CEO CFO

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The Most Powerful Name In Corporate News and Information

With Multiple Phase II Data Coming Up From Its Autoimmune Programs In Rheumatoid Arthritis And IBD In 2010 As Well As In Oncology In 2011, 4SC AG Is A Stock To Watch

Healthcare
Drug Development – Autoimmune, oncology
(FSCGF-OTCPK, VSC-F)

Dr. Ulrich Dauer
Chief Executive Officer

BIO:
Dr Ulrich Dauer, Chief Executive Officer
Dr Dauer is a founding member of 4SC and took over the role as CEO in 1999. Prior to this he held a manager position at Tripos, a leading provider of screening libraries, software and systems integration in the life sciences business. In this role, he was responsible for key accounts and the acquisition of new business in Central and Eastern Europe. Dr Dauer earned his Doctorate in chemistry at the Institute of Organic Chemistry, University of Würzburg, Germany.

Company Profile:
4SC AG (ISIN DE0005753818) is a drug discovery and development company focused on autoimmune and cancer indications.

Vidofludimus (4SC-101), a small molecule, is currently in a Phase IIb study in rheumatoid arthritis and a Phase IIa exploratory study in inflammatory bowel disease.

The company's lead oncology compound, resminostat (4SC-201), a pan histone deacetylase (HDAC) inhibitor, is in Phase II trials in hepatocellular carcinoma and Hodgkin's lymphoma.

4SC also has two further oncology candidates in Phase I trials; the kinase-inhibitor 4SC-203 and an Eg5-inhibitor, 4SC-205. A second, selective-HDAC-inhibitor is due to commence clinical trials in 2010.

4SC develops drug candidates until proof-of-concept in order to generate value creating partnerships with the pharmaceutical industry in return for advance and milestone payments as well as royalties.

4SC was founded in 1997, has 91 employees, and is listed on the Prime Standard of the Frankfurt Stock Exchange since December 2005.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Dr. Dauer, what was the vision when you founded 4SC, and where are you today?

Dr. Dauer: The vision of 4SC was to translate a specific technology that we have invented, into value in therapeutic programs. Today we have four clinical compounds and six clinical trials in indications like rheumatoid arthritis, IBD (inflammatory bowel disease) and in hepatocellular carcinoma, Hodgkin's lymphoma as well as other oncological indications.

CEOCFO: Would you explain your technology and why it is different?
Dr. Dauer: Our technology is a computer-based screening technology which we apply to select candidate molecules from huge sets of compounds that you theoretically could synthesize. So it is a technology that is kind of mimicking the process that pharma companies are using in early research when they are doing high-throughput screening. This is when they are screening biological assays with 100 thousands of compounds to find hits, which they want to pursue further into drug candidates. This process is translated to the computer at 4SC.

CEOCFO: Is this technology unique to 4SC?
Dr. Dauer: What we have is unique and we also have a patent that has been granted in the United States, so it is a proprietary technology. It is unique in three ways; first of all because of the applicability to huge data sets, so we can screen billions of compounds in a very short period of time. It is also unique because of the quality of the method, the predictability, and it is as it is closely integrated in the overall process of Structure Colion development.

CEOCFO: Would you tell us about your programs?

Dr. Dauer: The most advanced program in our development pipeline is a new substance, which is called vidofludiums (4SC-101). We have two Phase II trials underway with this compound, and one is in rheumatoid arthritis. The Phase II b study has 200 patients in 15 study centers in 4 European countries. It is important to mention that this is our most advanced program. The second trial, which we have underway in IBD is a smaller open label Phase IIa trial. In contrast to many biologicals, vidofludimus is more convenient to the patient, it is orally available and it is also a disease modifying drug, meaning that the bone erosion in rheumatoid arthritis is positively impacted. So it is not just a pain killer, but it is really a drug that is altering the cause of the disease. The second Phase II compound that we have in development is resminostat (4SC-201), which is a cancer compound, a so-called pan histone deacetylase (HDAC) inhibitor. With this compound we have two indications, one in liver cancer or hepatocellular carcinoma, which is an indication of a very high medical need and the second indication, is Hodgkin's lymphoma, where we also see a very high medical need and we are addressing very interesting markets in these two indications. Then we have two Phase I programs in oncology, a multikinase inhibitor where the target indication is AML. The second Phase I trial is 4SC-205 and it is a so-called Eg5 inhibitor, which is addressing various haematologic and solid indications. These are our current clinical programs that we have underway. The first two trials will report this year. IBD will be finalized in the first half of the year. At the end of this year we will have the final data of the rheumatoid arthritis trial.

CEOCFO: Are you doing these on your own or are you partnering? How are you working out the financial strategy for the development?

Dr. Dauer: We are 100% owners of the projects. However, we are not doing everything on our own. If we are talking about clinical trials, we are working together with so-called CROs who are helping us in doing the clinical trials and helping us to do the communication between the clinical side and 4SC, but the project management and the full control of the development is at 4SC. Now the strategy is really to develop those programs up to clinical approval of concept and up to a stage in the development where we can show that these drug candidates are safe and more importantly efficacious in patients. Then we want to partner those programs with pharmaceutical and global biotech companies who then would do late-stage development and the market introduction.

CEOCFO: What is the financial picture like today?

Dr. Dauer: We did a secondary capital raise last November where we raised an additional 30 million Euros, so at the end of last year we had 35.96 million Euros in cash. The monthly cash requirement is at a level of approximately 1.4 million Euros, so we have quite a comfortable cash position.

What I would like to emphasis is that really the year '2010' as-well-as '2011' are going to be the key period in our company's development. So we will have a very dense clinical news flow in that period of time with Phase II data coming up from our autoimmune programs, in rheumatoid arthritis and in IBD and in the following year with our resminostat compound in two oncology indications. - Dr. Ulrich Dauer

CEOCFO: In your particular areas of focus, is there much competitive research going on?

Dr. Dauer: The higher the medical need the more competitive the research is, but we are very well positioned. If you look on liver cancer or hepatocellular carcinoma, the current situation is that there is only one drug that is on the market, which is approved for advanced stages of this disease, and this is Nexavar from Bayer. There is no second-line treatment option available for patients, so there is a high medical need in this indication. This also applies for other indications or markets where we are active, as we want to make sure that we are highly competitive in what we are doing. On top of that, cancer is not just one indication, it is more than 200 single diseases and that is why cancer is still a field where we see a lot of research and development activity. Yet it is still the area where the medical need is highest.

CEOCFO: Is the financial community paying attention to 4SC?

Dr. Dauer: We are a public company and people are looking at our stock, so I think we are reasonably positioned in the capital market. What we also are trying to do, and to underline with our IR activities, is to get more visibility, especially in the US, which is also very important for us. However, we still have a way to go to attract a broad international investment community.

CEOCFO: Why should potential investors look at 4SC?

Dr. Dauer: Potential investors should consider 4SC because we have a sustainable pipeline. We have a pipeline that is not only based on one key product and therefore we have diversified the risk over six clinical programs. We have programs that are addressing key markets, especially those markets that are of high interest to big pharma companies who are urgently looking for new development programs to compliment their internal pipelines in order to avoid losing revenue potential through patents that are running out. The third important point is that we have a very committed shareholder base. Almost half of our shares are being owned by a family office that offers strong ties into the life sciences industry and they understand very well the timelines and success factors in biotechnology.

CEOCFO: Final thoughts, what should people remember most about 4SC?

Dr. Dauer: What I would like to emphasis is that really the year '2010' as-well-as '2011' are going to be the key period in our company's development. So we will have a very dense clinical news flow in that period of time with Phase II data coming up from our autoimmune programs, in rheumatoid arthritis and in IBD and in the following year with our resminostat compound in two oncology indications.