# CYXONE

559020-5471

Interim Report
January 1st to September 30th, 2019

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## Summary of the Interim Report

First nine months (January 1st to September 30th, 2019)

- Operating revenue KSEK 0 (0)
- Income after financial items KSEK -14 894 (-10 893)
- Earnings per share -0,40 (-0,55)
- Cash and cash equivalents as of 30 September KSEK 12 307 (10 478)
- Equity ratio as of September 30th 92,7 (90,7) %

Third Quarter (July 1st to September 30th, 2019)

- Operating revenue KSEK 0 (0)
- Income after financial items KSEK -5 765 (-4 390)
- Earnings per share -0,15 (-0,22)

Significant events during the third quarter of 2019

- In July, an application was submitted to the Central Ethics Committee (CEC) in Poland for permission to initiate a phase 2b clinical trial with the drug candidate Rabeximod for rheumatoid arthritis (RA). Applications in up to eight additional European countries will follow in the next six months, with recruitment planned to start during H1 2020.
- In July, it was announced that the first healthy male volunteer received the first dose of the drug candidate T20K as part of the First-in-Human, phase 1 study.
- In July, it was announced that Cyxone signed an agreement with EGeen Inc., a clinical research organization (CRO), to conduct the upcoming phase 2b clinical trial with Rabeximod for RA in selected Eastern European countries.
- In early August, it was confirmed that the phase 1 clinical trial with drug candidate T20K successfully achieved its aim of confirming T20K's safety and tolerability in humans and the study showed no reports of serious adverse events.
- In August, it was announced that Cyxone strengthens the team with Malin Berthold as project manager for the company's development programs.
- In September, Cyxone's board of directors decided to explore the possibilities of an orphan drug designation (ODD) of the drug candidate Rabeximod.
- At the end of September, it could be determined that the exercise rate of the warrants TO3 corresponded to 66%, which means a capital injection of approximately 62.4 MSEK before issue costs.

Significant events after the end of the period

- In November, the company's Board of Directors announced the decision to find a new CEO. Ola Skanung, CFO, acts as interim CEO effective immediately while the recruitment process to meet new CEO is ongoing.

## Chairman of the Board Bert Junno comments

Earlier this week, the Board of Cyxone resolved to appoint a new CEO. The company has in a relatively short time developed from an early stage research company to the promising clinical development company it is today. Combined with the recently completed capital increase, we are well positioned toward our bigger ambitions and the next phase for the company. With the team we have in place, our planned activities and projects will progress at the same time as the recruitment process to find a new CEO. If we regress to a summary of this year's third quarter, we see the milestones that we have achieved with our two drug candidates in focus; successful clinical study results with T20K, submitted applications for phase 2b study with Rabeximod and a positive outcome of TO3 that points to a high level of commitment and trust from our shareholders. It has been an intense year, but we also see the results that the company's efforts lead to in the steps taken towards the goal of being able to offer new effective and safe drugs that can improve the quality of life for those affected by autoimmune diseases.

## Positive outcome of TO3

Once the outcome of the series 3 warrants was completed, it was revealed that 66% of the warrants had been exercised bringing in 62.4 million SEK to the company. These will come in good use for driving Rabeximod through both toxicology studies and into phase 2b studies as well as taking T20K further in the oral development program. We are grateful for the confidence shown in us and the opportunity to continue to push Cyxone's two candidates toward the next stage of development.

## Plans for T20K

In July, we announced that the clinical phase 1 trial with drug candidate T20K successfully achieved its goal of confirming T20K's safety and tolerability in humans. There were also no reports of serious adverse events. In other words, this is now a closed chapter and the next step working to develop an oral formulation for T20K has already started. Discussions with experts and potential partners have been conducted to identify the best way to formulate T20K into a tablet or capsule form. Once T20K has been prepared in an oral formulation, a further phase 1 clinical trial is planned to confirm the safety and tolerability in humans with the new substance.

## Development of the phase 2b study with Rabeximod

We were able to announce in July that we have reached so far in the work that we were able to submit the first of up to nine applications for permits to initiate a clinical phase 2b trial with Rabeximod. The plan is to conduct a multicenter study in a number of Eastern and Western European countries, which requires coordinated work with good partners since each country has its own application process. Mutual for the different countries is, however, that the assessment is carried out by a national ethics committee as well as approval by the respective competent authority. At the time of writing, we have received positive responses from ethical committees in two countries and are either preparing supplementary material or awaiting response to move the process forward. The documentation for the respective competent authority is called an IMPD, Investigational Medicinal Product Dossier, and must contain all the details of the study and is now in the final stages to be completed. It is thanks to our

dedicated and committed team that these processes have been able to run as expected in recent months.

The two bigger nearest milestones in the project, in addition to the permit process, is the execution of a six-month toxicology study in two animal species that the authorities require, and the capsulation of the GMP quality Rabeximod substance that was included in the acquisition of the project from OxyPharma.

### Orphan Drug Designation exploration of Rabeximod

A parallel track that is being evaluated is the possibility of an Orphan Drug Designation (ODD) for Rabeximod. We have seen a big trend for a while, where the interest in orphan drugs and all its benefits has increased. Therefore, the decision to explore an Orphan Drug Designation for Rabeximod is very interesting.

### Presence in Switzerland

With our wholly owned subsidiary in Basel, Switzerland, a major step was taken towards increasing the company's exposure to pharmaceutical companies as well as long term investors this summer. Another initiative in Switzerland during the quarter was the company's participation in the 'Biotech in Europe Forum' organized by the industry-renowned Sachs Associates. A very interesting conference focusing on investments and partnering where business developers from pharmaceutical companies and representatives from investment funds make up the majority of participants. We received attention from international parties that we might not otherwise have come in contact with, which meant that it was time well spent.

Thank you for the support and the commitment you show Cyxone.

Follow our news and information about our presence at investment events via Nasdaq First North and the company's website: www.cyxone.com

Bert Junno
Chairman of the Board, Cyxone AB

## Disclaimer

This is a translation of the original Swedish version of the interim report. In case of any discrepancy between this translation and the Swedish original, the latter shall prevail.

## Cyxone AB

### Operations

Cyxone AB is a clinical biotech company with a portfolio of immunomodulating drugs for the treatment of autoimmune diseases such as multiple sclerosis (MS) and rheumatoid arthritis (RA). The company's drug portfolio is based on two technological in the form of oral molecules and cyclotide-based drugs that inhibit key processes in the body's cells that are typically associated with various immune-related disorders. Cyxone's technologies have the potential to address an unmet need to develop new effective and safe medicines that can improve the quality of life for patients affected by autoimmune diseases. The company's development portfolio comprises Rabeximod in a clinical phase II program for RA and T20K that soon will enter clinical phase I for MS. The company continues to develop its strategy to maximize the opportunities within autoimmune diseases with the existing portfolio and potentially open to in-licensing of other suitable substances.

### The cyclotide technology

Cyclotides are considered to be an ideal "template" to develop novel drugs because of their good oral availability, excellent biological stability and for the high number of new structures that can be created. Cyclotides can potentially become a new class of highly specific, low toxicity drugs for several immune-related diseases and cancer. Cyclotides may be changed, while the original cyclotide structure is kept, in order to develop new substances with interesting pharmaceutical characteristics for selected diseases. This provides Cyxone with a great opportunity to build a diversified product portfolio over time.

### Thought-through portfolio strategy – Acquisition of Rabeximod

Cyxone was founded with a long-term vision of establishing itself as a clinical phase company within autoimmune diseases with a world class portfolio. The risk-minimizing strategy ensures not only continuous development of the company's value, but also strengthens the negotiation opportunities with potential partners. The work reached its peak in 2017, when Cyxone entered an acquisition agreement with OxyPharma over the drug candidate Rabeximod in clinical phase II for rheumatoid arthritis (RA). The deal included an arrangement that the company could choose to decide when the transaction would be completed, and payment paid under specific conditions, which took place in June 2018. Rabeximod belongs to a new class of molecules that have shown a statistically significant therapeutic effect in a placebo-controlled phase II study within RA, which included more than 200 patients. The acquisition of the candidate meant a great organizational change of the company, which went from a pre-clinical company to a company in clinical development phase with several candidates within autoimmune diseases. The acquisition of Rabeximod is, therefore, one of the most important milestones for Cyxone since its foundation.

### Business strategy

Cyxone is a resource efficient company, built by an international network of specialists, focused on developing drugs that inhibit key processes in the body's cells, which are typical

for severe immune-related disorders. The company focuses on developing a diversified development portfolio in autoimmune diseases through a virtually constructed organization, where expertise and leading collaboration partners within their areas of research and development are taken in when needed, to work both time and cost effectively. Since Cyxone acts as a principal instead of building its own laboratory, the company has low fixed costs and a flexible and agile way of working. With a wide network of universities and pharmaceutical companies, promising substances can be in-licensed at an early development phase, develop to clinical phase III and later out-licensed to resourceful pharmaceutical companies for continued phase III development and commercialization.

Cyxone's management has many years of experience in leading virtual drug development within autoimmune diseases, and the company's board has solid experience leading academic research to public development companies and providing strategic management of companies in the various phases of the development process. Members of the Cyxone board also have great expertise in negotiating license and cooperation agreements between small development companies and big pharmaceutical companies.

## Aims

The overarching aim of the company is to develop novel pharmaceutical drugs that significantly can improve quality of life for patients with severe autoimmune diseases. Today's available drugs can reduce disease symptoms but are often associated with serious side effects that limit long term usage. Thus, there is a great need for new effective drugs with less severe and fewer side effects and, in best case can prevent autoimmune diseases, in order to offer those affected an improved quality of life. This is the core of Cyxone's driving force.

As a business strategy, Cyxone works with a wide network of universities and pharmaceutical companies to in-license promising substances in early development phase, develop the substances up to phase III, and then out-license to a resourceful pharmaceutical company for phase III development and commercialization. The company's existing development portfolio comprises Rabeximod in clinical phase II program for RA and T20K that will soon enter clinical phase I for MS. In the future, Cyxone will also use its cyclotide technology to develop new structures that may benefit patients in other areas of disease.

The drug candidate T20K has soon passed the preclinical research stage, which shortens time to value-increasing events such as clinical trials scheduled to begin in 2018. The properties of T20K shown in cell and animal studies have the potential to develop the substance into a breakthrough product to treat MS patients in different disease states.

The drug candidate Rabeximod has previously undergone a phase IIb clinical trial with a confirmed effect and safety profile but failed to meet significant effect due to short study time. A new clinical phase IIb study with longer study time is planned, which is expected to start as soon as financing is in place.

## Vision

Cyxone's vision is to address an unmet medical need by developing new effective and safe drugs that can improve the quality of life for patients affected by autoimmune diseases.

## The share

The company was established on July 13, 2015. Shares in the company have been traded since June 7, 2016 on the Nasdaq First North Growth Market stock exchange with ticker CYXO. The company's Certified Adviser on the Nasdaq First North Growth Market is Mangold Fondkommission AB, telephone +46 (0)8-503 015 50 and e-mail ca@mangold.se.

## Changes in share capital

| Year | Event | Increase in share capital (SEK) | Total share capital (SEK) | Change in number of shares | Total number of shares | Quota value (SEK) |
|---|---|---|---|---|---|---|
| 2015 | Formation of company | 50 000 | 50 000 | 500 | 500 | 100 |
| 2015 | Shaer issue for patent work | 450 000 | 500 000 | 4 500 | 5 000 | 100 |
| 2015 | Split (1:1 000) | - | 500 000 | 4 995 000 | 5 000 000 | 0,1 |
| 2016 | Split (1000:1 325) | - | 500 000 | 1 625 000 | 6 625 000 | 0,075 |
| 2016 | Share issue | 98 113 | 598 113 | 1 300 000 | 7 925 000 | 0,075 |
| 2016 | Share issue (First North Listing) | 377 358 | 975 472 | 5 000 000 | 12 925 000 | 0,075 |
| 2017 | Issue TO1 | 181 584 | 1 157 056 | 2 405 992 | 15 330 992 | 0,075 |
| 2017 | Issue TO2 | 186 198 | 1 343 254 | 2 467 119 | 17 798 111 | 0,075 |
| 2018 | Cash issue | 144 632 | 1 487 886 | 1 916 372 | 19 714 483 | 0,075 |
| 2018 | Share issue and issue of TO3 | 1 339 098 | 2 826 984 | 17 743 034 | 37 457 517 | 0,075 |

## Shares and share capital

The total number of shares in Cyxone is, as of September 30th, 2019, 37,457,517 and share capital amounts to SEK 2,826,983.99. On October 2nd, 2019, new shares were registered through option rights. The number of shares amounts to 49,080,380 and share capital to SEK 3,704,181.68 after the registration.

## Principles for the preparation of this interim report

The company applies the Swedish Annual Accounts Act (1995:1554) and the Accounting Standards Board 2012:1 Annual report and consolidated reporting (K3).

## Group, parent company and subsidiary

The company is a parent company, but with reference to the exception in the Swedish Annual Accounts Act (1995:1554), chapter 7, section 3a, no consolidated accounts are prepared.

## Additional information

Capitalization of development costs is registered in the company's balance sheets. Due to changes in K3 accounting recommendations, from 2016, a reserve corresponding to capitalized development costs will be made to restricted equity from unrestricted equity.

## Auditing

The company's auditors have not formally reviewed this report.

## Upcoming financial reports

February 14th, 2020 Year-end Report, 2019

## Submission of interim report

Malmö
November 15th, 2019

The Board of Directors
Cyxone AB

## Contact

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This contains such information that Cyxone AB is required to make public under the EU's Market Abuse Regulation. The information was provided under the auspices of the above contact person for publication on November 15, 2019 at 08.55 CET.

*This report contains forward-looking statements that constitute subjective estimates and forecasts about the future. Assessments about the future are only valid on the date they are made and are, by their nature, similar to research and development work in the biotech field, associated with risk and uncertainty. In light of this, actual outcomes may differ substantially from what is described in this press release.*

## About Cyxone

Cyxone AB is a clinical stage biotech company with a portfolio of immunomodulating drugs for the treatment of autoimmune diseases such as multiple sclerosis (MS) and rheumatoid arthritis (RA). The company's drug portfolio is based on two technological pillars in the form of oral molecules and cyclotide-based drugs that inhibit key processes in the body's cells that are typically associated with various immune-related disorders. Cyxone's technologies have the potential to address an unmet need and provide new effective and safe medicines that can improve the quality of life for patients affected by autoimmune diseases. The company has two drug candidates, T20K for MS in a preclinical program and Rabeximod for RA in clinical phase II-program. Cyxone's Certified Adviser on the Nasdaq First North Growth Market is Mangold Fondkommission AB, telephone +46 (0)8-503 015 50 and e-mail ca@mangold.se.
www.cyxone.com

## Income statement in summary
KSEK

| | 2019-07-01 2019-09-30 | 2018-07-01 2018-09-30 | 2019-01-01 2019-09-30 | 2018-01-01 2018-09-30 | 2018-01-01 2018-12-31 |
|---|---|---|---|---|---|
| Operating income | 0 | 0 | 0 | 0 | 0 |
| Other income | 0 | 0 | 36 | 0 | 1 |
| **Total operating income** | **0** | **0** | **36** | **0** | **1** |
| Operating costs | 0 | 0 | 0 | 0 | 0 |
| Other external costs | -4 138 | -3 711 | -11 122 | -9 360 | -12 893 |
| Personnel costs | -1 477 | -562 | -3 443 | -1 417 | -2 231 |
| Depreciation and amortisation of fixed assets | -78 | -101 | -235 | -112 | -311 |
| Other variable costs | 0 | 0 | 0 | 0 | 0 |
| **Total operating costs** | **-5 693** | **-4 374** | **-14 800** | **-10 889** | **-15 435** |
| **Operating result** | **-5 693** | **-4 374** | **-14 764** | **-10 889** | **-15 434** |
| Income from financial investments | 0 | 0 | 0 | 0 | 0 |
| Other financial income | 0 | 0 | 0 | 0 | 0 |
| Financial costs | -72 | -16 | -130 | -4 | 0 |
| **Total income from financial investments** | **-72** | **-16** | **-130** | **-4** | **0** |
| **Income after financial items** | **-5 765** | **-4 390** | **-14 894** | **-10 893** | **-15 434** |
| **Income for the period** | **-5 765** | **-4 390** | **-14 894** | **-10 893** | **-15 434** |

## Balance sheet in summary
KSEK

| | 2019-09-30 | 2018-09-30 | 2018-12-31 |
|---|---|---|---|
| **Assets** | | | |
| | | | |
| **Fixed assets** | | | |
| Intangible assets | | | |
| Capitalised development costs | 39 988 | 24 557 | 29 870 |
| Patents, licenses and similiar rights | 6 333 | 6 248 | 6 532 |
| | | | |
| **Total intangible assets** | **46 321** | **30 805** | **36 402** |
| | | | |
| Financial assets | | | |
| Shares in group companies | 955 | 0 | 0 |
| | | | |
| **Total financial assets** | **955** | **0** | **0** |
| | | | |
| **Total fixed assets** | **47 276** | **30 805** | **36 402** |
| | | | |
| **Current assets** | | | |
| Receivables | | | |
| Accounts receivable | 0 | 0 | 2 |
| Other current receivables | 312 | 194 | 291 |
| Pre-payments and accrued income | 169 | 1 449 | 259 |
| | | | |
| **Total current receivables** | **481** | **1 643** | **552** |
| | | | |
| Cash and bank balances | 12 307 | 10 478 | 38 716 |
| | | | |
| **Total current assets** | **12 788** | **12 121** | **39 268** |
| | | | |
| **Total assets** | **60 064** | **42 926** | **75 670** |

| | 2019-09-30 | 2018-09-30 | 2018-12-31 |
|---|---|---|---|
| **Equity and liability** | | | |
| | | | |
| **Equity** | | | |
| Restricted equity | | | |
| Share capital | 2 827 | 1 488 | 2 827 |
| Reserve for capitalised development costs | 39 988 | 24 557 | 29 870 |
| **Total restricted equity** | **42 815** | **26 045** | **32 697** |
| | | | |
| Unrestricted equity | | | |
| Other unrestricted equity | 27 734 | 23 773 | 53 286 |
| Net loss | -14 894 | -10 893 | -15 434 |
| **Total unrestricted equity** | **12 840** | **12 880** | **37 852** |
| | | | |
| **Total equity** | **55 655** | **38 925** | **70 549** |
| | | | |
| **Current liabilities** | | | |
| Trade payables | 2 935 | 2 283 | 4 026 |
| Current tax liabilities | 0 | 77 | 49 |
| Other current liabilities | 182 | 83 | 158 |
| Accrued costs and deferred income | 1 292 | 1 558 | 888 |
| **Total current liabilities** | **4 409** | **4 001** | **5 121** |
| | | | |
| **Total equity and liabilities** | **60 064** | **42 926** | **75 670** |
| | | | |
| Pledged assets (KSEK) | 0 | 0 | 0 |
| | | | |
| Contingent liabilities (KSEK) | 0 | 0 | 0 |

## Equity changes in summary
KSEK
1 January to 30 September 2019

| | Share capital | Reserve for development costs | Other unrestricted equity | Result for the period | Total unrestricted capital | Total equity |
|---|---|---|---|---|---|---|
| Balance at beginning of period | 2 827 | 29 870 | 53 286 | -15 434 | 37 852 | 70 549 |
| Allocation of this year's earnings | | | -15 434 | 15 434 | 0 | 0 |
| Transfer of development cost reserve | | 10 118 | -10 118 | | -10 118 | 0 |
| Result for the period | | | | -14 894 | -14 894 | -14 894 |
| **Balance at the end of the period** | **2 827** | **39 988** | **27 734** | **-14 894** | **12 840** | **55 655** |

## Cashflow statement in summary

| KSEK | 2019-07-01<br>2019-09-30 | 2018-07-01<br>2018-09-30 | 2019-01-01<br>2019-09-30 | 2018-01-01<br>2018-09-30 | 2018-01-01<br>2018-12-31 |
|---|---|---|---|---|---|
| Cashflow from operations | -5 687 | -4 289 | -14 659 | -10 781 | -15 123 |
| Changes in operating capital | 706 | 265 | -641 | -1 432 | 779 |
| **Total cash flow from operations** | **-4 981** | **-4 024** | **-15 300** | **-12 213** | **-14 344** |
| Cash flow from investment activities | -6 584 | -16 001 | -11 109 | -23 352 | -29 148 |
| Cash flow from financing activities | 0 | 12 686 | 0 | 12 686 | 48 851 |
| **Total cash flow from the period** | **-11 565** | **-7 339** | **-26 409** | **-22 879** | **5 359** |
| Cash and cash equivalents at the beginning of the period | 23 872 | 17 817 | 38 716 | 33 357 | 33 357 |
| Cash and cash equivalents at the end of the period | 12 307 | 10 478 | 12 307 | 10 478 | 38 716 |
| **Change in cash and cash equivalents** | **-11 565** | **-7 339** | **-26 409** | **-22 879** | **5 359** |

## Key figures

| | 2019-07-01<br>2019-09-30 | 2018-07-01<br>2018-09-30 | 2019-01-01<br>2019-09-30 | 2018-01-01<br>2018-09-30 | 2018-01-01<br>2018-12-31 |
|---|---|---|---|---|---|
| Net sales (KSEK) | 0 | 0 | 0 | 0 | 0 |
| Profit after financial items (KSEK) | -5 765 | -4 390 | -14 894 | -10 893 | -15 434 |
| Total assets (KSEK) | 60 064 | 42 926 | 60 064 | 42 926 | 75 670 |
| Equity (%) * | 92,7 | 90,7 | 92,7 | 90,7 | 93,2 |
| Earnings per share CB (SEK) * | -0,15 | -0,22 | -0,40 | -0,55 | -0,41 |
| Earnings per share OB (SEK) * | -0,15 | -0,25 | -0,40 | -0,61 | -0,87 |
| Number of shares CB | 37 457 517 | 19 714 483 | 37 457 517 | 19 714 483 | 37 457 517 |
| Number of shares OB | 37 457 517 | 17 798 111 | 37 457 517 | 17 798 111 | 17 798 111 |
| Average number of shares | 37 457 517 | 18 756 297 | 37 457 517 | 18 756 297 | 27 627 814 |

* Definitions of key figures

Equity ratio, adjusted equity in percentage of total assets

Earnings per share CB, earnings diluted by number of shares, Closing Balance, at the end of the period.

Earnings per share OB, diluted by number of shares, Opening Balance, at the beginning of the period (SEK).