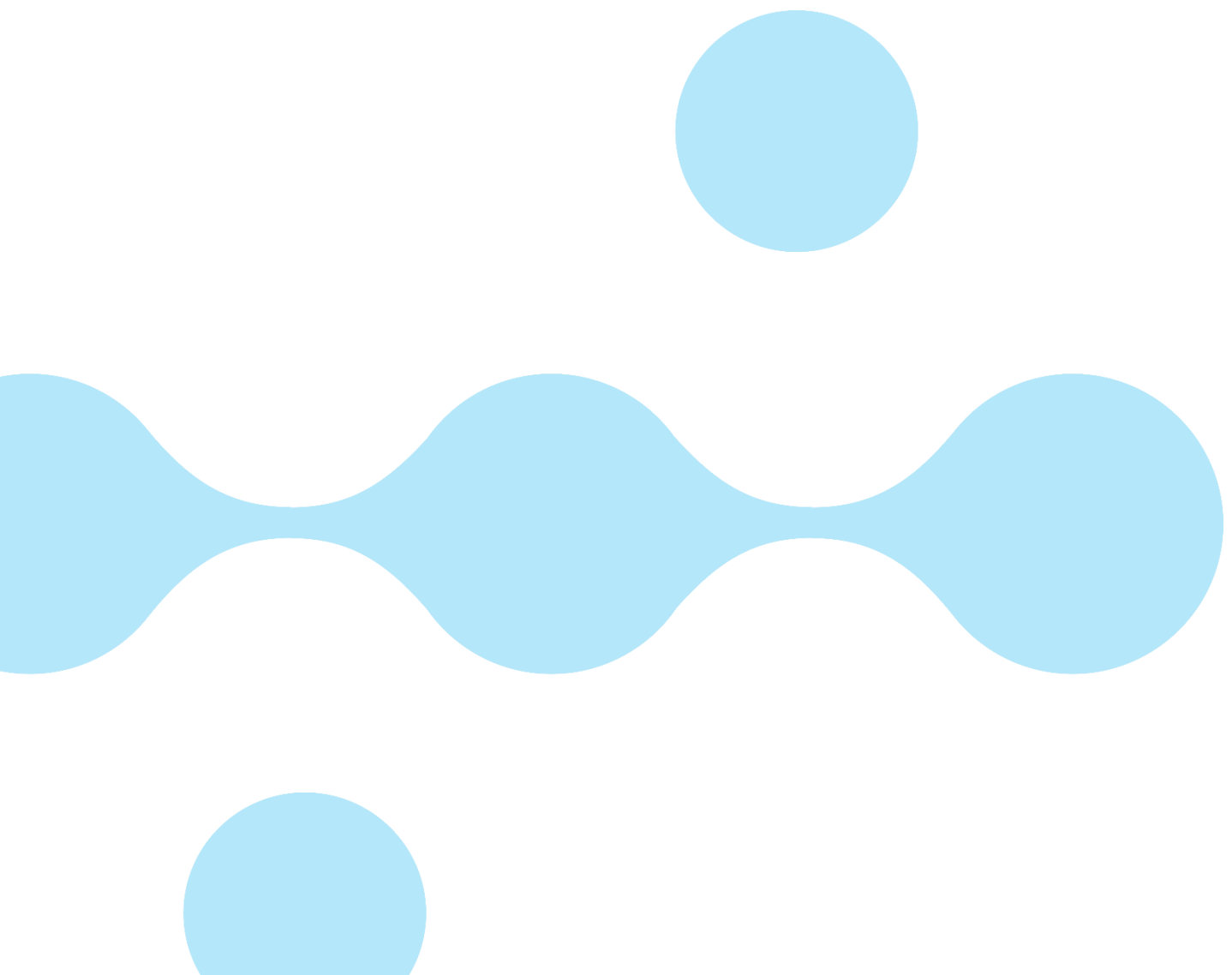




# Half-Year Report 2019



## IN GENERAL



### About 4SC

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

4SC's pipeline is protected by a comprehensive portfolio of patents and currently comprises two drug candidates in clinical development: resminostat and domatinostat.

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 47 employees as of 30 June 2019 and is listed on the Prime Standard of the Frankfurt Stock Exchange (FSE Prime Standard: VSC; ISIN: DE000A14KL72).

### About this report

This Half-Year Report as of 30 June 2019 is comprised of the interim management report and the condensed interim financial statements of 4SC AG (4SC) as of 30 June 2019 and complemented by a responsibility statement. It should be read in conjunction with 4SC's Annual Report for the 2018 financial year and Q1 Announcement as of 31 March 2019.

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 2018 and also in this Half-Year Report as of 30 June 2019. 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.

# INTERIM MANAGEMENT REPORT



## 1 Course of business and outlook

### 1.1 SECTOR ENVIRONMENT

In the first 6 months of 2019 global stock markets recovered somewhat despite continuing trade tension in the APAC region sparked by the hostility between the US and China. A look at the wider biotech markets shows the recovery seen in the Nasdaq Biotechnology Index in the first quarter of the year has been sustained, and other healthcare indices have also risen, with the 12% jump in the Thomson Reuters European Healthcare index being of particular note.

According to Global Data Deal Database, in the first half of the year, a total of 287 deals (mergers and acquisitions and/or strategic alliances) were announced and completed worldwide involving companies with oncology assets. In 85 cases the deal values were disclosed, for a total putative value of about US-\$40 billion.

In the biotech sector there were a total of 27 initial public offerings (IPO) completed worldwide, but only four were from European companies. The total capital raised in these IPO was of about US-\$3.5 billion.

Two of the major asset transaction deals involved two of the four FDA-approved HDAC inhibitors. Namely, in March 2019 Secura Bio, Inc acquired the global rights to Farydak (panobinostat) from Novartis Pharma (financials remain undisclosed). Also in March 2019, Spectrum Pharmaceuticals, Inc., completed the sale of its portfolio of seven FDA-approved hematology / oncology products to Acrotech Biopharma LLC, including (among the seven products) the injectable HDAC inhibitor BELEODAQ (belinostat). For this divestiture, Spectrum received an upfront payment of US-\$160 million.

### 1.2 BUSINESS REVIEW

4SC is currently in clinical development with two drug candidates; resminostat and domatinostat and has a number of programs partnered or licensed to third party companies for further development.

### 1.2.1 RESMINOSTAT

Resminostat is an orally administered class I, IIb and IV 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 cutaneous T-cell lymphoma (CTCL).

The RESMAIN study is focused on patients with advanced-stage 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 a maintenance treatment – prolonging the period patients are stable and not progressing combined with a beneficial decrease of disease-related itching.

The design of the RESMAIN study is based on the advice of external experts and the European Medicines Agency (EMA). The study will likely include more than 180 patients. It is currently being conducted at more than 50 centers across 11 European countries, and at 5 centers in Japan where Yakult Honsha Co., Ltd., 4SC's Japanese development partner for resminostat, is responsible for the conduct of the study.

The Data Safety Monitoring Board, an independent committee of clinical and drug safety experts, evaluated data after 50 and 100 patients have been treated in the study and observed no safety issues. The committee recommended continuation without modification of the study protocol.

To date more than two thirds patients have been enrolled in the RESMAIN study and 4SC expects that sufficient patients will be enrolled during 2019 to accumulate the 125 events – i.e. patients experiencing disease progression – required to unblind the study

around the middle of 2020. Top-line results from the study would be available as soon as possible thereafter.

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 on track

In April 2018, 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. The study is fully enrolled and final results are expected to be available in the first half of 2020.

### 1.2.2 DOMATINOSTAT

Domatinostat is an orally administered small molecule class I selective HDAC inhibitor. It has been investigated in a Phase I study in 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 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 the infiltration of immune cells into the tumor.

These characteristics make domatinostat a potential combination partner for checkpoint inhibitors, particularly in patients with high unmet medical needs; such as melanoma or Merkel cell carcinoma (MCC) patients who are refractory to checkpoint blockade; or patients that show little response to treatment with checkpoint inhibitors such as microsatellite-stable gastrointestinal cancers.

### Domatinostat in combination with checkpoint inhibitors

In order to evaluate domatinostat's combination potential, two Phase Ib/II clinical trials were initiated, in 2017 and 2019 respectively, with domatinostat in combination with a checkpoint inhibitor.

The Phase Ib/II SENSITIZE study is a dose escalation study of domatinostat in combination with the checkpoint inhibitor pembrolizumab – an anti-PD-1 antibody approved in the U.S. and the EU as a cancer immunotherapy against melanoma – initially being conducted in up to 40 patients with advanced-stage melanoma who are refractory to anti-PD-1 antibody treatment.

In November 2017, the first patient was enrolled in the study. The Safety Review Committee – consisting of clinical and drug safety experts – positively evaluated the safety data from the three initial dose cohorts. Based on these results, the SENSITIZE study will be expanded to include a further two cohorts. Taken together, the data from all cohorts will give 4SC important information on how to optimally combine domatinostat with checkpoint blockade and inform the planned clinical studies of domatinostat in other indications.

The Phase Ib/II EMERGE study, which was initiated in January 2019, is also a dose escalation study, conducted initially in up to 15 patients with microsatellite-stable gastrointestinal cancer. The study will evaluate domatinostat, in combination with the checkpoint inhibitor avelumab (an anti-PD-L1 antibody) as part of an investigator sponsored trial (IST) conducted by Professor David Cunningham at The Royal Marsden NHS Foundation Trust (London, UK).

Both SENSITIZE and EMERGE are being conducted in two parts, an initial part to evaluate the safety of domatinostat in combination with checkpoint inhibitors and to determine a recommended Phase II dose, potentially followed by a second “expansion” part in order to obtain a larger data-set through the addition of more patients at the preferred dose. 4SC expects to publish results from part 1 of these two trials in the second half of 2019.

The initial target indications were chosen because they offer the opportunity to evaluate the combined safety and anti-tumor activity of domatinostat with an approved PD-1 and a PD-L1 inhibitor (different checkpoint inhibitor types) at different doses combined with an ability to biopsy patients before and during treatment in order to generate data on a patient's tumor microenvironment to investigate and support the preclinical data and proposed mechanism of action of domatinostat.

### Domatinostat in Merkel cell carcinoma

In addition, it is also 4SC's intention - based on preclinical investigations and data from the SENSITIZE and EMERGE Phase Ib/II studies outlined above - to advance domatinostat into additional Phase II clinical studies in patients with MCC.

MCC is a highly immunogenic, orphan type of non-melanoma skin cancer. In 2017, avelumab was approved in both the EU and U.S. for advanced metastatic MCC followed in December 2018 by pembrolizumab which was approved in the U.S. for the same indication. Although PD-1 and PD-L1 inhibitors are now standard of care in metastatic MCC, around half of all such patients still progress and currently lack any effective therapeutic options and suffer from high mortality.

A clinical cooperation partner of 4SC presented preclinical data at the American Association for Cancer Research Annual Meeting (AACR) in April 2019 that confirmed domatinostat's mode of action in MCC. Domatinostat increased the presentation of tumor signals on the cells' surface, stopped MCC cells from dividing and induced cell death. All these effects were specific for MCC cell lines and did not occur in healthy control cells.

To address the unmet medical need in advanced-stage MCC, 4SC intends to initially evaluate domatinostat in combination with checkpoint inhibition in up to 30 checkpoint naïve MCC patients (the MERKLIN-1 study), as well as in up to 25 MCC patients progressed on treatment with checkpoint inhibitors (the MERKLIN-2 study).

Assuming an overall response rate exceeding 15% is reached in this first part of the MERKLIN-2 study, an additional 40-60 patients could be added in a second part to the study, which combined, could potentially be considered by regulators as pivotal and sufficient for registration purposes.

It is estimated that the two MERKLIN studies could start in late 2019 and early 2020 and provide initial top-line data in the first half of 2021.

### Domatinostat as (multi-)combination drug in melanoma

In addition to the studies described above for MCC, it is also 4SC's intention, based on preclinical investigations conducted in 2017 and 2018 and data from the SENSITIZE and EMERGE Phase Ib/II studies outlined above, to advance domatinostat into additional clinical studies in patients with cutaneous melanoma. For patients with advanced-stage III or IV metastatic cutaneous melanoma checkpoint inhibition is also currently standard of care, but as in MCC, around half of these melanoma patients progress on checkpoint

blockade and subsequently have very few therapeutic options and high mortality.

It is 4SC's intention to evaluate domatinostat in combination with checkpoint blockade in checkpoint naïve melanoma patients because the Company believes the tolerability and immuno-modulatory qualities of domatinostat can significantly improve the overall response rate of such patients (in combination with checkpoint blockade) and significantly reduce the number of progressive patients.

4SC is currently in discussions with a leading U.S. cancer center to conduct such a study in stage III/IV metastatic cutaneous melanoma patients potentially starting in the fourth quarter of 2019, with top-line data expected in late 2020.

All the studies described above are focused on advanced-stage patients because these have the greatest medical need, but it is becoming clear that for cancer immunotherapy, the earlier treatment is given the higher the probability the patient will experience a durable response.

The term "neoadjuvant therapy" refers to an approach in which a form of therapy, for example immunotherapy, chemotherapy or radiation therapy, is given as a first step to shrink a tumor before the main treatment, which is usually surgery. Neoadjuvant therapy is already an approved clinical strategy in breast cancer and is rapidly gaining support in melanoma.

Alongside addressing later stage patients (as described above), 4SC believes that utilizing domatinostat as neoadjuvant therapy is a novel and strategically important positioning for the drug and as such, the Company intends to collaborate with a leading melanoma expert to support a Phase II clinical study (DONIMI) in resectable stage III melanoma patients. The study will evaluate combining domatinostat and checkpoint blockade as neoadjuvant therapy in biomarker-selected sub-groups of such patients and is expected to start in late 2019. Top-line data from this neoadjuvant study could be available as early as H2 2020.

### Evaluation of further combination partners

In 2018, 4SC presented a poster with preclinical data supporting double and triple combinations of domatinostat and checkpoint inhibitors and a collaborator of 4SC presented an additional poster with preclinical data supporting the combination of domatinostat with chemotherapy in cancer.

In April 2019, Dynavax Technologies Corporation (Dynavax) presented preclinical data at AACR on the combination of orally available domatinostat with Dynavax's intra-tumoral TLR9 agonist SD-101. The combined treatment induced a systemic anti-tumoral

immune response in tumor mouse models, resulting in significant decrease in tumor size of both target tumors and distant site metastases. Dynavax also compared domatinostat to other class-I-selective HDAC inhibitors, with domatinostat demonstrating the most significant benefit in combination with SD-101.

### 1.2.3 4SC-208

4SC-208, an orally available hedgehog/GLI signaling inhibitor, is currently being evaluated in preclinical models.

### 1.2.4 OUT-LICENSED PROGRAMS

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

In April 2019, Immunic, Inc. (Immunic) completed a merger with Vital Therapies, Inc. leading to a NASDAQ listing (ticker symbol: IMUX). Following such merger and as part of the agreement concluded in September 2016 with Immunic to sell 4SC's non-core immunology portfolio to Immunic, 4SC became a minority shareholder of the listed entity and continues to be entitled to receive royalties.

### 1.2.5 SIGNIFICANT CORPORATE EVENTS

In June 2019, 4SC implemented a cash capital increase from authorized capital. A total of 4,676,703

offered shares were placed at a subscription price of EUR 2.37 resulting in gross proceeds of circa EUR 11 million. As a result of the transaction, share capital increased to EUR 35,325,216 or 35,325,216 shares, up from EUR 30,648,513 or 30,648,513 shares previously. The 4,676,703 new shares were registered with the Commercial Register on 2 July 2019, and trading of the new shares on the Frankfurt Stock Exchange commenced on 4 July 2019.

## 1.3 STAFF

As of 30 June 2019, the headcount of 4SC totaled 47 employees, including 4SC's Management Board (31 December 2018: 47). The percentage of female employees was at 64% on 30 June 2019, with no significant changes since the end of 2018 (66%).

On average, 47 employees (headcount) worked for 4SC in H1 2019 (H1 2018: 46). The Company had a total of 43 full-time equivalents (FTEs) as of 30 June 2019 (31 December 2018: 42), taking account of part-time employees and employees on parental leave. As of the end of H1 2019, 76% of these FTEs (31 December 2018: 74%) worked in Research and Development, with the remaining 24% (31 December 2018: 26%) working in Business Development and Administration.

## 2 Results of operations, financial position and net assets

4SC AG, reports figures for the first six months of the 2019 financial year and the comparative period of the 2018 financial year. The description of results of operations, financial positions and net assets during the reporting period is limited to the most important/material events.

### 2.1 RESULTS OF OPERATIONS

#### 2.1.1 REVENUE

In Q2 2019, revenue increased by 14% to €1,209 thousand (Q2 2018: €1,064 thousand), and in H1 2019 decreased by 51% to €2,030 thousand (H1 2018: €4,117 thousand). In both Q2 2019 and H1 2019 revenue is mainly driven by milestone payments received from our cooperation partners Maruho Co., Ltd. (Maruho) and Guangzhou LingSheng Pharma Tech Co., Ltd. (Link Health).

#### 2.1.2 OPERATING EXPENSES

Operating expenses, comprising cost of sales, distribution costs, research and development costs and

administrative costs, were €4,353 thousand in Q2 2019 (Q2 2018: €5,085 thousand) and €8,660 thousand in H1 2019 (H1 2018: €10,717 thousand). Operating expenses were 14% (Q2 2019) and 19% (H1 2019) less the levels seen in the previous year as a result of 4SC's expanded clinical studies and the one-time expenses for drug development in the prior-year period.

Research and development costs amounted to €3,334 thousand in Q2 2019 (€4,313 thousand in Q2 2018) and to €6,739 thousand in H1 2019 (€8,933 thousand in H1 2018). Research and development costs continue to make up the majority of expenses.

Cost of sales, distribution and administrative costs increased to €1,019 thousand in Q2 2019 (Q2 2018: €772 thousand) and to €1,921 thousand in H1 2019 (H1 2018: €1,784 thousand).



Other operating income rose to €995 thousand in H1 2019 (H1 2018: €2 thousand), mainly driven by the one-time effect of the Settlement Agreement with Immunic Inc., which was settled in shares with a value of €994 thousand.

### 2.1.3 NET LOSS

The net loss for the period decreased by 49% in Q2 2019 to €2,082 thousand (Q2 2018: net loss of €4,113 thousand) and by 17% in H1 2019 to €5,574 thousand (H1 2018: €6,693 thousand).

## 2.2 NET ASSETS

### 2.2.1 ASSETS

Non-current assets amounted to €7,195 thousand as of 30 June 2019 (31 December 2018: €5,645 thousand) and consist primarily of intangible assets totaling €4,584 thousand (31 December 2018: €4,955 thousand) and the new right of use for future rental payments in the amount of €1,925 thousand as a result of the first-time application of IFRS 16, which is allocated to the intangible assets.

Current assets decreased to €21,228 thousand on 30 June 2019 (31 December 2018: €25,611 thousand), mainly due to lower cash and cash equivalents of €17,751 thousand (€25,036 thousand on 31 December 2018).

### 2.2.2 EQUITY

The decline in equity from €28,452 thousand on 31 December 2018 to €22,926 thousand on 30 June 2019 was primarily driven by the loss for the period of €5,574 thousand, increasing the accumulated deficit from €177,476 thousand at the end of 2018 to €183,050 thousand as of 30 June 2019. Furthermore, the transaction costs related to the capital increase implemented in Q2 2019 reduced the share premium. As a result, the equity ratio fell from 91.0% at the end of the 2018 to 80.7% at the end of H1 2019.

### 2.2.3 LIABILITIES

Non-current liabilities increased by 200% to €1,719 thousand on 30 June 2019 (31 December 2018: €82 thousand) with €1,686 thousand being due to a lease liability in connection with the first-time application of IFRS 16.

Current liabilities increased by 39% to €3,778 thousand (31 December 2018: €2,722 thousand). This item includes trade accounts payable of €1,216 thousand (31 December 2018: €1,120 thousand), leasing liability due to IFRS 16 of €245 thousand and other liabilities of €2,317 thousand (31 December 2018: €1,602 thousand).

## 2.3 FINANCIAL POSITIONS

### 2.3.1 CASH FLOWS FROM OPERATING ACTIVITIES

Cash flows from operating activities amounted to €-6,927 thousand in H1 2019 (H1 2018: €-7,100 thousand), reflecting mainly the net loss for the period of €5,574 thousand (H1 2018: net loss of €6,693 thousand).

### 2.3.2 CASH FLOWS FROM FINANCING ACTIVITIES

The cash flows from financing activities in H1 2019 amounted to €-315 thousand (H1 2018: €-8 thousand). These negative cash flows resulted on the one hand from costs of €175 thousand in connection with the capital increase in June 2019 and on the other hand from rental expenses of €-140 thousand in connection with IFRS 16.

### 2.3.3 CASH BALANCE/FUNDS

Cash and cash equivalents amounted to €17,751 thousand as of 30 June 2019 (31 December 2018: €25,036 thousand). The average monthly use of cash from operating activities was €1,185 thousand in H1 2019 (H1 2018: €1,198 thousand).

## 3 Report on opportunities and risks

Please see pages 18 to 25 of the Annual Report 2018 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.

Compared to March of this year, when the Annual Report 2018 was published, 4SC's risks with respect to sufficient equity coverage were slightly reduced, but not significantly changed, by a capital increase completed in June 2019, which generated gross proceeds of approximately €11 million. In order to

achieve its corporate and development goals and in particular to finance the associated clinical studies, the company still has a high capital requirement in the short to medium term. In order to cover these needs, the company must be able to generate sufficient income from licensing or cooperation agreements or sufficiently secure financing by other means. If the costs of product development exceed earnings and the company's own reserves are no longer sufficient, additional equity and/or debt capital must be raised. There is no guarantee that 4SC will be able to realize the financing on time, to the required extent, at economically reasonable conditions or in principle. 4SC's management is currently evaluating further possibilities. This could result in 4SC being hampered

in its further development and important investments, e.g. in product development, not being able to be made or forced to discontinue the development of one or more products. This could adversely affect the Company's competitive position and adversely affect its net assets, financial position and results of operations.

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.

## 4 Report on expected development

### 4.1 SECTOR DEVELOPMENT

Though M&A activity is expected to continue in the sector generally, a few factors may slow momentum in the second half of 2019. For example, if the Trump administration passes a law to reduce the price of drugs, it may hurt sentiment towards the sector and have a subsequent effect on M&A activity.

Buysiders who spoke to BioCentury said the sector right now is lacking the standout programs that can draw in generalist investors, as was seen in the early days of immuno-oncology. They also cited a more general lack of enthusiasm for biotech based on recent ho-hum clinical data, large caps failing to refill their pipelines, a slate of macro worries like the trade tensions between the United States and China, Brexit, and the fizzling out of the M&A spree that kicked off the year.

Nonetheless, despite these fears, the pace of M&A activity in the pharma sector is still expected to be brisk over the rest of 2019 due to the availability of capital for biotech/pharma firms and continuing innovation in the sector.

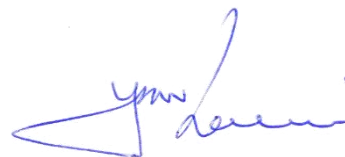
### 4.2 COMPANY OUTLOOK

4SC's future development plans are included in section 1.2 Business review starting on page 3.

### 4.3 FINANCIAL FORECAST

4SC held cash balance/funds amounting to €17,751 thousand at the end of H1 2019. Taking into account the proceeds from the June 2019 cash capital increase in the net amount of circa €10.5 million, current financial planning and the intended operational activities, the Management Board of 4SC maintains its existing financial forecast for the full year 2019 of an average monthly use of cash from operations of between €1,400 thousand and €1,600 thousand. The planned extension of the development program is subject to further financing. The Management Board estimates that current funds should be sufficient to finance 4SC for at least the next twelve months.

Planegg-Martinsried, Germany, 7 August 2019



Jason Loveridge, Ph.D.  
Sole Managing Director



# INTERIM IFRS FINANCIAL STATEMENTS

FOR THE PERIOD FROM 1 JANUARY TO 30 JUNE 2019



## STATEMENT OF COMPREHENSIVE INCOME

(In € 000's, unless stated otherwise)	Q2 2019	Q2 2018	6M 2019	6M 2018
Revenue	1,209	1,064	2,030	4,117
Cost of sales	-144	-36	-253	-269
<b>Gross profit</b>	<b>1,065</b>	<b>1,028</b>	<b>1,777</b>	<b>3,848</b>
Distribution costs	-85	-105	-227	-232
Research and development costs	-3,334	-4,313	-6,739	-8,933
Administrative costs	-790	-631	-1,441	-1,283
Other income	994	2	995	2
<b>Operating profit/loss</b>	<b>-2,150</b>	<b>-4,019</b>	<b>-5,635</b>	<b>-6,598</b>
Share in the profit of equity-accounted investments	0	0	0	0
Finance income	185	2	186	7
Finance costs	-11	-2	-19	-8
<b>Net finance income/loss</b>	<b>174</b>	<b>0</b>	<b>167</b>	<b>-1</b>
<b>Earnings before taxes</b>	<b>-1,976</b>	<b>-4,019</b>	<b>-5,468</b>	<b>-6,599</b>
Income tax expense	-106	-94	-106	-94
<b>Profit/loss for the period = Comprehensive income/loss</b>	<b>-2,082</b>	<b>-4,113</b>	<b>-5,574</b>	<b>-6,693</b>
<b>Earnings per share (basic and diluted, in €)</b>	<b>-0.07</b>	<b>-0.13</b>	<b>-0.18</b>	<b>-0.22</b>


 ❖ STATEMENT OF FINANCIAL POSITIONS – ASSETS

(In € 000's)	30 Jun 2019	31 Dec 2018
<b>Non-current assets</b>		
Intangible assets	4,584	4,955
Property, plant and equipment	2,503	589
Other financial assets	100	100
Other assets	8	1
<b>Total non-current assets</b>	<b>7,195</b>	<b>5,645</b>
<b>Current assets</b>		
Trade accounts receivable	1,942	14
Cash and cash equivalents	17,751	25,036
Current income tax assets	0	12
Other financial assets	1,178	0
Other assets	357	549
<b>Total current assets</b>	<b>21,228</b>	<b>25,611</b>
<b>Total assets</b>	<b>28,423</b>	<b>31,256</b>

❖ STATEMENT OF FINANCIAL POSITIONS – EQUITY AND LIABILITIES

(In € 000's)	30 Jun 2019	31 Dec 2018
<b>Equity</b>		
Subscribed capital	30,649	30,649
Share premium	171,577	172,092
Reserves	3,750	3,187
Accumulated deficit	-183,050	-177,476
<b>Total equity</b>	<b>22,926</b>	<b>28,452</b>
<b>Non-current liabilities</b>		
Other financial liabilities	1,686	0
Other liabilities	33	82
<b>Total non-current liabilities</b>	<b>1,719</b>	<b>82</b>
<b>Current liabilities</b>		
Trade accounts payable	1,216	1,120
Other financial liabilities	2,118	1,096
Other liabilities	444	506
<b>Total current liabilities</b>	<b>3,778</b>	<b>2,722</b>
<b>Total equity and liabilities</b>	<b>28,423</b>	<b>31,256</b>


 ❖ STATEMENT OF CASH FLOWS

(In € 000's)	6M 2019	6M 2018
<b>Cash flows from operating activities</b>		
Earnings before taxes	-5,468*	-6,598*
<i>Adjustment for statement of comprehensive income items</i>		
Depreciation, amortization	555	419
Net finance income/loss	-167	0
Stock options	563	381
Other non-cash items	78	3
<i>Changes in statement of financial position items</i>		
Trade accounts receivable	-1,928	-987
Current income tax assets	12	11
Other assets	-993	-323
Trade accounts payable	96	-252
Other liabilities	327	298
Deferred income	0	-49
Interest received	1	5
Interest paid	-3	-8
Income taxes paid	0*	0*
<b>Total cash flows from operating activities</b>	<b>-6,927</b>	<b>-7,100</b>

\* The withholding tax regarding milestone payments from Link Health received in H1 2019 and H1 2018, respectively, were not paid until they had become due at the start of Q3 2019 and Q3 2018, respectively.

To be continued on the following page.

## STATEMENT OF CASH FLOWS

(In € 000's)	6M 2019	6M 2018
<b>Cash flows from investing activities</b>		
Purchase of intangible assets	0	0
Purchase of property, plant and equipment	-43	-90
<b>Total cash flows from investing activities</b>	<b>-43</b>	<b>-90</b>
<b>Cash flows from financing activities</b>		
Payments to subscribed capital	0	0
Payments to share premium	0	0
Payments expenditures related to the implementation of resolved capital increase	-175	-8
Repayment of lease liabilities from right of use asset	-124	0
Accumulation of lease liabilities from right of use asset	-16	0
<b>Total cash flows from financing activities</b>	<b>-315</b>	<b>-8</b>
<b>Net change in cash and cash equivalents</b>	<b>-7,285</b>	<b>-7,198</b>
+ Cash and cash equivalents at the beginning of the period	25,036	41,327
<b>= Cash and cash equivalents at the end of the period</b>	<b>17,751</b>	<b>34,129</b>


 ❖ STATEMENT OF CHANGES IN EQUITY

(In € 000's)	Reserves					Total
	Subscribed capital	Share premium	Stock options	Retained earnings	Accumulated deficit	
<b>Balance on 1 Jan 2018 as reported 31 Dec 2017</b>	<b>30,649</b>	<b>172,100</b>	<b>2,187</b>	<b>67</b>	<b>-160,310</b>	<b>44,693</b>
Effect of initial application of IFRS 15					493	493
<b>Balance on 1 Jan 2018</b>	<b>30,649</b>	<b>172,100</b>	<b>2,187</b>	<b>67</b>	<b>-159,817</b>	<b>45,186</b>
Options issued (ESOP 2016/2016)*			208			208
Options issued (ESOP 2016/2017)*			57			57
Options issued (ESOP 2017/2017)*			116			116
Costs in connection with the capital increase on 11 July 2017		-8				-8
Comprehensive income/loss 6M 2018					-6,693	-6,693
<i>Consolidated profit/loss 6M 2018</i>					-6,693	-6,693
<b>Balance on 30 Jun 2018</b>	<b>30,649</b>	<b>172,092</b>	<b>2,568</b>	<b>67</b>	<b>-166,510</b>	<b>38,866</b>
<b>Balance on 1 Jan 2019</b>	<b>30,649</b>	<b>172,092</b>	<b>3,120</b>	<b>67</b>	<b>-177,476</b>	<b>28,452</b>
Options issued (ESOP 2016/2016)*			68			68
Options issued (ESOP 2016/2017)*			18			18
Options issued (ESOP 2016/2018)*			210			210
Options issued (ESOP 2017/2017)*			143			143
Options issued (ESOP 2017/2018)*			124			124
Expenditures related to the implementation of the resolved capital increase		-515				-515
Comprehensive income/loss 6M 2019					-5,574	-5,574
<i>Profit/loss 6M 2019</i>					-5,574	-5,574
<b>Balance on 30 Jun 2019</b>	<b>30,649</b>	<b>171,577</b>	<b>3,683</b>	<b>67</b>	<b>-183,050</b>	<b>22,926</b>

\* ESOP: Employee Share Option Program.



# SELECTED NOTES

## TO THE INTERIM IFRS FINANCIAL STATEMENTS FOR THE PERIOD FROM 1 JANUARY TO 30 JUNE 2019



### 1 Summary of significant accounting policies

#### 1.1 BASIS OF PREPARATION

These interim financial statements were created in accordance with the accounting principles of the International Financial Reporting Standard (IFRS) – as adopted by the EU – in consideration of IAS 34 (interim financial reporting) in accordance with the requirements of the International Accounting Standards Board (IASB). The recommendations of the Standing Interpretations Committee (SIC) and the International Financial Reporting Interpretations Committee (IFRIC) have been taken into account. New standards issued by the IASB and adopted by the European Commission are applied without exception starting in the financial year in which their application becomes mandatory.

#### 1.2 COMPANIES INCLUDED IN THE FINANCIAL STATEMENTS

These interim financial statements as at 30 June 2019 comprise 4SC AG, based in Planegg-Martinsried, Germany. The following company was also taken into account in these financial statements:

Company / domicile	Measured as	Measured according to
Panoptes Pharma Ges.m.b.H., Vienna, Austria	Associate	IAS 28

#### 1.3 RELEASE OF THE FINANCIAL STATEMENTS

The interim report was approved for publication by the Management Board on 7 August 2019. The discussion of the interim report by the Audit Committee and the Management Board in line with the German Corporate Governance Code (as amended on 7 February 2017) was held via telephone conference on 25 July 2019.

#### 1.4 GENERAL DISCLOSURES

The accounting policies applied and estimates made essentially correspond to those used for the financial statements for the year ending 31 December 2018, except for the adoption of IFRS 16, Leases as of 1 January 2019. For lessees, IFRS 16 introduces a uniform approach for the recognition of leases in the balance sheet, according to which assets for the rights to use the leased assets and liabilities for the payment obligations entered into must be recognized for all leases in the balance sheet. Until 31 December 2018, leases were accounted for in accordance with IAS 17 and the related interpretations (IFRIC 4, SIC 15, SIC 27), whereby all leases were classified as operating leases. IFRS 16 was applied for the first time on 1 January 2019 in accordance with the modified retrospective method (IFRS 16.C5(b)). Consequently, comparative figures for the 2018 financial year were not adjusted retrospectively. In accordance with IFRS 16.C8(b)(ii), a right of use in the amount of the lease liability was recognized as of 1 January 2019. The right of use must first be measured at the present value of the future lease payments plus initial direct costs and then depreciated over the term of the lease. The lease liability is measured as the present value of the lease payments due during the term of the lease. In subsequent measurement, the carrying amount of the lease liabilities is compounded at the interest rate or marginal borrowing rate underlying the lease and reduced by the lease payments made. For

leased assets of low value and for short-term leases (term less than twelve months), use is made of the application simplifications (IFRS 16.5). The lease payments are recognized as expenses over the term of the lease (IFRS 16.6). IFRS 16 has an impact on the presentation of 4SC's net assets, financial position and results of operations. As of 1 January 2019, a right to use the existing rental agreement for the office building was recognized in property, plant and equipment and a lease liability of €2,055 thousand was recognized in the balance sheet. As a result of this balance sheet extension, the equity ratio decreased. Since 1 January 2019, the rental expenses recognized in the statement of comprehensive income up to and including 2018 have been replaced by depreciation of the right of use (€130 thousand until 30 June 2019) or by interest expense from the compounding of the lease liability (€16 thousand until 30 June 2019). This means that, compared with IAS 17, the expense is shown in different items of the statement of comprehensive income and differs in the total amount. However, the first-time application of IFRS 16 has no material impact on EBIT. As of 30 June 2019, a right of use of €1,925 thousand in property, plant and equipment and a lease liability of €1,931 thousand in other liabilities are recognized in the balance sheet (current liabilities €245 thousand / non-current liabilities €1,686 thousand).

## 2 Revenue

4SC's development of revenues is included in section 2.1 Results of operations on page 6. Revenues are classified by geographical region as follows:

(In € 000's)	Q2 2019	Q2 2018	6M 2019	6M 2018
Germany	0	1	0	23
Europe	0	0	0	0
Asia	1,209	1,063	2,030	4,094
Rest	0	0	0	0
<b>Total Revenue</b>	<b>1,209</b>	<b>1,064</b>	<b>2,030</b>	<b>4,117</b>

## 3 Earnings per share

The basic earnings per share are calculated in accordance with IAS 33.9 ff. by dividing the profit/loss for the period attributable to the shareholders (numerator) by the average weighted number of shares outstanding in the reporting period (denominator).

	Q2 2019	Q2 2018	6M 2019	6M 2018
Based on net profit/loss for the period (in € 000's)	-2,082	-4,113	-5,574	-6,693
Based on average number of shares (in thousand)	30,649	30,649	30,649	30,649
<b>Earnings per share (basic and diluted, in €)</b>	<b>-0.07</b>	<b>-0.13</b>	<b>-0.18</b>	<b>-0.22</b>

Given 4SC's loss, all of the stock options exercisable are currently "out of money", thus the options exercisable are not dilutive. As a result, the diluted and basic earnings per share are identical.

## 4 Notes to the cash balance/funds

4SC holds cash and cash equivalents and had no other financial assets, borrower's note loans and bearer notes as of the reporting date. Taken together, these items comprise the cash balance/funds:

(In € 000's)	30 Jun 2019	31 Dec 2018	30 Jun 2018
Cash and cash equivalents at the end of the period	17,751	25,036	34,129
Other financial assets	0	0	0
<b>Cash balance/funds</b>	<b>17,751*</b>	<b>25,036</b>	<b>34,129</b>

\* The Company's liquidity position improved as a result of the completion of a capital increase in June 2019, generating gross issue proceeds of circa €11 million.

## 5 Shareholdings and managers' transactions

In H1 2019 no reportable transactions pursuant to Article 19 MAR were made with shares or options by members of the Management Board or Supervisory Board.

The following overview tables show the shares and stock options held by members of the Management Board and Supervisory Board as of the 30 June 2019 reporting date as well as changes in these holdings compared to the start of the year.

(number of shares)	Shares 1 Jan 2019	Purchase	Sale	Shares 30 Jun 2019
<b>Supervisory Board</b>				
Clemens Doppler, Ph.D.	7,923	0	0	7,923
Prof. Helga Rübamen-Schaeff, Ph.D.	3,700	0	0	3,700
Manfred Rüdiger, Ph.D.	2,500	0	0	2,500
<b>Shares held by the Supervisory Board</b>	<b>14,123</b>	<b>0</b>	<b>0</b>	<b>14,123</b>

(number of stock options)	Options 1 Jan 2019	Additions	Expired	Exercised	Options = maximum number of shares 30 Jun 2019
<b>Management Board</b>					
Jason Loveridge, Ph.D.	800,000	0	0	0	800,000
<b>Options held by the Management Board</b>	<b>800,000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>800,000</b>

## 6 Related party transactions

4SC engaged in the following significant business transactions with related parties in the period from 1 January to 30 June 2019:

### **BioNTech and BioNTech Small Molecules (other related parties)**

4SC maintains legal relations with BioNTech AG, Mainz, Germany and its subsidiary BioNTech Small Molecules GmbH, which are both members of the Santo Holding (Deutschland) GmbH Group, Holzkirchen, Germany.

In the first half of 2019, the transaction volume with BioNTech amounted to €null (H1 2018: €21 thousand) and with BioNTech Small Molecules to €1 thousand (H1 2018: €2 thousand). As of 30 June 2019 as at the end of 2018, there were no receivables from BioNTech and BioNTech Small Molecules. As of 30 June 2019, there were no liabilities to BioNTech AG (31 December 2018: null€) and BioNTech Small Molecules (31 December 2018: €1 thousand).

### **Other related party transactions**

Beyond this, there were no further business transactions with related parties.

## 7 Review report

These interim financial statements and the interim management report as of 30 June 2019 have been subjected to a review by Baker Tilly GmbH & Co. KG Wirtschaftsprüfungsgesellschaft, Düsseldorf, Germany.

## 8 Events after the reporting period

4SC had announced the following events by the time this Half-Year Report was published:

- The capital increase completed in June 2019 was recorded with the commercial register after the end of the reporting period. An additional €11 million gross or €10.5 million net thus accrued to 4SC.
- The Safety Review Committee (SRC) consisting of clinical and drug safety experts evaluated the safety data from the third dose cohort in the Phase Ib/II SENSITIZE study. The combination of domatinostat and pembrolizumab was confirmed as safe and well tolerated by the SRC at this third and highest predefined dose cohort. Thereafter, the SENSITIZE study was expanded by further two cohorts.
- In a second SRC meeting, the safety data of the first dose cohort of the Phase Ib/II study EMERGE was evaluated and the SRC recommended continuation with the second dose cohort. Patient recruitment for the second dose cohort has been initiated.

# REVIEW REPORT



*To 4SC AG, Planegg-Martinsried, District of Munich, Germany*

We have reviewed the interim financial statements - comprising the statement of comprehensive income, the statement of financial position, the statement of cash flows, the statement of changes in equity as well as selected explanatory notes - together with the interim management report of 4SC AG, Planegg-Martinsried, District of Munich, Germany, for the period from 1 January to 30 June 2019 that are part of the half-year financial report according to Section 115 WpHG ("Wertpapierhandelsgesetz": "German Securities Trading Act"). The preparation of the interim financial statements in accordance with the IFRS as adopted by the EU and of the interim management report in accordance with the provisions of the German Securities Trading Act applicable to interim management reports is the responsibility of the Company's legal representatives. Our responsibility is to issue a review report on the interim financial statements and the interim management report of 4SC AG based on our review.

We performed our review of the interim financial statements and the interim management report in accordance with German generally accepted standards for the review of financial statements promulgated by the Institut der Wirtschaftsprüfer (IDW). Those standards require that we plan and perform the review so that we can preclude through critical evaluation, with a certain level of assurance, that the interim financial statements have not been prepared, in material respects, in accordance with the IFRS applicable to interim financial

reporting as adopted by the EU and that the interim management report has not been prepared, in material respects, in accordance with the provisions of the German Securities Trading Act applicable to interim management reports. A review is limited primarily to inquiries of Company employees and analytical assessments and therefore does not provide the assurance attainable in a financial statements audit. Since, in accordance with our engagement, we have not performed a financial statements audit, we cannot issue an auditor's report.

Based on our review, no matters have come to our attention that cause us to presume that the interim financial statements have not been prepared, in all material respects, in accordance with the IFRS applicable to interim financial reporting as adopted by the EU, or that the interim management report has not been prepared, in all material respects, in accordance with the requirements of the German Securities Trading Act applicable to interim management reports.

Munich, dated 7 August 2019

**Baker Tilly GmbH & Co. KG**  
**Wirtschaftsprüfungsgesellschaft (Düsseldorf)**

Hund  
 German CPA

Grigo  
 German CPA

## RESPONSIBILITY STATEMENT



„To the best of my knowledge, and in accordance with the applicable reporting regulations, the financial statements for the first six months 2019 give a true and fair view of the assets, liabilities, financial position and profit and loss of 4SC, and the interim management report includes a fair review of the development and performance of the business and the position of 4SC, together with a description of the material opportunities and risks associated with the expected development of 4SC.”

Planegg-Martinsried, Germany, 7 August 2019

Jason Loveridge, Ph.D.  
Sole Managing Director

## PUBLISHING INFORMATION



### PUBLICATION DATE

8 August 2019

### EDITOR

4SC AG, Fraunhoferstrasse 22, 82152 Planegg-Martinsried, Germany

### 4SC ON THE INTERNET

More information about 4SC, its products and development programs, is available on its 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

### CORPORATE COMMUNICATIONS & INVESTOR RELATIONS

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**4SC** 