
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 substantial commercial opportunities. All of the portfolio companies are developing potentially ground-breaking treatments for medical conditions with a substantial need for improved therapies, including leukaemia, endometriosis, serious viral infections, bone defects, and hepatic encephalopathy. To date, two of the companies have launched their first products.

For further information, see www.karolinskadevelopment.com

Financial Update

First quarter

- The net profit/loss for the first quarter was SEK -24.9 million (SEK -126.1 million in the first quarter of 2020). Earnings per share totalled SEK -0.14 (SEK -0,7 in the first quarter of 2020).
- The result of the Change in fair value of shares in portfolio companies for the first quarter amounted to SEK -15.8 million (SEK -122.7 in the first quarter of 2020). The result is largely due to the negative development of the share price regarding the listed holding in OssDesign.
- The total fair value of the portfolio was SEK 931.8 million at the end of March 2021, corresponding to a decrease of SEK 1.4 million from SEK 933.2 million at the end of the previous quarter. The net portfolio fair value at that time was SEK 758.1 million, corresponding to a decrease of SEK 12.2 million from SEK 770.3 million at the end of the previous quarter.
- Net sales totalled SEK 0.6 million during the first quarter of 2021 (SEK 1.1 million during the first quarter of 2020).
- Karolinska Development invested a total of SEK 3.3 million in portfolio companies during the first quarter. First quarter investments in portfolio companies by Karolinska Development and other specialised life sciences investors totalled SEK 9.5 million.
- Cash and cash equivalents decreased by SEK 14.3 million during the first quarter, totalling SEK 61.6 million on 31 March 2021.
- The Parent Company equity totalled SEK 775.4 million on 31 March 2021.

Significant events during the first quarter

- The Extraordinary General Meeting in Karolinska Development on 19 February, 2021, elected Anna Lefevre Skjöldebrand and Ben Toogood as new directors, and elected Björn Cochlovius as new chairman of the Board of Directors. Further more, the Extra General Meeting approved the Board of Directors' proposal regarding principles for remuneration to executive management (February 2021).
- Johan Dighed has been appointed as Deputy CEO. He takes up the position immediately and will

in addition to his new duties, continue to hold his current role as the company's General Counsel (February 2021).

- Per Aniansson has been appointed as new CFO and Investment Director from 7 March 2021 (March 2021).
- The portfolio company OssDesign has decided to carry out a fully guaranteed rights issue of SEK 240 million in combination with over-allotment options of up to approximately SEK 30 million – a total of approximately SEK 270 million. The purpose of the financing is, among other things, to accelerate the company's development through the new strategy program ASCENT25 (March 2021).
- The portfolio company Forendo Pharma announced a successfully completed Phase 1 program for FOR-6219 – a candidate drug aimed for the treatment of endometriosis. Based on the positive results generated in this program, Forendo Pharma is now preparing a Phase 2 study in the US (March 2021).
- The portfolio company Modus Therapeutics announced an updated strategy that sees the Company focus on the clinical development of sevuparin as a new, important potential treatment for sepsis/septic shock, and possibly other severe inflammatory complications. The company is preparing a listing on Nasdaq First North Growth Market in Stockholm during 2021 to facilitate the financing (March 2021).

Significant post-period events

- The portfolio company Dilafor announced that it has completed the inclusion of patients to its study of tafoxiparin – a drug candidate with the potential to shorten the delivery time in women receiving treatment to initiate labor (April 2021).
- The portfolio company Aprea Therapeutics announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to their drug candidate eprenetapopt for the treatment of acute myeloid leukemia (AML) (April 2021).
- The portfolio company Umecrine Cognition announced that they have published results from the recently conducted phase 2a study of the drug candidate golexanolone in the highly regarded scientific journal Journal of Hepatology (April 2021).

Viktor Drvota, CEO of Karolinska Development, comments:

"In early 2021, Forendo Pharma presented positive results from a phase 1 study of FOR-6219, OssDesign launched a new corporate strategy that will be financed through a fully guaranteed rights issue, and Modus Therapeutics announced plans for a stock market listing and a development programme for sevuparin in the field of sepsis/septic shock. In addition, Dilafor recently completed patient inclusion for its phase 2b trial of tafoxiparin – a candidate drug with the potential to facilitate childbirth, and thereby reduce the risk of injury to women and new-borns. The year has thus started with high activity in the portfolio companies, which we hope will result in several value-adding events in the coming year".

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Chief Executive's Report

The opening quarter of 2021 was characterised by important progress by four of our portfolio companies. Forendo Pharma announced positive results from a phase 1 study of the FOR-6219 candidate drug, OssDsign launched a new corporate strategy that will be financed through a fully guaranteed rights issue, and Modus Therapeutics announced its plans to list the company and initiate a development programme for sevuparin in the field of sepsis/septic shock. Dilafor also announced, after the end of the reporting period, that the ongoing pandemic notwithstanding, they had successfully completed patient inclusion for their phase 2b trial of tafoxiparin.

Positive phase 1 results pave the way for further development of Forendo's FOR-6219

Forendo Pharma announced plans to initiate a phase 2 study in patients with endometriosis – a chronic inflammatory disease that affects ca. 10% of all women of fertile age – in conjunction with the presentation of positive results from a comprehensive phase 1 programme for its FOR-6219 candidate drug. All of the primary endpoints of the phase 1 study were met, and no serious adverse events were recorded. Current treatments for endometriosis have numerous shortcomings and risk giving rise to osteoporosis and other serious side effects. The positive safety profile for Forendo Pharma's candidate drug, together with its pharmacokinetic profile, which offers the potential for a single daily dose, provide a compelling platform for its continued clinical development.

OssDsign builds financial strength to enable aggressive strategic plan

OssDsign has decided to carry out a fully guaranteed rights issue of SEK 240 million in combination with overallotment options of up to SEK 30 million. The purpose of the issue is to finance an ambitious strategic programme that will see the company achieve a net turnover of SEK 300-400 million by 2025, and a positive cash flow by 2024. One important component of the strategy entails optimising the potential offered by the recently completed acquisition of Sirakoss Ltd in the field of orthobiology – an important new subsidiary market that quintuples OssDsign's market potential.

Modus Therapeutics targets stock exchange and plans septic shock development programme

Septic shock is one of the most common causes of death in intensive care units worldwide, with mortality rates typically exceeding 30%. There is currently no specific pharmaceutical treatment available for the treatment of sepsis and, as a result, it is one of the costliest conditions to treat in the hospital care setting. The recently presented results of preclinical trials led Modus to initiate planning of a clinical development programme in the field of sepsis/septic shock for its candidate drug, sevuparin. The goal is to counteract the inflammatory process that characterises this serious medical condition. Sevuparin has already undergone extensive clinical trials in other patient groups and has demonstrated a favourable safety and tolerability profile. Modus Therapeutics intends to list the company later in 2021 as part of its efforts to secure financing for the new development programme.

Patient inclusion completed for Dilafor's phase 2 study of tafoxiparin – despite the ongoing pandemic

Approximately one in four of all pregnant women receive treatment to induce labour, but more than half of these treatments fail. This leads to a prolonged birth process that increases the risk of complications in both the mother and the child. In a previous phase 2a trial, Dilafor's candidate drug, tafoxiparin, showed a significant positive effect with an improved maturation of the cervix and shortened delivery time in connection with induced labour.

Dilafor has now reached its target inclusion of 170 patients in a double-blind, placebo-controlled phase 2b trial in first time mothers with immature cervix, who are scheduled for labour induction. The study is being conducted to document the effect of tafoxiparin on cervical maturation and delivery time. The fact that the recruitment to the clinical study has been successfully completed – despite the ongoing pandemic – reflects the great need for treatments that can reduce the risk of complications in mothers and children in conjunction with childbirth. We are now looking forward to the results from the study, which are scheduled for presentation before the end of the second quarter.

A good return demands strong financial resources

The past quarter has, therefore, seen several of our portfolio companies pass important milestones that will increase the commercial potential of their innovations. We are, at the same time, continuing to evaluate opportunities for investment in additional life science projects with the potential to develop into new, ground-breaking treatments for medical conditions for which existing treatments are unsatisfactory, and are working intensively on our financial position in order to enable further investments in both existing and future holdings. In early March, we welcomed Per Aniansson as our new CFO and Investment Director, and we look forward to his contribution to this important process. Per's extensive experience of investments and commercial development within the life science industry will be exceedingly valuable during Karolinska Development's ongoing journey. Life science investments are not only capital-intensive, they demand patients, but the recent progress is just one of the factors strengthening me in my conviction that our structured and unwavering efforts will result in better lives for patients worldwide and a healthy return for our owners.

Solna, 29 April 2021

Viktor Drvota
Chief Executive Officer

Portfolio Companies

High potential for continued value generation

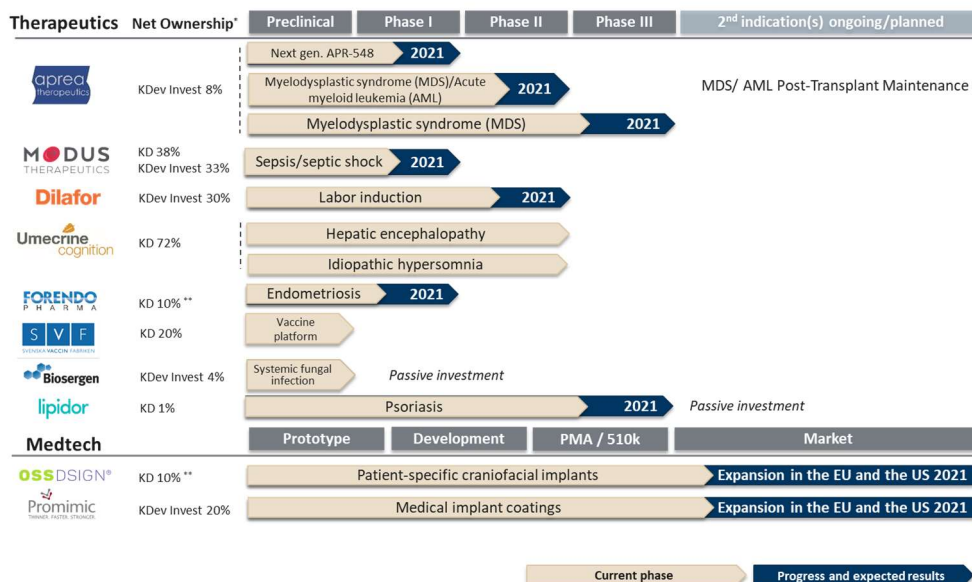
Karolinska Development's investments in therapeutic companies are conducted in syndicates with other professional life science investors, normally until proof-of-concept is demonstrated in Phase 2 trials, at which point different exit options are evaluated. For medtech companies, the business model is 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.

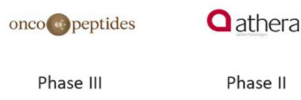
During the past years, Karolinska Development has optimized the clinical programs of the portfolio companies to reach clinically meaningful value-inflection points. The majority of Karolinska Development's portfolio companies are well-financed for their ongoing development and commercialisation work and are well-positioned to meet decisive value-generating milestones over the next two years. The ongoing pandemic has affected the portfolio companies to varying degrees, but the majority have been able to develop in accordance with previously set timetables.

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 a further two 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 8.4%

Other investors
HealthCap,
Consonance Capital,
Versant Ventures,
Redmile Group,
Fidelity Management &
Research Co

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 Inc



Unique approach to treating a broad range of cancers

Aprea Therapeutics (Boston, USA and Stockholm, Sweden) develops novel anticancer drugs targeting the tumour suppressor protein, p53. Mutations of the p53 gene occur in around 50% of all human tumours and are associated with poor overall survival. Aprea's candidate drug, eprenetapopt (APR-246), has shown an ability to reactivate mutant p53 protein, inducing programmed cell death in many cancer cells. Early this year, eprenetapopt received a Breakthrough Therapy Designation from the American Food and Drugs Administration, the FDA.

The company presented positive results during the second quarter of the year from a phase 1b/2 study of eprenetapopt in combination with azacitidine for the treatment of TP53-mutated myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML). The results indicated better survival rates in patients treated with the candidate drug. The study has now been expanded to evaluate combination therapy with venetoclax, and further results are expected in 2021.

The FDA approved an Investigational New Drug (IND) application for APR-548 – a next generation candidate drug being developed for oral administration – during the third quarter. The company is now initiating a clinical development programme for APR-548 in the treatment of TP53-mutated MDS.

Top-line data from a phase 3 study of eprenetapopt in patients with p53-mutated myelodysplastic syndrome (MDS) were reported in December. The percentage achieving complete remission was higher (33%) in the experimental arm that received a combination of eprenetapopt and azacitidine than in the arm that only received azacitidine (22.4%). The difference did not, however, achieve statistical significance and an in-depth data analysis will now be conducted ahead of any decision on the further development of the candidate drug. A separate study to document the effect of eprenetapopt as maintenance treatment in MDS patients who have undergone stem cell transplantation is also ongoing.

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

The market

Eprenetapopt has the potential for use in many different types of cancer as mutations in p53 are found in around 50% of all diagnosed cancers. The lead target indications thus far include blood tumours such 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

- The FDA accepts an Investigational New Drug (IND) application for APR-548 for the treatment of patients with TP53-mutated (October 2020).
- Presentation of the results of a phase 1b/2 study of eprenetapopt in combination with azacitidine for the treatment of TP53-mutated myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML) (December 2020).
- The U.S. Food and Drug Administration (FDA) has granted orphan drug designation to Aprea Therapeutics drug candidate eprenetapopt for the treatment of acute myeloid leukemia (AML) (April 2021).

Expected milestones

- Secondary data from the phase 3 study of MDS is expected in the first half of 2021.

Project (First-in-class)

Sevuparin

Primary indication

Sepsis/Septic shock

Development Phase

Phase II

Holding in company*

Karolinska Development 38%

KDev Investments 33%

Other investors

The Foundation for Baltic and

East European Studies,

Praktikerinvest

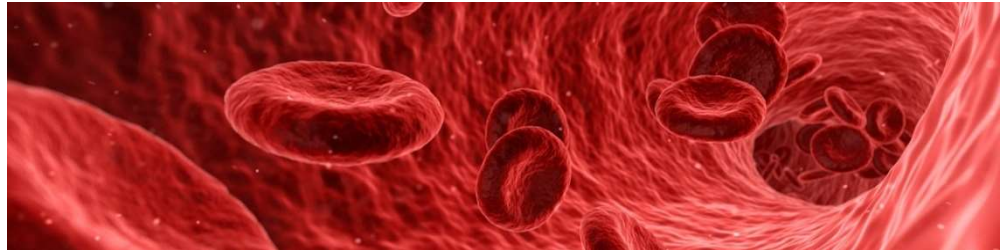
Origin

Karolinska Institutet, Uppsala

University

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

Modus Therapeutics AB



Establishing new treatments of sepsis/septic shock

Modus Therapeutics (Stockholm, Sweden) is developing sevuparin as a treatment of sepsis/septic shock, a potentially life-threatening condition that is currently lacking efficient pharmaceutical therapies. Patients that are affected by sepsis are exposed to a risk of developing multi-organ failure and – in severe cases – decease. Sevuparin is a polysaccharide drug candidate with a multimodal mechanism of action, including anti-inflammatory, anti-adhesive and anti-aggregate effects. It acts by interfering with the harmful agents generated by white blood cells during systemic inflammation. This interference could potentially break the molecular chain of events that lead to vascular damage and plasma leakage in patients with sepsis/septic shock and other systemic inflammatory manifestations. Data from pre-clinical animal as well as in vitro human cell models has revealed that sevuparin was able to protect blood vessels and counteract lung plasma leakage during systemic inflammation.

Previous clinical trials in other patient groups have shown that sevuparin is well tolerated and has a favorable safety profile. In March 2021, Modus Therapeutics announced its intention to initiate a clinical development program in sepsis/septic shock. Sevuparin is believed to have a beneficial effect on the severe systemic inflammation that characterizes this condition. The company intends to finance the development within the new indication through a rights issue in connection with the intention to list at the Nasdaq First North Growth Market. Modus also continues to collaborate with academic partners to identify additional indications where sevuparin has potential to create substantial therapeutic value.

The market

Septic shock is a leading cause of death in intensive care units, with mortality rates typically exceeding 30 percent. There is currently no specific pharmaceutical treatment available for the treatment of sepsis. As a result, it is one of the costliest conditions to treat in the hospital care setting. In 2019, US in-patient care costs for patients with sepsis was estimated to USD 23 billion. Sepsis/septic shock is triggered by an infection and causes the same form of severe uncontrolled inflammation that can occur in conjunction with extensive surgery, trauma, burns and autoimmunity.

Recent progress

- Modus Therapeutics announced an updated strategy that sees the Company focus on the clinical development of sevuparin as a new, important potential treatment for sepsis/septic shock, and possibly other severe inflammatory complications. The company is preparing a listing on Nasdaq First North Growth Market in Stockholm during 2021 to facilitate the financing (March 2021).

Expected milestones

- Phase 1b LPS challenge study, with Q4 2021 as the estimated start date.
- Phase 2 proof-of-concept (PoC) for sepsis/septic shock with an estimated start date of Q2 2022.
- Presentation of the sepsis/septic shock PoC study in Q2 2023.

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.*

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

Dilafor AB



Reducing complications with childbirth

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

About one quarter of all pregnant women undergo induction in labor. In just over half of all cases, the induction fails, leading to protracted labor that entails an increased risk for both mother and child due to medical complications. Between 25 and 40% of women who experience protracted labor 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 labor 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.

It is thought that it is tafoxiparin's interaction with the body's immune system that causes the candidate drug to have a certain suppressive effect in conjunction with viral infections that can trigger a hyperinflammatory condition. Dilafor accordingly entered into a partnership with Liverpool University in the second quarter, studying the effect of tafoxiparin as a treatment for COVID-19.

The market

Approximately one quarter of all pregnant women require labor 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

- 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 2b study during the second quarter of 2021.



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 (GR3027) – 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 impairments and sleep disturbances. 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 2a study of golexanolone in patients with hepatic encephalopathy (HE) – a serious neuropsychiatric and neurocognitive condition that occurs in conjunction with acute and chronic hepatic damage with underlying cirrhosis – was conducted during the year. The results showed that the candidate drug was well-tolerated, that the safety profile was good, and that the pharmacokinetic profile was favourable. One of the effect parameters – 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 extreme daytime fatigue. There was no significant effect, however, on other secondary outcome measures. In December, the company announced that, based on these study results, it had established a plan for the further development of the candidate drug.

The market

HE is a serious disease with a large unmet need that affects up to 1% of the population in the USA and EU. 180,000-290,000 patients are hospitalised every year in the USA due to complications of HE. Once HE develops, mortality reaches 22-35% after five years. HE is also associated with substantial societal 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 presented positive phase 2a data for the candidate drug, golexanolone, for the hepatic encephalopathy indication at The Liver Meeting Digital Experience™, between 13 and 16 November 2020.
- Umecrine Cognition announced that they have published results from the recently conducted phase 2a study of the drug candidate golexanolone in the highly regarded scientific journal *Journal of Hepatology* (April 2021)

Going forward

- Financing/licensing projects for the further development of the candidate drug are in progress.



Project (First-in-class)
FOR-6219


Primary indication
Endometriosis

Development Phase
Phase 1b

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 one clear disadvantage of these types of treatment is that they disrupt the systemic oestrogen balance, giving rise to osteoporosis and other serious side effects that hinder their long-term usage.

Forendo's candidate drug, FOR-6219, inhibits the HSD17B1 enzyme – a previously unresearched but powerful drug target for tissue-specific regulation of hormone activity. Forendo has demonstrated proof of mechanism 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. Forendo announced in March 2021 the successfully completed Phase 1 program for FOR-6219 – a candidate drug aimed for the treatment of endometriosis. Based on the positive results generated in this program, Forendo Pharma is now preparing a Phase 2 study in the US.

The company has also, since late 2019, been developing new pharmaceuticals for the treatment of chronic hepatic disease in partnership with the pharmaceutical company, Novartis. The development programme is evaluating the effect of the company's HSD inhibitor in the treatment of gynaecological conditions and is currently in the preclinical discovery phase.

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

- Novartis enters into license and collaboration agreement and invests in Forendo (December 2019).
- Successfully completed Phase 1 program for FOR-6219 – a candidate drug aimed for the treatment of endometriosis. Based on the positive results generated in this program, Forendo Pharma is now preparing a Phase 2 study in the US (March 2021)

Expected milestones

- Initiation of Phase 2 study in endometriosis at the end of 2021.

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

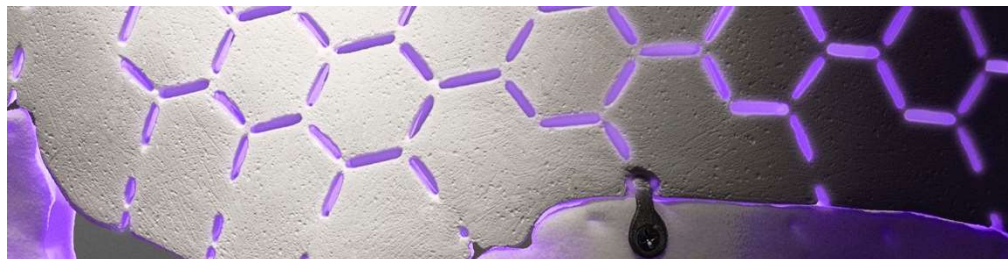

ossdsign.com

* 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 currently preparing commercial activities in Japan after the approval of the company's OSSDSIGN® Cranial PSI product. Upon completion of a successful and over-subscribed share issue that yielded SEK 65 million, OssDsign acquired Sirakoss Ltd, a company operating in the field of bone graft substitutes. This strategic acquisition means a fivefold increase in the company's addressable market.

During the year, the company worked intensively to increase sales. The US subsidiary has been actively working since 2019 on strengthening the company's position in the USA through long-term, sound customer relationships. A recent patent application from the US Patent Office further enhances OssDsign's potential for future growth in the USA.

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

- Morten Henneveld appointed as the company's new CEO (August 2020).
- An article describing the portfolio company, OssDsign's unique regenerative implant, is published in the respected scientific publication, PNAS (Proceedings of the National Academy of Sciences of the United States) (October 2020).
- OssDsign acquires Sirakoss Ltd – a company operating in the field of bone graft substitutes. The acquisition brings with it a fivefold increase in OssDsign's addressable market and is partly financed through a directed share issue for SEK 65 million before transaction costs.

Expected milestones

- Financing for continued roll-out of the product internationally and market introduction of the Sirakoss product.


Project

 HA^{nano} Surface

Primary indication

Implant surface coatings

Development Phase

Marketed

Holding in company*


KDev Investments 20%

Other investors

 K-Svets Ventures,
ALMI Invest,
Chalmers Ventures

Origin

 Chalmers University of
Technology

More information
 promimic.com

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

**Deal values for similar
projects**

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

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.

HA^{nano} 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 USA 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 commercialising dental implants coated with HA^{nano} Surface, and one with 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 and 2020 by entering into partnerships with Onkos Surgical and INNOVASIS Inc. The partnership with Onkos Surgical includes the development and commercialisation of products treated with the HA^{nano} Surface technology for limb salvage surgery. INNOVASIS Inc. manufactures and sells 3D-printed spinal implants treated with HAnano Surface® in order to improve osseointegration and stimulate new bone formation and bone growth on the implant surface.

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 2021.



Project (First-in-class)
SVF-001

Primary indication
Hepatit B och D
SARS-CoV-2 and other Corona
virus

Development Phase
Preclinical

Holding in company
Karolinska Development 20%

Origin
Karolinska Institutet

Avtalsvärden för liknande projekt

- USD 546 miljoner Affinivax tar in Serie B och C finansiering 2020
- USD 1,4 miljarder MYR Gmbh (uppköpt) & Gilead Sciences Inc (köpare) 2020

Svenska Vaccinabriken Produktion AB



Developing therapeutic proteins and DNA vaccines

Svenska Vaccinabriken Produktion AB ("SVF") develops therapeutic proteins and DNA vaccines against hepatitis B and hepatitis D, as well as vaccines to prevent infections by SARS-CoV-2 and potential future Coronaviruses. Therapeutic vaccines, unlike preventative vaccines, have the potential to cure already infected patients.

Despite the availability of preventative vaccines and antiviral treatments, over 250 million people live with a chronic hepatitis B infection. One million chronic carriers die each year due to complications caused by the virus, such as liver cirrhosis and liver cancer. The closely related hepatitis D virus infects 15-25 million hepatitis B carriers and exacerbates the progression of the disease.

Svenska Vaccinabriken is using an in-house developed vaccine platform to produce a specific form of antibodies that blocks the ability of the hepatitis virus to invade human cells. The company has generated promising efficacy data in a preclinical animal model and is now continuing its preclinical development with the goal of enabling a phase 1 study to be initiated in 2021.

Although Coronavirus infections are usually mild, some virus types can lead to life-threatening conditions. This has been the case in the outbreaks of SARS-CoV in 2003, MERS-CoV in 2012, and during the ongoing Covid-19 pandemic. SVF has also developed a platform to address and prevent severe infections of this kind and which is expected to afford the potential for quickly developing and producing vaccines against both existing and new forms of Coronaviruses. The company submitted a patent application specifically linked to a potential Covid-19 vaccine during the year.

The market

Svenska Vaccinabriken is currently focusing its innovative vaccine platform on the market for therapeutic vaccines for hepatitis B and D, and preventative vaccines for respiratory viral diseases, such as Covid-19. The 2017 Kuick research report, "Global Hepatitis Drug Market & Clinical Trials Insight 2023" estimated the value of the annual global market for hepatitis B at between USD 4 and 5 billion, growing to USD 5-6 billion by 2023. The annual global market for hepatitis D, by contrast, is estimated at around USD 1 billion. There is substantial competition between vaccine developers, who comprise both smaller biotech companies and international pharmaceutical companies. Svenska Vaccinabriken's business model is based on guiding their vaccine projects to the clinical development phase and then licensing them out global pharmaceutical companies with established distribution networks. Investors' interest in early vaccine companies and platforms similar to Svenska Vaccinabriken's has increased markedly in recent years. This is thought to be due to an increased awareness of the potential for the commercialisation of vaccines based on next generation technology, such as RNA vaccines and DNA vaccines. Interest in therapies to treat hepatitis B and D has further intensified – two areas in which the unmet medical need is still significant.

Recent progress

- Karolinska Development invested in SVF in March and October 2020. Karolinska Development's ownership, after the add-on investment, now totals 20%.
- SVF granted US-patent regarding chimeric genes for immunotherapy against chronic hepatitis B and D virus infections (February 2021).

Expected milestones

- The establishment of a cooperation agreement with one or more international partners during 2021 ahead of the continued development of the products.
- Phase 1 studies of hepatitis D and B vaccines could potentially be initiated in 2022.

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	2021 Jan-Mar	2020 Jan-Mar	2020 Full-year
Condensed income statement			
Change in fair value of shares in portfolio companies	-15.5	-122.7	-215.4
Net profit/loss	-24.9	-126.1	-207.5
Balance sheet information			
Cash and cash equivalents	61.6	9.1	75.9
Net asset value (Note 1)	778.7	893.1	805.8
Net debt (Note 1)	-15.7	-60.9	0.0
Share information			
Earnings per share, weighted average before dilution (SEK)	-0.1	-0.7	-1.2
Earnings per share, weighted average after dilution (SEK)	-0.1	-0.7	-1.2
Net asset value per share (SEK) (Note 1)	4.4	5.1	4.6
Equity per share (SEK) (Note 1)	4.4	5.0	4.6
Share price, last trading day in the reporting period (SEK)	1.8	3.5	1.8
Portfolio information			
Investments in portfolio companies	3.3	7.7	40.0
Of which investments not affecting cash flow	0.4	1.0	0.9
Portfolio companies at fair value through profit or loss	758.1	932.5	770.3

Financial Development for the Investment Entity in 2021

Investments (comparable numbers 2020)

Investments in the portfolio in the first quarter 2021 by external investors and Karolinska Development amounted to SEK 9.5 (23.7) million, whereof 65% (68%) by external investors.

Karolinska Development invested during the first quarter SEK 3.3 (7.7) million, of which SEK 2.9 (6.7) million was cash investments. Investments were made in Dilafor SEK 2.9 million and Umecrine Cognition SEK 0.4. Non-cash investments (accrued interest on loans) amounted to SEK 0.4 (1.0) million.

Investments by external investors in the portfolio companies during the first quarter amounted to SEK 6.2 (16.1) million and were made in Dilafor.

Portfolio Fair Value

Fair Value of the portfolio companies owned directly by Karolinska Development decreased by SEK 12.2 million during the first quarter 2021. The main reason for the decrease in Fair value of the portfolio companies were the downturn in the share price of the listed holding OssDsign.

Fair Value of the portfolio companies owned indirectly via KDev Investments increased by SEK 10.8 million during the first quarter 2021. The main reasons for the increase in Fair value was the upturn in the share price of the listed holding Aprea and the investment in Dilafor.

Total Fair Value from portfolio companies owned directly by Karolinska Development and indirectly via KDev Investments decreased by SEK 1.4 million in the first quarter 2021.

As a consequence of the increase in Fair Value of the part of the portfolio owned via KDev Investments, the potential distribution to Rosetta Capital increased by SEK 10.8 million, resulting in Net Portfolio Fair Value decreasing by SEK 12.2 million in the first quarter 2021.

SEKm	31 Mar 2021	31 Dec 2020	Q1 2021 vs Q4 2020
Karolinska Development Portfolio Fair Value (unlisted companies)	733.2	732.5	0.7
Karolinska Development Portfolio Fair Value (listed companies)	24.9	37.8	-12.9
KDev Investments Portfolio Fair Value	173.7	162.9	10.8
Total Portfolio Fair Value	931.8	933.2	-1.4
Potential distribution to Rosetta Capital of fair value of KDev Investments	-173.7	-162.9	-10.8
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	758.1	770.3	-12.2

Profit development 2021 (comparable numbers 2020)

During the first quarter 2021, Karolinska Development's revenue amounted to SEK 0.6 (1.1) million and consists primarily of services provided to portfolio companies.

Change in fair value of shares in portfolio companies of in total SEK -15.5 (-122.7) million includes the difference between the change in Net Portfolio Fair Value during the first quarter 2021 with SEK -12.2 million and the net of investments in the portfolio companies of SEK 3.3 million. Change in fair value of other financial assets and liabilities amounted to SEK -1.5 (3.9) million and are the consequence of changes in valuation of earn-out deals.

During the first quarter 2021 other expenses amounted to SEK 1.9 (2.3) million and personnel costs amounted to SEK 5.4 (5.3) million.

The operating profit/loss in the first quarter 2021 amounted to SEK -23.9 million compared to SEK -125.5 million in the first quarter 2020.

Financial net declined during the first quarter 2021 compared to the first quarter 2021 and amounted to SEK -1.0 (-0.6) million.

The Investment Entity's Net profit/loss amounted to SEK -24.9 (-126.1) million in the first quarter 2020.

Financial position

The Investment Entity's equity to total assets ratio amounted to 90% on 31 March 2021, compared to 88% on 31 March 2020.

The net profit/loss of SEK -24.9 million for the full year resulted in the equity on 31 March 2021 decreasing to SEK 775.4 million compared to SEK 881.6 million on 31 March 2021.

Interest-bearing liabilities consisted of a bridge loan including accrued interest amounting to SEK 77.3 million on 31 March 2021 (in April 2021 extended to 31 December 2022), compared to SEK 71.6 million on 31 Mars 2020.

After paying operational costs and investments for the first quarter 2020, cash and cash equivalents amounted to SEK 61.6 million on 31 March 2021 compared to SEK 9.1 million on 31 March 2020. Net debt amounted to SEK 15.7 million on 31 March 2021 compared to SEK 60.9 million on 31 March 2020.

Financial Development – Parent Company

The Parent Company refers to Karolinska Development AB (comparable numbers 2020).

During the first quarter 2021, the Parent Company's Net profit/loss amounted to SEK -24.9 (-126.1) million.

Due to the negative result for the first quarter 2020, the equity decreased from SEK 800.3 million as of 31 December 2020 to SEK 775.4 million 31 March 2021.

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 31 March 2021 was SEK 1.6, and the market capitalization amounted to SEK 272 million.

The share capital of Karolinska Development on 31 March 2021 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 31 March 2021 amounted to 175,665,409 shares and 189,193,291 votes.

Ownership

On March 31, 2021, Karolinska Development had 5,597 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%
Stift För Främjande & Utveckling	1,503,098	2,641,389	2.36%	9.34%
Östersjöstiftelsen	0	3,889,166	2.21%	2.06%
OTK Holding A/S	0	3,000,000	1.71%	1.59%
Coastal Investment Management LLC	0	2,470,541	1.41%	1.31%
Karolinska Institutet Holding AB	0	2,126,902	1.21%	1.12%
Tredje AP-Fonden	0	1,977,432	1.13%	1.05%
Försäkringsaktiebolaget Avanza Pension	0	1,261,166	0.72%	0.67%
Friheden Invest A/S	0	1,000,000	0.57%	0.53%
Sum Top 10 Shareholders	1,503,098	126,370,501	72.79%	74.74%
Sum Other Shareholders	0	47,791,810	27.21%	25.26%
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 2020.

Signing of the report

Solna, 29 April 2021

Viktor Drvota
CEO

This report has not been reviewed by the Company's auditors.

Dates for Publication of Financial Information

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 29 April 2021.

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	2021 Jan-Mar	2020 Jan-Mar	2020 Full-year
Revenue		629	1,104	2,651
Change in fair value of shares in portfolio companies	2,3	-15,518	-122,729	-215,378
Change in fair value of other financial assets and liabilities		-1,534	3,913	43,077
Other expenses		-1,860	-2,312	-8,466
Personnel costs		-5,442	-5,301	-23,620
Depreciation of right-of-use assets		-173	-176	-690
Operating profit/loss		-23,898	-125,501	-202,426
Financial net		-990	-642	-5,061
Profit/loss before tax		-24,888	-126,143	-207,487
Taxes		-	-	-
NET PROFIT/LOSS FOR THE PERIOD		-24,888	-126,143	-207,487

Condensed statement of comprehensive income for the Investment Entity

SEK 000	Note	2021 Jan-Mar	2020 Jan-Mar	2020 Full-year
Net profit/loss for the period		-24,888	-126,143	-207,487
Total comprehensive income/loss for the period		-24,888	-126,143	-207,487

Earnings per share for the Investment Entity

SEK	Note	2021 Jan-Mar	2020 Jan-Mar	2020 Full-year
Earnings per share, weighted average before dilution		-0.14	-0.72	-1.18
Number of shares, weighted average before dilution		175,421,124	175,421,124	175,421,124
Earnings per share, weighted average after dilution		-0.14	-0.72	-1.18
Number of shares, weighted average after dilution		175,421,124	175,421,124	175,421,124

Condensed balance sheet for the Investment Entity

SEK 000	Note	31 Mar 2021	31 Mar 2020	31 Dec 2020
ASSETS				
Tangible assets				
Right-of-use assets		1,207	1,232	690
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2,3	758,113	932,528	770,320
Loans receivable from portfolio companies		-	1,833	-
Total non-current assets		759,320	935,593	771,010
Current assets				
Accounts receivable		3	50	3
Receivables from group company		80	-	80
Receivables from portfolio companies		1,143	992	243
Other financial assets		39,996	58,065	41,181
Other current receivables		857	861	768
Prepaid expenses and accrued income		804	770	929
Cash and cash equivalents		61,573	9,053	75,869
Total current assets		104,456	69,791	119,073
TOTAL ASSETS		863,776	1,005,384	890,083
EQUITY AND LIABILITIES				
Total equity				
		775,400	881,614	800,267
Long-term liabilities				
Long-term liabilities to related parties	4	77,264	-	-
Total long-term liabilities		77,264	0	0
Current liabilities				
Current interest liabilities to related parties	4	-	70,000	75,864
Other financial liabilities		3,706	38,382	5,726
Accounts payable		851	5,853	617
Liability to make lease payment		1,207	1,240	711
Other current liabilities		1,215	1,768	1,373
Accrued expenses and prepaid income		4,133	6,527	5,525
Total current liabilities		11,112	123,770	89,816
Total liabilities		88,376	123,770	89,816
TOTAL EQUITY AND LIABILITIES		863,776	1,005,384	890,083

Condensed statement of changes in the Investment Entity's equity

SEK 000	Not	2021-03-31	2020-03-31	2020-12-31
Opening balance, equity				
		800,267	1,007,732	1,007,732
Net profit/ loss for the period		-24,880	-126,131	-207,466
Closing balance, equity		775,400	881,614	800,267

Condensed statement of cash flows for the Investment Entity

SEK 000	Note	2021 Full-year	2020 Jan-Mar
Operating activities			
Operating profit/loss		-23,898	-125,501
Adjustments for items not affecting cash flow			
Depreciation		173	176
Change in fair value		17,052	118,816
Other items		-	-178
Cash flow from operating activities before changes in working capital and operating investments		-6,673	-6,687
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables		-1,030	-1,032
Increase (+)/Decrease (-) in operating liabilities		-1,158	-28,660
Cash flow from operating activities		-8,861	-36,379
Investment activities			
Part payment from earn-out deal		-2,886	-
Acquisitions of shares in portfolio companies		-2,370	-6,700
Cash flow from investment activities		-5,256	-6,700
Financing activities			
Amortization of lease liabilities		-179	-
Cash flow from financing activities		-179	0
Cash flow for the period		-14,296	-43,079
Cash and cash equivalents at the beginning of the year		75,869	52,132
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		61,573	9,053

Condensed income statement for the Parent Company

SEK 000	Note	2021 Jan-Mar	2020 Jan-Mar	2020 Full-year
Revenue		629	1,104	2,651
Change in fair value of shares in portfolio companies		-15,518	-122,729	-215,378
Change in fair value of other financial assets and liabilities		-1,534	3,913	43,077
Other expenses		-2,039	-2,490	-9,180
Personnel costs		-5,442	-5,301	-23,620
Operating profit/loss		-23,904	-125,503	-202,450
Financial net		-976	-628	-5,016
Profit/loss before tax		-24,880	-126,131	-207,466
Tax		-	-	-
NET PROFIT/LOSS FOR THE PERIOD		-24,880	-126,131	-207,466

Condensed statement of comprehensive income for the Parent Company

SEK 000	Note	2021 Jan-Mar	2020 Jan-Mar	2020 Full-year
Net profit/loss for the period		-24,880	-126,131	-207,466
Total comprehensive income/loss for the period		-24,880	-126,131	-207,466

Condensed balance sheet for the Parent Company

SEK 000	Note	31 Mar 2021	31 Mar 2020	31 Dec 2020
ASSETS				
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2,3	758,113	932,528	770,320
Loans receivable from portfolio companies		-	1,833	-
Total non-current assets		758,113	934,361	770,320
Current assets				
Accounts receivable		3	50	3
Receivables from group companies		80	-	80
Receivables from portfolio companies		1,143	992	243
Other financial assets		39,996	58,065	41,181
Other current receivables		857	861	768
Prepaid expenses and accrued income		804	770	929
Cash and cash equivalents		61,573	9,053	75,869
Total current assets		104,456	69,791	119,073
TOTAL ASSETS		862,569	1,004,152	889,393
EQUITY AND LIABILITIES				
Total equity		775,408	881,622	800,288
Long-term liabilities				
Long-term liabilities to related parties	4	77,264	-	-
Total long-term liabilities		77,264	0	0
Current liabilities				
Current interest liabilities	4	-	70,000	75,864
Other financial liabilities		3,706	38,382	5,726
Accounts payable		851	5,853	617
Other current liabilities		1,207	1,768	1,373
Accrued expenses and prepaid income		4,133	6,527	5,525
Total current liabilities		9,897	122,530	89,105
Total liabilities		87,161	122,530	89,105
TOTAL EQUITY AND LIABILITIES		862,569	1,004,152	889,393

Condensed statement of changes in equity for the Parent Company

SEK 000	Not	31 Mar 2021	31 Mar 2020	31 Dec 2020
Opening balance, equity		800,288	1,007,753	1,007,753
Net profit/ loss for the period		-24,880	-126,131	-207,466
Closing balance, equity		775,408	881,622	800,288

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 was during April 2021 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 – March 2021.

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.

rNPV: "risk-adjusted net present value" is a method to value risky future cash flows. rNPV is the standard valuation method in the drug development industry, where sufficient data exists to estimate success rates for all R&D phases

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 758.1 million), cash and cash equivalents (SEK 61.4 million), and net of financial assets and liabilities minus interest-bearing liabilities (SEK 36.3 million minus SEK 77.3 million), in relation to the number of shares outstanding (175,421,124) on the closing date (31 March 2021).

Net debt: Interest-bearing liabilities (SEK 77.3 million) reduced with cash and cash equivalents (SEK 61.6 million).

NOTE 2 Shares in portfolio companies, at fair value through profit or loss

Change in fair value of portfolio companies

SEK 000	2021 Full-year	2020 Jan-Mar	2020 Full-year
Result level 1			
Listed companies, realized	-	-	-12,109
Listed companies, unrealized	-12,837	-33,261	-24,542
Total level 1	-12,837	-33,261	-36,651
Result level 3			
Unlisted companies, realized	-682	-3,759	8,215
Unlisted companies, unrealized	-1,999	-85,709	-186,942
Total level 3	-2,681	-89,468	-178,727
Total	-15,518	-122,729	-215,378

Shares in portfolio companies, at fair value through profit or loss

SEK 000	2021-03-31	2020-03-31	2020-12-31
Accumulated acquisition cost			
At the beginning of the year	770,320	1,047,600	1,047,600
Investments during the year	3,311	7,658	39,954
Sales during the year	-	-	-101,856
Changes in fair value in net profit/loss for the year	-15,518	-122,729	-215,378
Closing balance	758,113	932,528	770,320

The significant holding Umechrine Cognition

The fair value of the holding in Umechrine Cognition, as of 31 March 2021, totalled SEK 639.6 million (SEK 384.9 million as of 31 March 2020) and as of 31 December 2020, totalled SEK 639.2 million (SEK 378.3 million on 31 Dec. 2019) and comprised, both on 31 March 2021 and 31 December 2020, 83% (36% as of 31 Dec. 2019) of the portfolio's fair value.

The increase in the book value of the holding by SEK 234 million is due partly to Umechrine Cognition's presentation of positive phase 2a data in 2020, and partly to the company's establishment of a further clinical development plan for the golexanolone candidate drug in the field of hepatic encephalopathy. In December 2020, Karolinska Development commissioned an external, independent valuation institute to conduct a valuation of Umechrine Cognition (the same valuation institute that conducted the valuation in 2017). The external valuation is based on, amongst other things, pharmaceutical reference prices, market size, and market share, which have been discounted and resulted in an rNPV value. The rNPV value was then risk-adjusted to reflect both an assumed pricing in conjunction with a market flotation and the need to secure development financing.

The valuation of Umechrine Cognition between 2017 and December 2020 was based on an external valuation (based on an out-licensing scenario) conducted in October 2017 which resulted, at that time, in an rNPV value of SEK 239.6 million. The valuation was subsequently increased to SEK 378.3 million due to investments made after the 2017 external valuation was conducted. Similar valuation techniques were used in both of the external valuations. The change in value over time is based on the study's development and the previously announced positive phase 2a result. The discount rates for the valuations conducted in 2020 and 2017 are 13% and 15%, respectively – a fixed, standard parameter in both of the valuations, and one which takes into account the phase of the study in question.

Karolinska Development is of the opinion that, after the discount rate – which is set in a standard way based on the then current project phase – the candidate drug price (which comprises prices from reference groups in the market) is the second most significant non-observable input data in the valuation model. The market size and market share have equivalent effects, but as these parameters are similarly proportional in the sensitivity analysis, the effect of all of these parameters can be grasped through the lens of the valuation date sensitivity, by simulating increases and decreases in the assumed price. The sensitivity analysis therefore relates to the change in the discount rate and the price of the candidate drug and shows the effect on Karolinska Development's value for Umecrine Cognition of various changes in the discount rate and the price. See tables below.

Sensitivity analysis on fair value of Umecrine Cognition, 31 March 2021 and 31 December 2020

The amounts refer to changes in fair value in Umecrine Cognition:

Discount rate of 11, 12, 14 respectively 15% (13% is used in the valuation)

	11%		12%		14%		15%	
	Result/ equity MSEK	SEK/share	Result/ equity MSEK	SEK/share	Result/ equity MSEK	SEK/share	Result/ equity MSEK	SEK/share
Effect of a change in the discount rate ¹	172,699	0.98	54,130	0.31	-46,397	-0.26	-134,035	-0.76

¹Sensitivity on the fair value (from the rNPV value which has been risk adjusted to reflect an assumed pricing in conjunction with an IPO and the need to secure development financing) on performed external valuation based on a change of +/- 1 respectively +/- 2 percentage points. The discount rate used in the valuation amounts to 13%.

The price of the drug candidate

	5%		-5%		+/- 15%		+/- 30%	
	Result/ equity MSEK	SEK/share	Result/ equity MSEK	SEK/share	Result/ equity MSEK	SEK/share	Result/ equity MSEK	SEK/share
Effect of a change in the price of the drug candidate ²	36,086	0.21	-33,509	-0.19	+/- 105,682	+/- 0.6	+/- 211,364	+/- 1.2

²Sensitivity on fair value (from the rNPV value which has been risk adjusted to reflect an assumed pricing in conjunction with an IPO and the need to secure development financing) on performed external valuation based on a change in the assumed sales price (reference price) of the drug candidate which has been used in the valuation, the sensitivity analysis shows change at +/- 5%, +/- 15% and +/- 30% respectively.

Sensitivity analysis of significant holdings, 31 December 2019

KSEK	5%		-5%		+15%		-15%	
	Result/ equity MSEK	SEK/share	Result/ equity MSEK	SEK/share	Result/ equity MSEK	SEK/share	Result/ equity MSEK	SEK/share
Umecrine Cognition ¹	7,356	0.04	-8,750	-0.05	24,023	0.14	-29,621	-0.17
KDev Investments ²	31,839	0.18	-29,488	-0.17	95,515	0.54	-84,065	-0.48

KSEK	+ 30%		- 30%	
	Result/ equity		Result/ equity	
	MSEK	SEK/share	MSEK	SEK/share
Umecrine Cognition ¹	46 967	0,27	-52 738	-0,30
KDev Investments ²	191 030	1,09	-165 930	-0,95

¹Sensitivity on fair value (from the rNPV value) on performed external valuation based on a change in the assumed sales price (reference price) of the drug candidate which has been used in the valuation, the sensitivity analysis shows change at +/- 5%, +/- 15% and +/- 30% respectively.

²Sensitivity on fair value, which is mainly driven by the share price of the listed holding Aprea Therapeutics.

NOTE 3 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 31 March 2021

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	24,929	-	733,184	758,113
Other financial assets	-	-	39,996	39,996
Cash and cash equivalents	61,573	-	-	61,573
Total	86,502	0	773,180	859,682
Financial liabilities				
Other financial liabilities	-	-	3,706	3,706
Total	-	0	3,706	3,706

Fair value as of 31 March 2020

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	129,509	-	803,019	932,528
Loans receivable from portfolio companies	-	1,833	-	1,833
Other financial assets	-	-	58,065	58,065
Accounts receivable	-	50	-	50
Receivables from portfolio companies	-	992	-	992
Cash, cash equivalents and short-term investments	9,053	-	-	9,053
Total	138,562	2,875	861,084	1,002,521
Financial liabilities				
Other financial liabilities	-	-	38,382	38,382
Accounts payable	-	5,853	-	5,853
Total	-	5,853	38,382	44,235

Fair value (level 3) as of 31 March 2021

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At beginning of the year	732,554	41,181	5,726
Acquisitions	3,311	-	-
Disposals/ compensations	0	0	-2,370
Gains and losses recognized through profit or loss	-2,681	-1,185	350
Closing balance 31 March 2021	733,184	39,996	3,706
Realized gains and losses for the period included in profit or loss	-682	0	0
Unrealized gains and losses in profit or loss for the period included in profit or loss	-1,999	-1,185	350

Fair value (level 3) as of 31 March 2020

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At beginning of the year	884,829	62,620	46,851
Acquisitions	7,658	-	-
Gains and losses recognized through profit or loss	-89,468	-4,555	-8,469
Closing balance 31 March 2020	803,019	58,065	38,382
Realized gains and losses for the period included in profit or loss	-3,759	-	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	-85,709	-4,555	8,469

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 162.9 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 43.6 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.

KDev Investments' partial divestment of Aprea Therapeutics in December 2020, which provided KDev Investments with SEK 50.7 million, means that in 2020 KDev Investments was able to pay a dividend to Rosetta Capital of SEK 28.5 million, which in turn was paid to Karolinska Development for redemption as part of a claim on deferred purchase price Karolinska Development has on Rosetta Capital. The dividend began the closure of the waterfall with a corresponding amount.

"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	31 Mar 2021	31 Mar 2020	31 Dec 2020
Karolinska Development Portfolio Fair Value (unlisted companies)	733,184	479,515	732,554
Karolinska Development Portfolio Fair Value (listed companies)	24,929	129,508	37,766
KDev Investments Portfolio Fair Value	173,674	760,599	162,916
Total Portfolio Fair Value	931,787	1,369,622	933,236
Potential distribution to Rosetta Capital of fair value of KDev Investments	-173,674	-437,094	-162,916
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	758,113	932,528	770,320

* SEK 43.6 million repayment of investments in KDev Investments made by Rosetta Capital and SEK 119.3 million distribution of dividends to preference shares and common shares.

NOTE 4 Current interest liabilities to related parties

SEK 000	2021-03-31	2020-03-31	2020-12-31
Long-term liabilities to related parties			
Sino Biopharmaceutical ¹	70,000	-	-
Accrued interest Sino Biopharmaceutical	7,264	-	-
Current interest liabilities			
Sino Biopharmaceutical ¹	-	70,000	70,000
Accrued interest Sino Biopharmaceutical	-	-	5,864
Total	77,264	70,000	75,864

¹ The bridge loan from Sino Biopharmaceutical has during April 2022 been extended to 31 December 2022. The interest rate amounts to 8% and falls due on 31 December 2022.

NOTE 5 Pledge assets and contingent liabilities

SEK 000	2021-03-31	2020-03-31	2020-12-31
Pledge assets			
Capital Adequacy Guarantee for portfolio company	2,000	-	-
Contingent liabilities			
Investment agreement in portfolio company	-	3,000	-
Summa	2,000	3,000	0