Q3 Announcement 2018

ABOUT THIS ANNOUNCEMENT

This Q3 Interim Communication as of 30 September 2018 should be read in conjunction with 4SC's Annual Report for the 2017 financial year, the Q1 Announcement as of 31 March 2018 and the Half-Year Report as of 30 June 2018.

The report at hand contains certain forward-looking statements that are subject to risks and uncertainties that are described, with no claim to be exhaustive, in the section entitled "Report on opportunities and risks" in the Annual Report 2017, and also in the "Opportunities and risks" section of this Q3 Announcement. In many cases, these risks and uncertainties are outside of 4SC's control and may cause actual results to differ materially from those contemplated in these forward-looking statements. 4SC expressly does not assume any obligation for updating or revising forward-looking statements to reflect any changes in expectations or in events, conditions or circumstances on which such statements are based.

ABOUT 4SC

4SC is a clinical-stage biopharmaceutical company developing small-molecule drugs that can target key indications in cancer with high unmet medical needs.

4SC's pipeline is protected by a comprehensive portfolio of patents and currently comprises three key drug candidates in various stages of development: resminostat, domatinostat (4SC-202) and 4SC-208.

4SC aims to generate future growth and enhance its enterprise value by entering into partnerships with pharmaceutical and biotech companies and/or the eventual marketing and sales of approved drugs in select territories by 4SC itself.

4SC is headquartered in Planegg-Martinsried near Munich, Germany. The Company had 46 employees as of 30 September 2018 and is listed on the Prime Standard of the Frankfurt Stock Exchange (FSE Prime Standard: VSC; ISIN: DE000A14KL72).

BUSINESS REVIEW IN Q3 2018 / YTD AND OUTLOOK

Key events in Q3 2018 and beyond were each made public via a press release. Details can be found in the relevant releases available at www.4sc.com.

RESMINOSTAT

Resminostat is an orally administered Class I, IIb and IV histone deacetylase (HDAC) inhibitor that potentially offers an approach to treating different kinds of cancer. Resminostat demonstrated that it is well tolerated and can inhibit tumor growth and proliferation, cause tumor regression, and strengthen the body's immune response to cancer.

Pivotal RESMAIN study in CTCL on track

In 2016, 4SC started the pivotal RESMAIN study – a randomized, double-blind, placebo-controlled clinical Phase II study of resminostat in a total of 150 patients.

The RESMAIN study is focused on patients with advanced-stage cutaneous T-cell lymphoma (CTCL). Such patients suffer from painful and itchy skin lesions resulting in disfigurement and a severely impaired quality of life. None of the current therapeutic options achieve sustainable clinical benefit, with most patients progressing within six months (on average). Resminostat is being evaluated as maintenance treatment – prolonging the period patients are stable and not progressing with decrease of disease-related itching.

In January 2018, the Data Safety Monitoring Board, an independent committee of clinical and drug safety experts, evaluated data from the first 50 patients treated in the study and observed no safety issues. The committee recommended continuation without modification of the study protocol.

At the end of March 2018, Yakult Honsha Co., Ltd. (Yakult Honsha), 4SC's development partner in Japan, elected to join the RESMAIN study – triggering a milestone payment to 4SC. Yakult Honsha enrolled the first patients in Japan in early April 2018. RESMAIN is being conducted in more than 50 study centers across 11 European countries and in Japan.

4SC expects to complete recruitment of at least the first 100 patients in 2018 and to see top-line results in late 2019. If the study results are positive, 4SC plans to submit applications for marketing approval of resminostat in CTCL in Europe and potentially the U.S. and Yakult Honsha will submit in Japan. If approved, resminostat would be the first HDAC inhibitor approved for CTCL in Europe and the first and only drug approved for maintenance therapy in this indication in either Europe, Japan or the U.S.

Phase II study in biliary tract cancer initiated

Yakult Honsha initiated a randomized, double-blind, placebo-controlled, multi-center Phase II study evaluating the combination of resminostat and S-1 chemotherapy versus S-1 chemotherapy plus placebo as second-line treatment in 100 Japanese patients with unresectable or recurrent biliary tract cancer.

The study is based on a positive Phase I clinical study which was completed in September 2017.

S-1 is a chemotherapy combination drug which is approved for the treatment of several solid tumor types including biliary tract cancer in Asia. The main goal of the study is to prolong progression free survival (PFS) and secondary objectives include efficacy and safety parameters. Final results are expected to be available by mid-2020.

DOMATINOSTAT (4SC-202)

Domatinostat is an orally administered small molecule Class I selective HDAC inhibitor. It strengthens the body's own anti-tumor immune response, influences the tumor and tumor microenvironment making the tumor more visible to the immune system and facilitates infiltration of immune cells into the tumor.

Domatinostat has been investigated in a Phase I study with 24 heavily pretreated patients with several types of advanced hematologic cancers and was well tolerated. Positive signs of anti-tumor efficacy were also observed; with one complete remission (28 months) and one partial responder (8 months).

Domatinostat in combination with checkpoint inhibitors

4SC initiated the Phase Ib/II SENSITIZE study of domatinostat in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab in patients with advanced-stage melanoma. In November 2017, the first patient was enrolled in the study's first dose cohort and in July 2018 enrollment of the second dose cohort of patients into the study commenced.

In August 2018, the U.S. Food and Drug Administration (FDA) approved 4SC's Investigational New Drug (IND) application for domatinostat in melanoma and 4SC will look to expand the study into the U.S. in 2019. The study is expected to complete in H1 2019.

In a second Phase II study EMERGE, domatinostat will also be tested in combination with another checkpoint inhibitor, the anti-PD-L1 antibody avelumab, for treating microsatellite-stable gastrointestinal tumors. Such tumors are generally not responsive to checkpoint inhibition. 4SC expects safety data in Q2 2019 and early efficacy data in H2 2019.

These two studies – SENSITIZE and EMERGE – are designed to serve several purposes:

- Together they provide safety data for domatinostat in combination with the two main classes of checkpoint inhibitors, anti-PD-1 and anti-PD-L1,
- Potentially provide evidence to support the efficacy of domatinostat in checkpoint inhibitor refractory/non-responding patients in a major immunogenic tumor indication (melanoma) or in a historically checkpoint inhibitor non-responsive major indication (microsatellite-stable gastrointestinal tumors cancer)
- Provide sufficient data to initiate a potentially pivotal clinical trial with domatinostat in combination with a checkpoint inhibitor as soon as possible in the skin cancer Merkel-cell carcinoma.

Evaluation of further combination partners

In April 2018, 4SC presented a poster with preclinical data supporting double and triple combinations of domatinostat and checkpoint inhibitors and, in September 2018, a collaborator of 4SC presented an additional poster with preclinical data supporting the combination of domatinostat with chemotherapy in cancer. Based on these promising preclinical results, 4SC is currently evaluating further clinical studies of domatinostat in different combinations.

4SC-208

In January 2018, 4SC was granted composition of matter patents in further geographic regions for a group of molecules including 4SC-208, an orally-available hedgehog/GLI signaling inhibitor. The patents now not only provide 4SC with market exclusivity until 2033 in the U.S. but also in China, Japan, Singapore, Australia and New Zealand.

4SC-208 is currently being evaluated in preclinical cancer models.

OUT-LICENSED PROGRAMS

4SC continues to explore partnering opportunities in line with its strategy to monetize non-core assets.

DEVELOPMENT OF CASH FUNDS IN Q3 2018 AND FINANCIAL FORECAST

As of 30 September 2018, 4SC holds cash balance/ funds of €30,766 thousand as compared to €34,129 thousand as of 30 June 2018. The monthly use of cash from operations was below the range forecasted for 2018 amounting to €1,173 thousand on average in the first nine months of 2018 (9M 2017: €739 thousand).

The increase of the monthly use of cash and the decrease in cash balance/funds in the first nine months of 2018 was mainly driven by costs for the ongoing clinical studies RESMAIN and SENSITIZE.

Based on current financial planning and operating activities, the Management Board is expecting a lower average monthly cash burn rate from operations of between €1,300 thousand and €1,500 thousand for 2018 as compared to the earlier assumptions of €1,800 thousand to €2,000 thousand. The Management Board of 4SC confirms that the funds should be sufficient to finance 4SC into 2020.

OPPORTUNITIES AND RISKS

As 4SC's opportunities and risks have remained virtually unchanged, please see pages 22 to 29 of the Annual Report 2017 for a detailed description of the opportunities and risks arising from the Company's business activities as well as its IT-based risk management and controlling system.

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.

FINANCIAL CALENDAR 2019

Annual Report 2018	20 March 2019
Q1 Announcement 2019	18 April 2019
Annual General Meeting 2019	24 May 2019
Half-Year Report 2019	8 August 2019
Q3 Announcement 2019	17 October 2019

PUBLISHING INFORMATION

PUBLICATION DATE

25 October 2018

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4SC ON THE INTERNET

More information about 4SC, its products and development programs, is available on the Company's website, www.4sc.com, as well as the following information:

- Previous reports on 4SC's progress and outlook
- Audio recordings of conference calls
- Presentations
- General investor information

CORPORATE COMMUNICATIONS & INVESTOR RELATIONS

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