

Press Release: 4SC announces financial results for the first nine months and the third quarter of 2014

4SC AG / Key word(s): 9-month figures/Quarter Results

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Press Release

4SC announces financial results for the first nine months and the third quarter of 2014

Planegg-Martinsried, Germany, 6 November 2014 - 4SC AG (Frankfurt, Prime Standard: VSC), a discovery and development company of targeted small molecule drugs for cancer and autoimmune diseases, today published the financial results of the 4SC Group for the first nine months of 2014 (1 January - 30 September 2014). A public telephone conference in English will be held today at 3:00 pm CET (9:00 am EST).

Key operating events in research and development in Q3 2014 and beyond:

- 4SC Discovery GmbH: Funds received for researching new epigenetic cancer drugs with collaboration partner CRELUX (July 2014).
- Resminostat: Successful completion of Phase I and start of the randomised Phase II of the clinical trial being conducted by the Company's Japanese partner Yakult Honsha on Asian patients with liver cancer (HCC). Safety and tolerability confirmed (September 2014).
- Resminostat: Safety and tolerability demonstrated in Asian patients with non-small-cell lung cancer (NSCLC) in Phase I of the clinical trial being conducted by 4SC's Japanese partner Yakult Honsha; Phase II started (October 2014).
- Resminostat: Patent for the resminostat manufacturing process granted in the USA. Overall, this means that the production process for the compound is protected until 2029 in almost all key markets around the world (October 2014).

Key financial figures for the first nine months of 2014:

- Revenue up 66% to EUR 6.18 million (9M 2013: EUR 3.72 million)
- Operating loss (EBIT) reduced by 25% to EUR 6.21 million (9M 2013: EUR 8.25 million); earnings per share increased accordingly to EUR -0.12 (9M 2013: EUR -0.16)
- Solid third quarter: 25% improvement in revenue; operating loss up 12% due to increased cost of sales and additional development expenses in the manufacturing process for resminostat
- 4SC AG: Draw-down of the second tranche of convertible bonds in the nominal amount of EUR 0.5 million as part of the financing agreement with Yorkville and draw-down of a second tranche of EUR 2.0 million from the shareholder loan from Santo Holding (September 2014).

Enno Spillner, CEO of 4SC AG, commented:

"We are pleased with our performance in the third quarter. The encouraging interim results from the two Phase I/II trials in Asia in the indications of liver cancer and non-small-cell lung cancer that are being conducted by Yakult Honsha and the start of the randomised Phase II part of both trials demonstrate the strong commitment of our partner Yakult and strengthen our dedication to pushing forward with our further clinical development of resminostat, especially in the indication of liver cancer."

Enno Spillner continued: "Also underpinning our positive attitude is the work of 4SC Discovery. Together with its collaboration partner CRELUX, it will use the funding received for research into new epigenetic anti-cancer compounds, which we hope will give us promising starting points for innovative drugs. However, our primary goal is still to secure the further clinical development of resminostat so as to continue to work towards market approval of our lead product."

Detailed financial review (9 months 2014 and Q3 2014):

The 4SC Group, which comprises 4SC AG and its wholly-owned subsidiary 4SC Discovery GmbH, reports consolidated figures for the Group in accordance with International Financial Reporting Standards (IFRSs) and financial figures for the two operating segments Development (resminostat, 4SC-202 and 4SC-205) and Discovery & Collaborative Business (drug discovery and early-stage research activities as well as their commercialisation through the service business and research collaborations). The figures for the 4SC Group are reported below; for more information on segment reporting, see the full 9-

month financial report at (4sc.de/de/investors/financial-reports).

9 months 2014:

In the first nine months of 2014, consolidated revenue increased by 66% year on year to EUR 6.18 million (9M 2013: EUR 3.72 million). This primarily comprises revenue generated under the cooperation agreements with BioNTech AG and LEO Pharma. 4SC also generated revenue of EUR 3.55 million in the reporting period with its partner Yakult Honsha Co., Ltd. (9M 2013: EUR 1.38 million). The Development segment saw revenue jump considerably by 75% to EUR 1.63 million (9M 2013: EUR 0.93 million). Revenue in the Discovery & Collaborative Business segment rose by 12% to EUR 2.63 million (9M 2013: EUR 2.35 million).

The loss from operations (EBIT) improved by 25% to EUR 6.21 million in the reporting period (9M 2013: EUR 8.25 million) due to higher revenue. The loss for the period decreased by 23% to EUR 6.31 million (9M 2013: EUR 8.19 million), which corresponds to earnings per share of EUR -0.12 (9M 2013: EUR -0.16).

This results in an average monthly outflow of cash from operations amounting to EUR 0.72 million in the first nine months of 2014 (9M 2013: EUR 0.59 million). As at 30 September 2014, the Company had cash totalling EUR 3.37 million, compared with EUR 3.90 million as at the close of 2013.

Q3 2014:

Compared with the third quarter of the previous year, consolidated revenue increased by 25% in the reporting quarter to EUR 2.20 million (Q3 2013: EUR 1.77 million). Despite an increase in revenue, the Company's loss from operating activities increased by 12% in the third quarter to EUR 2.34 million (Q3 2013: EUR 2.08 million). This was due mainly to higher cost of sales in connection with the production of the resminostat compound for Yakult and higher development expenses in the context of optimising the resminostat manufacturing process. The loss for the period increased by 11% to EUR 2.33 million in the third quarter (Q3 2013: EUR 2.11 million), resulting in earnings per share of EUR -0.05 (Q3 2013: EUR -0.04).

In the reporting quarter, the Company drew down a second tranche totalling EUR 2.0 million from the loan agreement signed in June 2014 with 4SC principal shareholder Santo Holding (Deutschland) GmbH to finance 4SC AG in the short and medium term and to carry out the operational preparations for the further clinical development of resminostat. In addition, a second tranche of the agreement signed with US investor Yorkville in the first quarter of 2014 was issued as a convertible bond in the nominal amount of EUR 0.5 million.

Review of research and development operations in Q3 2014 as well as key developments at Group level and outlook:

Development segment (clinical development activities of 4SC AG)

Resminostat:

Progress was made again in the reporting period in the operational preparations for the planned double-blind randomised controlled Phase II trial in advanced liver cancer (hepatocellular carcinoma, HCC). In this trial, resminostat in combination with sorafenib is to be examined as first-line therapy of patients with advanced HCC compared with the current standard treatment (monotherapy with sorafenib). The above study also aims to further qualify the potential predictive biomarker ZFP64 for possible investigation in a Phase III registration trial. The existing study protocol was optimised and advanced in collaboration with clinical liver cancer experts. 4SC also improved the production process for the resminostat compound during the reporting period. 4SC is in talks with potential partners and investors in order to secure funding for the planned Phase II trial.

Yakult Honsha, 4SC's Japanese development partner, is swiftly pushing the development of resminostat in Japan. In the third quarter, the company successfully completed the Phase I part clinical trial with resminostat in patients with advanced liver cancer (HCC). The results confirmed the safety and good tolerability of resminostat in combination with the cancer drug sorafenib using the planned dosage regime in Asian patients. The subsequently started randomised Phase II part of the study will focus on investigating the efficacy of the resminostat-sorafenib combination in comparison to the current HCC standard of care, sorafenib monotherapy. The study will also continue to evaluate the ZFP64 biomarker.

Furthermore, Yakult Honsha started the Phase II part of a trial in the non-small-cell lung cancer (NSCLC) indication. This trial investigates the epigenetic compound in combination with the established cancer drug docetaxel versus docetaxel monotherapy in Asian patients. The completed Phase I part confirmed the good profiles of safety and tolerability of the resminostat docetaxel combination.

4SC-202:

4SC's second epigenetic anti-cancer compound currently in clinical development is 4SC-202, a selective inhibitor of the epigenetic regulators LSD1 and HDAC isoforms 1, 2 and 3.

In June 2014, 4SC had published positive initial data from 4SC-202's clinical Phase I TOPAS trial in 24 patients with advanced haematological tumours at the ASCO Annual Meeting in Chicago. This data had shown the compound's safety and good tolerability as well as promising indications of anti-tumour efficacy. One patient continues to be treated with 4SC-202. He has participated in the study for about two years and has responded to the treatment with a complete remission of the tumorous lesions that persists to this day. On the strength of the positive trial results, 4SC commenced initial negotiations with potential partners in the third quarter regarding possible clinical development partnerships for 4SC-202.

4SC-205:

The Company's third anti-cancer compound is the oral Eg5 kinesin inhibitor 4SC-205. It has now entered the last study phase of the Phase I AEGIS trial, where it is being intensively trialled in patients with a specific disease condition (lung tumour/metastases). Patient recruitment was completed successfully in the reporting quarter and completion of the study is expected in the near future.

Discovery & Collaborative Business segment (research at 4SC Discovery GmbH)

The existing research collaborations and partnerships, including those with Mainz-based BioNTech AG and Danish pharmaceutical company LEO Pharma S/A, continued to develop encouragingly.

Along with its strategic partner CRELUX GmbH, Martinsried, 4SC Discovery GmbH received subsidies for researching new epigenetic anti-cancer drugs during the reporting quarter. This project is receiving funding under the Munich m⁴ leading-edge biotech cluster programme. It aims to use the i2c joint research platform of CRELUX and 4SC Discovery to identify bromodomain inhibitors and investigate their potential future use in personalised medicine. Bromodomain proteins are considered promising targets for new drugs. Their specific blocking mechanism aims to influence tumour in such a way that these are either identified and destroyed by the immune system or driven to programmed cell death (apoptosis).

Key developments at Group level:

In August 2014, Supervisory Board members Dr Thomas Werner and Klaus Kühn stepped down for personal reasons effective at the end of the day on 18 September 2014. The Company has found suitable candidates for the vacant positions and proposed them to the responsible Registration Court for appointment. At the end of October 2014, Joerg von Petrikowsky, an experienced auditor and tax adviser for companies in the biotech and pharmaceutical industry, was appointed to the Supervisory Board. The Company is confident that the second person proposed will also be appointed in the foreseeable future. The Supervisory Board has been fully quorate all the time.

Financial outlook:

4SC had funds of 3.37 million at the end of the third quarter of 2014. In view of short- and medium-term revenue and expense planning and utilisation of the convertible note agreement with Yorkville as well as the further opportunity to draw down tranches from the loan agreement with Santo Holding, 4SC continues to believe that these funds are sufficient to finance the Company's operations until approximately the end of 2015.

Despite the positive revenue performance the expected average monthly operating cash burn rate for 2014 as a whole increased measurably from the originally planned rate. On the expense side, this was due to the increased length of the clinical studies with the 4SC-202 and 4SC-205 drug candidates over the original estimates and the additional development costs for the optimisation of the resminostat manufacturing process incurred in connection with the preparations for the planned Phase II trial. On the revenue side, the incoming payments which the Company originally assumed would be received by 4SC Discovery GmbH in 2014 are anticipated to be delayed until next year. For this reason, the Company currently forecasts a cash burn rate for the coming year that is significantly lower than originally planned. For 2014, 4SC now expects an average monthly operating cash burn rate of between EUR 0.7 million and EUR 0.9 million.

Given its continued overall positive business development to date, 4SC Discovery could still achieve break-even in terms of operating cash flow in 2014. The 2014 operating loss at Group level is likely to decrease further year on year.

In the event of funding being secured and the start of further clinical trials - for instance a planned Phase II liver cancer study with resminostat - the Company's cost structure will change markedly, with significant rises in both development expenses and the cash burn rate.

Telephone conference

Today, on 6 November 2014, at 3:00 pm CET (9:00 am EST), 4SC will host a telephone conference in English, in which the Management Board of 4SC AG will report on the principal developments in the first nine months of 2014 and beyond. To participate in the telephone conference, please use the following data:

+49-89-1214 00698 (Germany)
+44-20 3427 1929 (UK)
+1-646 254 3387 (USA)
+49-89-1214 00698 (other countries)
Conference ID: 6125329

After the conference call a replay will be available in the section "Investors" / "Events & Presentations" / "Conference Calls & Webcasts" of the website www.4sc.com.

Ends

About 4SC

The Group managed by 4SC AG (ISIN DE0005753818) discovers and develops targeted, small-molecule drugs for treating diseases with high unmet medical needs in various cancer and autoimmune indications. These drugs are intended to provide innovative treatment options that are more tolerable and efficacious than existing therapies, and provide a better quality of life. 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 a headcount of 65 employees (55 FTEs) at 30 September 2014. 4SC AG has been listed on the Prime Standard of the Frankfurt Stock Exchange since December 2005.

Cautionary statement regarding forward-looking statements

This press release contains certain forward-looking statements. Any forward-looking statement applies only on the date of this press release. By their nature, forward-looking statements are subject to a number of known and unknown risks and uncertainties that may or may not occur in the future and as a result of which the actual results and performance may differ substantially from the expected future results or performance expressed or implied in the forward looking statements. No warranties or representations are made as to the accuracy, achievement or reasonableness of such statements, estimates or projections, and 4SC AG has no obligation to update any such information or to correct any inaccuracies herein or omission herefrom which may become apparent.

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