
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 second quarter was SEK 2.1 million (SEK 21.4 million in the second quarter of 2019). Earnings per share totalled SEK 0.01 (SEK 0.12 in the second quarter of 2019). Net profit/loss for the period January – June 2020 amounted to SEK -124.0 (-11.2) million.
- The result of the Change in fair value of shares in portfolio companies amounted to SEK 7.4 million (SEK -115.3 in the second quarter of 2019). The result was largely attributable to the upturn in share price of the listed holdings Aprea Therapeutics and Lipidor. The result of the Change in fair value of shares in portfolio companies for the period January – June 2020 amounted to SEK -115.3 (21.8) million.
- The total fair value of the portfolio was SEK 1,331.8 million at the end of June 2020, corresponding to a decrease of SEK 37.8 million from SEK 1,369.6 million at the end of the previous quarter. The net portfolio fair value at that time was SEK 885.2 million, corresponding to a decrease of SEK 47.3 million from SEK 932.5 million at the end of the previous quarter.
- Net sales totalled SEK 0.6 million during the second quarter of 2020 (SEK 1.6 million during the second quarter of 2019). Net sales for the period January – June 2020 totalled SEK 1.7 (1.9) million.
- Karolinska Development invested a total of SEK 7.6 million in portfolio companies during the second quarter, which this quarter also corresponded to the total investments in portfolio companies.
- Cash and cash equivalents increased by SEK 35.2 million during the second quarter, totalling SEK 46.1 million on 30 June 2020.
- The Parent Company equity totalled SEK 883.7 million on 30 June 2020.

Significant events during the second quarter

- In this quarter, Umeocrine Cognition completed a phase IIa study of its candidate drug golexanolon in patients at risk of developing hepatic encephalopathy. Golexanolon was tolerated well and demonstrated both a positive safety profile and favourable pharmacokinetics. One of the effect parameters used – 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 (April and May 2020).
- The portfolio company, Dilafor, entered 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 being developed primarily for use against prolonged labour, but the substance is also believed to be effective in treating certain viral infections (April 2020).
- Karolinska Development sold some of its shares in the portfolio company Aprea Therapeutics. KCIF Co-investment Fund KB and Karolinska Development sold shares in Aprea Therapeutics in the same transaction. The transaction amounted to 1 per cent of all shares outstanding in Aprea Therapeutics and netted approximately SEK 59 million for Karolinska Development. Karolinska Development's remaining holding in Aprea Therapeutics, including indirect holding through KCIF Co-investment Fund, thereafter amounted to approximately 1 per cent of the total shares outstanding. KDev Investments' holding in Aprea Therapeutics remains unchanged at approximately 9.5% of the total number of outstanding shares (April 2020).
- Karolinska Development recruited Dr John Öhd for the position of Chief Scientific Officer. He has a solid scientific background and extensive experience from senior positions in global pharmaceutical companies' research organisations, including AstraZeneca and Shire Pharmaceuticals. John Öhd assumes the position on a half-time basis, allowing for a parallel commitment as CEO of Modus Therapeutics, one of Karolinska Development's portfolio companies (May 2020).
- OssDsign has appointed Morten Henneveld to the role of CEO. He takes up his new position on 1 September, 2020 in conjunction with the retirement of current CEO Anders Lundqvist. Henneveld has extensive international experience in the medical technology sector, most recently in the position of Senior Vice President of Business Transformation and Strategy at GN Hearing, a global leader in hearing aids (June 2020).
- Aprea Therapeutics completed enrolment in a phase III study for the evaluation of its candidate drug eprenetapopt in combination with azacitidine in patients with a TP53 mutant myelodysplastic syndrome (MDS). The top line results are expected to be ready to be presented at the end of 2020. Aprea plans to include the study results in filing for registration with the American pharmaceutical authority, FDA, and its European counterpart, EMA, which it expects to submit in 2021 (June 2020).
- Aprea Therapeutics presented the results from a phase Ib/II study of APR-246 (eprenetapopt) in combination with azacitidine for the treatment of TP53 mutant myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML). 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 (June 2020).

- At its Annual General Meeting, Karolinska Development voted to, among other things, re-elect Hans Wigzell, Tse Ping, Magnus Persson and Theresa Tse to its Board of Directors, to elect Björn Cochlovius as new board member, and to elect Hans Wigzell Chairman of the Board (June 2020).

Significant post-period events

- Karolinska Development AB has sold shares in the portfolio company Aprea Therapeutics, Inc. KCIF Co-investment Fund KB and Karolinska Development has sold shares in Aprea in the same transaction. In total, the transaction comprises 1 percent of the total outstanding shares in Aprea and brings net approx. SEK 39 million to Karolinska Development. After the transaction, Karolinska Development has a remaining holding in Aprea through KDev Investment, which remains unchanged at approximately 9.5 percent of the total number of outstanding shares in Aprea (July 2020)
- Aprea Therapeutics has decided to expand the enrollment of patients in its Phase 1 clinical trial evaluating eprenetapopt in TP53 mutant Acute Myeloid Leukemia (AML). Following the completion of the safety lead-in portion of the clinical trial, the first expansion cohort will evaluate the combination of eprenetapopt with venetoclax and azacitidine in frontline TP53 mutant AML.

Viktor Drvota, CEO of Karolinska Development, comments:

“Although the COVID-19 pandemic continues to hold the world in its “iron grip”, we still have been able to continue with our internal work largely unabated minimizing the impact of the crisis on our investments but also taking advantage of the opportunities that may arise. The stock markets also recovered during the quarter after their sharp decline earlier in the year. Karolinska Development's portfolio companies made significant new advances this quarter, and our financial result improved dramatically compared with the previous quarter. Aprea Therapeutics completed enrolment for its phase III program and also presented positive results from a phase I/II study. At the same time, work began to define the plan to further develop Umechrone Cognition's candidate drug golexanolon based on the strong efficacy signals that emerged in an in-depth analysis of the results of a recently concluded phase IIa study.”

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Chief Executive's Report

A positive financial result

Although the COVID-19 pandemic continues to hold the world in its “iron grip”, we have been able to continue with our internal work largely unabated minimizing the impact of the crisis on our investments but also taking advantage of the opportunities that may arise. The stock markets recovered during the quarter after their sharp decline earlier in the year. This has increased the value of our holdings in Aprea and Lipidor, which explains the good financial results of the quarter. At the end of the quarter, the reported net asset value was SEK 891 million, while for comparison our market capitalization at the same point in time was SEK 527 million. In order to reduce the significant difference between net asset value and market capitalization, we will intensify our work to illuminate the potential of our business model and investment portfolio for current and potential new investors. We will also evaluate the opportunities to further strengthen our financial position and – above all – continue our active work to support the portfolio companies in creating value.

Further successes for Aprea Therapeutics

Aprea Therapeutics, the first of Karolinska Development's portfolio companies to be listed on the stock exchange in the USA, continues to deliver good news. During this quarter, the last patients were enrolled in the on-going phase III study of the candidate drug APR-246, and Aprea is still expecting to present top line data before the end of the year. Assuming positive results from the study, the next step will be to file for registration in the USA for the myelodysplastic syndrome (MDS) indication. The American Food and Drug Administration has previously announced that the application may follow the guidelines for Breakthrough Therapy Designation, which means a shorter regulatory review for the candidate drug. At the close of the quarter, Aprea's market cap amounted to the equivalent of SEK 8.6 billion. After the divestitures of shares both in the quarter as well as after the end of the quarter, a strategy to strengthen our balance sheet and reduce our risk exposure, Karolinska Development's indirect holding in Aprea via KDev Investments amounts to 9.5 per cent. . The positive phase Ib/II results presented in June are the latest of several clear signs that Aprea's candidate drug has the potential to revolutionise the treatment of a highly vulnerable patient cohort, and we are now eagerly looking forward to reviewing the data generated by the phase III study.

In-depth analysis of study data strengthens Umechrine Cognition

At the start of the quarter, Umechrine Cognition reported top line data from its phase IIa study of the candidate drug golexanolon in patients at risk of developing hepatic encephalopathy. Golexanolon was tolerated well and demonstrated both a positive safety profile and favourable pharmacokinetics. The first results presented comprised three effect parameters. These demonstrated a tendency for improved cognition, though with no substantial difference between patients who were given active treatment and those who were given a placebo. Later in the quarter, another predefined effect parameter was presented – a well-established and sensitive form of EEG study that 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.

Our agenda for adding value from Nordic innovations in Asia

Karolinska Development has an explicit ambition to establish partnerships between innovative Nordic life science companies and leading Asian life science actors. Asia is in many ways an unexploited market for

Nordic life science, and this initiative aims to combine our established position in local medical innovation clusters with Asian partners' networks, market awareness and financial muscle. Karolinska Development has initiated a partnership with Sino Biopharma, one of the leading pharmaceutical companies in China, but at the same time we are open to additional strong alliances. Our investment in Svenska Vaccinfabriken was made with this Asian agenda in mind. Among other things, the company is developing therapeutic proteins and DNA vaccines for hepatitis B and hepatitis D, two serious conditions that are unusually prevalent in Asia. During this past quarter, Svenska Vaccinfabriken has made further progress not just in its hepatitis projects but also in the development of vaccines for SARS-CoV-2 and other coronaviruses.

Active work in the portfolio companies

Karolinska Development is a long-term owner that actively supports its portfolio companies in their value creation. Several of the companies have already launched their first products, and Aprea is getting close to filing for government registration for a unique candidate drug to treat a form of cancer with unusually poor prognosis. In other companies, larger investments are needed to optimise the on-going development and commercialisation strategies on pace with the generation of new study data. Two examples of the latter category of companies are Modus Therapeutics and Umecrine Cognition. In both cases, we are participating in intensive board work to ensure the best possible conditions for positive value generation. We have recently been able to welcome John Öhd to two parallel new positions – one as CEO of Modus, the other as Chief Scientific Officer in our own organisation. His long experience in research and drug development has already given us new approaches to the challenges and opportunities that are continually arising in our innovative and complex sector. John is now leading the work to evaluate new and interesting areas in which Modus's candidate drug sevuparin can benefit patients around the world. When it comes to Umecrine Cognition, a comprehensive effort is under way to adapt the strategy to further develop golexanolon based on the positive results from the newly conducted clinical phase IIa study. In sum, we can conclude that development in our portfolio companies has been favourable during the past quarter and that we see great opportunities for value generation in the days ahead.

Solna, 20 August 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.

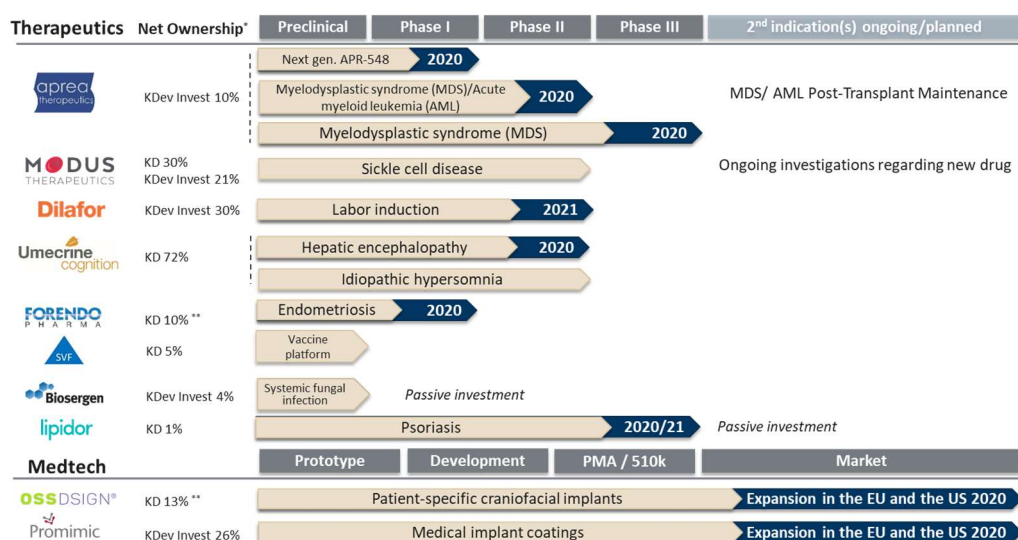
Karolinska Development has a focused portfolio of therapeutic and medtech companies with significant value-generating potential. The portfolio companies are developing highly differentiated and commercially attractive products that have the potential to deliver compelling clinical and health economic 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 are supposed to present Phase II proof-of-concept data and Phase III data. 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



KD: Karolinska Development – KDev Invest: KDev Investments
 * Fully diluted ownership based on current investment plans
 ** Includes indirect holdings through KCIF Co-Investment Fund

Current phase Progress and expected results

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 also started a phase 2 study evaluating APR-246 in combination with azacitidine in patients with p53-mutated AML/MDS following bone marrow transplantation. Furthermore, Aprea aims to start a study in non-Hodgkin's lymphoma as well as a study in solid tumours in combination with anti-PD1 therapy. In addition, the company intends to initiate Phase I studies with the next generation oral P53 reactivator.

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

- FDA granted APR-246 Fast Track designation and Orphan Drug designation for treatment of patients with TP53 mutated MDS (April 2019).
- Aprea Therapeutics was on 3 October listed on Nasdaq Global Select Market, USA (October 2019)
- FDA granted Breakthrough Therapy Designation for APR-246 in combination with azacytidine (January 2020).

Expected milestones

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

Project (First-in-class)

Sevuparin

Primary indication

Sickle cell disease (SCD)


Development Phase

Phase II

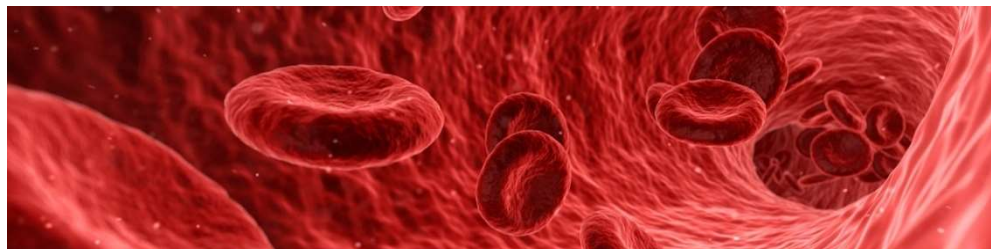
Holding in company*

Karolinska Development 30%

KDev Investments 21%

Other investorsThe 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.*

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 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.

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.



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 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 2a 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 2a 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.



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.

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 1b study are delayed due to the Corona pandemic.

OSSDSIGN®

Project

OSSDSIGN® Cranial and
OSSDSIGN® Facial

Primary indication

Cranial implants

Development Phase

Marketed

Holding in company*

Karolinska Development 13%**

Other investors

SEB Venture Capital,
Fouriertransform

Origin

Karolinska University Hospital,
Uppsala University

More information



ossdsign.com

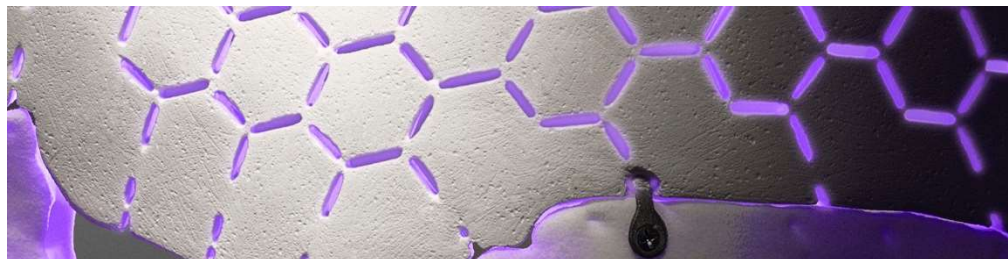
* Fully-diluted ownership based on
current investment plans

** 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

- OssDsign announced a share issue of SEK 151,3 in connection with the company's listing on Nasdaq First North (May 2019).
- Preparations for launch in Japan of OSSDSIGN® Cranial following regulatory filing in Japan (August 2019).
- OssDsign announced that they have been granted 510(k) clearance by the US Food and Drug Administration (FDA) to market OssDsign Cranial PSI Accessories in the US (October 2019).
- OssDsign reports favourable outcome data on OSSDSIGN Cranial PSI (November 2019).

Expected milestones

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

Project

 HA^{nano} Surface

Primary indication

Implant surface coatings

Development Phase

Marketed

Holding in company*


KDev Investments 26%

Other investors

 ALMI Invest,
 K-Svets Ventures,
 Chalmers Ventures

Origin

 Chalmers University of
 Technology

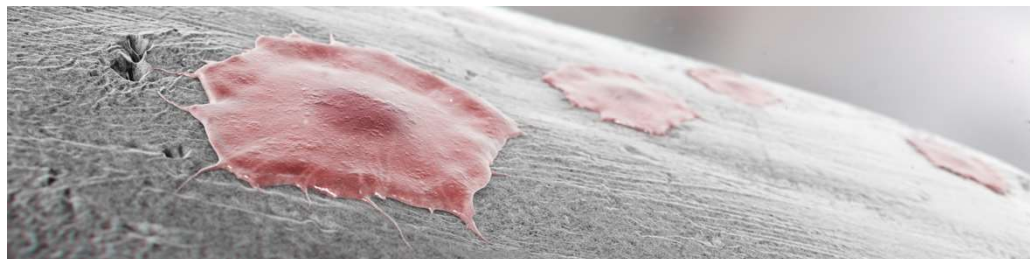
More information
 promimic.com

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

**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 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.

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).

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 5%

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 will own five percent of the shares in SVF. Further, an option agreement gives the opportunity to increase the ownership to a total of 25 percent within a defined period of time and at a predetermined price. 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 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Full-year
Condensed income statement					
Change in fair value of shares in portfolio companies	7.4	21.8	-115.3	21.8	415.1
Net profit/loss	2.1	7.5	-124.0	-11.2	303.0
Balance sheet information					
Cash, cash equivalents and short-term investments	46.1	36.1	46.1	36.1	52.1
Net asset value (Note 1)	891.3	269.3	891.3	269.3	1027.3
Net debt (Note 1)	-23.9	-469.9	-23.9	-469.9	-37.8
Share information					
Earnings per share, weighted average before dilution (SEK)	0.0	0.1	-0.7	-0.2	4.1
Earnings per share, weighted average after dilution (SEK)	0.0	0.1	-0.7	-0.2	4.1
Net asset value per share (SEK) (Note 1)	5.1	4.2	5.1	4.2	5.9
Equity per share (SEK) (Note 1)	5.0	4.4	5.0	4.4	5.7
Share price, last trading day in the reporting period (SEK)	3.0	3.8	3.0	3.8	3.5
Portfolio information					
Investments in portfolio companies	7.6	15.9	15.2	33.0	48.9
Of which investments not affecting cash flow	-0.3	0.4	0.6	0.6	1.9
Portfolio companies at fair value through profit or loss	885.2	652.0	885.2	652.0	1,047.6

Financial Development for the Investment Entity in 2020

Investments (comparable numbers 2019)

Investments in the portfolio in the second quarter 2020 by external investors and Karolinska Development amounted to SEK 7.6 (194.5) million, whereof 0% (95%) by external investors.

Karolinska Development invested SEK 7.6 (15.9) million, of which SEK 7.9 (15.5) million was cash investments. Investments were made in Umecline Cognition with SEK 3.0 million and in Modus Therapeutics with SEK 4.9 million. Non-cash investments (accrued interest on loans) amounted to -0.3 (0.4) million due to an adjustment.

No investments were made by external investors in the portfolio companies during the second quarter (SEK 184.9 million second quarter 2019).

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-Q2 2020
Umecrine Cognition	9.3	0.3	9.6
Modus Therapeutics	5.4	2.0	7.4
Dilafor	0.0	13.6	13.6
Svenska Vaccinfabriken Produktion	0.5	0.0	0.5
Total	15.3	15.9	31.1

Portfolio Fair Value

Fair Value of the portfolio companies owned directly by Karolinska Development decreased by SEK 64.9 million during the second quarter 2020. Fair value decreased mainly as a result of the partly divestment of Aprea but increased through the upturn in the share price of the listed holdings Aprea and Lipidor and with investments in the form of loans to Umecrine Cognition and Modus Therapeutics.

Fair Value of the portfolio companies owned indirectly via KDev Investments increased by SEK 27.1 million during the second quarter 2020. The main reason for the increase in Fair value was the upturn 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 37.8 million in the second quarter 2020.

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 9.4 million, resulting in Net Portfolio Fair Value decreasing by SEK 47.3 million in the second quarter 2020.

SEKm	30 Jun 2020	31 Mar 2020	Q2 2020 vs Q1 2020
Karolinska Development Portfolio Fair Value (unlisted companies)	481.2	479.5	1.7
Karolinska Development Portfolio Fair Value (listed companies)	62.9	129.5	-66.6
KDev Investments Portfolio Fair Value	787.7	760.6	27.1
Total Portfolio Fair Value	1,331.8	1,369.6	-37.8
Potential distribution to Rosetta Capital of fair value of KDev Investments	446.5	437.1	9.4
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	885.2	932.5	-47.3

Total Portfolio Fair Value on 30 June 2020 amounted to SEK 1,331.8 million and the potential distribution to Rosetta Capital amounted to SEK 446.5 million. Net Portfolio Fair Value on 30 June 2020 amounted to SEK 885.2 million. Compared to 31 December 2019, the Total Portfolio Fair Value decreased with SEK 221.6 million and the Net Portfolio Fair Value decreased with SEK 162.4 million.

Profit development 2020 (comparable numbers 2019)

During the second quarter 2020, Karolinska Development's revenue amounted to SEK 0.6 (1.0) million and consists primarily of services provided to portfolio companies. The revenue for the period January - June 2020, amounted to SEK 1.7 (1.9) million

Change in fair value of shares in portfolio companies of in total SEK 7.4 (21.8) million includes the difference between the change in Net Portfolio Fair Value during the second quarter 2020 with SEK -47.3 million and the net of investments in the portfolio companies of SEK 7.6 million and divestments of SEK -62.3 million. Change in fair value of other financial assets and liabilities amounted to SEK 5.3 (9.4) million and are the consequence of changes in valuation of earn-out deals. For the period January - June 2020, the change in fair value of shares in portfolio companies amounted to SEK -115.3 (21.8) million and the change in fair value of other financial assets amounted to SEK 9.3 (13.6) million.

During the second quarter 2020 other expenses amounted to SEK 3.0 (4.0) million and personnel costs amounted to SEK 6.3 (6.6) million. For the period January – June 2020 other expenses amounted to SEK 5.3 (7.1) million and personnel cost amounted to 11.6 (12.5) million. The reduction in personnel costs compared with the first half of 2019 is due the stay-on bonuses paid to the personnel, which increased comparable costs in 2019.

The operating profit/loss in the second quarter 2020 amounted to SEK 3.9 million compared to SEK 21.4 million in the second quarter 2019. The operating profit/loss for the period January - June 2020 amounted to -121.6 (17.4) million.

Financial net improved during the second quarter 2020 compared to the second quarter 2019 and amounted to SEK -1.8 (-13.9) 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 - June 2020 the financial net amounted to SEK -2.4 (-28.5) million.

The Investment Entity's Net profit/loss amounted to SEK 2.1 (7.5) million in the second quarter 2020. Net profit/loss for the period January June 2020 amounted to SEK -124.0 (-11.2) million.

Financial position

The Investment Entity's equity to total assets ratio amounted to 88% on 30 June 2020, same as on 31 March 2020.

The net profit/loss of SEK 2.1 million in the second quarter resulted in the equity on 30 June 2020 increasing to SEK 883.7 million compared to SEK 881.6 million on 31 March 2020.

Interest-bearing liabilities consisted of a bridge loan amounting to SEK 70 million, compared to SEK 506.0 million on 30 June 2019.

After paying operational costs and investments in the second quarter 2020, cash and cash equivalents amounted to SEK 46.1 million on 30 June 2020 compared to SEK 36.1 million on 30 June 2019. Net debt amounted to SEK 23.9 million on 30 June 2020 compared to SEK 469.9 million on 30 June 2019.

Financial Development – Parent Company

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

During the second quarter 2020, the Parent Company's Net profit/loss amounted to SEK 2.1 million (SEK 7.5 million).

Due to the positive result for the second quarter 2020, the equity increased from SEK 881.6 million 31 March 2020 to SEK 883.7 million 30 June 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 June 2020 was SEK 3.00, and the market capitalization amounted to SEK 527 million.

The share capital of Karolinska Development on 30 June 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 June 2020 amounted to 175,665,409 shares and 189,193,291 votes.

Ownership

On June 30, 2020, Karolinska Development had 4,621 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	6,230,600	3.55%	3.29%
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%
Ribbskottet AB	0	1,000,000	0.57%	0.53%
Sum Top 10 Shareholders	1,503,098	130,362,503	75.07%	76.85%
Sum Other Shareholders	0	43,799,808	24.93%	23.15%
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 continuously on different financing options to refinance the company's bridge loan and 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, 20 August 2020

Hans Wigzell
Chairman

Tse Ping

Björn Cochlovius

Magnus Persson

Theresa Tse

Viktor Drvota
CEO

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

Dates for Publication of Financial Information

Interim Report January – September 2020

11 November 2020

Karolinska Development is required by law to publish the information in this interim report. The information was published on 20 August 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 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Full-year
Revenue		589	1,039	1,693	1,943	3,384
Change in fair value of shares in portfolio companies	2	7,387	21,778	-115,342	21,767	415,136
Change in fair value of other financial assets and liabilities		5,345	9,352	9,258	13,566	-28,215
Other expenses		-2,982	-4,045	-5,294	-7,059	-18,186
Personnel costs		-6,285	-6,555	-11,586	-12,499	-23,474
Depreciation of right- of-use assets		-176	-176	-352	-352	-704
Operating profit/loss		3,878	21,393	-121,623	17,366	347,941
Financial net		-1,779	-13,922	-2,421	-28,522	-44,964
Profit/loss before tax		2,099	7,471	-124,044	-11,156	302,977
Taxes		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		2,099	7,471	-124,044	-11,156	302,977

Condensed statement of comprehensive income for the Investment Entity

SEK 000	Note	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Full-year
Net/profit loss for the period		2,099	7,471	-124,044	-11,156	302,977
Total comprehensive income/loss for the period		2,099	7,471	-124,044	-11,156	302,977

Earnings per share for the Investment Entity

SEK	Note	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Full-year
Earnings per share, weighted average before dilution		0.01	0.12	-0.71	-0.17	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		0.01	0.12	-0.71	-0.17	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 Jun 2020	30 Jun 2019	31 Dec 2019
ASSETS				
Tangible assets				
Right-of-use assets		1,055	1,056	704
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2	885,215	651,985	1,047,600
Loans receivable from portfolio companies		1,772	5,127	1,768
Other financial assets		0	27,609	0
Total non-current assets		888,042	685,777	1,050,072
Current assets				
Accounts receivable		114	-	39
Receivables from portfolio companies		1,232	1,483	322
Other financial assets		64,264	65,987	62,620
Other current receivables		1,040	22,829	787
Prepaid expenses and accrued income		868	2,771	732
Short-term investments, at fair value through profit or loss		0	25,129	0
Cash and cash equivalents		46,132	10,971	52,132
Total current assets		113,650	129,170	116,632
TOTAL ASSETS		1,001,692	814,947	1,166,704
EQUITY AND LIABILITIES				
Total equity		883,695	284,858	1,007,732
Long-term liabilities				
Other financial liabilities		0	11,423	0
Total long-term liabilities		0	11,423	0
Current liabilities				
Convertible loan	3	0	456,043	19,964
Current interest liabilities		70,000	50,000	70,000
Other financial liabilities		36,123	0	46,851
Accounts payable		989	2,786	11,484
Liability to make lease payment		1,091	1,070	726
Other current liabilities		1,926	1,586	2,991
Accrued expenses and prepaid income		7,868	7,181	6,956
Total current liabilities		117,997	518,666	158,972
Total liabilities		117,997	530,089	158,972
TOTAL EQUITY AND LIABILITIES		1,001,692	814,947	1,166,704

Condensed statement of changes in the Investment Entity's equity

SEK 000	Not	2020-06-30	2019-06-30	2019-12-31
Opening balance, equity				
		1,007,732	296,007	296,007
Net profit/ loss for the period		-124,044	-11,156	302,977
Effect of IFRS 16		7	7	14
Share capital		-	-	1,113
Prospectus costs direct issue 2019		-	-	-13,545
Share premium		-	-	421,166
Closing balance, equity		883,695	284,858	1,007,732

Condensed statement of cash flows for the Investment Entity

SEK 000	Note	2020 Jan-Jun	2019 Jan-Jun
Operating activities			
Operating profit/loss		-121,623	17,366
Adjustments for items not affecting cash flow			
Depreciation		352	352
Change in fair value	2	106,084	-35,333
Other items		-357	-358
Proceeds from short-term investments		-	-525
Interest paid/received		-	-1,007
Cash flow from operating activities before changes in working capital and operating investments		-15,544	-19,505
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables		-1,375	-123
Increase (+)/Decrease (-) in operating liabilities		-33,614	2,902
Cash flow from operating activities		-50,533	-16,726
Investment activities			
Part payment from earn-out deal		-3,114	-
Proceeds from sale of shares in portfolio companies		62,287	-
Acquisitions of shares in portfolio companies		-14,640	-32,442
Proceeds from sale of short-term investments ¹		-	44,296
Cash flow from operating activities		44,533	11,854
Financing activities			
Convertible debentures issue		-	-
Cash flow from financing activities		0	0
Cash flow for the period		-6,000	-4,872
Cash and cash equivalents at the beginning of the year		52,132	15,843
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		46,132	10,971
Supplemental disclosure¹			
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		46,132	10,971
Short-term investments, market value at closing date		0	25,129
CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS AT THE END OF THE PERIOD		46,132	36,100

¹Surplus 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 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Full-year
Revenue		589	1,039	1,693	1,943	3,384
Change in fair value of shares in portfolio companies		7,387	21,778	-115,342	21,767	415,136
Change in fair value of other financial assets		5,345	9,352	9,258	13,566	-28,215
Other expenses		-3,161	-4,223	-5,651	-7,416	-18,901
Personnel costs		-6,285	-6,555	-11,586	-12,499	-23,474
Operating profit/loss		3,875	21,391	-121,628	17,361	347,930
Financial net		-1,766	-13,911	-2,394	-28,496	-44,917
Profit/loss before tax		2,109	7,480	-124,022	-11,135	303,013
Tax		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		2,109	7,480	-124,022	-11,135	303,013

Condensed statement of comprehensive income for the Parent Company

SEK 000	Note	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Full-year
Net profit/loss for the period		2,109	7,480	-124,022	-11,135	303,013
Total comprehensive income/loss for the period		2,109	7,480	-124,022	-11,135	303,013

Condensed balance sheet for the Parent Company

SEK 000	Note	30 Jun 2020	30 Jun 2019	31 Dec 2019
ASSETS				
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2	885,215	651,985	1,047,600
Loans receivable from portfolio companies		1,772	5,127	1,768
Other financial assets		-	27,609	-
Total non-current assets		886,987	684,721	1,049,368
Current assets				
Accounts receivable		114	-	39
Receivables from portfolio companies		1,232	1,483	322
Other financial assets		64,264	65,987	62,620
Other current receivables		1,040	22,829	787
Prepaid expenses and accrued income		868	2,771	732
Short-term investments at fair value through profit or loss		-	25,129	-
Cash and cash equivalents		46,132	10,971	52,132
Total current assets		113,650	129,170	116,632
TOTAL ASSETS		1,000,637	813,891	1,166,000
EQUITY AND LIABILITIES				
Total equity		883,731	284,872	1,007,754
Long-term liabilities				
Other financial liabilities		-	11,423	-
Total long-term liabilities		0	11,423	0
Current liabilities				
Convertible loan	3	-	456,043	19,964
Current interest liabilities		70,000	50,000	70,000
Other financial liabilities		36,123	0	46,851
Accounts payable		989	2,786	11,484
Other current liabilities		1,926	1,586	2,991
Accrued expenses and prepaid income		7,868	7,181	6,956
Total current liabilities		116,906	517,596	158,246
Total liabilities		116,906	529,019	158,246
TOTAL EQUITY AND LIABILITIES		1,000,637	813,891	1,166,000

Condensed statement of changes in equity for the Parent Company

SEK 000	Note	30 Jun 2020	30 Jun 2019	31 Dec 2019
Opening balance, equity		1,007,753	296,007	296,007
Net profit/ loss for the period		-124,022	-11,135	303,013
Share capital		-	-	1,113
Prospectus costs direct issue 2019		-	-	-13,545
Share premium reserve		-	-	421,166
Closing balance, equity		883,731	284,872	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

No significant changes or transactions regarding related parties have occurred during the interim period.

Definitions

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.

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

Reporting period: January – June 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.

Net asset value and net asset value per share: Net Portfolio Fair Value of the total portfolio (SEK 885.2 million), loans receivable from portfolio companies (SEK 1.8 million), cash and cash equivalents (SEK 46.1 million), and net of financial assets and liabilities minus interest-bearing liabilities (SEK 28.1 million minus SEK 70.0 million), in relation to the number of shares outstanding (175,421,124) on the closing date (30 June 2020).

Net debt: Interest-bearing liabilities (SEK 70.0 million) reduced with cash and cash equivalents (SEK 46.1 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 June 2020

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	62,921	-	822,294	885,215
Loans receivable from portfolio companies	-	1,772	-	1,772
Other financial assets	-	-	64,264	64,264
Receivables from portfolio companies	-	1,232	-	1,232
Cash, cash equivalents and short-term investments	46,132	-	-	46,132
Total	109,053	3,054	886,558	998,665
Financial liabilities				
Other financial liabilities	-	-	36,123	36,123
Accounts payable	-	989	-	989
Liability to make lease payment	-	1,091	-	1,091
Total	-	2,080	36,123	38,203

Fair value as of 30 June 2019

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	69,823	-	582,162	651,985
Loans receivable from portfolio companies	-	5,127	-	5,127
Other financial assets	-	-	93,596	93,596
Receivables from portfolio companies	-	1,483	-	1,483
Cash, cash equivalents and short-term investments	36,100	-	-	36,100
Total	105,923	6,610	675,758	788,291
Financial liabilities				
Other financial liabilities	-	-	11,423	11,423
Accounts payable	-	2,786	-	2,786
Liability to make lease payment	-	1,070	-	1,070
Total	-	3,856	11,423	15,279

Fair value (level 3) as of 30 June 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	15,245	-	-
Disposals/ compensations	-	-	-3,114
Gains and losses recognized through profit or loss	-77,781	1,644	-7,614
Closing balance 30 June 2020	822,294	64,264	36,123
Realized gains and losses for the period included in profit or loss	146	-	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	-77,927	1,644	-7,614

Fair value (level 3) as of 30 June 2019

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At beginning of the year	618,927	80,030	11,423
Acquisitions	17,093	-	-
Gains and losses recognized through profit or loss	-11	4,214	-
Closing balance 30 June 2019	636,009	84,244	11,423
Realized gains and losses for the period included in profit or loss	49	-	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	-60	4,214	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 446.5 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 Jun 2020	30 Jun 2019	31 Dec 2019
Karolinska Development Portfolio Fair Value (unlisted companies)	481,161	439,641	446,658
Karolinska Development Portfolio Fair Value (listed companies)	62,921	69,823	162,771
KDev Investments Portfolio Fair Value	787,679	485,823	943,946
Total Portfolio Fair Value	1,331,761	995,287	1,553,375
Potential distribution to Rosetta Capital of fair value of KDev Investments	446,546	343,302	505,775
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	885,215	651,985	1,047,600

* SEK 43.3 million repayment of investments in KDev Investments made by Rosetta Capital and SEK 403.2 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 on 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 Pledge assets and contingent liabilities

SEK 000	2020-06-30	2019-06-30	2019-12-31
Pledge assets			
The right to payment under Earn-out agreement regarding Oncoceptides shares ¹	-	65,987	-
Contingent liabilities			
Investment agreement in portfolio company	3,950	-	2,000
Summa	3,950	65,987	2,000

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