

Q1

## 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. Nine of the 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 project results during 2019, offering the potential for substantially increased opportunities for attractive divestments or licensing deals. Comparable candidate drugs for our active holdings in the portfolio have, in recent years, been out-licensed or sold for contract values of between SEK 1.8 and 7.7 billion for the individual projects. The portfolio companies have been strengthened in the past year through the recruitment of senior executives with a documented ability to close international business deals in the life sciences sector.

For further information, see www.karolinskadevelopment.com

## Financial Update

### First quarter

- The net profit/loss for the first quarter was SEK -18.6 million (SEK 14.9 million in the first quarter of 2018). Earnings per share totalled SEK -0.3 (SEK -0.3 in the first quarter of 2018).
- The result of the Change in fair value of shares in portfolio companies amounted to SEK -0.01 million (SEK -4.8 during the first quarter of 2018).
- The total fair value of the portfolio was SEK 970.0 million at the end of March 2019, corresponding to an increase of SEK 17.7 million from SEK 952.3 million at the end of the previous quarter. The net portfolio fair value at that time was SEK 636.0 million, corresponding to an increase of SEK 17.1 million from SEK 618.9 million at the end of the previous quarter.
- Net sales totalled SEK 0.9 million during the first quarter of 2019 (SEK 0.7 million during the first quarter of 2018).
- Karolinska Development invested a total of SEK 17.1 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 121.4 million.
- Cash and cash equivalents decreased by SEK 24.0 million during the first quarter, totalling SEK 61.8 million on 31 March 2019.
- The Parent Company's equity on 31 March 2019 was SEK 277.4 million.



# Significant events during the first quarter

- Negotiations on the solution of the convertible loan are ongoing. There is still no solution, but the
  management and the board continue to work intensively with various possible solutions to solve
  the financial situation. The objective is to be able to present a proposal to the Annual General
  Meeting
- Modus Therapeutics announced that patient enrollment for the Phase II study of sevuparin in patients with sickle cell disease (SCD) has been completed. (January 2019).
- Umecrine Cognition presented the results of its Phase IIa study of the GR3027 candidate drug in patients with idiopathic hypersomnia. The primary study objectives were met in regard to safety and pharmacokinetics. The study also showed preliminary evidence of clinical efficacy in a subset of patients. Umecrine Cognition will analyze the data further before a decision to potentially move forward with the development of GR3027 in idiopathic hypersomnia or other sleep disorders. In parallel, Umecrine Cognition will continue the clinical development of GR3027 for hepatic encephalopathy (January 2019).
- OssDsign announced the closing of a private placement of SEK 64 million. Swedish private investors and the French investment company Alto Invest took part in the private placement. (February 2019).
- Modus Therapeutics announced that they had successfully dosed the first cohort of patients in their Phase I study of subcutaneously administered sevuparin. The study is examining pharmacokinetics, safety, and tolerability in healthy subjects (February 2019).
- Aprea Therapeutics announced that investment funds managed by Janus Henderson Investors
  have joined the Series C financing of the company as a new investor, raising the total amount of
  the financing from EUR 50 million to EUR 55 million (February 2019).
- Forendo Pharma presented positive results from a Phase la study with the drug candidate FOR 6219 for the treatment of endometriosis. The results found FOR 6219 to be safe and well tolerated, with good pharmacokinetics at the doses tested (March 2019).
- Promimic announced a new partnership with the US company, Onkos Surgical<sup>®</sup> to commercialize
  Promimic's proprietary Hydroxyapatite Surface Technologies in Limb Salvage Surgery (March
  2019).
- Aprea Therapeutics appointed Dr. Eyal C. Attar as Senior Vice President and Chief Medical Officer. Dr. Attar joins Aprea from Agios Pharmaceuticals, where he was Senior Medical Director and IDH Hematology Medical Lead (March 2019).

# Significant post-period events

- Aprea Therapeutics presented promising results from studies of APR-246 in combination with immuno-oncology agents. The results showed that APR-246 can improve the effects of immunooncology treatments (April 2019).
- Aprea Therapeutics announced that APR-246 had been granted Orphan Drug Designation and Fast Track Designation by the FDA, for treatment of patients with MDS (April 2019).
- Dilafor announced completion of a capital raising and plans to start a new Phase 2b study of tafoxiparin to soften the cervix prior to labor induction. The transaction will increase the value of



- Karolinska Development's holding in Dilafor and gives a positive effect on earnings by approximately SEK 16.8 million (April 2019).
- The Annual Report contained an update from The Board of Directors in Karolinska Development regarding the company's financial situation and actions taken to strengthen the company's financials. The annual report also contains an emphasis of matter paragraph from the Auditor regarding going concern (April 2019).
- OssDsign announced application for listing on Nasdaq First North and published a prospectus in connection with a share issue of SEK 151,3 million (May 2019).
- The results of the Phase II study of sevuparin by our portfolio company, Modus Therapeutics, did
  not show any meaningful clinical effect in conjunction with acute Vaso Occlusive Crisis (VOC) in
  patients with sickle cell disease (SCD). Modus is now considering alternative options for the
  further development of sevuparin (May 2019).

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

"We are working to solve Karolinska Development's convertible loan and negotiations are in progress with the largest holder of the convertible loan, but we have not yet reached a solution. The company also works with alternative solutions together with financial institutions. The objective is to be able to present a proposal to the Annual General Meeting.

Several of the portfolio companies reported progress in their clinical development projects during the first quarter of the year. Umecrine Cognition's GR3027 showed a good safety profile, favourable pharmacokinetics, and indications of efficacy in a Phase II study, while Forendo presented positive results from a Phase I study of FOR6219. After the quarter end, Dilafor secured financing for the continued development of tafoxiparin and OssDsign submitted a request for listing on the NASDAQ First North Exchange. Aprea Therapeutics also announced positive results from a study of APR-246 in combination with immune checkpoint blockade, and the candidate drug received both Orphan Drug and Fast Status Designations from the FDA. The results of Modus Therapeutics' Phase II study of sevuparin, however, were not what we had hoped for, with no clinically meaningful effect observed from the treatment."

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# Chief Executive's Report

# Progress in several of the portfolio companies' clinical development projects

Several of the portfolio companies reported progress in their clinical development projects during the first quarter of the year

Umecrine Cognition presented Phase IIa results for GR3027 in idiopathic hypersomnia, which is a severe and debilitating disease characterized by chronic, extensive daytime sleepiness with no other known cause. There were, the relatively short treatment period notwithstanding, indications of clinical efficacy and the candidate drug showed favorable pharmacokinetics and a good safety profile. GR3027 is also being developed for hepatic encephalopathy indications, and the results of an ongoing Phase IIa study are expected early next year.

Forendo Pharma also took an important step forward during the quarter. Positive results were presented from a Phase Ia study of the FOR6219 candidate drug, which is being developed for the treatment of endometriosis. FOR6219 was well tolerated and showed a favorable pharmacokinetic profile. Endometriosis is a chronic condition that affects up to 10% of women of fertile age and which causes severe pain, infertility, and a deterioration in quality of life. Available treatments for endometriosis often have limited efficacy and many of them have harmful side effects.

Positive results from a study of Aprea's APR-246 in combination with immune checkpoint blockade were announced after the period end. The results suggest that APR-246 has real potential for improving the effect of immuno-oncology agents, which is the fastest growing field in the oncology sphere. Shortly afterwards, Aprea announced that the FDA had awarded APR-246 Orphan Drug Designation for the treatment of TP53-mutated myelodysplastic syndrome (MDS). The FDA also awarded Fast Track Designation for the same indication. The FDA's decisions demonstrate the importance and strength of the data for APR-246 presented by Aprea. The candidate drug has considerable potential for helping cancer patients for whom effective treatment is currently lacking. A number of clinical studies of APR-246 are currently in progress, including a Phase III study of patients with myelodysplastic syndrome (MDS). APR-246 is one of the world's most advanced TP53-targeted candidate drugs.

The results of Modus Therapeutics' Phase II study of sevuparin in patients with sickle cell disease, however, were a setback, with no clinically meaningful effect observed from the treatment, but the company is currently evaluating other potential indications where the substance's multimodal mechanism of action and its strong safety profile could help generate patient benefit.

### Strong interest in our portfolio companies by international investors

OssDsign announced its intention, in conjunction with the company's strengthening of its financial position through a private placement of SEK 64 million, to list the share on Nasdaq First North in 2019. In May the company published the prospectus in connection with a share issue of SEK 151,3 million and the planned listing on 24 May. A listing would be proof of Karolinska Development's ability to support life science companies' development during their maturation phase and improve the potential for realizing the holding on favorable terms at an appropriate time. OssDsign develops, manufactures, and distributes regenerative implants for bone tissue repairs.

Aprea Therapeutics announced, during the guarter, that Janus Henderson Investors have joined in the



financing of the company as a new investor, raising the total amount of the most recent round of financing from EUR 50 million to EUR 55 million.

Dilafor announced, after the end of the quarter, that the company had secured financing for continued development of tafoxiparin. The candidate drug is being developed to address the problems associated with protracted labor – an area where no new treatments have been introduced for over 70 years. The next stage in the development will entail a Phase IIb study of softening the cervix prior to labor induction.

### Working to strengthen the company's financial situation

A significant portion of the recent years' investments in Karolinska Development's portfolio companies has been enabled by the convertible loan that matures at the end of this year, with a repayment amount of approximately. SEK 484 million in the absence of any prior conversion to shares. The company also has an outstanding credit facility of SEK 50 million, which falls due in November 2019. The Board is actively working to solve the financial situation. The discussions being held with Sino Biopharmaceutical Ltd – the biggest holder of convertibles in the company and one of its major shareholders – with a view to implementing an offset issue of Sino Biopharmaceutical's convertibles, is part of the work in this area. This also includes the possibility of a rights issue during the second half of 2019 and has appointed DNB Markets as financial advisor. The company is also working with financial institutions on identifying alternative solutions.

### Several important clinical results in the pipeline

Aprea Therapeutics is expected to present the full results of the Phase II study of myelodysplastic syndrome (MDS) later this year. Interim data presented in December 2018 shows an Overall Response Rate (ORR) of 95% and a Complete Remission (CR) rate of 70%. Results from a Phase II study of APR 246 in patients with platinum-sensitive high-grade serous ovarian cancer (HGSOC) will also be presented. Karolinska Development owns 2% of the company directly and a further 11% through KDev Investments (fully diluted). A few years ago, a licensing deal was signed for a similar pharmaceutical project with a contract value of more than SEK 4 billion. The average probabilities of positive Phase II data for projects addressing ovarian cancer and MDS are 27% and 33%, respectively.

In early 2020, our portfolio company Umecrine Cognition is expected to present the results of a Phase II study of its GR3027 candidate drug in patients with hepatic encephalopathy. Karolinska Development owns 72% of Umecrine Cognition (fully diluted). Two licensing deals involving similar pharmaceutical projects were signed in recent years with contract values of over SEK 3 billion and SEK 1.8 billion, respectively. The average probability of positive Phase 2 results for this type of project is 34%.

Solna, 21 May 2019

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.

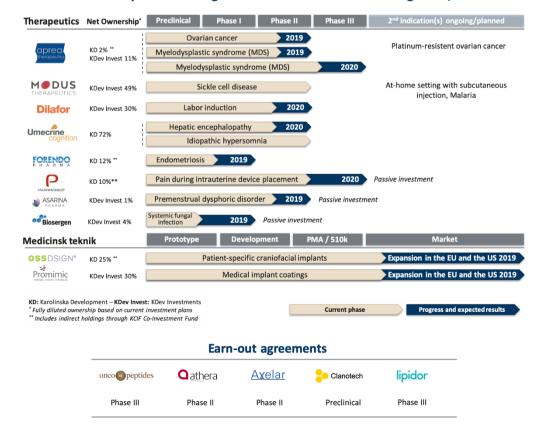
Karolinska Development has a focused portfolio of therapeutic and medtech companies with significant valuegenerating potential. The portfolio companies are developing highly differentiated and commercially attractive products that have the potential to deliver compelling clinical and health economic 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 in 2019 and 2020. 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 within the next two years.

The therapeutics companies' next key value-generating milestones are expected within the next two years, when several of the companies are supposed to present Phase II proof-of-concept data. The medtech companies OssDsign and Promimic are revenue generating and have significant milestones mapped out in 2019 and 2020 regarding execution of their commercial strategies.

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

### Our current portfolio – significant value-inflection during 2019/2020







Project (First-in class) APR-246

Primary indication

Development Phase Phase III

Holding in company\*
Karolinska Development 2%\*\*
KDev Investments 11%

#### 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.
- \*\* Includes indirect holdings through KCIF Co-Investment Fund

# 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 (Stockholm, Sweden and Boston, US) is a biotech company developing novel anticancer compounds targeting the tumor suppressor protein p53. Mutations of the p53 gene occur in around 50% of all human tumors. These mutations are often associated with resistance to anticancer drugs and poor overall survival, representing a major unmet medical need in the treatment of cancer. Aprea's lead drug candidate APR-246 is a first-in-class compound that reactivates mutant p53 protein, inducing programmed cell death in human cancer cells.

APR-246 is currently in a Phase lb/II clinical study in myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML), investigating the drug candidate's safety and efficacy in combination with standard chemotherapy (azacitidine) for the treatment of TP53 mutated MDS and AML. Aprea presented positive interim data at key congresses during 2018. The overall response rate (ORR) in 20 evaluable patients was 95%, with 70% patients achieving a complete remission (CR) at data cutoff. In comparison, the ORR in corresponding patient group receiving standard of care is 30-50% and CR is 20-30%. No safety or tolerability issues have so far been recorded. Final results from the study are expected in 2019.

Following the promising development in MDS, Aprea has initiated a pivotal Phase III study in patients with TP53 mutated MDS from which results are anticipated in 2020. The company also aims to start a Phase Ib/II trial in 2019 evaluating APR-246 in MDS patients in the post-transplantation maintenance setting.

Among solid tumors, APR-246 is evaluated in a Phase II study in platinum-sensitive high-grade serous ovarian cancer (HGSOC) and in a Phase Ib study in platinum-resistant HGSOC. Results are expected in 2019, although the company has yet to decide whether to continue development in solid tumors.

### 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 tumors 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

- First patient included in pivotal Phase III study (January 2019).
- Janus Henderson Investors joined the financing round announced in Dec 2019 and invested EUR 5 million (February 2019).
- FDA granted APR-246 Fast Track designation and Orphan Drug designation for treatment of patients with TP53 mutated MDS (April 2019).

#### **Expected milestones**

- Results from Phase II study in platinum-sensitive HGSOC expected in 2019.
- Final results from Phase Ib/IIa study in MDS expected in 2019.





Project (First-in-class) Sevuparin

Primary indication Sickle cell disease (SCD)

Development Phase

Holding in company\* KDev Investments 49%

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

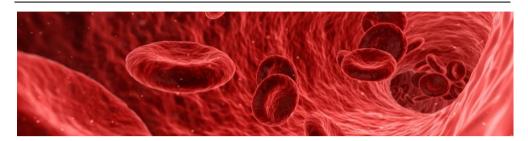
#### Origin Karolinska Institute

Karolinska Institutet, Uppsala University

More information modustx.com

\*Fully-diluted ownership based on current investment plans

## Modus Therapeutics AB



# Focuses on restoring healthy blood flow in debilitating diseases

Modus Therapeutics (Stockholm, Sweden) is developing sevuparin, an innovative drug which has the potential to restore blood flow and prevent further microvascular obstructions in a number of diseases.

Sevuparin is an innovative, proprietary polysaccharide drug with anti-adhesive, anti-aggregate and anti-inflammatory effects due to its multimodal mechanism of action. The drug candidate has the potential to restore blood flow and prevent further microvascular obstructions in a number of diseases.

Modus has completed a global Phase II study of sevuparin in hospitalized sickle cell disease (SCD) patients. The randomized, double blinded study included 144 SCD-patients at clinical sites across Europe, the Middle East and the Caribbean. The study compared intravenously (IV) administered sevuparin with placebo in patients admitted to the hospital with an acute vaso-occlusive crisis (VOC) associated with SCD. 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 its options for further development of sevuparin.

A Phase I study of subcutaneously administered sevuparin is ongoing and results are expected in 2019. This treatment approach has the potential to become a home-based, self-administered therapeutic option for SCD patients to prevent and treat VOC.

#### The market

SCD, an orphan disease, leads to progressive organ damage that limits the life expectancy of patients. Lifetime medical care costs can exceed USD 1 million per patient with an estimated USD 1 billion spent annually on the disease in the US alone, where sickle cell disease is believed to affect approximately 100,000 individuals. The population grows significantly outside of the US and EU with over 1 million patients in the Middle East and over 5 million patients in Africa.

### **Recent progress**

- Patient enrollment completed in Phase II study in SCD (January 2019).
- First cohort dosed in Phase I study with subcutaneously administered sevuparin (February 2019).
- Results from Phase II trial in SCD presented (May 2019)

#### **Expected milestones**

Results from Phase I study with subcutaneously administered sevuparin anticipated in 2019.



# **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. The company's primary goal with tafoxiparin is to minimize the risk for protracted labor and associated complications.

About a quarter of all pregnant women are subject to labor induction. More than half of these inductions fail, which leads to protracted labor that entail an increased risk of complications for both mother and child as well as substantial health care costs. Between 25 and 40 percent ends up requiring emergency caesarean sections.

In a previous phase IIa study, subcutaneous administration of Dilafor's drug candidate tafoxiparin has shown a significant positive effect with a shortened time to delivery and an enhanced ripening of the cervix in patients induced into labor. A soft and ripe cervix is a prerequisite for successful labor induction. Dilafor is now proceeding with a phase IIb study to investigate in a larger group whether treatment with subcutaneously administered tafoxiparin can soften the cervix and improve the outcome of labor induction, thereby shortening the time to delivery.

#### The market

It has been estimated that about a quarter of all pregnant women are in need of labor induction, i.e. they do not have a spontaneous onset of labor. The procedure using standard of care such as prostaglandins and oxytocin often - in more than 50% of cases associated with failed induction - lead to protracted labor and emergency cesarean sections or other maternal and fetal 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 (April 2019).

### **Expected milestones**

Start of Phase IIb study in labor induction during 2019





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,
Partnerlnyest

**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 a therapy that represents a new target class for several major CNS-related disorders. The lead compound GR3027 is presently in clinical development for hepatic encephalopathy (HE), a serious neuropsychiatric and neurocognitive complication in acute and chronic liver disease (including cirrhosis). The drug candidate is also being clinically evaluated as a new treatment of idiopathic hypersomnia (IH), which is a severe orphan disease characterized by chronic excessive daytime sleepiness despite normal sleep.

An increase in the inhibitory GABA system in the CNS is believed to be a main driver for the clinical signs and symptoms in a wide range of cognitive and sleep disorders, including HE and IH. This makes GABA-receptor modulating steroid antagonists that act on the neurosteroid enhancement of GABA receptor activation, as developed by Umecrine Cognition, a credible therapeutic class to explore.

GR3027 has been shown to restore different types of neurological impairments in experimental models. The drug candidate enters the CNS and reverses the inhibitory effects of the neurosteroid allopregnanolone on brain function in humans. Positive Phase Ib data from the ongoing combined Phase Ib/IIa study in HE shows that GR3027 is well tolerated, does not cause any dose-limiting side effects and has a favorable pharmacokinetic profile. GR3027 has now advanced into the phase IIa part of the study, from which results are expected in early 2020.

A Phase IIa study in 10 patients with IH has been completed. The primary study objectives were met in regard to safety and pharmacokinetics. The study also showed preliminary evidence of clinical efficacy in a subset of patients. Umecrine Cognition will analyze the data further before a decision to potentially move forward with the development of GR3027 in idiopathic hypersomnia or other sleep disorders.

#### 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.

There are no approved treatments for IH but several wake-promoting agents are used off-label. However, they are inadequate to alleviate symptoms in most patients, and refractory or intolerance symptoms occur in one-quarter of patients.

### Recent progress

• Results from Phase IIa study in IH presented (January 2019).

### **Expected milestones**

 Results from the Phase IIa part of the combined Phase Ib/IIa study in HE expected in early 2020.





Project (First-in-class) FOR-6219

**Primary indication**Endometriosis

**Development Phase**Phase la

Holding in company\* Karolinska Development 12%\*\*

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

**Origin**University of Turku, Finland

More information forendo.com

Innovestor

- \* 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.

Endometriosis is an estrogen dependent disease that affects women in reproductive age and is caused by cells normally lining uterus being present outside of the uterine cavity, which induces chronic inflammation. 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 estrogen synthesis, but due to systemic estrogen disturbances these therapies are also associated with harmful side effects that limit the use of them. The risk of osteoporosis is for example well known in association with estrogen elimination therapies.

Forendo's drug candidate FOR-6219 is an inhibitor of the HSD17B1 enzyme, a novel drug target for tissue specific regulation of hormone activity. Proof of efficacy for this novel mechanism has been demonstrated in preclinical models in which the compound has been shown to locally block formation of estrogen in endometrial tissue, cause regression of endometriosis and relief of the associated inflammatory pain without impacting systemic estrogen levels. A Phase Ia trial found FOR-6219 to be safe and well tolerated, with good pharmacokinetic profile. These results support the initiation of a Phase Ib study in healthy postmenopausal women with the aim to demonstrate Proof of Mechanism. Study start is expected in mid 2019.

Forendo has also a second program, a dual HSD inhibitor for the treatment of broader gynecological conditions in 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**

- EUR 4 million raised from new investor Vesalius Biocapital III Partners (September 2018).
- Positive Phase la results presented (March 2019)

### **Expected milestones**

Phase Ib study start in 2019.



# **OSS**DSIGN®

### **Project**

OSSDSIGN® Cranial and OSSDSIGN® Facial

Primary indication Cranial implants

**Development Phase** Marketed

Holding in company\*
Karolinska Development 25%\*\*

Other investors

SEB Venture Capital, Fouriertransform

#### Origin

Karolinska University Hospital, Uppsala University

## More information

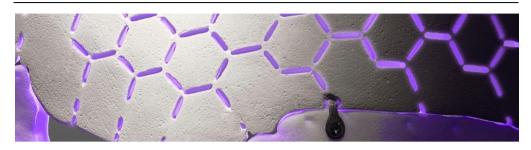
ossdsign.com

- \* 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 innovator, designer and manufacturer of implants and material technology for bone regeneration. Its lead products – OSSDSIGN® Cranial and OSSDSIGN® Facial – are already being sold on several European markets including Germany, the UK and the Nordic region, as well as selected non-European markets including Singapore and Israel. The company is commercializing its cranial implant in the US and is also undertaking regulatory and commercial activities in Japan.

The commercial strategy is focused on building sales of the innovative products through a combination of an internal sales organization and distribution partnerships. A US subsidiary has been established to strengthen the market presence.

OssDsign's personalized bone regeneration technology provides improved healing properties that are clinically proven to enhance patient outcomes. By combining a regenerative ceramic material reinforced with titanium, with tailored patient-specific designs enabled by state-of-the-art computer-aided design, 3D printing and moulding techniques, the technology platform aims to contribute to the permanent healing of a range of bone defects. Enhanced healing means a better implant solution for patients and cost savings for hospitals.

#### The market

OssDsign is focusing on the market for craniomaxillofacial (CMF) implants. The total market size was estimated to USD 1,8 billon 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 pursues a focused business strategy on a well-defined patient population. The advantages are that the targeted procedures are carried out in a limited number of easily identifiable hospitals around the world. The indications are relatively price insensitive and easy to access on many markets from a regulatory perspective.

### Recent progress

- 510(k) clearance granted by US FDA to market OssDsign's latest product Cranioplug in the US (October 2018).
- SEK 64 million raised from Swedish private investors and the French investment management company Alto Invest (February 2019).
- OssDsign announced application for listing on Nasdaq First North and published a prospectus in connection with a share issue of SEK 151,3 million (May 2019).

#### **Expected milestones**

 Launch of OssDsign's products on new EU markets and selected markets outside of Europe during 2019.





**Project** HA<sup>nano</sup> Surface

Primary indication Implant surface coatings

**Development Phase** Marketed

Holding in company\* KDev Investments 30%

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<sup>nano</sup> Surface, which increases their integration into bone and anchoring strength.

The HA<sup>nano</sup> Surface is nanometer thin, which helps preserve the micro-structure of the implant and reduces the risk of cracks in the coating. The coating is unique because it can be applied to any implant geometry and material, including porous materials and 3D structures. Furthermore, the HA<sup>nano</sup> coating technology offers a fast way to market since the technology that the coating is based on has been approved by FDA, whereby a new implant coated with HA<sup>nano</sup> Surface can receive marketing approval through the 510(k) route. The coating process is easy to implement in the industrial scale production of implants.

Promimic has established a sales operation in the US and a series of development and commercial partnerships, including with Sistema de Implante Nacional (S.I.N), a leading provider of dental implants in Brazil. S.I.N. is commercializing dental implants coated with HA<sup>nano</sup> Surface in USA, amongst other countries. A manufacturing facility for HA<sup>nano</sup> coated implants to supply the US and Chinese markets has also been established by the Promimic's partner, Danco Anodizing. In 2019, Promimic strengthened its position in the orthopedic space through the partnership with the US company Onkos Surgical. The partners will develop and commercialize the HAn<sup>ano</sup> Surface technology in combination with Onkos Sugical's products for limb salvage surgery.

#### The market

Promimic is focusing on the markets for dental and orthopedic implants, which collectively represents a worldwide market opportunity of USD 600 - 800 million. The implant industry is a large, high-growth market which delivers high profit margins. The competition amongst implant manufacturers is fierce and each market segment is dominated by four-to-eight global companies. The strategies of many of these companies rely on in-licensing new technologies in order to differentiate their products and strengthen their market position. Promimic has a business model designed to meet these needs. It is centered on out-licensing its HA<sup>nano</sup> Surface technology to leading implant manufacturers so that they can incorporate it into their products.

#### Recent progress

Entered into partnership with the US company Onkos Surgical (March 2019).

### **Expected milestones**

Further product launches and license agreements with major manufacturers during 2019.



## 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	2019 Jan-Mar	2018 Jan-Mar	2018 Full-year
Condensed income statement			
Change in fair value of shares in portfolio companies	0.0	-4.8	58.5
Net profit/loss	-18.6	-19.7	30.5
Balance sheet information			
Cash, cash equivalents and short-term investments	61.8	145.7	85.8
Net asset value (Note 1)	226.6	254.1	247.1
Net debt (Note 1)	-430.4	-245.7	-392.5
Share information			
Earnings per share, weighted average before dilution (SEK)	-0.3	-0.3	0.5
Earnings per share, weighted average after dilution (SEK)	-0.3	-0.3	0.5
Net asset value per share (SEK) (Note 1)	3.5	4.0	3.8
Equity per share (SEK) (Note 1)	4.3	3.9	4.6
Share price, last trading day in the reporting period (SEK)	5.9	5.0	6.2
Portfolio information			
Investments in portfolio companies	17.1	13.4	124.6
Of which investments not affecting cash flow	0.2	2.0	7.3
Portfolio companies at fair value through profit or loss	636.0	456.4	618.9

## Financial Development for the Investment Entity in 2019

### Investments (comparable numbers 2018)

Investments in the portfolio in the first quarter 2019 by external investors and Karolinska Development amounted to SEK 121.4 (18.0) million, whereof 86% (25%) by external investors.

Karolinska Development invested SEK 17.1 (13.4) million, of which SEK 16.9 (11.4) million was cash investments. Investments were made in Umecrine Cognition SEK 10.5 million and Forendo Pharma SEK 6.6 million. Non-cash investments (accrued interest on loans) amounted to 0.2 (2.0) million.

Investments by external investors in the portfolio companies amounted to SEK 104.3 (4.6) million. Investments were made in Umecrine Cognition and Forendo Pharma.



### Portfolio Fair Value

Fair Value of the portfolio companies owned directly by Karolinska Development increased by SEK 17.4 million during the first quarter 2019. Fair value increased as a result of investments in and loan to portfolio companies Forendo Pharma and Umecrine Cognition.

Fair Value of the portfolio companies owned indirectly via KDev Investments increased by SEK 0.3 million during the first quarter 2019.

Total Fair Value from portfolio companies owned directly by Karolinska Development and indirectly via KDev Investments increased by SEK 17.7 million in the first quarter 2019.

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 0.6 million, resulting in Net Portfolio Fair Value increasing by SEK 17.1 million in the first quarter 2019.

SEKm	31 Mar 2019	31 Dec 2018	Q1 2019 vs Q4 2018
Karolinska Development Portfolio Fair Value (unlisted companies)	510.0	492.6	17.4
KDev Investments Portfolio Fair Value	460.0	459.7	0.3
Total Portfolio Fair Value	970.0	952.3	17.7
Potential distribution to Rosetta Capital of fair value of KDev Investments	334.0	333.4	0.6
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	636.0	618.9	17.1

Total Portfolio Fair Value on 31 March 2019 amounted to SEK 970.0 million and the potential distribution to Rosetta Capital amounted to SEK 334.0 million. Net Portfolio Fair Value on 31 March 2019 amounted to SEK 636.0 million. Compared to 31 March 2018, the Total Portfolio Fair Value increased with SEK 241.4 million and the Net Portfolio Fair Value increased with SEK 179.6 million.



### Profit development 2019 (comparable numbers 2018)

During the first quarter 2019, Karolinska Development's revenue amounted to SEK 0.9 (0.7) million and consists primarily of services provided to portfolio companies.

Change in fair value of shares in portfolio companies of in total SEK -0.01 (-4.8) million. Change in fair value of other financial assets amounted to SEK 4.2 (4.2) million and is mainly a consequence of the valuation of an earn-out deal.

During the first quarter 2019 other expenses amounted to SEK 3.0 (4.1) million and personnel costs amounted to SEK 5.9 (5.4) million.

The operating profit/loss in the first quarter 2019 amounted to SEK -4.0 million compared to SEK -9.4 million first quarter 2018.

Financial net increased during the first quarter 2019 compared to the first quarter 2018 and amounted to SEK -14.6 (-10.3) million, which is primarily related to increased interest costs for the convertible bond (the interest is cumulative) and decreased income interest on loans to portfolio companies.

The Investment Entity's Net profit/loss amounted to SEK -18.6 (-19.7) million in the first quarter 2019.

### Financial position

The Investment Entity's equity to total assets ratio amounted to 35% on 31 March 2019 compared to 37% on 31 December 2018.

The Investment Entity's equity amounted to SEK 277.4 million on 31 March 2019 compared to SEK 296.0 million on 31 December 2018. The decrease was a consequence of the Net profit/Loss of SEK -18.6 million for the first quarter 2019.

Interest-bearing liabilities consist of a convertible loan and a one-year credit facility, and on March 31, 2019 amounted to SEK 492.2 million, compared with SEK 391.5 million on March 31, 2018.

After paying operational costs and investments in the first quarter 2019, cash and cash equivalents together with short-term investments, amounted to SEK 61.8 million on 31 March 2019 compared to SEK 145.7 million on 31 March 2018. Net debt amounted to SEK 430.4 million on 31 March 2019 compared to SEK 245.7 million on 31 March 2018.

### Financial situation

See section "Financial risks" for the Board's view of the company's financial situation, taking into account the convertible loan, which matures on December 31, 2019.

# Financial Development - Parent Company

The Parent Company refers to Karolinska Development AB (comparable numbers first quarter 2018).

During the first quarter 2019, the Parent Company's Net profit/loss amounted to SEK -18.6 million (SEK -19.7 million).

Due to the negative result for the first quarter 2019, the equity decreased from SEK 296.0 million 31 December 2018 to SEK 277.4 million 31 March 2019.



## **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 29 March 2019 was SEK 5.88, and the market capitalization amounted to SEK 370 million.

The share capital of Karolinska Development on 31 March 2019 amounted to SEK 0.6 million divided into 1,503,098 A shares, each with ten votes (15,030,980 votes) and 62,915,639 B shares, each with one vote (62,915,639 votes). The total number of shares and votes in Karolinska Development on 31 March 2019 amounted to 64,418,737 shares and 77,946,619 votes.

### **Ownership**

On December 31, 2018, Karolinska Development had 3,818 shareholders.

Shareholder	A-Shares	<b>B-Shares</b>	Cap %	Vote %
Karolinska Institutet Holding AB	1,503,098	2,126,902	5.64%	22.01%
Tredje AP-Fonden	0	6,371,600	9.89%	8.17%
Sino Biopharmaceutical Limited	0	4,853,141	7.53%	6.23%
Östersjöstiftelsen	0	3,889,166	6.04%	4.99%
Costal Investment Management LLC	0	3,470,466	5.39%	4.45%
OTK Holding A/S	0	2,300,000	3.57%	2.95%
Ribbskottet AB	0	1,700,000	2.64%	2.18%
Stift För Främjande&Utveckling	0	1,397,354	2.17%	1.79%
Försäkringsaktiebolaget Avanza Pension	0	1,196,955	1.86%	1.54%
Friheden Invest A/S	0	1,000,000	1.55%	1.28%
Sum Top 10 Shareholders	1,503,098	28,305,584	46.27%	55.60%
Sum Other Shareholders	0	34,610,055	53.73%	44.40%
Sum All Shareholders	1.503.098	62.915.639	100.00%	100.00%



## Information on Risks and Uncertainties

## **Investment Entity and Parent Company**

#### Financial risks

As of March 31, 2019, Karolinska Development had an outstanding convertible loan of nominally SEK 329 million with an annual nominal interest rate of 8 percent. The convertible loan matures on December 31, 2019 with a repayment amount of approximately SEK 484 million (the interest rate is cumulative) if it is not converted to shares before then. The company also has an outstanding credit facility of SEK 50 million, which matures in November 2019.

The company is in need of finding a solution for the convertible loan, the outstanding credit facility and secure the continued operation. The company is in discussions with the company's major convertible holder, Sino Biopharmaceutical Limited, also a major shareholder in the company, holding convertibles in the company with a nominal value of approximately SEK 273 million, regarding a set-off of Sino Biopharmaceutical Limited's convertibles, together with accrued interest, against shares in the company. In the discussions, Sino Biopharmaceutical Limited has stated in writing:

"We, Sino Biopharmaceutical Limited and Chia Tai Resource Limited (a wholly-owned subsidiary of Sino Biopharmaceutical Limited) (collectively referred to as "Sino Biopharmaceutical"), hereby express that Sino Biopharmaceutical, holding convertible loan in Karolinska Development of nominal value of SEK 272,858,294 in total, have received the proposal from Karolinska Development for a full conversion of Sino Biopharmaceutical's holding of the convertible loan in Karolinska Development and are now sincerely considering the proposal and working out the implementation details with Karolinska Development. The proposal and our final decision regarding settlement of the convertible loan shall be subject to approval by the board of directors of Sino Biopharmaceutical."

This also includes the possibility of a rights issue of shares to the company's shareholders, which is intended to be effectuated during the second half of 2019 and has appointed DNB Markets to assist with such rights issue. The company also works with other alternative solutions together with financial institutions. Should the Board of Directors not succeed with its plans to secure financing, there is a risk that conditions for going concern would not apply. However, the Board of Directors works actively with solutions to solve the financing. The company's financial reports have been prepared based on a going concern assumption.

For a detailed description of other risks and uncertainties, see the annual report 2018.

## Signing of the report

Solna, 21 May 2019

Viktor Drvota

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



# Dates for Publication of Financial Information

Annual General Meeting 2019 26 June 2019

Interim Report January-June 2019 21 August 2019

Interim Report January-September 2019 7 November 2019

Karolinska Development is required by law to publish the information in this interim report. The information was published on 21 May 2019. This interim report, together with additional information, is available on Karolinska Development's website: <a href="https://www.karolinskadevelopment.com">www.karolinskadevelopment.com</a>.

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	2019 Jan-Mar	2018 Jan-Mar	2018 Full-year
Revenue		904	734	3,073
Change in fair value of shares in				
portfolio companies	2	-11	-4,809	58,499
Change in fair value of other				
financial assets and liabilities		4,214	4,195	41,481
Other expenses		-3,014	-4,079	-14,017
Personnel costs		-5,944	-5,442	-14,993
Depreciation of right-of-use				
assets		-176	0	0
Operating profit/loss		-4,027	-9,401	74,043
Financial net		-14,600	-10,324	-43,533
Profit/loss before tax		-18,627	-19,725	30,510
Taxes		-	-	-
NET PROFIT/LOSS FOR THE				
PERIOD		-18,627	-19,725	30,510

## Condensed statement of comprehensive income for the Investment Entity

SEK 000	Note	2019 Jan-Mar	2018 Jan-Mar	2018 Full-year
Net/profit loss for the period		-18,627	-19,725	30,510
Total comprehensive income/loss for the period		-18,627	-19,725	30,510

## Earnings per share for the Investment Entity

SEK	Note	2019 Jan-Mar	2018 Jan-Mar	2018 Full-year
Earnings per share, weighted average before dilution		-0.29	-0.31	0.48
Number of shares, weighted average before dilution		64,174,452	64,116,921	64,136,941
Earnings per share, weighted average after dilution		-0.29	-0.31	0.48
Number of shares, weighted average after dilution		64,174,452	64,116,921	64,136,941



## Condensed balance sheet for the Investment Entity

SEK 000	Note	31 Mar 2019	31 Mar 2018	31 Dec 2018
ASSETS				
Tangible assets				
Right-of-use assets		1,231	-	-
Financial assets				
Shares in portfolio companies at fair value				
through profit or loss	2	636,008	456,423	618,927
Loans receivable from portfolio companies		5,113	3,480	5,098
Other financial assets		27,290	44,791	26,970
Total non-current assets		669,642	504,694	650,995
Current assets				
Receivables from portfolio companies		684	744	473
Other financial assets		56,955	-	53,060
Other current receivables		817	645	3,432
Prepaid expenses and accrued income		1,218	852	632
Short-term investments, at fair value through				
profit or loss		50,025	140,242	69,949
Cash and cash equivalents		11,742	5,475	15,843
Total current assets		121,441	147,958	143,389
TOTAL ASSETS		791,083	652,652	794,384
EQUITY AND LIABILITIES				
Total equity		277,384	247,396	296,007
Long-term liabilities				
Convertible loan	3	-	391,463	-
Other financial liabilities		11,423	4,807	11,423
Total long-term liabilities		11,423	396,270	11,423
Current liabilities				
Convertible loan	3	442,173	-	428,303
Current interest liabilities		50,000	-	50,000
Accounts payable		1,519	1,256	1,373
Liability to make lease payment		1,239	-	-
Other current liabilities		1,714	1,344	831
Accrued expenses and prepaid income		5,631	6,386	6,447
Total current liabilities		502,276	8,986	486,954
Total liabilities		513,699	405,256	498,377
TOTAL EQUITY AND LIABILITIES	·	791,083	652,652	794,384

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

SEK 000	Not	2019-03-31	2018-03-31	2018-12-31
Opening balance, equity		296,007	267,121	267,121
Net profit/ loss for the period		-18,627	-19,725	30,510
Effect of incentive programs etc		4	0	-1,624
Closing balance, equity		277,384	247,396	296,007



## Condensed statement of cash flows for the Investment Entity

Note	2019 Jan-Mar	2018 Jan-Mar
	-4,027	-9,401
	176	0
2	-4,203	614
	-179	-
	-252	-16
	-498	-
\$	-8,983	-8,803
	1,792	-407
	213	-3,159
	-6,978	-12,369
	-16,892	-11,448
	19,769	9,987
	2,877	-1,461
	-	-
	0	0
	-4,101	-13,830
ır	15,843	19,305
	11,742	
	2 s	176 2 -4,203 -179 -252 -498  s -8,983  1,792 213 -6,978  -16,892 19,769 2,877  0 -4,101

¹Surplus liquidity in the Investment Entity is invested in interest-bearing instruments and is recognized as short-term investments with a maturity exceeding three months. These investments are consequently not reported as cash and cash equivalents and are therefore included in the statement of cash flows from operating activities. The supplemental disclosure is 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	2019 Jan-Mar	2018 Jan-Mar	2018 Full-year
Revenue		904	734	3,073
Change in fair value of shares in portfolio companies		-11	-4,809	58,499
Change in fair value of other financial assets		4,214	4,195	41,481
Other expenses		-3,193	-4,079	-14,017
Personnel costs		-5,944	-5,442	-14,993
Operating profit/loss		-4,030	-9,401	74,043
Financial net		-14,585	-10,324	-43,533
Profit/loss before tax		-18,615	-19,725	30,510
Tax			-	-
NET PROFIT/LOSS FOR THE PERIOD		-18,615	-19,725	30,510

## Condensed statement of comprehensive income for the Parent Company

SEK 000	Note	2019 Jan-Mar	2018 Jan-Mar	2018 Full-year
Net profit/loss for the period		-18,615	-19,725	30,510
Total comprehensive income/loss for the period		-18,615	-19,725	30,510



## **Condensed balance sheet for the Parent Company**

SEK 000	Note	31 Mar 2019	31 Mar 2018	31 Dec 2018
ASSETS				
Financial assets				
Shares in portfolio companies at fair value				
through profit or loss	2	636,008	456,423	618,927
Loans receivable from portfolio companies		5,113	3,480	5,098
Other financial assets		27,290	44,791	26,970
Total non-current assets		668,411	504,694	650,995
Current assets				
Receivables from portfolio companies		684	744	473
Other financial assets		56,955	-	53,060
Other current receivables		817	645	3,432
Prepaid expenses and accrued income		1,218	852	632
Short-term investments at fair value through				
profit or loss		50,025	140,242	69,949
Cash and cash equivalents		11,742	5,475	15,843
Total current assets		121,441	147,958	143,389
TOTAL ASSETS		789,852	652,652	794,384
EQUITY AND LIABILITIES				
Total equity		277,392	247,396	296,007
Long-term liabilities				
Convertible loan	3	-	391,463	-
Other financial liabilities		11,423	4,807	11,423
Total long-term liabilities		11,423	396,270	11,423
Current liabilities				
Convertible loan	3	442,173	-	428,303
Current interest liabilities		50,000	-	50,000
Accounts payable		1,519	1,256	1,373
Other current liabilities		1,714	1,344	831
Accrued expenses and prepaid income		5,631	6,386	6,447
Total current liabilities		501,037	8,986	486,954
Total liabilities		512,460	405,256	498,377
TOTAL EQUITY AND LIABILITIES		789,852	652,652	794,384

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

SEK 000	Not	31 Mar 2019	31 Mar 2018	31 Dec 2018
Opening balance, equity		296,007	267,121	267,121
Net profit/ loss for the period		-18,615	-19,725	30,510
Effect of incentive programs		0	0	-1,624
Closing balance, equity		277,392	247,396	296,007



## 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.

### Changes in accounting principles 2019

At the introduction of IFRS 16 Leases, see below under New and revised accounting principles 2019.

The reduced corporate tax as of January 1, 2019 has no effect on the investment company's or the parent company's income statement and balance sheet, for details see the annual report 2018.

#### New and revised accounting principles 2019

IFRS 16 Leases entered into force on January 1, 2019. The standard changes the reporting of leases and requires all leases to be recognized in the balance sheet. The company only has operating leases for office premises, which has minor impact on the financial position and key ratios at transition. The Investment Entity has chosen to apply the transition rules for this standard in accordance with the simplified approach, which recognizes the accumulated effect of an initial application of the standard on the first day of application, January 1, 2019. Comparative information will not be restated, and it will continue to be reported in accordance with IAS 17 Leases and IFRIC 4 Determining Whether an Arrangement Contains a Lease. The Investment Entity has opted to exclude leases in which the value of the underlying asset is low. Leasing expenses for earlier operating leases will be replaced as of January 1, 2019, with write-downs on right-of-use assets and financial interest expenses for lease liabilities. Right-of-use assets will be measured at an amount corresponding to the lease liabilities on the date of transition. On January 1, 2019, the change in the reporting of leases impacted the balance sheet total by SEK 1,2 million (corresponding to less than 1 percent) without having an impact on equity.

### Significant assessments in the application of the accounting policies

### Going concern assumption

As of signing this interim report, the company has no new contracted financing to cover the financing need arising in 2019 in connection with the payment of the current convertible loan and the credit facility, the company has made assessments regarding the company's ability to subscribe for such funding in 2019 when it adopts its continued operation. Based on the financing work undertaken, the management and the board of directors believe that new funding to ensure the implementation of the company's business plan in the coming years will be possible in 2019.

### **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 – March 2019.



#### 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 KDey 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 636.0 million), loans receivable from portfolio companies (SEK 5.1 million), short-term investments (SEK 50.0 million), cash and cash equivalents (SEK 11.7 million), and net of financial assets and liabilities minus interest-bearing liabilities (SEK 72.8 million minus SEK 492.2 million), in relation to the number of shares outstanding (64 174 452) on the closing date (31 March 2019).

Net debt: Interest-bearing liabilities (SEK 492.2 million) reduced with short-term investments (SEK 50.0 million) and cash and cash equivalents (SEK 11.7 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) guoted 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 2019

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	-	-	636,008	636,008
Loans receivable from portfolio companies	-	5,113	-	5,113
Other financial assets	-	-	27,290	27,290
Receivables from portfolio companies Cash, cash equivalents and short-term	-	684	-	684
investments	61,767	=	-	61,767
Total	61,767	5,797	663,298	730,862
Financial liabilities				
Other financial liabilities	-	-	11,423	11,423
Accounts payable	-	1,519	-	1,519
Total	-	2,758	11,423	14,181



### Fair value as of 31 March 2018

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	11,592	-	444,831	456,423
Loans receivable from portfolio companies	0	3,480	_	3,480
Other financial assets	-	-	44,791	44,791
Receivables from portfolio companies Cash, cash equivalents and short-term	-	744	-	744
investments	145,717	-	-	145,717
Total	157,309	4,224	489,622	651,155
Financial liabilities				
Other financial liabilities	-	-	4,807	4,807
Accounts payable	-	1,256	_	1,256
Total	-	1,256	4,807	6,063

### Fair value (level 3) as of 31 March 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	0
Closing balance 31 Mar 2019	636,009	84,244	11,423
Realized gains and losses for the period included in profit			
or loss	49	0	0
Unrealized gains and losses in profit or loss for the period			
included in profit or loss	-60	4,214	0

### Fair value (level 3) as of 31 March 2018

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At beginning of the year	433,700	40,596	4,807
Acquisitions	13,449	=	-
Gains and losses recognized through profit or loss	-2,318	4,195	-
Closing balance 31 Mar 2018	444,831	44,791	4,807
Realized gains and losses for the period included in profit or loss	59	-	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	-2,377	4,195	-

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 334.0 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	31 Mar 2019	31 Mar 2018	31 Dec 2018
Karolinska Development Portfolio Fair Value (unlisted companies)	510,000	416,579	492,600
Karolinska Development Portfolio Fair Value (listed companies)	0	11,592	0
KDev Investments Portfolio Fair Value	460,045	300,456	459,740
Total Portfolio Fair Value	970,045	728,627	952,340
Potential distribution to Rosetta Capital of fair value of KDev Investments	334,037	272,204	333,413
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	636,008	456,423	618,927

<sup>\*</sup> SEK 43.3 million repayment of investments in KDev Investments made by Rosetta Capital and SEK 290.7 million distribution of dividends to preference shares and common shares.

### Information on fair value measurement in level 3

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

For detailed description, see the annual report 2018.

## NOTE 3 Convertible loan

Karolinska Development has issued convertible debentures, so called compound financial instruments, in which the holder has right to convert into shares, the number of shares to be issued are not affected by changes in fair value of the shares.

The debt portion of the compound financial instrument is initially recognized at fair value for a similar debt without a conversion right into shares. The equity portion is initially recognized as the difference between the total fair value of compound financial instrument and the fair value of the debt portion. Directly attributable transaction costs are allocated to the debt respectively equity portion based on their initial recognized values.

Post-acquisition the debt portion of the compound financial instrument is valued to amortized costs based on the effective interest method. The equity portion of the compound financial instrument is not revalued post-acquisition, except at conversion or redemption.

Karolinska Development issued convertible debentures with a nominal amount of SEK 387 million on 2 January 2015 which have a nominal interest rate of 8 percent. The nominal amount was reduced to SEK 329 million after the set-off issue in March 2017. The convertible debentures will fall due for payment on 31 December 2019 at the amount of SEK 484 million (as accrued interest is interest bearing), the convertibles grant a right at any time to convert into shares at a conversion rate of 22 SEK per series B share. The value of the debt and equity part (conversion right) was determined on the date of issuance.



The convertible debentures, previously presented as long-term liabilities are from 2019-03-31, presented in the balance sheet as current liabilities. Details shown in the below table.

SEK 000	31 Mar 2019	31 Mar 2018	31 Dec 2018
Nominal amount of convertible debentures			
issued on 2 January 2015	329,337	329,337	329,337
Issue costs	-23,982	-23,982	-23,982
Equity portion	-42,164	-42,164	-42,164
Debt at issuance date 2 January 2015	263,191	263,191	263,191
Accrued interest costs prior years	165,112	115,993	115,993
Debt prior this year's interest	428,303	379,184	379,184
Accrued interest costs this year	13,870	12,279	49,119
Total	442,173	391,463	428,303

## NOTE 4 Pledge assets and contingent liabilities

SEK 000	2019-03-31	2018-03-31	2018-12-31
Pledge assets			
The right to payment under Earn-out agreement regarding Oncopeptides shares <sup>1</sup>	56,955	-	53,060
Contingent liabilities			
Investment agreement in portfolio company	-	-	10,265
Summa	56,955	0	63,325

<sup>&</sup>lt;sup>1</sup> Also includes the right to payment under Earn-out agreements regarding Athera and Lipidor.