

3-MONTH GROUP COMMUNICATION 2016

EpiScience for Life

4SC 

ABOUT 4SC

4SC (www.4cs.com) is a biotechnology company dedicated to the research and development of small-molecule drugs focused on epigenetic mechanisms of action for the treatment of cancers with high unmet medical needs. These drugs are intended to provide innovative treatment options for cancer patients that are more tolerable and efficacious than existing therapies, provide a better quality of life and offer increased life expectancy. The Company's pipeline comprises promising products that are in various stages of clinical development. 4SC's aim is to generate future growth and enhance its enterprise value by entering into partnerships with pharmaceutical and biotech companies. Founded in 1997, 4SC had 71 employees at 31 March 2016. 4SC has been listed on the Prime Standard of the Frankfurt Stock Exchange since December 2005.

NEW FORMAT FOR QUARTERLY REPORTING

Since the end of November 2015, companies listed on the Prime Standard segment of the Frankfurt Stock Exchange have no longer been obliged to prepare full-length quarterly financial reports. Instead, the regulatory requirements for 3- and 9-month reporting have been limited to quarterly communication with a much less extensive minimum scope. 4SC has elected to take advantage of this new flexibility and has developed this interim management statement format that highlights the developments and key figures material to evaluating the Company. In this way, 4SC aims to more fully meet the needs of the capital market readership. 4SC is looking forward to receiving feedback – both positive and negative – on the new reporting format.

KEY EVENTS IN Q1 2016

RESMINOSTAT

4SC received scientific advice from the European Medicines Agency (EMA) for the execution of the planned Phase II trial of resminostat in cutaneous T-cell lymphoma (CTCL).

The US Food and Drug Administration (FDA) approved 4SC's Investigational New Drug (IND) application for running a clinical trial with resminostat in combination with the standard therapy sorafenib as first-line therapy for patients with advanced liver cancer (HCC).

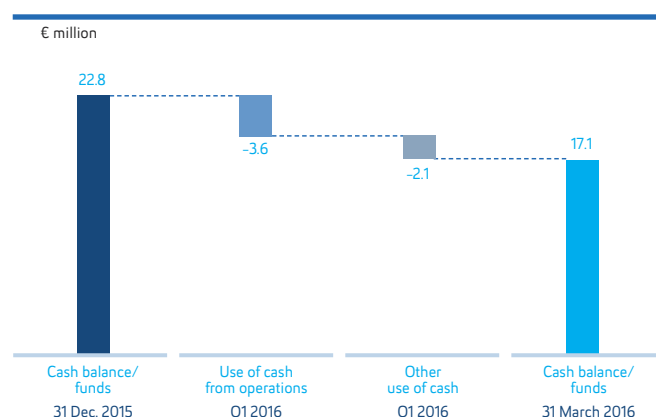
4SC-202

4SC presented very promising data from preclinical research into the epigenetic compound 4SC-202 at the ITOC3 conference in Munich. Extensive testing by the Company revealed that the compound strengthens the body's own immune response against cancer cells. This unlocks additional attractive options for further clinical development of the substance, which had already proved to be safe and well tolerated in a Phase I trial completed in the previous year.

GROUP

The Chairman of the Management Board of 4SC AG, Enno Spillner, notified 4SC's Supervisory Board that he will not accept the offer to extend his term of office ending on 31 March 2016. However, he will continue to serve as the Company's Chairman of the Management Board during a transition period ending 30 June 2016.

DEVELOPMENT OF CASH FUNDS IN Q1 2016



As of 31 March 2016, 4SC holds cash balance/funds of €17,121 thousand (31 December 2015: €22,794 thousand). The decrease was attributable to two major factors:

- An increased monthly use of cash from operations of €1,211 thousand on average in Q1 2016 after €1,001 thousand in Q4 2015. The figure for Q1 2016 is not far off from the figure forecast for 2016 as a whole of €1,200 thousand. The increase over the previous quarter is mainly due to higher costs for preparing and running the planned Phase II clinical trial of resminostat in the CTCL indication.

- The repayment in full of a shareholder loan from Santo Holding (Deutschland) GmbH in the amount of €1,500 thousand and the payment of interest on this loan, which was first drawn down in June 2014, totaling €483 thousand in Q1 2016 (included in other use of cash).

FINANCIAL FORECAST

The Management Board of 4SC confirms its existing financial forecast for the full year 2016 of an average monthly use of cash from operations of €1,200 thousand. The Management Board further estimates that the funds earmarked for the Company's financing will probably be sufficient until after the start of 2018 and will therefore fund the key portions of the planned trial of resminostat in the CTCL indication.

BUSINESS REVIEW Q1 2016 AND OUTLOOK

In the first quarter of 2016, 4SC further stepped up clinical research and development activities. A new corporate image was developed with the slogan “4SC – EpiScience for Life” in line with the Company's focus on epigenetic treatments to fight cancer and the Company's common vision of becoming a leader in the research and development of epigenetic compounds.

DEVELOPMENT SEGMENT

As of 31 March 2016, the Development segment comprised the oncology drug candidates resminostat, 4SC-202, 4SC-205 and the autoimmune candidate vidofludimus, with the two epigenetic drug candidates resminostat and 4SC-202 at the forefront of in-house development.

ONCOLOGY

Resminostat

Resminostat is an HDAC (histone deacetylase) inhibitor with an innovative epigenetic mechanism of action. Administered in tablet form, resminostat is 4SC's most advanced substance. It has already been tested in clinical trials for the treatment of patients with Hodgkin's lymphoma as well as liver, lung, colon, pancreatic and biliary tract cancer. The compound has many different applications in solid tumors and hematological malignancies. In new preclinical models, resminostat also showed promising anti-tumoral and immunomodulatory activity. Resminostat is expected to achieve its full therapeutic potential not merely when used as a monotherapy but especially when combined with other cancer drugs.

Following very constructive discussions, 4SC received scientific advice from the European Medicines Agency (EMA) in January 2016 for the performance of the planned Phase II trial in cutaneous T-cell lymphoma (CTCL). This was the basis for determining the final study design for this randomized, placebo-controlled clinical trial. Compared with the original estimate, the number of patients to be included into the trial increased from 120 to 150. Moreover, in Q1 2016, a service partner in the form of a contract research organization (CRO) was selected for the operational execution of the CTCL trial. Initial trial centers are expected to be opened at the end of Q2 2016. 4SC anticipates treating the first patients in this study at the end of Q3 2016, and initial significant trial data should be available in late 2018. If the results are positive, the Company plans to submit this data to the relevant regulators for market approval in 2019.

Also in January 2016, the US Food and Drug Administration (FDA) approved the Company's Investigational New Drug (IND) application for running a clinical trial with resminostat in combination with sorafenib as first-line therapy for patients with advanced liver cancer (HCC).

Yakult Honsha, 4SC's Japanese development partner, continues to actively pursue the clinical development of resminostat. Testing of the compound by Yakult Honsha is underway, including in a Phase II clinical trial in Asian patients with advanced HCC using a combination therapy with sorafenib. This is being contrasted with sorafenib monotherapy, which is currently the standard treatment for HCC. The study is also investigating the potential predictive biomarker ZFP64 under randomized conditions. 4SC is confident that the initial data from this trial will be available until the end of Q2 2016. This is particularly important for the Company, because 4SC also intends to continue developing resminostat in the indication of HCC in Europe and the USA in the medium term. In this application, the Company has already successfully completed a Phase IIa trial as second-line therapy and considers both the medical need and the market potential to be particularly high. To ensure that 4SC's own study plans are designed as well as possible, however, the Company intends to first wait for and analyze the results on progression-free survival, overall survival and the ZFP64 biomarker from the ongoing Phase II trial being conducted by Yakult Honsha in Asian HCC patients.

Menarini AP, 4SC's second development partner for resminostat, is currently reviewing the clinical development options for resminostat in the Asia-Pacific region excluding Japan.

4SC-202

4SC-202 is the Company's second epigenetic anti-cancer compound and administered in tablet form as well. In a Phase I trial of the treatment of advanced hematological cancer, 4SC-202 proved to be safe and well tolerated. In addition, initial indications of efficacy were determined. 4SC-202 has a unique mechanism of action and works as a selective inhibitor of LSD1 (lysine-specific demethylase) and HDAC (histone deacetylase) 1, 2 and 3. 4SC-202 uses epigenetic modifications to influence two key signal transduction pathways in cells: hedgehog and WNT. Both pathways play a key role in the development, growth and proliferation of cancer cells and are also present in cancer stem cells. To the best of 4SC's knowledge, 4SC-202 is the only blocker of the SMO protein-independent hedgehog pathway in clinical development and therefore could be a treatment option for those cancers for which other hedgehog inhibitors to date have shown no efficacy or a quick build-up of resistance. This constitutes an important unique feature for 4SC-202. Since 4SC-202 differs markedly from resminostat in terms of both its mechanism of action and its chemical structure, and as the compounds' potential fields of therapy are dissimilar, 4SC-202 optimally extends and expands the 4SC clinical product pipeline.

In an extensive analysis of the compound, in Q1 2016 the 4SC research team announced that 4SC-202 strengthens the body's own immune response to cancer cells. Preclinical tests in mice indicated that 4SC-202 attacks cancerous tissue using epigenetic and immunomodulatory mechanisms. Endogenous immune cells in the immediate vicinity of cancer tissue were no longer suppressed but strengthened, and therefore capable of entering and attacking these tumors. The compound ensures that genes silenced in cancer cells are read again or that excessively active genetic regions in cancer cells are downregulated. Researchers also demonstrated that 4SC-202 works synergistically with PD-1 inhibitors, thus possibly providing a more efficient way of fighting tumors. This extremely promising immunological data opens up additional possibilities for 4SC for the clinical development

of 4SC-202, particularly treatment strategies for patients with hematological tumors or small-cell lung cancer.

In a Phase I trial completed in 2015, 4SC-202 already produced excellent results in terms of safety and showed signs of efficacy in patients with advanced hematological malignancies. The new preclinical results confirm the potential of 4SC-202. 4SC is currently in talks with potential financing and industry partners to secure the further development of 4SC-202 in different clinical Phase II programs.

4SC-205

4SC-205 is the third oncology compound in clinical development at the Company. Administered in tablet form, the compound inhibits the human kinesin spindle protein Eg5, which plays a key role in cell division and therefore the growth of cancer cells. Cell division inhibitors, which are used in chemotherapy, for example, are deployed with great success in oncology, although they have serious side effects. Thanks to its special mode of action and an optimized dosing scheme, 4SC-205 does not exhibit some of the side effects typically seen with other compounds. To the best of the Company's knowledge, 4SC-205 is the only oral Eg5 inhibitor currently in clinical development anywhere in the world.

In a Phase I study completed in 2015, the substance has shown to be safe and well-tolerated. Building on these encouraging results, 4SC is currently exploring scenarios for a further clinical development with external experts and potential partners.

AUTOIMMUNE DISEASES

VIDOFLUDIMUS

Vidofludimus is a 4SC compound in the field of autoimmune diseases. This oral drug candidate has exhibited promising results in an initial clinical Phase IIa trial in the field of inflammatory bowel disease (IBD). In line with the focus of research and development activities on epigenetic compounds to fight cancer, 4SC is not investing any appreciable company resources in the further development of this compound at this time. That said, the Company aims to develop vidofludimus clinically – in the indication of Crohn's disease, for example – with external partners and investors.

DISCOVERY & COLLABORATIVE BUSINESS SEGMENT

The Discovery & Collaborative Business segment comprises the activities involved in the discovery, early-stage research and subsequent commercialization of drug compounds by 4SC Discovery GmbH (4SC Discovery). This segment focuses, among other things, on the research disciplines of epigenetics, cancer stem cells, cancer immunotherapy and cellular signaling pathways involved in the genesis of cancer and/or chronic inflammatory diseases. In addition to maintaining scientific collaborations with academic institutions, 4SC also cooperates with BioNTech AG and has a technology and sales partnership with CRELUX GmbH, among others.

In January 2016, 4SC Discovery reached an agreement with Berlin-based OMEICOS Therapeutics GmbH (OMEICOS) whereby 4SC will conduct pharmaceutical chemical analysis and synthesis activities for OMEICOS for a maximum period of one year.

EVENTS AFTER Q1 2016

On 29 April 2016, 4SC announced the sale of all key operating assets of 4SC Discovery to BioNTech Small Molecules GmbH (BioNTech Small Molecules) for €650 thousand. The assets were transferred directly to BioNTech Small Molecules. In addition and without financial compensation, 4SC was granted the right to temporarily utilize research services provided by BioNTech Small Molecules worth a person year. As of 1 May 2016, all 22 employees of 4SC Discovery were taken over in a transfer of operations and will continue to work at the existing facility in Planegg-Martinsried. 4SC Discovery will retain its preclinical research projects for the time being. 4SC will continue using the epigenetic schemes and the underlying intellectual property for itself, and in addition plans to out-license other projects.

OPPORTUNITIES AND RISKS

Please see pages 57 to 69 of the Annual Report 2015 for a detailed description of the risks and opportunities arising from the Company's business activities as well as its IT-based risk management and controlling system. The announcement of Enno Spillner, the Chairman of the Management Board, that he will only remain with the

Company until the end of June 2016 has increased administrative and other risks as compared with the presentation of these risks in the Annual Report 2015, although the Supervisory Board of 4SC has made finding a suitable replacement its top priority and is optimistic that it will be able to ensure a smooth transition of responsibilities. The Company's risks and opportunities have otherwise remained virtually unchanged. The occurrence of any one of the risks described in the annual report – alone or in conjunction with each other – could have a negative impact on the results of operations, financial position and net assets of 4SC.

EDITOR

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4SC ON THE INTERNET

ore information about 4SC, including its products and R&D programs, is available on the Company's website, www.4sc.com, as well as the following information:

- this interim communication
- previous interim reports
- annual reports
- audio recordings of conference calls
- presentations
- general investor information

CORPORATE COMMUNICATIONS & INVESTOR RELATIONS

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