



Q3 Interim Communication as of 30 September 2017

### ABOUT THIS REPORT

This Q3 Interim Communication as of 30 September 2017 should be read in conjunction with 4SC's Annual Report for the 2016 financial year, the Q1 Interim Communication as of 31 March 2017 and the Consolidated Half-Year Financial Report as of 30 June 2017.

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 2016, and also in the "Opportunities and risks" section of this Interim Communication. 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. Such drugs are intended to provide patients with innovative treatment options that are more tolerable and efficacious than existing therapies and provide a better quality of life. 4SC's pipeline is protected by a comprehensive portfolio of patents and comprises promising products that are in various stages of preclinical and clinical development. The 4SC product pipeline currently comprises three small-molecule drug candidates: resminostat, 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 had 47 employees as of 30 September 2017 and is listed on the Prime Standard of the Frankfurt Stock Exchange (FSE Prime Standard: VSC; ISIN: DE000A14KL72).

### KEY EVENTS IN Q3 2017

Key events were each made public via a press release. Details can be found in the relevant releases (available at [www.4sc.com](http://www.4sc.com)) and/or in the business review information in this Interim Communication.

### DEVELOPMENT OF CASH FUNDS IN Q3 2017 AND FINANCIAL FORECAST

As of 30 September 2017, 4SC holds cash balance/funds of €43,353 thousand as compared to €4,638 thousand as of 30 June 2017. The increase results from a successful cash capital increase in July with gross proceeds of ca. €41 million (read more in the "Business review Q3 and outlook" section). The monthly use of cash from operations was within the range forecasted for 2017 amounting to €739 thousand on average in the first nine months of 2017 (9M 2016 €857 thousand). The decrease in 2017 was mainly driven by the upfront payment from the licensing agreement with Maruho Co., Ltd. (Maruho) offset by an increase in expenses for the preparation of the Phase Ib/II clinical study SENSITIZE of 4SC-202. The Management Board of 4SC confirms that the proceeds of the capital raise will finance 4SC's main goals into 2020.

### BUSINESS REVIEW Q3 AND OUTLOOK

In Q3 2017, 4SC continued to focus its development strategy on drug candidates in the field of innovative anti-cancer therapies. The 4SC product pipeline currently comprises three small-molecule drug candidates: resminostat, 4SC-202 and 4SC-208.

In addition, 4SC aims to secure licensing deals for non-key assets, such as it has already completed for 4SC-205 and the Company's portfolio of Kv1.3 inhibitors, to ensure further development of these drug candidates and to achieve an inflow of non-dilutive funds while exploiting the development programs' value creation potential over the long term.

#### **Resminostat**

Resminostat is orally administered and potentially offers a novel approach to treating a wide variety of cancers, both as monotherapy and in combination therapy with other anti-cancer drugs. Resminostat demonstrated that it can inhibit tumor growth and proliferation, cause tumor regression, and strengthen the body's immune response to cancer.

Resminostat has been shown to be well tolerated in several clinical trials. In 2016, 4SC started the pivotal RESMAIN study – a randomized, double-blind, placebo-controlled clinical Phase II study with resminostat in cutaneous T-cell lymphoma (CTCL). This study is being conducted in order to examine the potential of resminostat as maintenance therapy intended to delay or prevent the progression of disease in patients with advanced CTCL who have benefitted from prior systemic therapy. 4SC finalized the study design in early 2016, following scientific advice provided by the European Medicines Agency (EMA), and enrolled the first patient in December 2016. The goal is to conduct the study with no more than 150 patients in more than 50 study centers across 11 European countries. Patient enrollment and opening of the study centers is currently on track and 4SC continues to expect top-line results to be available in H1 2019. If these results are positive, 4SC will submit applications for marketing approval of the drug in a number of distinct geographies.

In September, 4SC's development partner in Japan – Yakult Honsha Co., Ltd. (Yakult Honsha) – presented promising results from a Phase I study of resminostat in combination with S-1 chemotherapy in 27 Japanese patients with pre-treated biliary tract or pancreatic cancer at the ESMO 2017 Congress. Yakult Honsha confirmed further investigation of the efficacy of resminostat/S-1 combination treatment in Japanese second line biliary tract cancer patients in a subsequent Phase II study to commence in the near future.

#### **4SC-202**

4SC-202 is an orally administered small molecule with a unique mode of action that was designed to strengthen the body's own anti-tumor immune response, open the tumor microenvironment and encourage infiltration of immune cells into the tumor.

4SC-202 has been investigated in a Phase I study with 24 mostly heavily pretreated patients with several types of highly advanced hematologic cancers, and was proven to be tolerated. Positive signs of anti-tumor efficacy were observed with one complete remission for 28 months and one partial responder for 8 months.

In addition to its therapeutic potential in cancer monotherapy, 4SC is evaluating 4SC-202's capacity as a partner in combination therapies, specifically in the immuno-oncology area. In this respect, 4SC initiated the Phase Ib/II study SENSITIZE of 4SC-202 in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab (Keytruda®, Merck) in patients with advanced-stage melanoma in Q3 2017 with the opening of the first study center. 4SC expects the first patient to be enrolled in Q4 2017 and top-line results to be available in H2 2018.

In a second Phase II study – EMERGE – to be conducted by an internationally renowned academic institution starting in Q1 2018, 4SC-202 will also be tested in combination with a checkpoint inhibitor, the anti-PD-L1 antibody avelumab (Bavencio®, Merck), for treating gastrointestinal tumors. Such tumors account for around 80% of all intestinal cancers, and 4SC expects top-line results to be available in H2 2019.

Finally, 4SC plans to advance 4SC-202 into a pivotal study in combination with a checkpoint inhibitor in PD-(L)1 refractory patients with advanced Merkel-cell carcinoma (MCC).

#### 4SC-208

Data from several preclinical *in vivo* models has established the efficacy of 4SC-208 in inhibiting the Hedgehog/GLI signaling. Inhibition of this signaling pathway has emerged as a highly effective strategy in obstructing the tumorigenic capacity of cancer stem cells, as well as tumor development, proliferation and survival.

Available inhibitors of Hedgehog signaling target the pathway upstream of the transcription factor GLI, whereas 4SC-208 inhibits at the level of GLI and is thus potentially able to avoid the tumor recurrence and relapse observed in response to currently available inhibitors. In August, 4SC obtained a US composition-of-matter patent for a group of molecules including 4SC-208. The patent provides 4SC with US market exclusivity until at least 2033.

4SC believes that 4SC-208 is a promising drug candidate and expects to complete formal preclinical testing in 2018 and to enter into a Phase I/II clinical study immediately thereafter. Cancer indications that are particularly promising are those where resistance to therapies targeting

the Hedgehog/GLI pathway are emerging, such as in basal cell carcinoma.

### Significant events at Group level

#### Capital raise

In July, 4SC secured ca. €41 million from a capital increase. 11,681,867 offer shares were issued at a subscription price of €3.50 per share to existing shareholders, who made a significant contribution, as well as to a number of new institutional investors in a subsequent placement of rump shares. As a result of the transaction, share capital increased to €30,648,513 or 30,648,513 shares, up from €18,966,646 or 18,966,646 shares before. The proceeds of the capital raise will finance 4SC's stated goals into 2020 and facilitate the Company's accelerated development strategy for resminostat, 4SC-202 and 4SC-208.

#### Out-licensing

In line with 4SC's stated strategy to monetize non-core assets, 4SC had signed an exclusive worldwide licensing agreement with Maruho for preclinical compounds inhibiting the ion channel Kv1.3 in July. Under the agreement, 4SC is eligible to receive upfront as well as development and commercial milestone payments totaling up to EUR 208 million and single-digit royalties on commercial sales.

#### EVENTS AFTER Q3 2017

In October, 4SC announced new preclinical data underlining resminostat's potential to alleviate itching in CTCL patients. To date, the underlying molecular mechanism of itching in CTCL has not been well understood and established anti-itching drugs such as anti-histamines have proven ineffective in CTCL patients. In a CTCL cell line, resminostat reduces the expression of IL-31 – a messenger molecule which is associated with itching in CTCL patients. Given that time to symptom

worsening is one of the major endpoints in the pivotal RESMAIN study, these data support 4SC's clinical development plans to advance resminostat to market authorization and to offer a new and effective treatment option to CTCL patients and physicians.

#### OPPORTUNITIES AND RISKS

Please see pages 46 to 58 of the Annual Report 2016 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.

With the successful capital increase generating gross proceeds of ca. €41 million completed in July, 4SC's capital sufficiency risks have decreased significantly compared to when the Annual Report 2016 was released in March this year. Based on current funding and planning, 4SC can now finance its drug development strategy for resminostat, 4SC-202 and 4SC-208 into 2020. The Company's opportunities and risks 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.

#### FINANCIAL CALENDAR

Annual Report 2017	<b>28 March 2018</b>
Q1 Announcement 2018	<b>26 April 2018</b>
Annual General Meeting 2018	<b>17 May 2018</b>
Half-Year Report 2018	<b>9 August 2018</b>
Q3 Announcement 2018	<b>25 October 2018</b>

#### PUBLISHING INFORMATION

##### Publication date

26 October 2017

##### Editor

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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](http://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

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