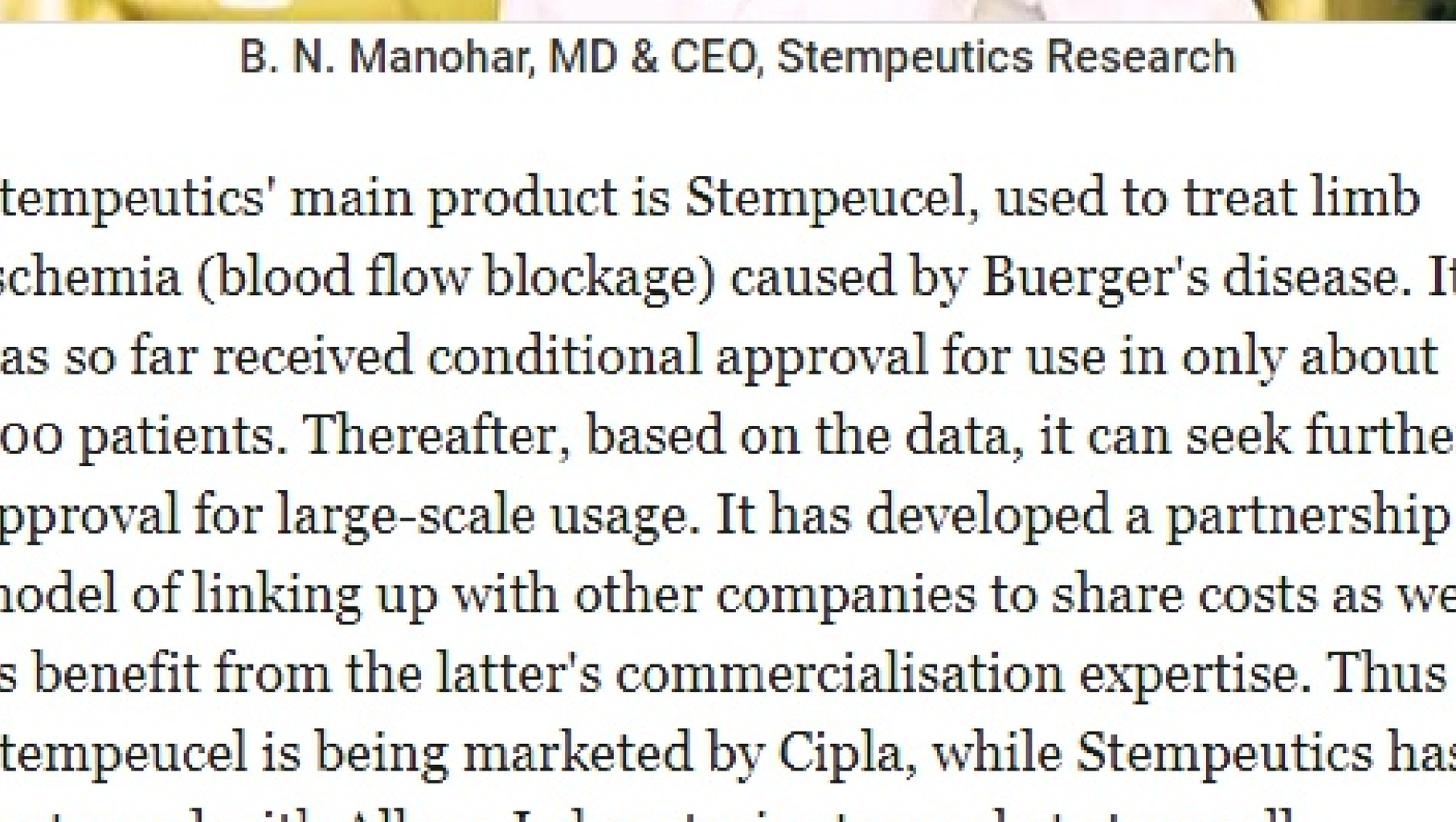
In the past two years, LifeCell has completely shifted from the private to the community model. "Ours is an annuity model, where people pay us a processing fee and an annual storage fee," says Abhaya. "It is a good model because it brings in revenues upfront, rather than making products where one has to go through the cycle of their clinical development." LifeCell charges Rs 20,000 as processing fee while accepting a stem cell sample for preservation, along with a storage fee of either Rs 4,000 a year, or a one-time payment of Rs 50,000.

Abhaya himself concedes that the banking segment is already crowded. "Multiple players have entered the field as India is the country with the largest number of births per year," he says. Venture capital funding, however, has kept away - even Helion Ventures, which had invested in LifeCell, has since exited. LifeCell, too, has faced growth challenges in the past two years, which Abhaya attributes to the company's shift from the private model to the community one.

Limited Applications

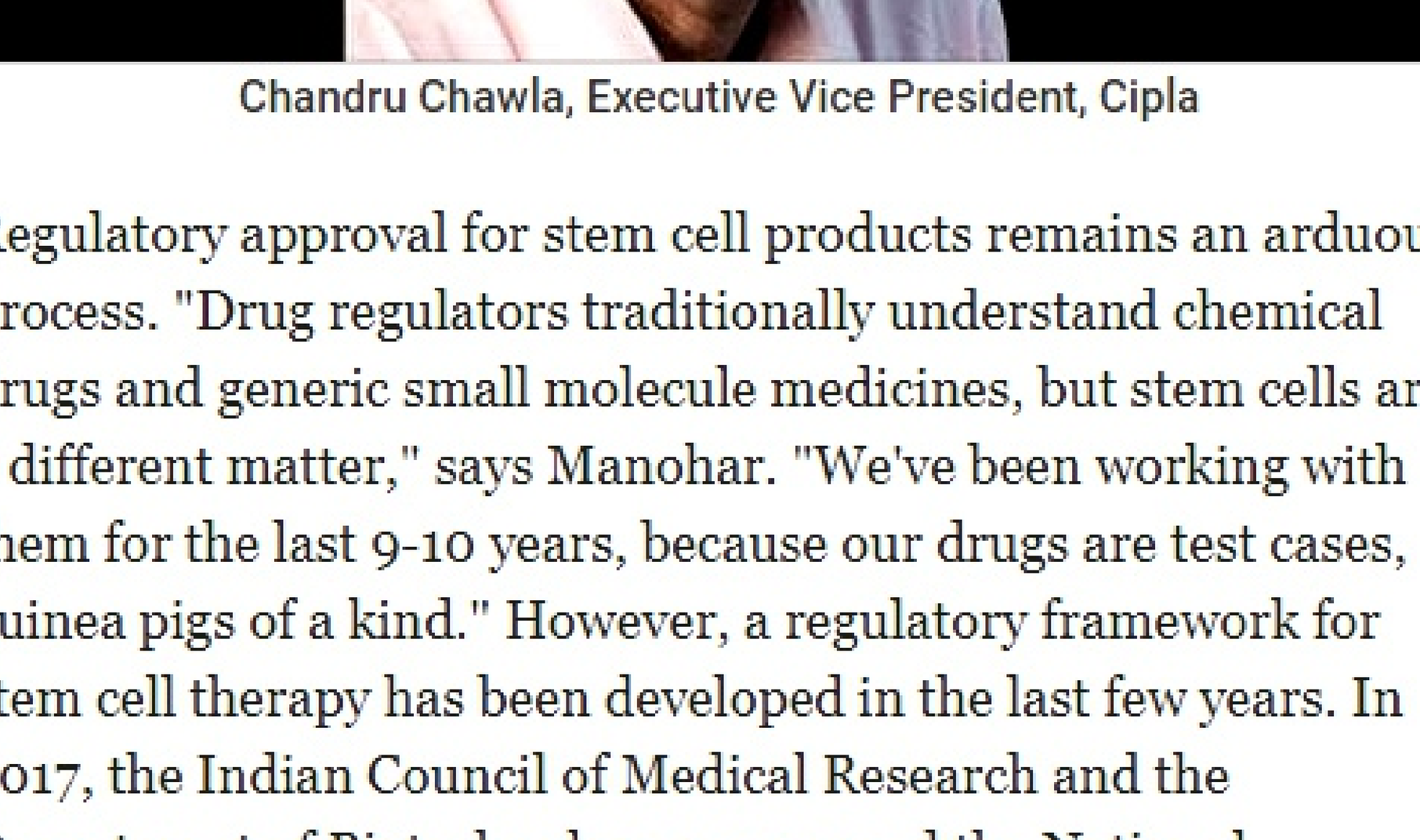
Growth in the banking segment will depend on three factors - awareness, affordability and applications. The last is the key, for as therapeutic applications increase, awareness about them is bound to follow, which will bring down costs. So far, stem cell therapy has helped children suffering from leukaemia, cerebral palsy and thalassemia - a blood-related ailment caused by faulty haemoglobin synthesis. Abhaya maintains 50 transplants have been carried out using LifeCell's banked cells. But India's progress in the field has been slow, compared to, say, South Korea, which already has about a dozen stem cell therapies in the market. Some in the industry also talk of a yet undiscussed topic of future liabilities that some may be building by the promises and commitments they make today. These could be provisions like free worldwide shipment of stem cell. Or, a promise that if no match is found within 14 days or so, the patient could be compensated up to Rs 20 lakh.

In the research and therapy domain, most in the industry talk of only a couple of Indian companies making a mark so far - Stempeutics - backed by Cipla, which holds 46 per cent stake - and Regrow Biosciences. The latter, in operation since 2009, has developed what it calls the world's first autologous (the same individual used as both donor and recipient) bone cell therapy product called Ossgrow, as well as the country's first autologous cartilage cell therapy product, Cartigrow. Stempeutics, a group company of Manipal Education and Medical Group, on the other hand, has preferred to focus on products that are non-immunogenic - which do not require matching - using a particular kind of stem cell called mesenchymal stromal cells (MSC). "In stem cell therapy, the process is the product," says B.N. Manohar, its CEO and Managing Director. "It is how one extracts, multiplies and processes MSC that matters. These have good potency for treating certain indications and can be made available like any other drug, off-the-shelf, after going through the standard drug development cycle."



B. N. Manohar, MD & CEO, Stempeutics Research

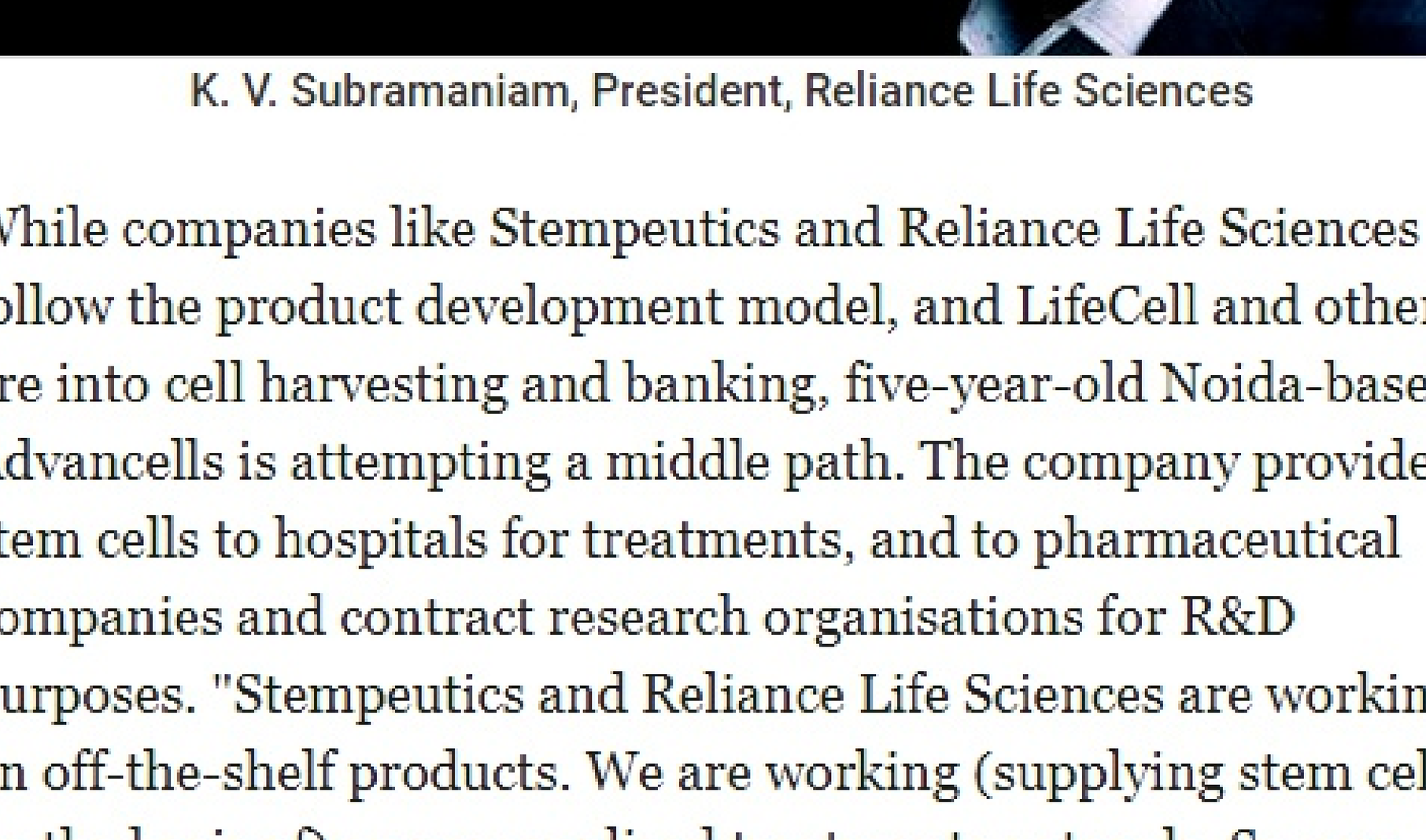
Stempeutics' main product is Stempeucel, used to treat limb ischemia (blood flow blockage) caused by Buerger's disease. It has so far received conditional approval for use in only about 200 patients. Thereafter, based on the data, it can seek further approval for large-scale usage. It has developed a partnership model of linking up with other companies to share costs as well as benefit from the latter's commercialisation expertise. Thus Stempeucel is being marketed by Cipla, while Stempeutics has partnered with Alkem Laboratories to market stem cell treatment for knee joint osteoarthritis. "A stem cell product has to be marketed in exactly the same way as any other drug - by visiting doctors and hospitals and showing them clinical data," says Chandru Chawla, Executive Vice President, Cipla. "But in addition it requires a lot more concept selling." Stempeutics is also looking for a partner to help market its stem cell cure for diabetic foot ulcer. "We hope to get the required approvals for both the osteoarthritis and the foot ulcer therapy by early 2020/21," says Manohar.



Chandru Chawla, Executive Vice President, Cipla

Regulatory approval for stem cell products remains an arduous process. "Drug regulators traditionally understand chemical drugs and generic small molecule medicines, but stem cells are a different matter," says Manohar. "We've been working with them for the last 9-10 years, because our drugs are test cases, guinea pigs of a kind." However, a regulatory framework for stem cell therapy has been developed in the last few years. In 2017, the Indian Council of Medical Research and the Department of Biotechnology announced the National Guidelines for Stem Cell Research to prevent unethical use of stem cells, characterising them as "investigative new drugs", and setting out the process for gaining drug approvals.

Another company majorly engaged in stem cell drug development is Reliance Life Sciences. It is carrying out clinical trials for stem cures of ischemic limb disease, graft versus host disease and Type 1 diabetes using stem cells drawn from adults and testing them in the autologous mode. "We have approvals from the Drug Controller General of India to carry out these trials and hope to have our product in the market by 2021," says K.V. Subramaniam, President, Reliance Life Sciences. "Umbilical cord blood banking is a promising business model, while stem cell research and clinical trials are currently in the exploratory phase," he says.



K. V. Subramaniam, President, Reliance Life Sciences

While companies like Stempeutics and Reliance Life Sciences follow the product development model, and LifeCell and others are into cell harvesting and banking, five-year-old Noida-based Advancells is attempting a middle path. The company provides stem cells to hospitals for treatments, and to pharmaceutical companies and contract research organisations for R&D purposes. "Stempeutics and Reliance Life Sciences are working on off-the-shelf products. We are working (supplying stem cells on the basis of) on personalised treatment protocols. So, our module is extremely personalised. Their module is one-size-fits-all. But all of us work with cells," says Vipul Jain, CEO, Advancells.

The company claims to have supplied over 3,000 cells for treatment and have contracts with 10 clinical research organisations. The grey area is regulation. "If a doctor wants a particular cell for therapy, we develop it and take it to him. Putting it back on the patient is the doctor's responsibility. We don't test the patient, we don't provide the medical advice, and we don't do any medical treatment part," Jain says.