KAROLINSKA DEVELOPMENT

INTERIM REPORT
**Jan – Sep 2020**

Q3

# Karolinska Development

Karolinska Development (Nasdaq Stockholm: KDEV) is an investment company which offers a unique opportunity to share in the growth in value of a number of Nordic life sciences companies with high commercial potential. Eight of the ten portfolio companies have candidate drugs in ongoing clinical studies or approved products in early commercial phase. Two of the portfolio companies are expected to present clinical phase II and III results during the remainder of 2020 and the beginning of 2021, offering the potential for substantially increased opportunities for attractive divestments or licensing deals. Comparable candidate drugs have, in recent years, been out-licensed or sold for contract values in the billions of kronor range for the individual projects.

For further information, see www.karolinskadevelopment.com

# Financial Update

- The net profit/loss for the third quarter was SEK -169.4 million (SEK -14.6 million in the third quarter of 2019). Earnings per share totalled SEK -1.0 (SEK -0.2 in the third quarter of 2019). Net profit/loss for the period January – September 2020 amounted to SEK -293.4 (-25.8) million.
- The result of the Change in fair value of shares in portfolio companies for the third quarter amounted to SEK -173.9 million (SEK 10.4 in the third quarter of 2019). The result was largely attributable to the downturn in share price of the listed holding Aprea Therapeutics. The result of the Change in fair value of shares in portfolio companies for the period January – September 2020 amounted to SEK -289.2 (415.1) million.
- The total fair value of the portfolio was SEK 1,024.1 million at the end of September 2020, corresponding to a decrease of SEK 307.7 million from SEK 1,331.8 million at the end of the previous quarter. The net portfolio fair value at that time was SEK 675.8 million, corresponding to a decrease of SEK 209.5 million from SEK 885.2 million at the end of the previous quarter.
- Net sales totalled SEK 0.4 million during the third quarter of 2020 (SEK 0.7 million during the third quarter of 2019). Net sales for the period January – September 2020 totalled SEK 2.1 (2.7) million.
- Karolinska Development invested a total of SEK 4.0 million in portfolio companies during the third quarter. Third quarter investments in portfolio companies by Karolinska Development and other specialised life sciences investors totalled SEK 29.1 million.
- Cash and cash equivalents increased by SEK 25.0 million during the third quarter, totalling SEK 71.1 million on 30 September 2020.
- The Parent Company equity totalled SEK 714.4 million on 30 September 2020.

# Significant events during the third quarter

- Karolinska Development sold part of its holding in the portfolio company Aprea Therapeutics. KCIF Co-investment Fund KB – a holding company that is jointly owned by the European Investment Fund and Karolinska Development – divested shares in Aprea as part of the same transaction. The transaction accounted for a total of 1% of all outstanding shares in Aprea and yielded a net total of approximately SEK 39 million for Karolinska Development. Karolinska Development retains an unchanged indirect holding in Aprea through KDev Investment after the transaction, comprising approximately 9.5% of the total number of shares outstanding (July 2020).
- Aprea Therapeutics decided to expand the enrolment of patients in its clinical phase 1 study evaluating eprenetapopt in TP53-mutant acute myeloid leukaemia (AML). Once the study's initial safety evaluation has been completed, the first expansion cohort will evaluate a combination of eprenetapopt with venetoclax and azacitidine in front line treatment of TP53-mutant AML (July 2020).
- Karolinska Development's Chairman of the Board, Hans Wigzell, resigned his position for personal reasons. The process of appointing a new Chairman has been initiated (August 2020).
- The portfolio company, OssDsign presented positive interim results from a study in which patients with bone defects in the oral cavity were treated with the company's patented calcium phosphate material. It is thought that this will open up opportunities for OssDsign's implant technology in new indication areas (August 2020).
- Magnus Persson left his position as a Member of the Board of Karolinska Development at his own request, due to his role as a founding partner in Eir Ventures, a recently started fund for investments in the life science sector (August 2020).
- The portfolio company, Promimic, announced that the company's partner, INNOVASIS Inc., had received a 501(k) FDA clearance for a 3D-printed spinal implant. The implant, which will be the first of its kind on the market, is treated using Promimic's bioactive HA$^{nano}$ Surface® technology that improves the integration process and stimulates new bone formation and bone ongrowth to the implant (August 2020).
- The portfolio company, Umecrine Cognition, announced that it will present the results of the recently conducted clinical phase IIa study of the candidate drug, golexanolone, at The Liver Meeting Digital Experience™ 2020 on November 13-16, 2020. Golexanolone is being developed for the treatment of hepatic encephalopathy (HE) (September 2020).
- Karolinska Development announced that the company's CFO and Deputy CEO, Fredrik Järrsten, has resigned from his position with the company. He will remain in his current role until a successor has been appointed, but no later than 7 March 2021 (September 2020).
- The portfolio company, OssDsign, has received a notice of allowance from the USA Patent and Trademarks Office for a patent related to the design of the company's Cranial PSI product. The notice of allowance strengthens the patent protection for OssDsign's technology in the company's most important geographical market (September 2020).
- Karolinska Development announced that the company's result for the third quarter of 2020 will be negatively affected by approximately SEK 190 million as a result of the recent share price development in the listed portfolio company, Aprea Therapeutics. The effect on the result will have no effect on Karolinska Development's cash flow (September 2020).

# Significant post-period events

- The US Food and Drug Administration (FDA) accepted Aprea Therapeutics' Investigational New Drug (IND) application for its novel candidate drug, APR-548, to treat TP53-mutant myelodysplastic syndrome (MDS). APR-548 is a next-generation reactivator of mutant p53 and is being developed for oral administration (October 2020).
- A scientific article describing the portfolio company OssDsign's unique regenerative implants has been published in the reputable scientific journal PNAS (Proceedings of the National Academy of Sciences of the United States). The article describes how OssDsign's implant concept and patented material composition contribute to bone regeneration and adhesion with existing bone (October 2020).
- The portfolio company OssDsign has acquired the bone graft substitute company Sirakoss Ltd. The acquisition, which is expected to immediately provide OssDsign with a five times larger addressable market, is partly financed by a heavily over-subscribed directed share issue of approximately SEK 65 million before transaction costs. A large number of Swedish and international investors took part in the issue (November 2020).

## Viktor Drvota, CEO of Karolinska Development, comments:

"Several of our portfolio companies have reported new advances during the past quarter and we are now looking forward with great anticipation to clinical results from Aprea, Dilafor and Forendo Pharma, which are scheduled for presentation at the end of this year or the beginning of 2021. It will, of course, be particularly interesting to see Aprea's topline results from the phase 3 study of eprenetapopt, which is the candidate drug closest to market registration and which has the potential to revolutionise the treatment of the deadly cancer, myelodysplastic syndrome."

## Contact information

For further information, please contact:

**Viktor Drvota,** Chief Executive Officer
+46 73 982 52 02
viktor.drvota@karolinskadevelopment.com

**Fredrik Järrsten,** Chief Financial Officer and deputy CEO
+46 70 496 46 28
fredrik.jarrsten@karolinskadevelopment.com

# Chief Executive's Report

## Negative earnings but positive cashflow

The share price development of the listed portfolio company, Aprea Therapeutics, during the quarter has affected the value of our holding and had a negative impact on the result of approximately SEK 190 million. This is the primary reason for the decline in earnings from levels in the previous quarter. A negative effect on the result due to a change in the value of a holding is, however, an unrealised loss, and it consequently has no negative effect on our cashflow. In fact, we reported a positive cashflow during the quarter due to the partial sale of shares in Aprea conducted in July which yielded a net of approximately SEK 39 million. This provided a welcome boost to our cash position, which totalled around SEK 71 million as of 30 September. A bridge loan for SEK 70 million that was originally scheduled to mature on 31 December 2020 was, furthermore, extended during the quarter and will now mature on 31 December 2021. Collectively, these measures give the company the stability and scope it needs to continue working with a number of financing alternatives that will secure our long-term capital requirement and thereby increase the degree of strategic and operational headroom for the future.

## Long-term engagement in Aprea Therapeutics bears fruit

Last summer, Aprea Therapeutics decided, once the study's initial safety evaluation was completed, to expand the enrolment of patients in its clinical phase I study of eprenetapopt in order to evaluate the candidate drug in combination with venetoclax and azacitidine as a front-line treatment of TP53-mutant acute myelodysplastic syndrome (AML). Aprea is also, in parallel with this work, conducting a phase III study of eprenetapopt in patients with myelodysplastic syndrome (MDS), and expects to present the topline results before the end of the year. The US Food and Drugs Administration (FDA) has previously announced that an application can be made in accordance with the Breakthrough Therapy Designation rules, which would entail an abbreviated registration process for the candidate drug.

The FDA also announced, after the end of the reporting period, that it had approved an application to start clinical trials of another of Aprea Therapeutics' candidate drugs, APR-548, which is being developed for oral administration. This approval further strengthens the company's position in the development of new pharmaceuticals for patients with p53-mutant cancer.

Karolinska Development was one of the earliest investors in Aprea Therapeutics – a company which, based on its unique candidate drugs for intractable types of cancer, has now progressed all the way from academic research at the Karolinska Institute to a NASDAQ listing in New York. Our long-term engagement has resulted in the creation of a company of which we can be proud. The development in the value of our holding has been positive and we have continued to realise part of this value over the past quarter.

## Umecrine Cognition presents study results at international liver conference

The portfolio company, Umecrine Cognition, will be presenting the results of its recently conducted clinical phase IIa study of the candidate drug, golexanolone, at The Liver Meeting Digital Experience™ 2020 in just a few days' time. The company's presentation has been selected as a *Poster of Distinction* at this highly prestigious scientific conference, in what is a clear quality mark for the presentation that will result in increased international attention. Golexanolone is being developed for the treatment of hepatic encephalopathy (HE) and has been shown to have a significant effect on the brain's signalling ability in a well-established and sensitive form of EEG examination. This effect correlates well with a reduction in daytime fatigue in the patients under treatment. Extreme daytime fatigue is a highly intractable symptom of

HE, but also occurs in a number of other CNS-related conditions, such as Alzheimer's disease and schizophrenia, and severely limits the patients' quality of life. A comprehensive programme is now being conducted with a view to adapting golexaolone's development strategy, going forward, in the light of these positive results.

## OssDsign expands its addressable market through in-house development and a strategic acquisition

In August, OssDsign reported positive interim results from a clinical study in which patients with bone defects in the oral cavity were treated with the company's patient calcium phosphate material. This is expected to open up opportunities for the use of OssDsign's implant technology in new indication areas. One month later, the company received a notice of allowance from the US Patient and Trademarks Office for a patent related to the design of the Cranial PSI product, resulting in stronger patent protection for their technology in the world's biggest market for implant products. After the end of the reporting period, an important strategic acquisition was made of Sikaross - a company active in bone graft substitutes. This is expected to cause OssDsign's addressable market to immediately increase fivefold. The acquisition was part-financed through a heavily oversubscribed directed share issue to a large number of Swedish and international investors. Karolinska Development is one of the biggest owners in the company, which has been listed on NASDAQ First North since last year.

## FDA approval for implant treated with unique surface from Promimic

During the past quarter, Promimic's partner, INNOVASIS Inc., received FDA clearance for a 3D-printed spinal implant. The implant, which will be the first of its kind on the market, is treated with Promimic's HA$^{nano}$ Surface® technology to improve the integration process and stimulate new bone formation and ongrowth to the implant. Promimic has established its own sales operations in the USA and has entered into a number of partnerships for the development and commercialisation of its technology. The company is focusing on the dental and orthopaedic implant markets which, collectively, are estimated to represent a global market opportunity worth USD 600-800 million.

## Changes in the organisation

The past quarter has seen changes in the board and in the company management. Hans Wigzell, who has been with the company since the start in 2003, decided to step down from his position as Chairman of the Board, while Magnus Persson resigned his seat on the Board due to his engagement in a newly-founded life science fund. The process of appointing a new Chairman of the Board is now underway and we have also initiated the recruitment of a successor for our CFO and Deputy CEO, Fredrik Järrsten, who after numerous dedicated and successful contributions, has decided to move on to an equivalent position in another life science company. Fredrik will remain in his current position until a successor has been appointed, but no later than 7 March 2021.

## Results of three clinical studies expected within six months

Overall, we note that several of our portfolio companies have reported new advances during the past quarter and that our operations have not been affected to any significant degree by the ongoing COVID-19 pandemic. We are now continuing to work tirelessly to support our portfolio companies' ongoing development, to identify new investment opportunities, and to further strengthen our financial position. We expect clinical results from three portfolio companies – Dilafor, Forendo Pharma, and Aprea Therapeutics – towards the end of this year or early next year. Successful clinical studies by these companies may result in substantial increases in the value of our holdings and it will, of course, be particularly interesting to see Aprea's topline results from the phase III study of eprenetapopt, which is the candidate drug closest to

market registration and which has the potential to revolutionise the treatment of the deadly cancer, myelodysplastic syndrome.

Solna, 11 November 2020

Viktor Drvota
Chief Executive Officer

# Portfolio Companies

## A Focused Portfolio with High Commercial Potential

Karolinska Development's investments in therapeutic companies are conducted in syndicates with other professional life science investors until proof-of-concept is demonstrated in Phase II trials, at which point different exit options are evaluated. For medtech companies, the business model is to finance the companies beyond break-even before realizing the investments.

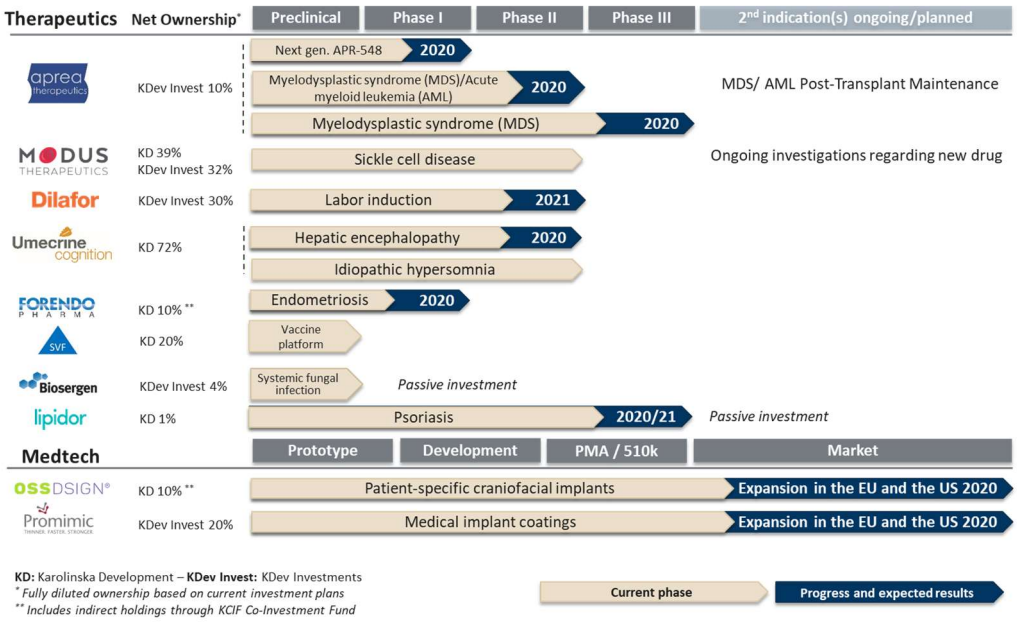
Karolinska Development has a focused portfolio of therapeutic and medtech companies with significant value-generating potential. The portfolio companies are developing highly differentiated and commercially attractive products that have the potential to deliver compelling clinical and health economic benefits, as well as attractive returns on investment.

During the past years, Karolinska Development has optimized the clinical programs of the portfolio companies to reach clinically meaningful value-inflection points. Experienced leadership has been recruited to the management and boards of the portfolio companies. Furthermore, Karolinska Development has supported the financing of the portfolio companies through syndication with experienced international and domestic professional life science investors. As a result, several of Karolinska Development's portfolio companies now are financed and well positioned to deliver key value-generating clinical or commercial milestones.

The therapeutics companies' next key value-generating milestones are expected during the remainder of 2020 and the beginning of 2021, when two of the companies (Aprea and Dilafor) are supposed to present Phase II proof-of-concept data and Phase III data. Forendo is expected to be able to present results from a phase Ib study at the end of 2020. The medtech companies OssDsign and Promimic are revenue generating and have significant milestones mapped out in 2020 regarding execution of their commercial strategies.

In addition to its active value creation in eight portfolio companies, Karolinska Development has passive investments in two portfolio companies and retained economic interests in the form of earn out-agreements in additionally three life science companies.

### Our current portfolio – potential for value-inflection




### Earn-out agreements

**Project (First-in class)**
APR-246

**Primary indication**
MDS

**Development Phase**
Phase III

**Holding in company***
KDev Investments 9.5%

**Other investors**
Redmile Group,
Rock Springs Capital,
Versant Ventures,
5AM Ventures,
HealthCap,
Sectoral Asset Management,
KCIF Co-Investment Fund KB

**Origin**
Karolinska Institutet

**More information**
aprea.com

** Fully-diluted ownership based on current investment plans.*

**Deal values for similar projects**

- USD 469 million MEI Pharma (licensor) & Helsinn Group (licensee) 2016
- USD 483 million Calithera Biosciences (licensor) & Incyte (licensee) 2017

# Aprea Therapeutics AB

## Unique approach to treating a broad range of cancers

Aprea Therapeutics (Boston, USA and Stockholm, Sweden) is a biotech company developing novel pharmaceutical substances that target the tumour suppressor protein, p53. Mutations of the p53 gene are found in 50% of all human tumours and are often associated with drug resistance and generally poor outcomes. There is a substantial need for new therapies that combat drug resistance in the treatment of cancer, and Aprea's lead drug candidate APR-246 is a first-in-class compound that reactivates mutant p53 protein, inducing programmed cell death in cancer cells.

APR-246 is currently in a pivotal phase III study of patients with p53-mutated myelodysplastic syndrome (MDS), the results of which are expected in the second half of 2020. Positive data from a phase Ib/II study to document the safety and efficacy of the candidate drug in combination with cytostatic agents (azacitidine) in the treatment of p53-mutated MDS and AML showed that the overall response rate (ORR) of 28 evaluable MDS patients reached 75%, with a 57% complete remission (CR) rate. With a median duration of follow-up of 9.7 months, the median overall survival (OS) for all enrolled patients, as well as for the MDS patients, was 12.1 months.

The company has now started studies with APR-246 combined with azacitidine which is given to patients with p53-mutated MDS / AML subsequent to bone marrow transplantation (phase II) as well as several studies in phase I; Non Hodgkin's lymphoma with Ibrutinib or Veneoclax; treatment of solid tumors in combination with anti-PD1 therapy, and in addition, a study for AML patients in which the combination with venetoclax is evaluated. They are also working on the phase I program for the next generation of oral reactivators of p53.

Aprea has been listed on the NASDAQ Global Select Market in the USA since October 2019.

**The market**

APR-246 has the potential to be used in many cancers as mutations in p53 are found in around 50% of all diagnosed cancers. The lead target indications thus far include blood tumours as MDS and AML. MDS is an orphan disease and represents a spectrum of hematopoietic stem cell malignancies. Approximately 30-40% of MDS patients progress to AML and mutations in p53 are found in up to 20% of MDS and AML patients, which is associated with poor overall prognosis.

**Recent progress**

- Aprea Therapeutics presents positive results from a Phase Ib/II study of APR-246 and azacitidine in MDS and AML (June 2020).
- Aprea Therapeutics expands clinical trial of eprenetapopt for TP53 mutant Acute Myeloid Leukemia (July 2020).
- FDA has accepted an Investigational New Drug (IND) application for its novel drug candidate APR-548 to treat TP53 mutant MDS October 2020).

**Expected milestones**

- Result from Phase III study expected in the second half of 2020.

MODUS THERAPEUTICS

**Project (First-in-class)**
Sevuparin

**Primary indication**
Sickle cell disease (SCD)

**Development Phase**
Phase II

**Holding in company***
Karolinska Development 39%
KDev Investments 32%

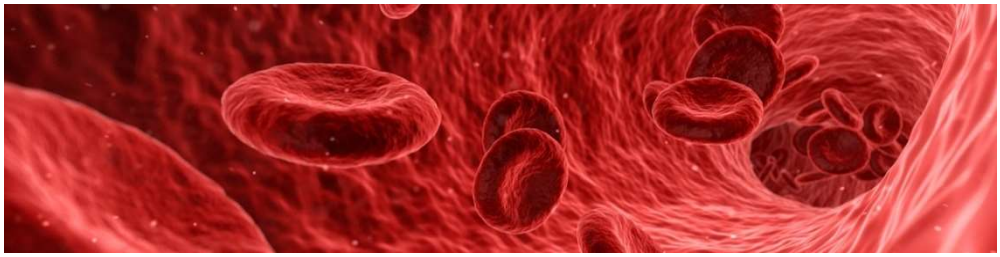
**Other investors**
The Foundation for Baltic and East European Studies, Praktikerinvest

**Origin**
Karolinska Institutet, Uppsala University

**More information**
modustx.com

**Fully-diluted ownership based on current investment plans*

# Modus Therapeutics AB



## Establishing new treatments for debilitating disease

Modus Therapeutics (Stockholm, Sweden) is developing new treatments in serious diseases. The company's patented candidate drug, sevuparin, has a multimodal mechanism of action that triggers anti-adhesive, anti-aggregate, and anti-inflammatory effects in the circulatory system.

Modus has completed a phase II study of sevuparin in patients hospitalised with sickle cell disease (SCD). The randomised, double-blinded study was conducted at study centres in Europe, the Middle East, and Caribbean, and included 144 SCD patients. The study compared intravenously (IV) administered sevuparin with a placebo in patients admitted to the hospital with an acute vaso-occlusive crisis (VOC) in conjunction with sickle cell disease. The study also assessed several pain-related secondary endpoints. Data from the study did not show a meaningful clinical effect of sevuparin in the management of acute VOC in the total study population, however, the data suggests that sevuparin, at the administered doses, is safe and well tolerated. Modus is now considering a new indication for further development of sevuparin.

**Recent progress**

- Results from Phase II trial in SCD presented and no significant efficacy was observed (May 2019).
- Modus is now considering a new indication for further development of sevuparin.

.

Dilafor

**Project (First-in-class)**
Tafoxiparin

**Primary indication**
Labor induction

**Development Phase**
Phase IIb

**Holding in company***
KDev Investments 30%

**Other investors**
The Foundation for Baltic and East European Studies,
Opocrin,
Praktikerinvest,
Rosetta Capital,
Lee's Pharmaceutical

**Origin**
Karolinska Institutet

**More information**
dilafor.com

** Fully-diluted ownership based on current investment plans.*

# Dilafor AB

## Reducing complications with childbirth

Dilafor (Solna, Sweden) is developing tafoxiparin for obstetric indications, with particular reference to protracted labour and associated complications.

About one quarter of all pregnant women undergo induction in labour. In just over half of all cases, the induction fails, leading to protracted labour that entails an increased risk for both mother and child due to medical complications. Between 25 and 40% of women who experience protracted labour eventually require an emergency caesarean section. Surgical intervention always entails not only a risk to the patient, but substantial health care costs. Tafoxiparin could eliminate patient suffering and save valuable health care resources.

Subcutaneous administration of tafoxiparin in an earlier phase IIa study showed a significantly positive effect with a shortened time to delivery and an enhanced ripening of the cervix in patients delivered after induction. A soft and ripe cervix is a prerequisite of successful labour induction. Tafoxiparin is now being evaluated in a phase IIb study with a larger patient base in order to document the effects of treatment with subcutaneously administered tafoxiparin.

**Deal values for similar projects**

- USD 397 million Velo Bio (seller) & AMAG Pharmaceuticals (buyer) 2018
- USD 465 million Palatin Technologies (licensor) & AMAG Pharmaceuticals (licensee) 2017

**The market**

Approximately one quarter of all pregnant women require labour induction. The current standard treatment includes administration of prostaglandins and oxytocin, but in over 50% of cases, the induction fails, leading to protracted labour, emergency caesarean sections, or other maternal and foetal complications.

**Recent progress**

- SEK 23,3 million raised from current investors, with the existing shareholder Opocrin S.p.A as the main investor, to fund a phase IIb study of tafoxiparin in labor induction. First patient included in the study (April and August 2019).
- Dilafor, enters into a partnership with Liverpool University to study the effects of the company's candidate drug, tafoxiparin, as a treatment for COVID-19. The candidate drug is also thought to potentially be effective in connection with certain viral infections (April 2020)

**Expected milestones**

- Result of Phase IIb study in labor induction during first quarter 2021.

Umecrine cognition

**Project (First-in-class)**
GR3027

**Primary indications**
Hepatic encephalopathy
Idiopathic hypersomnia

**Development Phase**
Phase IIa

**Holding in company***
Karolinska Development 72%

**Other investors**
Norrlandsfonden,
Fort Knox Förvaring AB,
PartnerInvest

**Origin**
Umeå University

**More information**
umecrinecognition.com

** Fully-diluted ownership based on current investment plans.*

**Deal values for similar projects**

- USD 397 million Aerial Biopharma (licensor) & Jazz Pharmaceuticals (licensee) 2014
- USD 201 million Vernalis (licensor) & Corvus Pharmaceuticals (licensee) 2015

# Umecrine Cognition AB

## Unique treatment approach for CNS-related disorders

Umecrine Cognition (Solna, Sweden) is developing golexanolone (GR3207) – a candidate drug in a new class of pharmaceuticals that affect the GABA system. An over-activation of the inhibitory GABA system in the CNS is suspected in conjunction with liver failure, causing very serious clinical symptoms. The over-activation is also thought to lay behind certain cognitive and sleep disorders. GABA-receptor modulating steroid antagonists, such as golexanolone, counter the increased activation of the GABA system and hence constitute a promising group of candidate drugs.

Golexanolone GR3027 has been shown to restore different types of neurological impairments in experimental models. The candidate drug enters the brain and works by reversing the inhibitory effects of the neurosteroid allopregnanolone on brain function in humans.

A clinical phase IIa study of the drug candidate golexanolone in patients at risk of developing hepatic encephalopathy has been performed. Results demonstrate a positive safety and tolerability profile. One predefined effect parameter – a well-established and sensitive form of EEG study – demonstrates that the candidate drug has a significant effect on brain signalling, with a correlated positive effect on excessive daytime sleepiness. This is a symptom that occurred in a series of CNS-related disorders and dramatically reduces patients' quality of life. Taken together, the study results open interesting opportunities for further development of the candidate drug.

**The market**

HE is a severe disorder with a large unmet need. In total, liver cirrhosis affects up to 1% of US and EU populations. Between 180,000 and 290,000 patients with cirrhosis in the US are hospitalized due to complications of HE. Once HE develops, mortality reaches 22-35% after five years. HE is also associated with large societal and individual costs.

**Recent progress**

- Umecrine Cognition has decided to prioritize the development of GR3027 in hepatic encephalopathy (HE) before idiopathic hypersomnia or other sleep disorders.
- Umecrine Cognition has reported positive top-line data from a clinical phase IIa study of the drug candidate golexanolone in patients at risk of developing hepatic encephalopathy has been performed. Karolinska Development will conduct an external valuation and thereafter disclose the impact on the book value of its holding.

**Going forward**

- Umecrine Cognition will present the results from its recently conducted clinical phase IIa study of the drug candidate golexanonole, that is in clinical development for hepatic encephalopathy at The Liver Meeting Digital Experience™ on November 13–16, 2020.

FORENDO PHARMA

**Project (First-in-class)**
FOR-6219

**Primary indication**
Endometriosis

**Development Phase**
Phase Ia

**Holding in company***
Karolinska Development 10%**

**Other investors**
Novo Seeds,
Novartis Venture Fund,
Merck Ventures,
Vesalius Biocapital,
Innovestor, Novartis

**Origin**
University of Turku, Finland

**More information**
forendo.com

** Fully-diluted ownership based on current investment plans*

*** Includes indirect holdings through KCIF Co-Investment Fund*

**Deal values for similar projects**

- USD 853 million Astellas (buyer) & Ogeda (seller) 2017
- USD 595 million Neurocrine Biosciences (licensor) & AbbVie (licensee) 2010

# Forendo Pharma Ltd

## Novel therapies for women's health.

Forendo (Turku and Oulu, Finland) is developing a new treatment for eliminating endometriosis while at the same time maintaining normal hormonal cycles. The company is also active in the field of hepatic disease.

Endometriosis is an oestrogen dependent disease that affects women in reproductive age and is caused by cells normally lining the uterus being present outside of the uterine cavity, which induces chronic inflammation in the surrounding tissue. The disease is manifested in many diverse ways and it often causes particularly painful menstruations or chronic pelvic pain. The existing drug therapies ameliorate the symptoms by suppressing oestrogen synthesis, but these therapies disturb the systemic oestrogen balance and are, consequently, associated with harmful side effects that limit their long-term usage. The risk of osteoporosis is, for example, well known in conjunction with oestrogen elimination therapies.

Forendo's candidate drug, FOR-6219, inhibits the HSD17B1 enzyme – a new drug target for tissue-specific regulation of hormone activity. Proof of mechanism has been demonstrated in preclinical models in which the candidate drug has been shown to block the local formation of oestrogen in the endometrium (the uterus' surface tissue). This may enable a regression of the endometriosis and relief in the associated inflammatory pain without impacting systemic oestrogen levels. A Phase Ia trial found FOR-6219 to be safe and well tolerated, with a good pharmacokinetic profile. These results support the initiation of a Phase Ib study in healthy postmenopausal women with the aim to demonstrate proof of concept, which was initiated in 2019. The results of this study are delayed due to the Corona pandemic and are expected in the end of 2020.

Forendo also has another development program, a dual HSD inhibitor for the treatment of gynaecological conditions, and which is currently in preclinical discovery phase. The company has also, since late 2019, been developing new pharmaceuticals for the treatment of chronic hepatic disease in partnership with Novartis.

**The market**

It is estimated that 10% of all fertile women are affected by endometriosis. This corresponds to a total of 176 million women in the world. Endometriosis has a detrimental effect on the well-being of the women affected and the socio-economic burden of the disease from e.g. sick leaves is profound due to the lack of safe and effective treatment. Forendo's approach to treat endometriosis therefore has a high potential to substantially impact future treatment regimens.

**Recent progress**

- EUR 5 million raised from new investor Sunstone Life Science Ventures (July 2019).
- Start of the Phase 1b study of its lead endometriosis program, FOR-6219 (August 2019).
- Novartis enters into license and collaboration agreement and invests in Forendo (December 2019).

**Expected milestones**

- Results from the Phase Ib study are expected in the end of 2020.

OSSDSIGN®

**Project**
OSSDSIGN® Cranial and OSSDSIGN® Facial

**Primary indication**
Cranial implants

**Development Phase**
Marketed

**Holding in company***
Karolinska Development 10%**

**Other investors**
SEB Venture Capital, Fouriertransform

**Origin**
Karolinska University Hospital, Uppsala University

**More information**
ossdsign.com

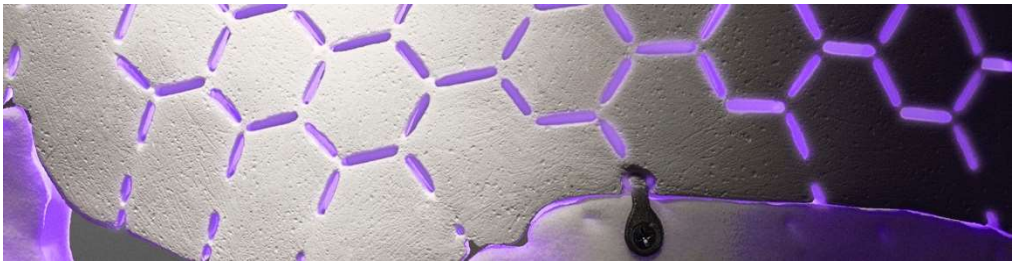
** Fully-diluted ownership based on current investment plans*

*** Includes indirect holdings through KCIF Co-Investment Fund*

**Deal values for similar projects**

- USD 330 million Baxter International (buyer) & ApaTech (seller) 2010
- USD 360 million Royal DSM (buyer) & Kensey Nash (seller) 2012

# OssDsign AB



## Commercializing the best craniofacial implants

OssDsign (Uppsala, Sweden) is an innovative company that designs and manufactures implants and material technology for bone regeneration. Its lead products, OSSDSIGN® Cranial and OSSDSIGN® Facial, are already being sold in several European markets, including Germany, the UK, and the Nordic region. The company is commercialising its cranial implant in the USA and is also undertaking regulatory and commercial activities in Japan.

OssDsign is working to build sales of the company's products through a combination of an internal sales organisation and close collaborations with distribution partners. A US subsidiary has been established to strengthen the company's presence in the market there and to enable additional, long-term, sound customer relationships.

OssDsign's clinically proven bone regeneration technology has better healing properties than similar products. The company uses cutting edge 3D printing, moulding, and regenerative medicine technology to customise solutions for individual patients. The result is a patient-specific, titanium-reinforced implant made from a ceramic material with regenerative properties that accelerates the natural tissue formation and enables permanent healing of a bone defects. The regenerative effect of the ceramic material helps ensure a shorter healing process and entails both reduced suffering for the patient and cost savings for hospitals.

### The market

OssDsign focuses on the market for craniomaxillofacial (CMF) implants. The total market size was estimated to USD 1.8 billion in 2016 and is expected to grow at an CAGR of 5-9% worldwide over the next five years. The market for OssDsign's lead product in cranioplasty alone is estimated to approximately USD 200 million. OssDsign's products target a well-defined patient population – the relevant type of operation is performed at a limited – and easily identifiable – number of hospitals worldwide. The price sensitivity is low, and the products are relatively easy to register in multiple markets.

### Recent progress

- Launch in Japan of OSSDSIGN® Cranial following regulatory approval in Japan (August 2020).
- Morten Henneveld appointed as new CEO (August 2020).
- Prestigious publication of scientific article describing OssDsign's unique regenerative implants has been published in the reputable scientific journal PNAS (Proceedings of the National Academy of Sciences of the United States) (October 2020).
- OssDsign has acquired the bone graft substitute company Sirakoss Ltd. The acquisition, which is expected to provide OssDsign with a five times larger addressable market, is partly financed by a heavily over-subscribed directed share issue of approximately SEK 65 million (November 2020).

### Expected milestones

- Launch of OssDsign's products on the Japanese market during 2020.

Promimic
THINNER. FASTER. STRONGER.

**Project**
HA$^{nano}$ Surface

**Primary indication**
Implant surface coatings

**Development Phase**
Marketed

**Holding in company***
KDev Investments 20%

**Other investors**
ALMI Invest,
K-Svets Ventures,
Chalmers Ventures

**Origin**
Chalmers University of Technology

**More information**
promimic.com

**Fully-diluted ownership based on current investment plans*

# Promimic AB

## Coatings to enhance the properties of medical implants

Promimic (Gothenburg, Sweden) is a biomaterials company that develops and markets a unique coating for medical implants called HA$^{nano}$ Surface, which increases their integration into bone and anchoring strength.

HAnano Surface is a sustainable, nanometre-thin coating that helps preserve the surface structure of the implant by reducing the risks of cracking. The coating is unique because it can be applied to any implant geometry and material, including porous materials and 3D structures. The technology on which HA$^{nano}$ is based is FDA-approved, which means that a new implant coated with HA$^{nano}$ Surface can receive marketing approval through the 510(k) route and reach a new market quickly. The coating process is easy to implement in the industrial scale production of implants.

Promimic has an established sales operation in the US and a series of development and commercial partnerships, including one with Sistema de Implante Nacional (S.I.N), a leading provider of dental implants in Brazil, which is commercializing dental implants coated with HA$^{nano}$ Surface. Another of Promimic's partners is Danco Anodizing, which has established a manufacturing facility for implants with HA$^{nano}$ Surface, targeting the US and Chinese markets. Promimic strengthened its position in the orthopaedic market in 2019 through its partnership with the US company Onkos Surgical. The partners will develop and commercialise the HA$^{nano}$ Surface technology in combination with Onkos Surgical's products for limb salvage surgery.

**Deal values for similar projects**

- USD 95 million Nobel Biocare (buyer) & AlphaBioTec (seller) 2008
- USD 120 million MAKO surgical (buyer) & Pipeline Biomedical (seller) 2013

**The market**

Promimic is focusing on the markets for dental and orthopaedic implants, which collectively represent a worldwide market opportunity of USD 600 - 800 million. The competition amongst implant manufacturers is fierce and each market segment is dominated by four to eight global companies. Promimic's business model is centred on out-licensing the HA$^{nano}$ Surface technology to leading implant manufacturers.

**Recent progress**

- Entered into partnership with the US company Onkos Surgical (March 2019).
- The company's first spinal device utilizing HA$^{nano}$ Surface to improve osseointegration has been 510(k) approved by the FDA (August 2019).
- Promimic's business partner Innovasis Inc. received 510(k) FDA clearance of a series of 3D printed implants used in spinal fusion surgery (August 2020).

**Expected milestones**

- Further product launches and license agreements with major manufacturers during 2020.

**Project**
Vaccin

**Primary indication**
Hepatit B och D
Corona virus

**Development Phase**
Preclinical

**Holding in company***
Karolinska Development 20%

**Origin**
Karolinska Institutet

** An option agreement gives the opportunity to increase the ownership to a total of 25% within a defined period of time and at a predetermined price.*

# Svenska Vaccinfabriken Produktion AB

## Developing therapeutic proteins and DNA vaccines

Svenska Vaccinfabriken Produktion AB ("SVF") develops therapeutic proteins and DNA vaccines against hepatitis B, hepatitis D and other viral diseases, as well as vaccines to prevent infections of Covid-19 and potential future Coronaviruses. SVF's innovative vaccine platform technology has been developed by researchers at the Karolinska Institute in Huddinge, Sweden. The projects are currently in the preclinical phase and the first clinical trials could potentially be initiated in 2021.

Despite the availability of preventative vaccines and antiviral treatments, over 250 million people live with a chronic hepatitis B infection, China being one of the most severely affected countries. One million chronic carriers die each year due to complications caused by the virus, such as liver cirrhosis and liver cancer. The hepatitis D virus infects 15-25 million hepatitis B carriers and exacerbates the progression of the disease. SVF utilizes a proprietary immunotherapy to produce a specific form of antibodies that block the ability of the virus to penetrate human host cells. The aim is to develop a therapeutic vaccine that, unlike preventative vaccines, has the potential to cure already infected patients. The company has generated promising efficacy data in a preclinical animal model and is now continuing its preclinical development with the goal that a phase 1 study can be initiated in 2021.

Coronaviruses occur in many different forms and usually cause colds, sore throats, coughs and pneumonia. Although Coronavirus infections are usually mild, some virus types can lead to life-threatening conditions. This has been the case in the outbreak of SARS-CoV in 2003, MERS-CoV in 2012 and during the ongoing covid-19 pandemic. SVF has developed a platform that is expected to provide an opportunity to quickly develop vaccines against both current and new forms of Coronaviruses and has recently filed a patent application specifically linked to a potential covid-19 vaccine.

**The market**

According to KuicK Research report June 2017 "Global Hepatitis Drug Market & Clinical Trials Insight 2023", the annual global market of hepatitis B is 4-5 billion USD that will grow to 5-6 billion USD in 2023. The annual global market of hepatitis D is estimated at a total of 1 billion USD.

**Recent progress**

- Karolinska Development invested in SVF in March 2020. With the initial investment, Karolinska Development own five percent of the shares in SVF. Karolinska Development made an additional investment after the end of the third quarter and the ownership now amounts to 20%.
- A patent application specifically linked to a potential covid-19 vaccine has been filed.

**Expected milestones**

- The establishment of a cooperation agreement with one or more international partners during 2020 ahead of the continued development and commercialization of the products.
- Phase I study hepatitis D and B vaccine could potentially be initiated in 2021.

# Financial Development

The following financial reporting is divided into one financial reporting for The Parent Company and one for The Investment Entity. The Parent Company and The Investment Entity are the same legal entity, but the reporting is divided in order to meet legal reporting requirements.

The Parent Company is reporting in accordance with the guidelines under the Swedish Annual Accounting Act and Swedish Financial Accounting Standards Council, RFR 2. The Investment Entity is required to meet the reporting requirements of listed companies and thus in accordance with IFRS adopted by the EU and the Swedish Annual Accounts Act

Amounts with brackets refer to the corresponding period previous year unless otherwise stated.

## Financial development in summary for the Investment Entity

| SEKm | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Full-year |
|---|---|---|---|---|---|
| **Condensed income statement** | | | | | |
| Change in fair value of shares in portfolio companies | -173.9 | 10.4 | -289.2 | 32.1 | 415.1 |
| Net profit/loss | -169.4 | -14.7 | -293.4 | -25.8 | 303.0 |
| **Balance sheet information** | | | | | |
| Cash, cash equivalents and short-term investments | 71.1 | 20.8 | 71.1 | 20.8 | 52.1 |
| Net asset value (Note 1) | 718.9 | 270.7 | 718.9 | 270.7 | 1,027.3 |
| Net debt (Note 1) | -3.3 | -484.1 | -3.3 | -484.1 | -37.8 |
| **Share information** | | | | | |
| Earnings per share, weighted average before dilution (SEK) | -1.0 | -0.2 | -1.7 | -0.4 | 4.1 |
| Earnings per share, weighted average after dilution (SEK) | -1.0 | -0.2 | -1.7 | -0.4 | 4.1 |
| Net asset value per share (SEK) (Note 1) | 4.1 | 4.2 | 4.1 | 4.2 | 5.9 |
| Equity per share (SEK) (Note 1) | 4.1 | 4.2 | 4.1 | 4.2 | 5.7 |
| Share price, last trading day in the reporting period (SEK) | 2.7 | 3.3 | 2.7 | 3.3 | 3.5 |
| **Portfolio information** | | | | | |
| Investments in portfolio companies | 4.0 | 9.1 | 19.3 | 42.1 | 48.9 |
| Of which investments not affecting cash flow | 0.1 | 0.6 | 0.7 | 1.1 | 1.9 |
| Portfolio companies at fair value through profit or loss | 675.8 | 669.7 | 675.8 | 669.7 | 1,047.6 |

## Financial Development for the Investment Entity in 2020

### ***Investments*** *(comparable numbers 2019)*

Investments in the portfolio in the third quarter 2020 by external investors and Karolinska Development amounted to SEK 29.1 (87.9) million, whereof 86% (90%) by external investors.

Karolinska Development invested SEK 4.0 (9.1) million, of which SEK 3.9 (8.5) million was cash investments. Investments were made in Umecrine Cognition. Non-cash investments (accrued interest on loans) amounted to 0.1 (0.6) million.

Investments by external investors in the portfolio companies amounted to SEK 25.1 (78.8) million. Investments were made in Promimic SEK 25.0 million and Umecrine Cognition 0.1 million.

During the year, Karolinska Development and external investors have made investments in the portfolio companies as follows:

| SEKm | Karolinska Development | External Investors | Total Invested Q1-Q3 2020 |
|---|---|---|---|
| Umecrine Cognition | 13.4 | 0.4 | 13.7 |
| Modus Therapeutics | 5.4 | 2.0 | 7.4 |
| Svenska Vaccinfabriken Produktion | 0.5 | - | 0.5 |
| Promimic | - | 25.0 | 25.0 |
| Dilafor | - | 13.6 | 13.6 |
| **Total** | **19.3** | **40.9** | **60.2** |

## *Portfolio Fair Value*

Fair Value of the portfolio companies owned directly by Karolinska Development decreased by SEK 26.5 million during the third quarter 2020. Fair value decreased mainly as a result of the partly divestment of Aprea but also through the downturn in the share price of the listed holdings Lipidor but Fair value increased due to the upturn in the share price of the listed holding OssDsign and with investments in the form of loans to Umecrine Cognition.

Fair Value of the portfolio companies owned indirectly via KDev Investments decreased by SEK 281.2 million during the third quarter 2020.The main reason for the decrease in Fair value was the downturn in the share price of the listed holding Aprea.

Total Fair Value from portfolio companies owned directly by Karolinska Development and indirectly via KDev Investments decreased by SEK 307.7 million in the third quarter 2020.

As a consequence of the decrease in Fair Value of the part of the portfolio owned via KDev Investments, the potential distribution to Rosetta Capital decreased by SEK 98.2 million, resulting in Net Portfolio Fair Value decreasing by SEK 209.5 million in the third quarter 2020.

| SEKm | 30 Sep 2020 | 30 Jun 2020 | Q3 2020 vs Q2 2020 |
|---|---|---|---|
| Karolinska Development Portfolio Fair Value (unlisted companies) | 478.9 | 481.2 | -2.3 |
| Karolinska Development Portfolio Fair Value (listed companies) | 38.7 | 62.9 | -24.2 |
| KDev Investments Portfolio Fair Value | 506.5 | 787.7 | -281.2 |
| **Total Portfolio Fair Value** | **1,024.1** | **1,331.8** | **-307.7** |
| Potential distribution to Rosetta Capital of fair value of KDev Investments | -348.3 | -446.5 | 98.2 |
| **Net Portfolio Fair Value** (after potential distribution to Rosetta Capital) | **675.8** | **885.2** | **-209.5** |

Total Portfolio Fair Value on 30 September 2020 amounted to SEK 1,024.1 million and the potential distribution to Rosetta Capital amounted to SEK 348.3 million. Net Portfolio Fair Value on 30 September 2020 amounted to SEK 675.8 million. Compared to 31 December 2019, the Total Portfolio Fair Value decreased with SEK 529.2 million and the Net Portfolio Fair Value decreased with SEK 371.8 million.

## *Profit development 2020 (comparable numbers 2019)*

During the third quarter 2020, Karolinska Development's revenue amounted to SEK 0.4 (0.7) million and consists primarily of services provided to portfolio companies. The revenue for the period January - September 2020, amounted to SEK 2.1 (2.7) million

Change in fair value of shares in portfolio companies of in total SEK -173,9 (10.4) million includes the difference between the change in Net Portfolio Fair Value during the third quarter 2020 with SEK -209.5 million and the net of investments in the portfolio companies of SEK 4.0 million and divestments of SEK -39.6 million. Change in fair value of other financial assets and liabilities amounted to SEK 14.5 (-4.8) million and are the consequence of changes in valuation of earn-out deals. For the period January - September 2020, the change

in fair value of shares in portfolio companies amounted to SEK -289.2 (32.1) million and the change in fair value of other financial assets amounted to SEK 23.8 (8.8) million.

During the third quarter 2020 other expenses amounted to SEK 1.1 (2.3) million and personnel costs amounted to SEK 7.8 (4.8) million. The increase in personnel costs compared with the third quarter 2019 is mainly due to bonus schemes related to exit of holding in portfolio company. For the period January – September 2020 other expenses amounted to SEK 6.4 (9.4) million and personnel cost amounted to 19.3 (17.3) million.

The operating profit/loss in the third quarter 2020 amounted to SEK -168.0 million compared to SEK -0.9 million in the third quarter 2019. The operating profit/loss for the period January - September 2020 amounted to -289.6 (16.4) million.

Financial net improved during the third quarter 2020 compared to the third quarter 2019 and amounted to SEK -1.3 (-13.7) million, which is primarily related to that the majority of the convertible loan was converted during 2019 and the remaining part repaid in January 2020. For the period January - September 2020 the financial net amounted to SEK -3.8 (-42.2) million.

The Investment Entity's Net profit/loss amounted to SEK -169.4 (-14.6) million in the third quarter 2020. Net profit/loss for the period January-September 2020 amounted to SEK -293.4 (-25.8) million.

### *Financial position*

The Investment Entity's equity to total assets ratio amounted to 87% on 30 September 2020, compared to 88% on 30 June 2020.

The net profit/loss of SEK -169.4 million in the third quarter resulted in the equity on 30 September 2020 decreasing to SEK 714.3 million compared to SEK 883.7 million on 30 June 2020.

Interest-bearing liabilities consisted of a bridge loan including accrued interest amounting to SEK 74.4 million, on 30 September 2020 (extended to 31 December 2021), compared to SEK 504.9 million on 30 September 2019.

After paying operational costs and investments in the third quarter 2020, cash and cash equivalents amounted to SEK 71.1 million on 30 September 2020 compared to SEK 20.8 million on 30 September 2019. The increase is the consequence of the partial divestment of Aprea shares during the quarter. Net debt amounted to SEK 3.3 million on 30 September 2020 compared to SEK 484.1 million on 30 September 2019.

## Financial Development – Parent Company

*The Parent Company refers to Karolinska Development AB (comparable numbers third quarter 2019).*

During the third quarter 2020, the Parent Company's Net profit/loss amounted to SEK -169.4 million (SEK -14.6 million).

Due to the negative result for the third quarter 2020, the equity decreased from SEK 883.7 million 30 June 2020 to SEK 714.4 million 30 September 2020.

## Shares

### The share and share capital

Trade in the Karolinska Development share takes place on Nasdaq Stockholm under the ticker symbol "KDEV". The last price paid for the listed B share on 30 September 2020 was SEK 2.67, and the market capitalization amounted to SEK 469 million.

The share capital of Karolinska Development on 30 September 2020 amounted to SEK 1.8 million divided into 1,503,098 A shares, each with ten votes (15,030,980 votes) and 174,162,311 B shares, each with one vote (174,162,311 votes). The total number of shares and votes in Karolinska Development on 30 September 2020 amounted to 175,665,409 shares and 189,193,291 votes.

### Ownership

On September 30, 2020, Karolinska Development had 5,335 shareholders.

| Shareholder | A-Shares | B-Shares | Cap % | Vote % |
|---|---|---|---|---|
| Sino Biopharmaceutical Limited | 0 | 75,727,285 | 43.11% | 40.03% |
| Worldwide International Investments Ltd | 0 | 32,276,620 | 18.37% | 17.06% |
| Karolinska Institutet Holding AB | 1,503,098 | 2,126,902 | 2.07% | 9.07% |
| Tredje AP-Fonden | 0 | 5,934,218 | 3.38% | 3.14% |
| Östersjöstiftelsen | 0 | 3,889,166 | 2.21% | 2.06% |
| OTK Holding A/S | 0 | 3,000,000 | 1.71% | 1.59% |
| Stift För Främjande & Utveckling | 0 | 2,641,389 | 1.50% | 1.40% |
| Coastal Investment Management LLC | 0 | 2,470,541 | 1.41% | 1.31% |
| Friheden Invest A/S | 0 | 1,000,000 | 0.57% | 0.53% |
| Gålöstiftelsen | 0 | 668,661 | 0.38% | 0.35% |
| Sum Top 10 Shareholders | 1,503,098 | 129,734,782 | 74.71% | 76.52% |
| Sum Other Shareholders | 0 | 44,427,529 | 25.29% | 23.48% |
| **Sum All Shareholders** | **1,503,098** | **174,162,311** | **100.00%** | **100.00%** |

# Information on Risks and Uncertainties

## Investment Entity and Parent Company

### Financial risks

Coronavirus's global spread affects the economy and society as a whole, including Karolinska Development and its portfolio companies. The value of listed companies can decline, delays in clinical trial programs may occur and that the opportunities for refinancing can be hampered. The Board monitors the evolvement of the crisis closely and Karolinska Development is working intensively to minimize the impact on the value of our investments and continues with different financing alternatives to secure the long-term capital requirement and thereby increase the degree of strategic and operational headroom for the future.

For a detailed description of other risks and uncertainties, see the Annual report.

# Signing of the report

Solna, 11 November 2020

Björn Cochlovius
Chairman

Tse Ping

Theresa Tse

Viktor Drvota
CEO

# Review report

Karolinska Development AB, corporate identity number 556707-5048

## Introduction

We have reviewed the condensed interim report for Karolinska Development AB, the Investment Entity, as at September 30, 2020 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

## Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 *Review of Interim Financial Statements Performed by the Independent Auditor of the Entity*. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

## Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Investment Entity, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Solna, 11 November 2020

Ernst & Young AB

Oskar Wall

Authorized Public Accountant

# Dates for Publication of Financial Information

| | |
|---|---|
| Year-End Report 2020 | 11 February 2021 |
| Annual Report 2020 | 25 March 2021 |
| Interim Report January – March 2021 | 29 April 2021 |
| Annual General Meeting 2021 | 5 May 2021 |
| Interim Report January – June 2021 | 19 August 2021 |
| Interim Report January – September 2021 | 18 November 2021 |

Karolinska Development is required by law to publish the information in this interim report. The information was published on 11 November 2020.

This interim report, together with additional information, is available on Karolinska Development's website: www.karolinskadevelopment.com.

*Note: This report is a translation of the Swedish interim report. In case of any discrepancies, the official Swedish version shall prevail.*

# Financial Statements

### Condensed income statement for the Investment Entity

| SEK 000 | Note | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Full-year |
|---|---|---|---|---|---|---|
| Revenue | | 430 | 713 | 2,123 | 2,656 | 3,384 |
| Change in fair value of shares in portfolio companies | 2 | -173,868 | 10,359 | -289,210 | 32,126 | 415,136 |
| Change in fair value of other financial assets and liabilities | | 14,499 | -4,758 | 23,757 | 8,808 | -28,215 |
| Other expenses | | -1,133 | -2,297 | -6,427 | -9,356 | -18,186 |
| Personnel costs | | -7,768 | -4,802 | -19,354 | -17,301 | -23,474 |
| Depreciation of right-of-use assets | | -176 | -176 | -528 | -528 | -704 |
| **Operating profit/loss** | | **-168,016** | **-961** | **-289,639** | **16,405** | **347,941** |
| Financial net | | -1,346 | -13,693 | -3,767 | -42,215 | -44,964 |
| **Profit/loss before tax** | | **-169,362** | **-14,654** | **-293,406** | **-25,810** | **302,977** |
| Taxes | | - | - | - | - | - |
| **NET PROFIT/LOSS FOR THE PERIOD** | | **-169,362** | **-14,654** | **-293,406** | **-25,810** | **302,977** |

### Condensed statement of comprehensive income for the Investment Entity

| SEK 000 | Note | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Full-year |
|---|---|---|---|---|---|---|
| Net/profit loss for the period | | -169,362 | -14,654 | -293,406 | -25,810 | 302,977 |
| **Total comprehensive income/loss for the period** | | **-169,362** | **-14,654** | **-293,406** | **-25,810** | **302,977** |

### Earnings per share for the Investment Entity

| SEK | Note | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Full-year |
|---|---|---|---|---|---|---|
| Earnings per share, weighted average before dilution | | -0.97 | -0.23 | -1.67 | -0.40 | 4.10 |
| Number of shares, weighted average before dilution | | 175,421,124 | 64,174,452 | 175,421,124 | 64,174,452 | 73,874,552 |
| Earnings per share, weighted average after dilution | | -0.97 | -0.23 | -1.67 | -0.40 | 4.10 |
| Number of shares, weighted average after dilution | | 175,421,124 | 64,174,452 | 175,421,124 | 64,174,452 | 73,874,552 |

## Condensed balance sheet for the Investment Entity

| SEK 000 | Note | 30 Sep 2020 | 30 Sep 2019 | 31 Dec 2019 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Tangible assets** | | | | |
| Right-of-use assets | | 858 | 880 | 704 |
| **Financial assets** | | | | |
| Shares in portfolio companies at fair value through profit or loss | 2 | 675,825 | 669,710 | 1,047,600 |
| Loans receivable from portfolio companies | | 1,779 | 7,664 | 1,768 |
| Other financial assets | | - | 27,928 | - |
| **Total non-current assets** | | **678,462** | **706,182** | **1,050,072** |
| **Current assets** | | | | |
| Accounts receivable | | 31 | 150 | 39 |
| Receivables from portfolio companies | | 1,866 | 258 | 322 |
| Other financial assets | | 64,774 | 60,909 | 62,620 |
| Other current receivables | | 1,224 | 1,291 | 787 |
| Prepaid expenses and accrued income | | 700 | 6,134 | 732 |
| Short-term investments, at fair value through profit or loss | | - | 17,156 | - |
| Cash and cash equivalents | | 71,098 | 3,627 | 52,132 |
| **Total current assets** | | **139,693** | **89,525** | **116,632** |
| **TOTAL ASSETS** | | **818,155** | **795,707** | **1,166,704** |
| **EQUITY AND LIABILITIES** | | | | |
| **Total equity** | | **714,337** | **270,208** | **1,007,732** |
| **Long-term liabilities** | | | | |
| Long-term liabilities to related parties | 3 | 74,433 | - | - |
| Other financial liabilities | | - | 11,423 | - |
| **Total long-term liabilities** | | **74,433** | **11,423** | **0** |
| **Current liabilities** | | | | |
| Convertible loan | | - | 469,914 | 19,964 |
| Current interest liabilities | 3 | - | 35,000 | 70,000 |
| Other financial liabilities | | 20,155 | - | 46,851 |
| Accounts payable | | 685 | 1,341 | 11,484 |
| Liability to make lease payment | | 898 | 898 | 726 |
| Other current liabilities | | 1,538 | 2,213 | 2,991 |
| Accrued expenses and prepaid income | | 6,109 | 4,710 | 6,956 |
| **Total current liabilities** | | **29,385** | **514,076** | **158,972** |
| **Total liabilities** | | **103,818** | **525,499** | **158,972** |
| **TOTAL EQUITY AND LIABILITIES** | | **818,155** | **795,707** | **1,166,704** |

## Condensed statement of changes in the Investment Entity's equity

| SEK 000 | Not | 2020-09-30 | 2019-09-30 | 2019-12-31 |
|---|---|---|---|---|
| **Opening balance, equity** | | **1,007,743** | **296,007** | **296,007** |
| Total comprehensive income/ loss for the period | | -293,406 | -25,810 | 302,977 |
| Effect of IFRS 16 | | - | 11 | 14 |
| Share capital | | - | - | 1,113 |
| Prospectus costs direct issue 2019 | | - | - | -13,545 |
| Share premium | | - | - | 421,166 |
| **Closing balance, equity** | | **714,337** | **270,208** | **1,007,732** |

## Condensed statement of cash flows for the Investment Entity

| SEK 000 | Note | 2020 Jan-Sep | 2019 Jan-Sep |
|---|---|---|---|
| **Operating activities** | | | |
| Operating profit/loss | | -289,639 | 16,405 |
| **Adjustments for items not affecting cash flow** | | | |
| Depreciation | | 528 | 528 |
| Change in fair value | | 265,453 | -40,934 |
| Other items | | -536 | -537 |
| Proceeds from short-term investments | | - | 594 |
| Interest paid/received | | - | -1,462 |
| **Cash flow from operating activities before changes in working capital and operating investments** | | **-24,194** | **-25,406** |
| **Cash flow from changes in working capital** | | | |
| Increase (-)/Decrease (+) in operating receivables | | -1,949 | -5,745 |
| Increase (+)/Decrease (-) in operating liabilities | | -33,063 | -15,387 |
| **Cash flow from operating activities** | | **-59,206** | **-46,538** |
| **Investment activities** | | | |
| Part payment from earn-out deal | | -5,092 | - |
| Proceeds from sale of shares in portfolio companies | | 101,853 | 23,444 |
| Acquisitions of shares in portfolio companies | | -18,590 | -40,958 |
| Proceeds from sale of short-term investments[1] | | - | 51,836 |
| **Cash flow from operating activities** | | **78,171** | **34,322** |
| **Cash flow for the period** | | **18,966** | **-12,216** |
| Cash and cash equivalents at the beginning of the year | | 52,132 | 15,843 |
| **CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD** | | **71,098** | **3,627** |

### Supplemental disclosure[1]

| | | | |
|---|---|---|---|
| **CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD** | | **71,098** | **3,627** |
| Short-term investments, market value at closing date | | 0 | 17,156 |
| **CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS AT THE END OF THE PERIOD** | | **71,098** | **20,783** |

[1]Surplus liquidity in the Investment Entity was invested in interest-bearing instruments and was recognized as short-term investments with a maturity exceeding three months. These investments were consequently not reported as cash and cash equivalents and were therefore included in the statement of cash flows from operating activities. The supplemental disclosure was presented to provide a total overview of the Investment Entity's available fund including cash, cash equivalents and short-term investments described here.

## Condensed income statement for the Parent Company

| SEK 000 | Note | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Full-year |
|---|---|---|---|---|---|---|
| Revenue | | 430 | 713 | 2,123 | 2,656 | 3,384 |
| Change in fair value of shares in portfolio companies | | -173,868 | 10,359 | -289,210 | 32,126 | 415,136 |
| Change in fair value of other financial assets | | 14,499 | -4,758 | 23,757 | 8,808 | -28,215 |
| Other expenses | | -1,312 | -2,476 | -6,963 | -9,892 | -18,901 |
| Personnel costs | | -7,768 | -4,802 | -19,354 | -17,301 | -23,474 |
| **Operating profit/loss** | | **-168,019** | **-964** | **-289,647** | **16,397** | **347,930** |
| Financial net | | -1,335 | -13,682 | -3,729 | -42,178 | -44,917 |
| **Profit/loss before tax** | | **-169,354** | **-14,646** | **-293,376** | **-25,781** | **303,013** |
| Tax | | - | - | - | - | - |
| **NET PROFIT/LOSS FOR THE PERIOD** | | **-169,354** | **-14,646** | **-293,376** | **-25,781** | **303,013** |

## Condensed statement of comprehensive income for the Parent Company

| SEK 000 | Note | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Full-year |
|---|---|---|---|---|---|---|
| Net profit/loss for the period | | -169,354 | -14,646 | -293,376 | -25,781 | 303,013 |
| **Total comprehensive income/loss for the period** | | **-169,354** | **-14,646** | **-293,376** | **-25,781** | **303,013** |

## Condensed balance sheet for the Parent Company

| SEK 000 | Note | 30 Sep 2020 | 30 Sep 2019 | 31 Dec 2019 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Financial assets** | | | | |
| Shares in portfolio companies at fair value through profit or loss | 2 | 675,825 | 669,710 | 1,047,600 |
| Loans receivable from portfolio companies | | 1,779 | 7,664 | 1,768 |
| Other financial assets | | - | 27,928 | - |
| **Total non-current assets** | | **677,604** | **705,302** | **1,049,368** |
| **Current assets** | | | | |
| Accounts receivable | | 31 | 150 | 39 |
| Receivables from portfolio companies | | 1,866 | 258 | 322 |
| Other financial assets | | 64,774 | 60,909 | 62,620 |
| Other current receivables | | 1,224 | 1,291 | 787 |
| Prepaid expenses and accrued income | | 700 | 6,134 | 732 |
| Short-term investments at fair value through profit or loss | | - | 17,156 | - |
| Cash and cash equivalents | | 71,098 | 3,627 | 52,132 |
| **Total current assets** | | **139,693** | **89,525** | **116,632** |
| **TOTAL ASSETS** | | **817,297** | **794,827** | **1,166,000** |
| **EQUITY AND LIABILITIES** | | | | |
| **Total equity** | | **714,377** | **270,226** | **1,007,754** |
| **Long-term liabilities** | | | | |
| Long-term liabilities to related parties | 3 | 74,433 | - | - |
| Other financial liabilities | | - | 11,423 | - |
| **Total long-term liabilities** | | **74,433** | **11,423** | **0** |
| **Current liabilities** | | | | |
| Convertible loan | | - | 469,914 | 19,964 |
| Current interest liabilities | 3 | - | 35,000 | 70,000 |
| Other financial liabilities | | 20,155 | - | 46,851 |
| Accounts payable | | 685 | 1,341 | 11,484 |
| Other current liabilities | | 1,538 | 2,213 | 2,991 |
| Accrued expenses and prepaid income | | 6,109 | 4,710 | 6,956 |
| **Total current liabilities** | | **28,487** | **513,178** | **158,246** |
| **Total liabilities** | | **102,920** | **524,601** | **158,246** |
| **TOTAL EQUITY AND LIABILITIES** | | **817,297** | **794,827** | **1,166,000** |

## Condensed statement of changes in equity for the Parent Company

| SEK 000 | Not | 30 Sep 2020 | 30 Sep 2019 | 31 Dec 2019 |
|---|---|---|---|---|
| **Opening balance, equity** | | **1,007,753** | **296,007** | **296,007** |
| Net profit/ loss for the period | | -293,376 | -25,781 | 303,013 |
| Share capital | | - | - | 1,113 |
| Prospectus costs direct issue 2019 | | - | - | -13,545 |
| Share premium reserve | | - | - | 421,166 |
| **Closing balance, equity** | | **714,377** | **270,226** | **1,007,754** |

# Notes to the Financial Statements

## NOTE 1 Accounting policies

This report has been prepared in accordance with the International Accounting Standard (IAS) 34 Interim Financial Reporting and the Annual Accounts Act. The accounting policies applied to the Investment Entity and the Parent Company correspond, unless otherwise stated below, to the accounting policies and valuation methods used in the preparation of the most recent annual report.

### Information on the Parent Company

Karolinska Development AB (publ) ("Karolinska Development," "Investment Entity" or the "Company") is a Nordic life sciences investment company. The Company, with Corporate Identity Number 556707-5048, is a limited liability company with its registered office in Solna, Sweden. The Company focuses on identifying medical innovations and investing in the creation and growth of companies developing these assets into differentiated products that will make a difference to patients' lives and provide an attractive return on investment to its shareholders. Investments are made in companies whose sole purpose is to generate a return through capital appreciation and investment income. These temporary investments, which are not investment entities, are designated "portfolio companies" below.

### New and revised accounting principles 2020

No new or revised IFRS standards or recommendations from IFRS Interpretations Committee has had significant impact on the Investment Entity.

### Related party transactions

The bridge loan of SEK 70 million from Sino Biopharmaceutical has been extended until 31 December 2021, otherwise on the same terms.

### Definitions

**Interim period**: The period from the beginning of the financial year through the closing date.

**Reporting period**: January – September 2020.

### Alternative Performance Measures

The Company presents certain financial measures in the year-end report that are not defined under IFRS. The Company believes that these measures provide useful supplemental information to investors and the company's management as they allow for the evaluation of the company's performance. Because not all companies calculate the financial measures in the same way, these are not always comparable to measures used by other companies. Therefore, these financial measures should not be considered as substitutes for measures as defined under IFRS.

**Portfolio companies**: Companies where Karolinska Development has made investments (subsidiaries, joint ventures, associated companies and other long-term securities holdings) which are active in pharmaceuticals, medtech, theranostics and formulation technology.

The Portfolio Fair Value is divided into Total Portfolio Fair Value and Net Portfolio Fair Value.

**Total Portfolio Fair Value**: The aggregated proceeds that would be received by Karolinska Development and KDev Investments if the shares in their portfolio companies were sold in an orderly transaction between market participants at the measurement date.

**Net Portfolio Fair Value** (after potential distribution to Rosetta Capital) is the net aggregated proceeds that Karolinska Development will receive after KDev Investments' distribution of proceeds to Rosetta Capital.

**Equity per share**: Equity on the closing date in relation to the number of shares outstanding on the closing date.

**Equity to total assets ratio:** Equity divided by total assets.

**Net asset value and net asset value per share**: Net Portfolio Fair Value of the total portfolio (SEK 675.8 million), loans receivable from portfolio companies (SEK 1.8 million), cash and cash equivalents (SEK 71.1 million), and net of financial assets and liabilities minus interest-bearing liabilities (SEK 44.6 million minus SEK 74.4 million), in relation to the number of shares outstanding (175,421,124) on the closing date (30 September 2020).

**Net debt**: Interest-bearing liabilities (SEK 74.4 million) reduced with cash and cash equivalents (SEK 71.1 million).

# NOTE 2 Fair value

The table below shows financial instruments measured at fair value based on the classification in the fair value hierarchy. The various levels are defined as follows:

**Level 1**- Fair value determined on the basis of observed (unadjusted) quoted prices in an active market for identical assets and liabilities
**Level 2**- Fair value determined based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
**Level 3**- Fair value determined based on valuation models where significant inputs are based on non-observable data

### Fair value as of 30 September 2020

| SEK 000 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| **Financial assets** | | | | |
| Shares in portfolio companies, at fair value through profit or loss | 38,710 | - | 637,115 | 675,825 |
| Loans receivable from portfolio companies | - | 1,779 | - | 1,779 |
| Other financial assets | - | - | 64,774 | 64,774 |
| Accounts receivable | - | 31 | - | 31 |
| Receivables from portfolio companies | - | 1,866 | - | 1,866 |
| Cash and cash equivalents | 71,098 | - | - | 71,098 |
| **Total** | **109,808** | **3,676** | **701,889** | **815,373** |
| | | | | |
| **Financial liabilities** | | | | |
| Other financial liabilities | - | - | 20,155 | 20,155 |
| Accounts payable | - | 685 | - | 685 |
| Liability to make lease payment | - | 898 | - | 898 |
| **Total** | **-** | **1,583** | **20,155** | **21,738** |

### Fair value as of 30 September 2019

| SEK 000 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| **Financial assets** | | | | |
| Shares in portfolio companies, at fair value through profit or loss | 71,360 | - | 598,350 | 669,710 |
| Loans receivable from portfolio companies | - | 7,664 | - | 7,664 |
| Other financial assets | - | - | 88,837 | 88,837 |
| Receivables from portfolio companies | - | 258 | - | 258 |
| Cash, cash equivalents and short-term investments | 20,783 | - | - | 20,783 |
| **Total** | **92,143** | **7,922** | **687,187** | **787,252** |
| | | | | |
| **Financial liabilities** | | | | |
| Other financial liabilities | - | - | 11,423 | 11,423 |
| Accounts payable | - | 1,341 | - | 1,341 |
| Liability to make lease payment | - | 898 | - | 898 |
| **Total** | **-** | **2,239** | **11,423** | **13,662** |

### Fair value (level 3) as of 30 September 2020

| SEK 000 | Shares in portfolio companies | Other financial assets | Other financial liabilities |
|---|---|---|---|
| At beginning of the year | 884,830 | 62,620 | 46,851 |
| Acquisitions | 19,290 | - | - |
| Disposals/ compensations | -13,500 | - | -5,094 |
| Gains and losses recognized through profit or loss | -253,504 | 2,154 | -21,603 |
| **Closing balance 30 September 2020** | **637,115** | **64,774** | **20,155** |
| Realized gains and losses for the period included in profit or loss | 8,289 | - | 5,094 |
| Unrealized gains and losses in profit or loss for the period included in profit or loss | -261,794 | 2,154 | -26,696 |

### Fair value (level 3) as of 30 September 2019

| SEK 000 | Shares in portfolio companies | Other financial assets | Other financial liabilities |
|---|---|---|---|
| At beginning of the year | 618,927 | 80,030 | 11,423 |
| Transfers to and from level 3 | -72,000 | - | - |
| Acquisitions | 42,103 | - | - |
| Disposals/ compensations | -21,725 | - | - |
| Gains and losses recognized through profit or loss | 31,045 | 8,808 | 0 |
| **Closing balance 30 September 2019** | **598,350** | **88,838** | **11,423** |
| Realized gains and losses for the period included in profit or loss | 13,128 | - | - |
| Unrealized gains and losses in profit or loss for the period included in profit or loss | 17,917 | 8,808 | 0 |

The Investment Entity recognizes transfers between levels in the fair value hierarchy on the date when an event or changes occur that give rise to the transfer.

### Impact of Portfolio Fair Value

In the table below, “Total Portfolio Fair Value” is as defined in Note 1.

### Impact on Portfolio Fair Value of the agreement with Rosetta Capital

“Potential distribution to Rosetta Capital”, SEK 348.3 million, is the amount that KDev Investments according to the investment agreement between Karolinska Development and Rosetta Capital is obligated to distribute to Rosetta Capital from the proceeds received by KDev Investments (KDev Investments Fair Value). The amount includes repayment of SEK 43.3 million that Rosetta Capital currently has invested in KDev Investments’ portfolio companies and the distribution of dividends from Rosetta Capital’s common and preference shares. The distribution to Rosetta Capital will only happen when KDev Investments distribute dividends. KDev Investments will only distribute dividends after all eventual payables and outstanding debt has been repaid.

“Net Portfolio Fair Value (after potential distribution to Rosetta Capital)” is as defined in Note 1.

### Expanded Portfolio Fair Value calculations taking the portfolio valuation and potential distribution to Rosetta Capital in consideration

| SEK 000 | 30 Sep 2020 | 30 Sep 2019 | 31 Dec 2019 |
|---|---|---|---|
| Karolinska Development Portfolio Fair Value (unlisted companies) | 478,938 | 456,882 | 446,658 |
| Karolinska Development Portfolio Fair Value (listed companies) | 38,711 | 71,360 | 162,771 |
| KDev Investments Portfolio Fair Value | 506,490 | 484,220 | 943,946 |
| **Total Portfolio Fair Value** | **1,024,139** | **1,012,462** | **1,553,375** |
| Potential distribution to Rosetta Capital of fair value of KDev Investments | -348,314 | -342,752 | -505,775 |
| **Net Portfolio Fair Value** (after potential distribution to Rosetta Capital) | **675,825** | **669,710** | **1,047,600** |

* SEK 43.3 million repayment of investments in KDev Investments made by Rosetta Capital and SEK 305.0 million distribution of dividends to preference shares and common shares.

### Information on fair value measurement in level 3

The valuation of the company's portfolio is based on the International Private Equity and Venture Capital Valuation Guidelines (IPEV) and IFRS 13 Fair Value Measurement. Based on the valuation criteria provided by these rules, an assessment is made of each company to determine a valuation method. This takes into account whether the companies have recently been financed or involved with a transaction that includes an independent third party or a valuation from an external independent valuation and if the companies recently have met significant milestones. If there is no valuation available based a recently refinancing or other third-party valuation and there is no valuation available based on a similar transaction or an external independent valuation, discounted cash flow models (DCF) may be used.

For detailed description, see the annual report 2019.

## NOTE 3 Liabilities to related parties

| KSEK | 2020-09-30 | 2019-09-30 | 2019-12-31 |
|---|---|---|---|
| **Long-term liabilities to related parties** | | | |
| Sino Biopharmaceutical[1] | 70,000 | - | - |
| Accrued interest Sino Biopharmaceutical | 4,433 | - | - |
| **Current interest liabilities** | | | |
| Sino Biopharmaceutical | - | - | 70,000 |
| **Summa** | **74,433** | **0** | **70,000** |

[1] The bridge loan from Sino Biopharmaceutical has been extended to 31 December 2021. The interest rate amounts to 8% and falls due on 31 December 2021.

## NOTE 4 Pledge assets and contingent liabilities

| SEK 000 | 2020-09-30 | 2019-09-30 | 2019-12-31 |
|---|---|---|---|
| **Pledge assets** | | | |
| The right to payment under Earn-out agreement regarding Oncopeptides shares[1] | - | 163,490 | - |
| **Contingent liabilities** | | | |
| Investment agreement in portfolio company | 3,000 | 6,000 | 2,000 |
| **Summa** | **3,000** | **169,490** | **2,000** |

[1] Also included the right to payment under Earn-out agreement regarding Athera and directly owned shares in Aprea, OssDsign and Lipidor.