
Karolinska Development

Karolinska Development (Nasdaq Stockholm: KDEV) is an investment company which offers a unique opportunity to share in the growth in value of a number of Nordic life sciences companies with substantial commercial opportunities. Nine of the portfolio companies have candidate drugs in ongoing clinical studies or approved products in early commercial phase. Three of the portfolio companies are expected to present clinical phase II project results during 2019 and 2020, 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 billions 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

Second quarter

- The net profit/loss for the second quarter was SEK 7.5 million (SEK 31.3 million in the second quarter of 2018). Earnings per share totalled SEK 0.1 (SEK 0.5 in the second quarter of 2018).
- The result of the Change in fair value of shares in portfolio companies amounted to SEK 21.8 million (SEK 26.0 during the second quarter of 2018).
- The total fair value of the portfolio was SEK 995.3 million at the end of June 2019, corresponding to an increase of SEK 25.3 million from SEK 970.0 million at the end of the previous quarter. The net portfolio fair value at that time was SEK 652.0 million, corresponding to an increase of SEK 16.0 million from SEK 636.0 million at the end of the previous quarter.
- Net sales totalled SEK 1.0 million during the second quarter of 2019 (SEK 0.8 million during the second quarter of 2018).
- Karolinska Development invested a total of SEK 15.5 million in portfolio companies during the second quarter. Second quarter investments in portfolio companies by Karolinska Development and other specialised life sciences investors totalled SEK 194.5 million.
- Cash and cash equivalents decreased by SEK 25.7 million during the second quarter, totalling SEK 36.1 million on 30 June 2019.
- The Parent Company's equity on 30 June 2019 was SEK 284.9 million.

Significant events during the second quarter

- Aprea Therapeutics presented promising results from studies with APR-246 in combination with immune checkpoint blockade. The results showed that APR-246 can improve the effects of immuno-oncology agents (April 2019).
- Aprea Therapeutics announced that APR-246 has received an Orphan Drug Designation and Fast Track Designation from the FDA for the treatment of MDS (April 2019).
- Dilafor announced the completion of a capital raising event and that it was planning to start a new Phase 2b study of its candidate drug, tafoxiparin, that will evaluate tafoxiparin's ability to soften the cervix prior to labor induction. The investment will entail an increase in the value of Karolinska Development's holding in Dilafor and have a positive effect on earnings of SEK 16.8 million in the second quarter of 2019 (April 2019).
- Karolinska Development's 2018 Annual Report contained an update by the Board of Directors on the Company's financial situation and the measures taken to strengthen the company's finances. The Annual Report also included an emphasis of matter paragraph from the Auditor regarding going concern assumptions (April 2019).
- OssDsign applied for listing on Nasdaq First North and published a prospectus in connection with a share issue of SEK 151.3 million (May 2019).
- OssDsign's share was listed on Nasdaq First North and the share issue in conjunction with the listing was oversubscribed. As of March 31, 2019, Karolinska Development's holdings in OssDsign amounted to 25% and, after the realised share issue, to approximately 18% after full dilution, including indirect holdings through KCIF Co-Investment Fund (May 2019).
- OssDsign made substantial progress in the process to have OSSDSIGN Cranial PSI covered by the French national reimbursement system (May 2019).
- The data from the Phase 2 study of sevuparin by the portfolio company, Modus Therapeutics, did not show any meaningful clinical benefit in the management of acute vaso-occlusive crisis (VOC) in patients with sickle cell disease. Modus is now considering its options for the further development of sevuparin (May 2019).
- Karolinska Development's Board of Directors resolved, subject to subsequent approval by the Annual General Meeting, to carry out a directed new issue of series B shares to the holders of the 2015 convertible loan. Sino Biopharmaceutical Limited ("Sino Biopharma") and other owners, who collectively hold 84% of the convertible loan, have committed, on certain terms and under certain conditions, to subscribe corresponding to their convertible loan holding, including accrued interest, with the provision that Sino Biopharma's share of the votes in the Company shall not exceed 49% after the directed new issue. Karolinska Development and Sino Biopharma simultaneously announced their intention to initiate a new cooperation in conjunction with the set-off issue, with the aim of opening the Asian market to Nordic innovations (May 2019).
- Karolinska Development and KCIF Investment Fund KB – a holding company jointly owned by the European Investment Fund and Karolinska Development – sold their entire holding in Pharmanest AB. The divestment yielded a total of approximately SEK 23 million for Karolinska Development (June 2019).
- Karolinska Development's Annual General Meeting resolved, amongst other things, to approve the Board of Directors' decision to carry out a directed new issue of series B shares to the holders of the 2015 convertible loan (June 2019).

Significant post-period events

- Karolinska Development's CFO Fredrik Järsten is appointed as Deputy CEO (July 2019)
- Karolinska Development published a prospectus for the directed new share issue to the holders of the Company's convertible loan (July 2019).
- The subscription period in the directed new share issue to the holders of the Company's convertible loan was extended four times and now ends on 12 September 2019 (July and August 2019).
- Dilafor has enrolled the first subject in its Phase 2b study with tafoxiparin in pregnant women planned for labor induction (July 2019).
- Forendo Pharma announced that Sunstone Life Science Ventures joins the existing international investor syndicate and has made a EUR 5 million investment in Forendo Pharma. The new financing will enable Forendo Pharma to progress its lead endometriosis program, FOR-6219, an HSD17B1 enzyme inhibitor, into the next phase of clinical studies after the successful completion of its Phase 1a study earlier this year (July 2019).
- Aprea Therapeutics announced the appointment of Scott Coiante as Senior Vice President and Chief Financial Officer (August 2019).
- Forendo Pharma announced the start of the Phase 1b study of its lead endometriosis program, FOR-6219 (August 2019).
- Promimic announced that the company's first spinal device utilizing HA^{nano} Surface to improve osseointegration has now been 510(k) approved by the FDA.

Viktor Drvota, CEO of Karolinska Development, comments:

"Karolinska Development's portfolio continues to enjoy a good risk spread and to offer substantial potential. The negative results of Modus' clinical study of sevuparin were a significant setback, but we are, at the same time, seeing significant progress by other portfolio companies such as Aprea, Dilafor and OssDesign. We are currently concentrating on ensuring that the ongoing set-off issue can be carried out, as strengthening our finances is vital if we are to continue our engagement in the portfolio companies ahead of impending and potentially value-enhancing milestones. For example, we expect to be able to access the results of two Phase 2 studies of Aprea's drug candidate APR-246 already before the end of 2019. In 2020, the results of Aprea's Phase 3 study in the indication MDS as well as Phase 2 data for Umecrine Cognition's and Dilafor's respective drug candidates await. We are also looking forward, in conjunction with the set-off issue, to initiating a new partnership with Sino Biopharma that will open the Asian market up to Nordic innovations."

Contact information

For further information, please contact:

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

Fredrik Järsten, Chief Financial Officer
+46 70 496 46 28
fredrik.jarsten@karolinskadevelopment.com

Chief Executive's Report

Ongoing set-off issue to strengthen the Company's finances

Karolinska Development's shareholders resolved, at the Annual General Meeting in June, to carry out a set-off issue in order to solve the Company's 2015 convertible loan, which was raised to enable the substantial investments made in the portfolio companies over the past few years. The largest holder of the convertible loan – the Hong Kong-based listed pharmaceutical group, Sino Biopharma – has undertaken to participate in the issue under certain conditions. Sino Biopharma requires, amongst other things, to ensure a subscription level for the issue of at least 95%. To date, undertakings corresponding to a subscription level of 84% have been received and we are now working hard on convincing the remaining convertible holders that the successful conclusion of this transaction is critical to the Company's future. We are also, next to the financial agreement with Sino Biopharma, looking forward to the opportunity to combine Karolinska Development's in-depth understanding of Nordic life science innovations with the network and market expertise of one of the biggest Chinese health care sector investors. Our aim is to work together on bringing new Nordic innovations to billions of patients across Asia.

USA Fast Track for Aprea Therapeutics

Karolinska Development's portfolio company, Aprea Therapeutics, develops novel anti-cancer compounds that normalise production of the p53 protein – the best known of the endogenous substances that suppress uncontrolled cell division. A genetic mutation is responsible for eliminating the normal functioning of p53 in approximately half of all tumours, increasing the tumour's potential for unchecked growth. Research has also demonstrated that a non-functional p53 gene increases the risk of the patient developing a resistance to anti-cancer drugs. Aprea is at the forefront of companies developing small-molecule substances to reactivate the p53 gene, which has generated substantial interest on the part of leading, global specialist investors. A study of Aprea's candidate drug, APR-246, in combination with immune checkpoint blockade presented positive data in April, with the results indicating that APR-246 could improve the effects of immuno-oncology agents – the fastest growing treatment type for a range of cancers. Shortly after the results were announced, the American FDA granted Orphan Drug Designation for APR-246 for the treatment of patients with p53-mutated myelodysplastic syndrome (MDS) and Fast Track Designation for the same indication. We expect to be able to access full results from a Phase 2 study in MDS later this year, and in 2020 the results from the already initiated pivotal Phase 3 study are anticipated. The company is also evaluating the same candidate drug in the treatment of platinum-sensitive, high-grade serous ovarian cancer, and publication of the results of a Phase IIa study of this patient group is expected as early as 2019.

OssDsign listed

OssDsign develops, manufactures and distributes regenerative implants for bone tissue repair. In May, the company carried out an over-subscribed new share issue in conjunction with the share's listing on Nasdaq First North. OssDsign recently made further progress towards having OSSDSIGN Cranial PSI covered by the French national reimbursement system and is now continuing to commercialise the company's products in the USA, EU, and other selected countries. The market size for the type of implant upon which OssDsign focuses was estimated at USD 1.8 billion in 2016.

Negative news from Modus Therapeutics

The data from the Phase II study of sevuparin by the portfolio company, Modus Therapeutics, did not show any meaningful clinical benefit in the management of acute vaso-occlusive crises (VOC) in patients with sickle cell disease. This was obviously a considerable disappointment, particularly given the absence of any treatment alternatives, for these patients that can reduce VOC duration or manage their pain, other than opioids. Modus is now considering its options for the further development of sevuparin for other indications where the substance's multimodal mechanism of action may be beneficial.

Dilafor continues its development of tafoxiparin

The second quarter saw Karolinska Development's portfolio company, Dilafor, secure financing for the ongoing development of tafoxiparin. The candidate drug is being developed to address the problems associated with protracted labour – an area where no new treatments have been introduced for over 70 years. A Phase IIb study designed to document tafoxiparin's ability to soften the cervix prior to labor induction was initiated after the end of the reporting period. Results from this study are expected to be available in 2020.

Divestment of Pharmanest holding yielded SEK 23 million

Karolinska Development and KCIF Investment Fund KB – a holding company jointly owned by the European Investment Fund and Karolinska Development – sold their entire holding in Pharmanest AB during the second quarter. The holding was received as an earn-out payment in 2017 and the divestment yielded a total of approximately SEK 23 million for Karolinska Development.

A key time for Karolinska Development

Karolinska Development's portfolio continues to enjoy a good risk spread and to offer substantial potential. The negative results of Modus' clinical study of sevuparin were a significant setback, but we are, at the same time, seeing significant progress by other portfolio companies such as Aprea, Dilafor and OssDesign. We are currently concentrating on ensuring that the ongoing offset issue can be carried out, as strengthening our finances is vital if we are to continue our engagement in the portfolio companies ahead of impending and potentially value-enhancing milestones. For example, we expect to be able to access the results of two Phase 2 studies of Aprea's drug candidate APR-246 already before the end of 2019. In 2020, the results of Aprea's Phase 3 study in the indication MDS as well as Phase 2 data for Umecrine Cognition's and Dilafor's respective drug candidates await. We are also looking forward, in conjunction with the set-off issue, to initiating a new cooperation with Sino Biopharma that will open the Asian market up to Nordic innovations.

Solna, 30 August 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.

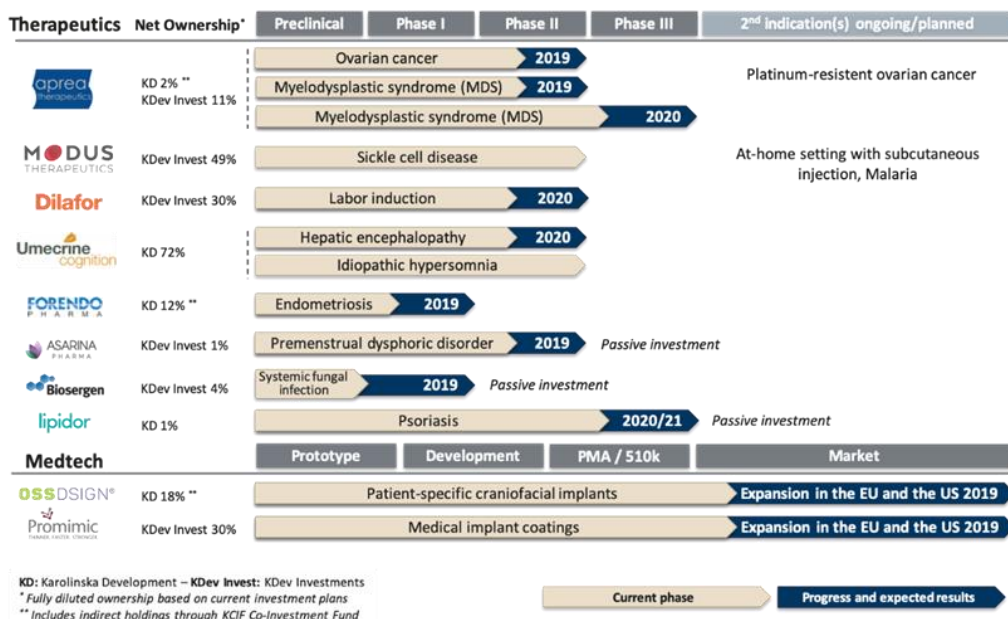
Karolinska Development has a focused portfolio of therapeutic and medtech companies with significant value-generating potential. The portfolio companies are developing highly differentiated and commercially attractive products that have the potential to deliver compelling clinical and health economic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

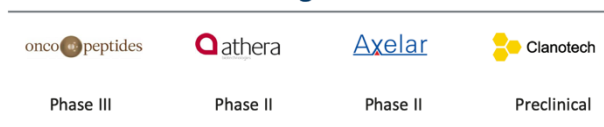
The therapeutics companies' next key value-generating milestones are expected in 2019 and 2020, when three of the companies are supposed to present Phase II proof-of-concept data. The medtech companies OssDsign and Promimic are revenue generating and have significant milestones mapped out in 2019 and 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 four life science companies.

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



Earn-out agreements





Project (First-in class)
APR-246

Primary indication
MDS

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 Ib/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 2018 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).
- Scott Coiante appointed Senior Vice President and Chief Financial Officer (August 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

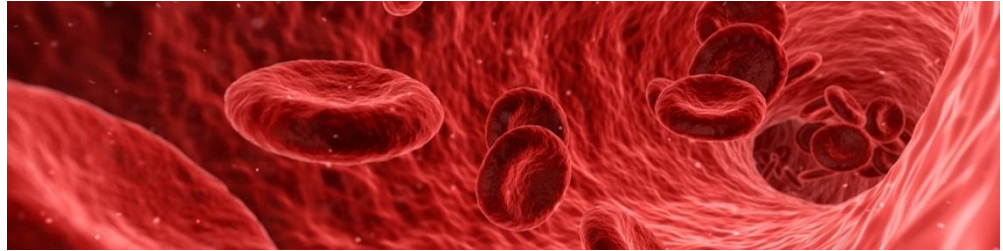
Phase II

Holding in company*

KDev Investments 49%

Other investorsHealthCap,
The Foundation for Baltic and
East European Studies,
Praktikerinvest**Origin**Karolinska Institutet, Uppsala
University**More information** modustx.com**Fully-diluted ownership based on
current investment plans*

Modus Therapeutics AB



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.

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 and no significant efficacy was observed (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. First patient included in the study (April and August 2019).

Expected milestones

- Result of Phase IIb study in labor induction during Q2 2020.



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 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 Ia

Holding in company*
Karolinska Development 12%**

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

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.

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 Ia results presented (March 2019).
- 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)

Expected milestones

- Result from the Phase 1b study in Q1 2020.

OSSDSIGN®
Project

OSSDSIGN® Cranial and
OSSDSIGN® Facial

Primary indication

Cranial implants

Development Phase

Marketed

Holding in company*

Karolinska Development 18%**

Other investors

SEB Venture Capital,
Fouriertransform

Origin

Karolinska University Hospital,
Uppsala University

More information

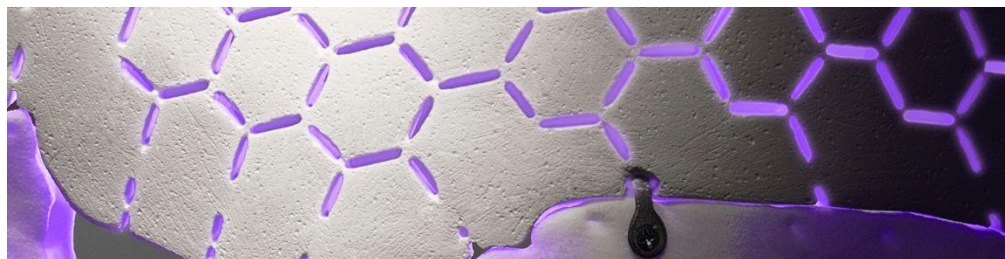

ossdesign.com

* 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.

OssDsign is listed on Nasdaq First North.

The market

OssDsign is focusing 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 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

- 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. The share issue was oversubscribed, and the company listed on Nasdaq First North (May 2019).
- Received initial positive notice regarding reimbursement for OSSDSIGN Cranial in France (May 2019).

Expected milestones

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


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

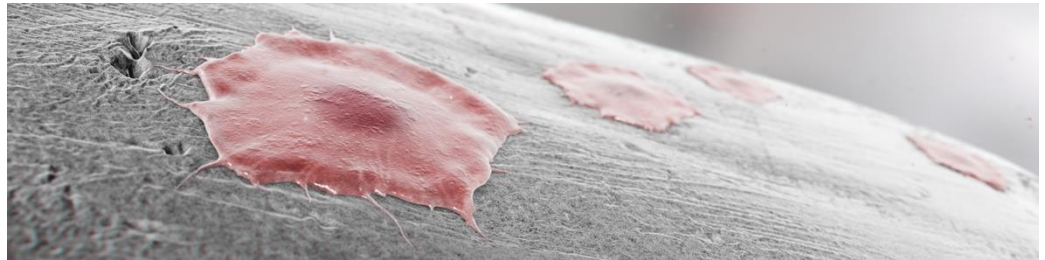
More information
 promimic.com

**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.

The HA^{nano} 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^{nano} 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^{nano} 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^{nano} Surface in USA, among other countries. A manufacturing facility for HA^{nano} 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^{ano} 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^{nano} 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).
- 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 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 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Full-year
Condensed income statement					
Change in fair value of shares in portfolio companies	21.8	26.0	21.8	21.2	58.5
Net profit/loss	7.5	31.3	-11.2	11.6	30.5
Balance sheet information					
Cash, cash equivalents and short-term investments	36.1	96.5	36.1	96.5	85.8
Net asset value (Note 1)	269.3	282.2	269.3	282.2	247.1
Net debt (Note 1)	-469.9	-307.2	-469.9	-307.2	-392.5
Share information					
Earnings per share, weighted average before dilution (SEK)	0.1	0.5	-0.2	0.2	0.5
Earnings per share, weighted average after dilution (SEK)	0.1	0.5	-0.2	0.2	0.5
Net asset value per share (SEK) (Note 1)	4.2	4.4	4.2	4.4	3.8
Equity per share (SEK) (Note 1)	4.4	4.3	4.4	4.3	4.6
Share price, last trading day in the reporting period (SEK)	3.8	5.0	3.8	5.0	6.2
Portfolio information					
Investments in portfolio companies	15.9	54.2	33.0	67.6	124.6
Of which investments not affecting cash flow	0.4	2.0	0.6	4.0	7.3
Portfolio companies at fair value through profit or loss	652.0	524.7	652.0	524.7	618.9

Financial Development for the Investment Entity in 2019

Investments (comparable numbers 2018)

Investments in the portfolio in the second quarter 2019 by external investors and Karolinska Development amounted to SEK 194.5 (123.4) million, whereof 95% (56%) by external investors.

Karolinska Development invested SEK 15.9 (54.2) million, of which SEK 15.5 (52.2) million was cash investments. Investments were made in Umeocrine Cognition SEK 10.1 million, OssDsign SEK 5.5 million and dilafor SEK 0.4 million. Non-cash investments (accrued interest on loans) amounted to 0.4 (2.0) million.

Investments by external investors in the portfolio companies amounted to SEK 184.9 (69.2) million. Investments were made in OssDsign SEK 145.8 million, Promimic SEK 20.0 million, Asarina Pharma SEK 6.8 million and Umeocrine Cognition SEK 0.8 million.

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

SEKm	Karolinska Development	External Investors	Total Invested Q1-Q2 2019
Umecrine Cognition	20.5	2.5	23.1
Forendo Pharma	6.6	51.2	57.8
OssDsign	5.5	145.8	151.3
Dilafor	0.4	11.5	11.8
Aprea Therapeutics	-	51.4	51.4
Promimic	-	20.0	20.0
Asarina Pharma	-	6.8	6.8
Total	33.0	289.2	322.2

Portfolio Fair Value

Fair Value of the portfolio companies owned directly by Karolinska Development decreased by SEK 0.6 million during the second quarter 2019. Fair value increased as a result of investments in and loan (including accrued interest) to portfolio companies Umecrine Cognition and OssDsign, but decreased as a result of a decline in the share price of the listed holding OssDsign and also from the divestment of Pharamanest.

Fair Value of the portfolio companies owned indirectly via KDev Investments increased by SEK 25.8 million during the second quarter 2019. The main reason for the increase was the valuation of Dilafor, made in connection with the financing of a Phase 2b study of tafoxiparin in pregnant women undergoing labor induction.

Total Fair Value from portfolio companies owned directly by Karolinska Development and indirectly via KDev Investments increased by SEK 25.3 million in the second 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 9.3 million, resulting in Net Portfolio Fair Value increasing by SEK 16.0 million in the second quarter 2019.

SEKm	30 Jun 2019	31 Mar 2019	Q2 2019 vs Q1 2019
Karolinska Development Portfolio Fair Value (unlisted companies)	439.6	510.0	-70.4
Karolinska Development Portfolio Fair Value (listed companies)	69.8	0.0	69.8
KDev Investments Portfolio Fair Value	485.8	460.0	25.8
Total Portfolio Fair Value	995.3	970.0	25.3
Potential distribution to Rosetta Capital of fair value of KDev Investments	343.3	334.0	9.3
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	652.0	636.0	16.0

Total Portfolio Fair Value on 30 June 2019 amounted to SEK 995.3 million and the potential distribution to Rosetta Capital amounted to SEK 343.3 million. Net Portfolio Fair Value on 30 June 2019 amounted to SEK 652.0 million. Compared to 30 June 2018, the Total Portfolio Fair Value increased with SEK 163.7 million and the Net Portfolio Fair Value increased with SEK 127.3 million.

Profit development 2019 (comparable numbers 2018)

During the second quarter 2019, Karolinska Development's revenue amounted to SEK 1.0 (0.8) million and consists primarily of services provided to portfolio companies. The revenue for the period January - June 2019, amounted to SEK 1.9 (1.5) million.

Change in fair value of shares in portfolio companies of in total SEK 21.8 (26.0) million includes the difference between the increase in Net Portfolio Fair Value during the second quarter 2019 with SEK 16 million and the net of investments in the portfolio companies of SEK 15.9 million and the divestment of the holding in Pharmanest of SEK 21.7 million. Change in fair value of other financial assets amounted to SEK 9.4 (21.3) million and is mainly a consequence of the valuation of an earn-out deal. For the period January - June 2019, the change in fair value of shares in portfolio companies amounted to SEK 21.8 (21.2) million and the change in fair value of other financial assets amounted to SEK 13.6 (25.5) million.

During the second quarter 2019 other expenses amounted to SEK 4.0 (3.6) million and personnel costs amounted to SEK 6.6 (2.7) million. The difference in personnel costs compared to the second quarter of 2018 is caused by reversed accrued costs at the end of the performance-related share program PSP 2015 that lowered comparable costs in 2018, but also a stay-on bonus to the employees which increased comparable costs in 2019. For the period January – June 2019 other expenses amounted to SEK 7.1 (7.7) million and personnel cost amounted to 12.5 (8.2) million.

The operating profit/loss in the second quarter 2019 amounted to SEK 21.4 million compared to SEK 41.7 million second quarter 2018. The operating profit/loss for the period January - June 2019 amounted to 17.4 (32.3) million.

Financial net increased during the second quarter 2019 compared to the second quarter 2018 and amounted to SEK -13.9 (-10.4) 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. For the period January - June 2019 the financial net amounted to SEK -28.5 (-20.7) million.

The Investment Entity's Net profit/loss amounted to SEK 7.5 (31.3) million in the second quarter 2019. Net profit/loss for the period January June 2019 amounted to SEK -11.2 (11.6) million.

Financial position

The Investment Entity's equity to total assets ratio amounted to 35% on 30 June 2019, same as on 31 March 2019.

The Investment Entity's equity amounted to SEK 284.9 million on 30 June 2019 compared to SEK 277.4 million on 31 March 2019. The increase was a consequence of the Net profit/Loss of SEK 7.5 million for the second quarter 2019.

Interest-bearing liabilities consist of a convertible loan and a credit facility, and on June 30, 2019 amounted to SEK 506.0 million, compared with SEK 403.7 million on June 30, 2018.

After paying operational costs and investments in the second quarter 2019, cash and cash equivalents together with short-term investments, amounted to SEK 36.1 million on 30 June 2019 compared to SEK 96.5 million on 30 June 2018. Net debt amounted to SEK 469.9 million on 30 June 2019 compared to SEK 307.2 million on 30 June 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 second quarter 2018).

During the second quarter 2019, the Parent Company's Net profit/loss amounted to SEK 7.5 million (SEK 31.3 million).

Due to the positive result for the second quarter 2019, the equity increased from SEK 277.4 million 31 March 2019 to SEK 284.9 million 30 June 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 28 June 2019 was SEK 3.80, and the market capitalization amounted to SEK 239 million.

The share capital of Karolinska Development on 30 June 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 30 June 2019 amounted to 64,418,737 shares and 77,946,619 votes.

Ownership

On June 30, 2019, Karolinska Development had 3,856 shareholders.

Shareholder	A-Shares	B-Shares	Cap %	Vote %
Karolinska Institutet Holding AB	1,503,098	2,126,902	5.64%	22.01%
Tredje AP-Fonden	0	6,376,600	9.90%	8.18%
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	2,000,000	3.10%	2.57%
Stift För Främjande & Utveckling	0	1,397,354	2.17%	1.79%
Friheden Invest A/S	0	1,000,000	1.55%	1.28%
Försäkringsaktiebolaget Avanza Pension	0	998,065	1.55%	1.28%
Sum Top 10 Shareholders	1,503,098	28,411,694	46.44%	55.73%
Sum Other Shareholders	0	34,503,945	53.56%	44.27%
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

On 5 July, 2019 Karolinska Development published a prospectus relating the directed new share issue to the holders of the Company's convertible loan

On January 2, 2015, the Company issued a convertible loan with a nominal amount of SEK 387 million, together with accrued interest until June 30, 2019 the total amounted is SEK 466 million. As mentioned in the Company's interim report for the first quarter of 2019, in the annual report for 2018 and in the prospectus from 5 July, 2019 regarding the directed new share issue, the board works actively to resolve the Company's long-term capital requirements and a conversion of the outstanding convertible loan is necessary to ensure the Company's survival. A conversion would also increase the degree of strategic and operational headroom for the future.

Sino Biopharma, one of the leading pharmaceutical groups in China, has undertaken to participate in the issue, with the provision that Sino Biopharma's share of the votes in the Company shall not exceed 49 percent after the Directed share issue, and that a certain degree of acceptance will be achieved in the Offer. Provided that a significant proportion of the convertible debt is offset in the Directed share issue, the Company will initiate a strategic initiative together with Sino Biopharma, open the Asian market for Nordic innovations. The focus will be on companies that are close to market launch, with the ambition to generate a positive cash flow to Karolinska Development, which can be reinvested in new innovative companies.

It is the board's assessment that the Company's existing working capital is not sufficient to cover the amount of capital required for the next 12 months. The Directed share issue to the holders of the convertible loan will not result in any liquid funds being transferred to the company, but the issue amount will be offset against parts or the entire convertible loan including accrued interest. Furthermore, the board of directors considers that the Directed share issue will not be sufficient to cover the company's working capital requirement even if the entire convertible loan should be offset. The company intends to investigate a number of different opportunities in the autumn of 2019 to finance the outstanding working capital requirement after the Directed share issue has been completed.

The Board of Directors is of the belief that the Directed share issue constitutes an attractive way of achieving the required restructuring of the Company's capital structure to the prevailing conditions.

For a detailed description of other risks and uncertainties, see the prospectus "Invitation to subscribe for shares in Karolinska Development AB (publ)".

Signing of the report

Solna, 30 August 2019

Hans Wigzell
Chairman

Tse Ping

Vlad Artamonov

Magnus Persson

Theresa Tse

Viktor Drvota
Board member, CEO

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

Dates for Publication of Financial Information

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 30 August 2019. 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	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Full-year
Revenue		1,039	758	1,943	1,492	3,073
Change in fair value of shares in portfolio companies	2	21,778	25,959	21,767	21,150	58,499
Change in fair value of other financial assets and liabilities		9,352	21,325	13,566	25,520	41,481
Other expenses		-4,045	-3,594	-7,059	-7,673	-14,017
Personnel costs		-6,555	-2,746	-12,499	-8,188	-14,993
Depreciation of right-of-use assets		-176	0	-352	0	0
Operating profit/loss		21,393	41,702	17,366	32,301	74,043
Financial net		-13,922	-10,394	-28,522	-20,718	-43,533
Profit/loss before tax		7,471	31,308	-11,156	11,583	30,510
Taxes		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		7,471	31,308	-11,156	11,583	30,510

Condensed statement of comprehensive income for the Investment Entity

SEK 000	Note	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Full-year
Net/profit loss for the period		7,471	31,308	-11,156	11,583	30,510
Total comprehensive income/loss for the period		7,471	31,308	-11,156	11,583	30,510

Earnings per share for the Investment Entity

SEK	Note	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Full-year
Earnings per share, weighted average before dilution		0.12	0.49	-0.17	0.18	0.48
Number of shares, weighted average before dilution		64,174,452	64,118,818	64,174,452	64,117,875	64,136,941
Earnings per share, weighted average after dilution		0.12	0.49	-0.17	0.18	0.48
Number of shares, weighted average after dilution		64,174,452	64,118,818	64,174,452	64,117,875	64,136,941

Condensed balance sheet for the Investment Entity

SEK 000	Note	30 Jun 2019	30 Jun 2018	31 Dec 2018
ASSETS				
Tangible assets				
Right-of-use assets		1,056	-	-
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2	651,985	524,662	618,927
Loans receivable from portfolio companies		5,127	3,493	5,098
Other financial assets		27,609	66,116	26,970
Total non-current assets		685,777	594,271	650,995
Current assets				
Receivables from portfolio companies		1,483	909	473
Other financial assets		65,987	-	53,060
Other current receivables		22,829	846	3,432
Prepaid expenses and accrued income		2,771	927	632
Short-term investments, at fair value through profit or loss		25,129	85,167	69,949
Cash and cash equivalents		10,971	11,328	15,843
Total current assets		129,170	99,177	143,389
TOTAL ASSETS		814,947	693,448	794,384
EQUITY AND LIABILITIES				
Total equity		284,858	277,080	296,007
Long-term liabilities				
Convertible loan	3	-	403,743	-
Other financial liabilities		11,423	4,807	11,423
Total long-term liabilities		11,423	408,550	11,423
Current liabilities				
Convertible loan	3	456,043	-	428,303
Current interest liabilities		50,000	-	50,000
Accounts payable		2,786	1,242	1,373
Liability to make lease payment		1,070	-	-
Other current liabilities		1,586	1,358	831
Accrued expenses and prepaid income		7,181	5,218	6,447
Total current liabilities		518,666	7,818	486,954
Total liabilities		530,089	416,368	498,377
TOTAL EQUITY AND LIABILITIES		814,947	693,448	794,384

Condensed statement of changes in the Investment Entity's equity

SEK 000	Note	2019-06-30	2018-06-30	2018-12-31
Opening balance, equity		296,007	267,121	267,121
Net profit/ loss for the period		-11,156	11,583	30,510
Effect of incentive programs etc		7	-1,624	-1,624
Closing balance, equity		284,858	277,080	296,007

Condensed statement of cash flows for the Investment Entity

SEK 000	Note	2019 Jan-Jun	2018 Jan-Jun
Operating activities			
Operating profit/loss		17 366	32 301
Adjustments for items not affecting cash flow			
Depreciation		352	0
Change in fair value	2	-35 333	-46 670
Other items		-358	-1 974
Proceeds from short-term investments		-525	-485
Interest paid/received		-1 007	-
Cash flow from operating activities before changes in working capital and operating investments		-19 505	-16 828
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables		-123	-469
Increase (+)/Decrease (-) in operating liabilities		2 902	-4 327
Cash flow from operating activities		-16 726	-21 624
Investment activities			
Proceeds from sale of shares in portfolio companies		-	11 971
Acquisitions of shares in portfolio companies		-32 442	-63 633
Proceeds from sale of short-term investments ¹		44 296	65 309
Cash flow from operating activities		11 854	13 647
Financing activities			
Convertible debentures issue		-	-
Cash flow from financing activities		0	0
Cash flow for the period		-4 872	-7 977
Cash and cash equivalents at the beginning of the year		15 843	19 305
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		10 971	11 328
Supplemental disclosure¹			
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		10 971	11 328
Short-term investments, market value at closing date		25 129	85 167
CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS AT THE END OF THE PERIOD		36 100	96 495

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 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Full-year
Revenue		1,039	758	1,943	1,492	3,073
Change in fair value of shares in portfolio companies		21,778	25,959	21,767	21,150	58,499
Change in fair value of other financial assets		9,352	21,325	13,566	25,520	41,481
Other expenses		-4,223	-3,594	-7,416	-7,673	-14,017
Personnel costs		-6,555	-2,746	-12,499	-8,188	-14,993
Operating profit/loss		21,391	41,702	17,361	32,301	74,043
Financial net		-13,911	-10,394	-28,496	-20,718	-43,533
Profit/loss before tax		7,480	31,308	-11,135	11,583	30,510
Tax		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		7,480	31,308	-11,135	11,583	30,510

Condensed statement of comprehensive income for the Parent Company

SEK 000	Note	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Full-year
Net profit/loss for the period		7,480	31,308	-11,135	11,583	30,510
Total comprehensive income/loss for the period		7,480	31,308	-11,135	11,583	30,510

Condensed balance sheet for the Parent Company

SEK 000	Note	30 Jun 2019	30 Jun 2018	31 Dec 2018
ASSETS				
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2	651,985	524,662	618,927
Loans receivable from portfolio companies		5,127	3,493	5,098
Other financial assets		27,609	66,116	26,970
Total non-current assets		684,721	594,271	650,995
Current assets				
Receivables from portfolio companies		1,483	909	473
Other financial assets		65,987	-	53,060
Other current receivables		22,829	846	3,432
Prepaid expenses and accrued income		2,771	927	632
Short-term investments at fair value through profit or loss		25,129	85,167	69,949
Cash and cash equivalents		10,971	11,328	15,843
Total current assets		129,170	99,177	143,389
TOTAL ASSETS		813,891	693,448	794,384
EQUITY AND LIABILITIES				
Total equity		284,872	277,080	296,007
Long-term liabilities				
Convertible loan	3	-	403,743	-
Other financial liabilities		11,423	4,807	11,423
Total long-term liabilities		11,423	408,550	11,423
Current liabilities				
Convertible loan	3	456,043	-	428,303
Current interest liabilities		50,000	-	50,000
Accounts payable		2,786	1,242	1,373
Other current liabilities		1,586	1,358	831
Accrued expenses and prepaid income		7,181	5,218	6,447
Total current liabilities		517,596	7,818	486,954
Total liabilities		529,019	416,368	498,377
TOTAL EQUITY AND LIABILITIES		813,891	693,448	794,384

Condensed statement of changes in equity for the Parent Company

SEK 000	Not	30 Jun 2019	30 Jun 2018	31 Dec 2018
Opening balance, equity		296,007	267,121	267,121
Net profit/ loss for the period		-11,135	11,583	30,510
Effect of incentive programs		0	-1,624	-1,624
Closing balance, equity		284,872	277,080	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 – June 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 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 652.0 million), loans receivable from portfolio companies (SEK 5.1 million), short-term investments (SEK 25.1 million), cash and cash equivalents (SEK 11.0 million), and net of financial assets and liabilities minus interest-bearing liabilities (SEK 82.2 million minus SEK 506.0 million), in relation to the number of shares outstanding (64 174 452) on the closing date (30 June 2019).

Net debt: Interest-bearing liabilities (SEK 506.0 million) reduced with short-term investments (SEK 25.1 million) and cash and cash equivalents (SEK 11.0 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 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 as of 30 June 2018

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	0	-	524,662	524,662
Loans receivable from portfolio companies	-	3,493	-	3,493
Other financial assets	-	-	66,116	66,116
Receivables from portfolio companies	-	909	-	909
Cash, cash equivalents and short-term investments	96,495	-	-	96,495
Total	96,495	4,402	590,778	691,675
Financial liabilities				
Other financial liabilities	-	-	4,807	4,807
Accounts payable	-	1,242	-	1,242
Total	-	1,242	4,807	6,049

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
Transfers to and from level 3	-69,823	-	0
Acquisitions	33,016	-	-
Disposals	-21,725	-	-
Gains and losses recognized through profit or loss	21,767	13,566	0
Closing balance 30 June 2019	582,162	93,596	11,423
Realized gains and losses for the period included in profit or loss	13,307	0	0
Unrealized gains and losses in profit or loss for the period included in profit or loss	8,460	13,566	0

Fair value (level 3) as of 30 June 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	67,639	-	-
Gains and losses recognized through profit or loss	23,323	25,520	-
Closing balance 30 June 2018	524,662	66,116	4,807
Realized gains and losses for the period included in profit or loss	0	-	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	23,323	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 343.3 million, is the amount that KDev Investments according to the investment agreement between Karolinska Development and Rosetta Capital is obligated to distribute to Rosetta Capital from the proceeds received by KDev Investments (KDev Investments Fair Value). The amount includes repayment of SEK 43.3 million that Rosetta Capital currently has invested in KDev Investments' portfolio companies and the distribution of dividends from Rosetta Capital's common and preference shares. The distribution to Rosetta Capital will only happen when KDev Investments distribute dividends. KDev Investments will only distribute dividends after all eventual payables and outstanding debt has been repaid.

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

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

SEK 000	30 Jun 2019	30 Jun 2018	31 Dec 2018
Karolinska Development Portfolio Fair Value (unlisted companies)	439,641	440,754	492,600
Karolinska Development Portfolio Fair Value (listed companies)	69,823	-	0
KDev Investments Portfolio Fair Value	485,823	390,828	459,740
Total Portfolio Fair Value	995,287	831,582	952,340
Potential distribution to Rosetta Capital of fair value of KDev Investments	343,302	306,920	333,413
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	651,985	524,662	618,927

* SEK 43.3 million repayment of investments in KDev Investments made by Rosetta Capital and SEK 300.0 million distribution of dividends to preference shares and common shares.

Information on fair value measurement in level 3

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

For detailed description, see the annual report 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 2018-12-31, presented in the balance sheet as current liabilities. Details shown in the below table.

SEK 000	30 June 2019 Current liabilities	30 June 2018 Long-term liabilities	31 Dec 2018 Current liabilities
Nominal amount of convertible debentures issued on 2 January 2015	329 337	329 244	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	263 098	263 191
Accrued interest costs prior years	165 112	116 085	115 993
Debt prior this year's interest	428 303	379 183	379 184
Accrued interest costs this year	27 740	24 560	49 119
Total	456 043	403 743	428 303

NOTE 4 Pledge assets and contingent liabilities

SEK 000	2019-06-30	2018-06-30	2018-12-31
Pledge assets			
The right to payment under Earn-out agreement regarding Oncoceptides shares ¹	65,987	-	53,060
Contingent liabilities			
Investment agreement in portfolio company	2,518	-	10,265
Summa	68,505	0	63,325

¹ Also includes the right to payment under Earn-out agreements regarding Athera and Lipidor.