
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. Eight out of nine of the portfolio companies have candidate drugs in ongoing clinical studies or approved products in early commercial phase. Several 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

Third quarter

- The net profit/loss for the third quarter was SEK -14.6 million (SEK 4.1 million in the third quarter of 2018). Earnings per share totalled SEK -0.2 (SEK 0.1 million in the third quarter of 2018).
- The result of the Change in fair value of shares in portfolio companies amounted to SEK 10.4 million (SEK 1.0 million during the third quarter of 2018).
- The total fair value of the portfolio was SEK 1,012.5 million at the end of September 2019, corresponding to an increase of SEK 17.2 million from SEK 995.3 million at the end of the previous quarter. The net portfolio fair value at that time was SEK 669.7 million, corresponding to an increase of SEK 17.7 million from SEK 652.0 million at the end of the previous quarter.
- Net sales totalled SEK 0.7 million during the third quarter of 2019 (SEK 0.7 million during the third quarter of 2018).
- Karolinska Development invested a total of SEK 9.1 million in portfolio companies during the third quarter. Third quarter investments in portfolio companies by Karolinska Development and other specialised life sciences investors totalled SEK 87.9 million.
- Cash and cash equivalents decreased by SEK 15.3 million during the third quarter, totalling SEK 20.8 million on 30 September 2019.
- The Parent Company's equity on 30 September 2019 was SEK 270.2 million.

Significant events during the third quarter

- Karolinska Development's CFO Fredrik Järsten was appointed as Deputy CEO (July 2019)
- Karolinska Development published a prospectus, and later also a prospectus supplement, for the directed new share issue to the holders of the Company's convertible loan (July and September 2019).
- The subscription period in the directed new share issue to the holders of the Company's convertible loan was extended additional times during the third quarter and ending on 14 October 2019 (July -September 2019). Further extensions of the subscription period took place after the end of the quarter, see Significant post-period events below.
- Dilafor 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.
- Aprea Therapeutics announced that they filed a registration statement with the U.S. Securities and Exchange Commission (SEC) relating to a potential listing of its shares of common stock on Nasdaq Select Market, USA (September 2019).

Significant post-period events

- Aprea Therapeutics announced that the price range was set to USD 15 for its IPO and was listed on Nasdaq Global Select Market, USA (October 2019)
- OssDsign announced that they have been granted 510(k) clearance by the US Food and Drug Administration (FDA) to market OssDsign Cranial PSI Accessories in the US (October 2019).
- Karolinska Development divested its indirect holding, through KDev Investments and KCIF Co-Investment Fund, of 1 % in the portfolio company Asarina Pharma. The divestment will have only a limited impact on Karolinska Development's net earnings (October 2019).
- In November, it was announced that unconditional subscription- and repurchase commitments corresponding to set-off and repurchase of 94.2 per cent of the Company's convertible loan have been entered in the ongoing directed new share issue. The result of the first partial registration in the directed new share issue shows that holders of the convertible have subscribed for shares corresponding to an amount of SEK 208 million of the convertible loan in nominal terms. Considering the remaining subscription commitments and a repurchase of 6.5% of the convertible, only 4.3% of the convertible loan is outstanding. The subscription period in the directed new share issue was at the same time extended to December 12, 2019. The directed

new share Issue will not result in any liquidity being transferred to the Company. The Company is therefore intensely working on a number of alternatives to finance the outstanding capital requirement after the directed new share issue has been completed. The short-term financing is currently expected to be construed either as a share issue and/or as a short-term credit facility.

- Karolinska Development published a prospectus supplement for the directed new share issue to the holders of the Company's convertible loan (November 2019).
- OssDsign reported favourable outcome data on OSSDSIGN Cranial PSI (November 2019).

Viktor Drvota, CEO of Karolinska Development, comments:

"After a long and complicated process, we were able to announce in the beginning of November that the proposed set off issue to solve the company's convertible loan can now be completed. This is a welcome and absolutely crucial step forward in our efforts to secure long-term financial sustainability. We deem that strong potential exists, in the wake of this success, for securing the remaining capital requirement to ensure the company's ongoing operations. Karolinska Development's portfolio continues to enjoy a good risk spread and to offer substantial potential, and we can now return to focusing fully on managing our portfolio. The successful listing of Aprea Therapeutics in the USA demonstrates that our long-term involvement as owners can help create significant value. We are now looking forward to the presentation of a number of important results from ongoing clinical studies of potentially ground-breaking candidate drugs from both Aprea and other portfolio companies as well as initiating the partnership with Sino Biopharma to open up the Asian market to Nordic innovations."

Contact information

For further information, please contact:

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

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

Chief Executive's Report

A decisive step towards financial stability

After a long and complicated process, we were able to announce in the beginning of November that the proposed set off issue to solve the company's convertible loan can now be completed. This is a gratifying and absolutely crucial step forward in our efforts to secure long-term financial sustainability. The transaction will mean that almost the entire convertible loan is solved, and that Sino Biopharma will become Karolinska Development's largest individual owner. Sino Biopharma is listed on the Hong Kong stock exchange and is one of China's leading pharmaceutical groups, posting RMB 20.9 billion in income (ca. SEK 29.0 billion) and a post-tax profit of RMB 10.7 billion (ca. SEK 14.8 billion) in 2018. Sino Biopharma and its subsidiaries collectively have almost 22,000 employees.

There is a remaining need for working capital, even once the convertible loan has been processed, but with the completion of the set-off issue, we are now of the opinion that there is a strong potential for securing financing for the company's ongoing operations.

Sino Biopharma's engagement in Karolinska Development is a clear evidence of the growing interest in Asia in Nordic innovations in the life sciences field. We are looking forward, over and above the purely financial agreement with Sino Biopharma, to the opportunity to combine our in-depth expertise and strong local roots with the networks and resources possessed by 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.

Successful listing of Aprea Therapeutics in the USA

Karolinska Development's portfolio company, Aprea Therapeutics, was listed on the Nasdaq Global Select Market in New York on 3 October. As one of the company's longest-standing shareholders, we are proud to have contributed to its successful journey from the start-up phase at the Karolinska Institute to a listed company in the USA. The successful listing offers clear evidence that our long-term and active ownership strategy is bearing fruit. Based on the issue price, the net profit effect of Karolinska Development's holding in Aprea amounts to approximately SEK 58 million. As of 27 November the share price in Aprea was USD 23.55] which would mean a net profit effect for Karolinska Development of approx. SEK 186 million in the fourth quarter. We are now looking forward to following our portfolio company's ongoing development of new cancer drugs that normalize production of the p53 protein – the best known of the body's endogenous proteins that inhibit uncontrolled cell division. We expect, later this year, to be able to access the full results of a Phase II study of the APR-246 candidate drug for the treatment of myelodysplastic syndrome, while in 2020, we anticipate publication of the results of a pivotal Phase III study that has already begun. 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 late 2019/early 2020.

OssDsign prepares for launch in Japan

OssDsign is another of our portfolio companies that has recently taken the important step from an unlisted to a listed environment. In August, the company filed for regulatory approval for OssDsign Cranial in the Japanese market. OssDsign Cranial is a bioceramic implant that improves the healing of bone defects in cranioplasty. After the reporting period OssDsign reported favourable outcome data on OSSDSIGN Cranial

PSI and also announced that they has been granted regulatory approval OssDsign Cranial PSI Accessories in the US. OssDsign intends, subject to regulatory approval in Japan, to launch OssDsign Cranial PSI in 2020 in collaboration with a local commercial partner. A number of selected Japanese neurosurgeons have already obtained ethical approval for the use of OssDsign Cranial in cranioplasty. If regulatory approval is granted, OssDsign Cranial will be the first product of its kind in Japan – the world's second largest market for cranial implants.

Forendo attracts new investor and launches Phase Ib study

In July, Forendo Pharma announced that Sunstone Life Science Ventures had joined Forendo's existing international investor syndicate by making a EUR 5 million investment. A Phase Ib study evaluating the efficacy of the company's FOR-6219 candidate drug for endometriosis – a chronic condition that affects up to 10% of women of reproductive age and which causes severe pain, infertility, and impaired quality of life – was launched shortly thereafter. Currently available treatments for endometriosis often have limitations in efficacy and many of them cause harmful side effects. A positive result for this important Phase Ib study would further strengthen the hypothesis that FOR-6219 has the potential to change the treatment of endometriosis, based on its unique ability to selectively inhibit local formation of estrogen.

Dilafor continues development of tafoxiparin

During the quarter, Karolinska Development's portfolio company, Dilafor, initiated a Phase IIb study to document the ability of its candidate drug, tafoxiparin, to soften the cervix prior to labor induction. Results from this study are expected to be available in 2020. Tafoxiparin is being developed to address the problems associated with protracted labor – an area in which no new treatments have been introduced for over 70 years.

Promimic's orthopedic implant gains FDA approval

Promimic's first orthopedic implant received approval from the American FDA during the quarter. The implant uses a unique coating technology, HA^{nano} Surface, which increases anchoring strength and osseointegration with the surrounding bone tissue. Promimic launched its sales operations in the USA two years ago and the FDA approval naturally represents a massive breakthrough for the company in this important geographical market.

Strong preconditions for value creation

Karolinska Development's portfolio continues to enjoy a good risk spread and to offer substantial value potential. We are, furthermore, now able to move from our strained position linked to the convertible loan, which posed a threat to our financial stability and inhibited our development. We expect to get the results of two Phase II studies of Aprea's APR-246 candidate drug before the fast-approaching end of the year and in 2020, we expect the results of Aprea's Phase III study of the myelodysplastic syndrome indication, as well as Phase II data for Umecrine Cognition's and Dilafor's respective candidate drugs. We are now looking forward to initiate the partnership with Sino Biopharma to open up the Asian market to Nordic innovations.

Solna, 29 November 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 several of the companies are supposed to present Phase II proof-of-concept data. The medtech companies OssDesign 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 two 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

Therapeutics	Net Ownership*	Preclinical	Phase I	Phase II	Phase III	2 nd indication(s) ongoing/planned
	KD 2% ** KDev Invest 10%	Ovarian cancer		2019		
		Myelodysplastic syndrome (MDS)/Acute myeloid leukemia (AML)		2019		MDS/ AML Post-Transplant Maintenance
		Myelodysplastic syndrome (MDS)			2020	
	KDev Invest 60%	Sickle cell disease				At-home setting with subcutaneous injection, Malaria
	KDev Invest 30%	Labor induction		2020		
	KD 72%	Hepatic encephalopathy		2020		
		Idiopathic hypersomnia				
	KD 10% **	Endometriosis		2019		
	KDev Invest 4%	Systemic fungal infection	Passive investment			
	KD 1%	Psoriasis			2020/21	Passive investment
Medtech		Prototype	Development	PMA / 510k	Market	
	KD 18% **	Patient-specific craniofacial implants				Expansion in the EU and the US 2019
	KDev Invest 26%	Medical implant coatings				Expansion in the EU and the US 2019

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

Current phase Progress and expected results

Earn-out agreements

			
Phase III	Phase II	Phase II	Preclinical



Project (First-in class)
APR-246

Primary indication
MDS

Development Phase
Phase III

Holding in company*
Karolinska Development 2%**
KDev Investments 10%

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 and Boston) 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 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 during 2019. 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.

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

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.
- Result from Phase III study expected in 2020.

Project (First-in-class)

Sevuparin

Primary indication

Sickle cell disease (SCD)

Development Phase

Phase II

Holding in company*


KDev Investments 60%

Other investors

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

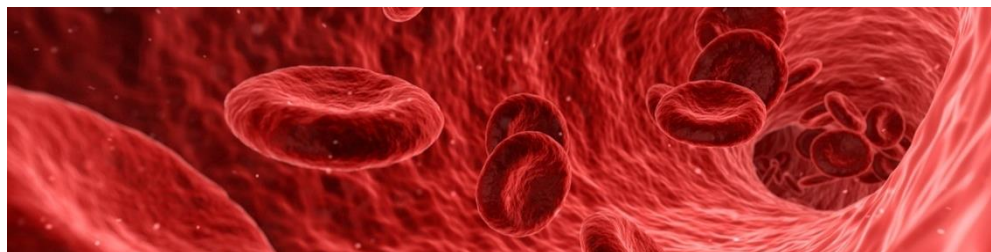
Origin

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 a new indication 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).
- Modus is now considering a new indication for further development of sevuparin.

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

Umechrine Cognition AB



Unique treatment approach for CNS-related disorders

Umechrine 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).

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 Umechrine 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. After further analysis of the data, Umechrine Cognition has decided to prioritize the development of GR3027 in hepatic encephalopathy (HE) before 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.

Recent progress

- Results from Phase IIa study in IH presented (January 2019).
- Umechrine Cognition has decided to prioritize the development of GR3027 in hepatic encephalopathy (HE) before idiopathic hypersomnia or other sleep disorders

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 10%**

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



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. 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 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

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

Expected milestones

- Launch of OssDsign's products on new EU markets 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

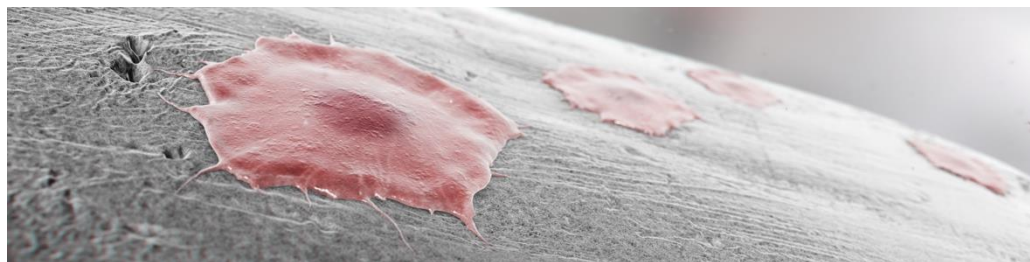
More information
 promimic.com

**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 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Full-year
Condensed income statement					
Change in fair value of shares in portfolio companies	10.4	1.0	32.1	22.1	58.5
Net profit/loss	-14.7	4.1	-25.8	15.7	30.5
Balance sheet information					
Cash, cash equivalents and short-term investments	20.8	88.0	20.8	88.0	85.8
Net asset value (Note 1)	270.7	288.0	270.7	288.0	247.1
Net debt (Note 1)	-484.1	-328.0	-484.1	-328.0	-392.5
Share information					
Earnings per share, weighted average before dilution (SEK)	-0.2	0.1	-0.4	0.2	0.5
Earnings per share, weighted average after dilution (SEK)	-0.2	0.1	-0.4	0.2	0.5
Net asset value per share (SEK) (Note 1)	4.2	4.5	4.2	4.5	3.8
Equity per share (SEK) (Note 1)	4.2	4.4	4.2	4.4	4.6
Share price, last trading day in the reporting period (SEK)	3.3	8.1	3.3	8.1	6.2
Portfolio information					
Investments in portfolio companies	9.1	13.5	42.1	81.1	124.6
Of which investments not affecting cash flow	0.6	2.5	1.1	6.5	7.3
Portfolio companies at fair value through profit or loss	669.7	539.1	669.7	539.1	618.9

Financial Development for the Investment Entity in 2019

Investments (comparable numbers 2018)

Investments in the portfolio in the third quarter 2019 by external investors and Karolinska Development amounted to SEK 87.9 (92.3) million, whereof 90% (79%) by external investors.

Karolinska Development invested SEK 9.1 (13.5) million, of which SEK 8.5 (11.0) million was cash investments. Investments was made in Umeçrine Cognition SEK 9.1 million. Non-cash investments (accrued interest on loans) amounted to 0.6 (2.5) million.

Investments by external investors in the portfolio companies amounted to SEK 78.8 (78.8) million. Investments were made in Forendo Pharma SEK 53.6 million and Lipidor SEK 25.2 million.

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

SEKm	Karolinska Development	External Investors	Total Invested Q1-Q3 2019
Umecrine Cognition	29.6	2.5	32.1
Forendo Pharma	6.6	104.8	111.4
OssDsign	5.5	145.8	151.3
Dilafor	0.4	11.5	11.8
Aprea Therapeutics	0.0	51.4	51.4
Lipidor	0.0	25.2	25.2
Promimic	0.0	20.0	20.0
Asarina Pharma	0.0	6.8	6.8
Total	42.1	368.0	410.1

Portfolio Fair Value

Fair Value of the portfolio companies owned directly by Karolinska Development increased by SEK 18.8 million during the third quarter 2019. Fair value increased as a result of loan (including accrued interest) to portfolio company Umecrine Cognition, increase in the share price of the listed holding Lipidor and the increased fair value of Forendo Pharma (due to investment from third part). But the fair value decreased as a result of a decline in the share price of the listed holding OssDsign.

Fair Value of the portfolio companies owned indirectly via KDev Investments decreased by SEK 1.6 million during the third quarter 2019. The main reason for the decrease was the decrease in the share price of the listed holding Asarina Pharma.

Total Fair Value from portfolio companies owned directly by Karolinska Development and indirectly via KDev Investments increased by SEK 17.2 million in the third quarter 2019.

As a consequence of the decrease in Fair Value of the part of the portfolio owned via KDev Investments, the potential distribution to Rosetta Capital decreased by SEK 0.5 million, resulting in Net Portfolio Fair Value increasing by SEK 17.7 million in the third quarter 2019.

SEKm	30 Sep 2019	30 Jun 2019	Q3 2019 vs Q2 2019
Karolinska Development Portfolio Fair Value (unlisted companies)	456.9	439.7	17.2
Karolinska Development Portfolio Fair Value (listed companies)	71.4	69.8	1.6
KDev Investments Portfolio Fair Value	484.2	485.8	-1.6
Total Portfolio Fair Value	1,012.5	995.3	17.2
Potential distribution to Rosetta Capital of fair value of KDev Investments	342.8	343.3	-0.5
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	669.7	652.0	17.7

Total Portfolio Fair Value on 30 September 2019 amounted to SEK 1,012.5 million and the potential distribution to Rosetta Capital amounted to SEK 342.8 million. Net Portfolio Fair Value on 30 September 2019 amounted to SEK 669.7 million. Compared to 30 September 2018, the Total Portfolio Fair Value increased with SEK 163.7 million and the Net Portfolio Fair Value increased with SEK 130.6 million.

Profit development 2019 (comparable numbers 2018)

During the third quarter 2019, Karolinska Development's revenue amounted to SEK 0.7 (0.7) million and consists primarily of services provided to portfolio companies. The revenue for the period January - September 2019, amounted to SEK 2.7 (2.2) million.

Change in fair value of shares in portfolio companies of in total SEK 10.4 (1.0) million includes the difference between the increase in Net Portfolio Fair Value during the third quarter 2019 with SEK 17.1 million and the net of investments in the portfolio companies of SEK 9.1 million and the divestment of the holding in Pharmanest (owned via KCIF KB) of SEK 1.7 million. Change in fair value of other financial assets amounted to SEK -4.8 (19.1) million and is mainly a consequence of the valuation of an earn-out deal. For the period January - September 2019, the change in fair value of shares in portfolio companies amounted to SEK 32.1 (22.1) million and the change in fair value of other financial assets amounted to SEK 8.8 (44.6) million.

During the third quarter 2019 other expenses amounted to SEK 2.3 (2.8) million and personnel costs amounted to SEK 4.8 (4.1) million. The difference in personnel costs compared to the third quarter of 2018 is caused by a stay-on bonus to the employees which increased comparable costs in 2019. For the period January - September 2019 other expenses amounted to SEK 9.4 (10.5) million and personnel cost amounted to 17.3 (12.3) million. The difference in personnel costs compared to the third 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.

The operating profit/loss in the third quarter 2019 amounted to SEK -0.9 million compared to SEK 14.0 million third quarter 2018. The operating profit/loss for the period January - September 2019 amounted to 16.4 (46.3) million.

Financial net increased during the third quarter 2019 compared to the third quarter 2018 and amounted to SEK -13.7 (-9.9) 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 - September 2019 the financial net amounted to SEK -42.2 (-30.6) million.

The Investment Entity's Net profit/loss amounted to SEK -14.6 (4.1) million in the third quarter 2019. Net profit/loss for the period January - September 2019 amounted to SEK -25.8 (15.7) million.

Financial position

The Investment Entity's equity to total assets ratio amounted to 34% on 30 September 2019, compared to 35% on 30 June 2019.

The Investment Entity's equity amounted to SEK 270.2 million on 30 September 2019 compared to SEK 284.9 million on 30 June 2019. The decrease was a consequence of the Net profit/Loss of SEK -14.6 million for the third quarter 2019.

Interest-bearing liabilities consist of a convertible loan and a credit facility, and on September 30, 2019 amounted to SEK 505.0 million, compared with SEK 416.0 million on September 30, 2018.

After paying operational costs and investments in the third quarter 2019, cash and cash equivalents together with short-term investments, amounted to SEK 20.8 million on 30 September 2019 compared to SEK 88.0 million on 30 September 2018. Net debt amounted to SEK 484.1 million on 30 September 2019 compared to SEK 328.0 million on 30 September 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 third quarter 2018).

During the third quarter 2019, the Parent Company's Net profit/loss amounted to SEK -14.6 million (SEK 4.1 million).

Due to the negative result for the third quarter 2019, the equity decreased from SEK 284.9 million 30 June 2019 to SEK 270.2 million 30 September 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 30 September 2019 was SEK 3.30, and the market capitalization amounted to SEK 209 million.

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

Ownership

On September 30, 2019, Karolinska Development had 3,956 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%
Försäkringsaktiebolaget Avanza Pension	0	1,015,156	1.58%	1.30%
Friheden Invest A/S	0	1,000,000	1.55%	1.28%
Sum Top 10 Shareholders	1,503,098	28,428,785	46.46%	55.76%
Sum Other Shareholders	0	34,486,854	53.54%	44.24%
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 28 June 2019, the Annual General Meeting approved the board of director's decision regarding a Directed New Share Issue ("The Directed Issue") to the holders of the Company's convertible loan.

The result of the first partial registration in the Directed Issue, is that holders of the convertible have subscribed for 78,770,586 class B shares. Considering this and the remaining unconditional commitments for subscribing in the Directed Issue and an executed repurchase of 6.5% of the convertible, only 4.3% of the convertible loan remains.

The conversion of the convertible loan through the Directed Issue was necessary in order to improve the financial stability and to enable financing activities. The conversion will also increase the degree of strategic and operational headroom for the future. The Directed Issue will however not result in any liquidity being transferred to the Company. Due to the increasingly strained liquidity, Management is therefore intensely working on a number of alternatives to finance the additional capital requirement for the Company. The short-term financing is currently expected to be construed as a directed new share issue amounting to MSEK 90-100 aimed towards a few identified investors. A process has been initiated together with DNB Markets as financial adviser with the aim of completion before year-end 2019.

Should the company not succeed with its plans to secure the financing there is a risk that conditions for going concern would not apply

The Board of Directors has considered all these facts and circumstances when preparing the Company's financial interim report as of September 30 and decided that it should be based on a going concern assumption.

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

Signing of the report

Solna, 29 November 2019

Hans Wigzell
Chairman

Tse Ping

Vlad Artamonov

Magnus Persson

Theresa Tse

Viktor Drvota
Board member, CEO

Review report

Karolinska Development AB, corporate identity number 556707-5048

Introduction

We have reviewed the condensed interim report for Karolinska Development AB, the Investment Entity, as at September 30, 2019 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

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

Conclusion

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

Considerable uncertainty relating to the going concern assumption

We want to draw attention to the board's information in the interim report on page 18 and 26, which states that due to the financial conditions, the company is working intensely on a number of alternatives to finance the remaining capital requirement. Should the company not succeed with its plans to secure the financing there is a risk that conditions for going concern would not apply. These conditions indicate that there is significant uncertainty that can lead to considerable doubt regarding the company's ability to continue its operations. We have not modified our opinion because of this.

Solna, 29 November 2019

Ernst & Young AB

Björn Ohlsson

Authorized Public Accountant

Dates for Publication of Financial Information

Year-end Report 2019

13 February 2020

Karolinska Development is required by law to publish the information in this interim report. The information was published on 7 November 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 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Full-year
Revenue		713	728	2,656	2,220	3,073
Change in fair value of shares in portfolio companies	2	10,359	979	32,126	22,129	58,499
Change in fair value of other financial assets and liabilities		-4,758	19,134	8,808	44,654	41,481
Other expenses		-2,297	-2,790	-9,356	-10,463	-14,017
Personnel costs		-4,802	-4,100	-17,301	-12,288	-14,993
Depreciation of right- of-use assets		-176	0	-528	0	0
Operating profit/loss		-961	13,951	16,405	46,252	74,043
Financial net		-13,693	-9,878	-42,215	-30,596	-43,533
Profit/loss before tax		-14,654	4,073	-25,810	15,656	30,510
Taxes		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		-14,654	4,073	-25,810	15,656	30,510

Condensed statement of comprehensive income for the Investment Entity

SEK 000	Note	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Full-year
Net/profit loss for the period		-14,654	4,073	-25,810	15,656	30,510
Total comprehensive income/loss for the period		-14,654	4,073	-25,810	15,656	30,510

Earnings per share for the Investment Entity

SEK	Note	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Full-year
Earnings per share, weighted average before dilution		-0.23	0.06	-0.40	0.24	0.48
Number of shares, weighted average before dilution		64,174,452	64,174,452	64,174,452	64,136,941	64,136,941
Earnings per share, weighted average after dilution		-0.23	0.06	-0.40	0.24	0.48
Number of shares, weighted average after dilution		64,174,452	64,174,452	64,174,452	64,136,941	64,136,941

Condensed balance sheet for the Investment Entity

SEK 000	Note	30 Sep 2019	30 Sep 2018	31 Dec 2018
ASSETS				
Tangible assets				
Right-of-use assets		880	-	-
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2	669,710	539,114	618,927
Loans receivable from portfolio companies		7,664	5,100	5,098
Other financial assets		27,928	76,587	26,970
Total non-current assets		706,182	620,801	650,995
Current assets				
Accounts receivable		150	-	-
Receivables from portfolio companies		258	637	473
Other financial assets		60,909	-	53,060
Other current receivables		1,291	976	3,432
Prepaid expenses and accrued income		6,134	843	632
Short-term investments, at fair value through profit or loss		17,156	70,123	69,949
Cash and cash equivalents		3,627	17,902	15,843
Total current assets		89,525	90,481	143,389
TOTAL ASSETS		795,707	711,282	794,384
EQUITY AND LIABILITIES				
Total equity		270,208	281,153	296,007
Long-term liabilities				
Convertible loan	3	-	416,023	-
Other financial liabilities		11,423	4,807	11,423
Total long-term liabilities		11,423	420,830	11,423
Current liabilities				
Convertible loan	3	469,914	-	428,303
Current interest liabilities		35,000	-	50,000
Accounts payable		1,341	1,030	1,373
Liability to make lease payment		898	-	-
Other current liabilities		2,213	1,328	831
Accrued expenses and prepaid income		4,710	6,941	6,447
Total current liabilities		514,076	9,299	486,954
Total liabilities		525,499	430,129	498,377
TOTAL EQUITY AND LIABILITIES		795,707	711,282	794,384

Condensed statement of changes in the Investment Entity's equity

SEK 000	Not	2019-09-30	2018-09-30	2018-12-31
Opening balance, equity		296,007	267,121	267,121
Net profit/ loss for the period		-25,810	15,656	30,510
Effect of incentive programs etc		11	-1,624	-1,624
Closing balance, equity		270,208	281,153	296,007

Condensed statement of cash flows for the Investment Entity

SEK 000	Note	2019 Jan-Sep	2018 Jan-Sep
Operating activities			
Operating profit/loss		16,405	46,252
Adjustments for items not affecting cash flow			
Depreciation		528	0
Change in fair value	2	-40,934	-66,783
Other items		-537	-1,624
Proceeds from short-term investments		594	-595
Interest paid/received		-1,462	-
Cash flow from operating activities before changes in working capital and operating investments		-25,406	-22,750
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables		-5,745	-1,418
Increase (+)/Decrease (-) in operating liabilities		-15,387	-2,846
Cash flow from operating activities		-46,538	-27,014
Investment activities			
Part payment from earn-out deal		-	8,663
Proceeds from sale of shares in portfolio companies		23,444	11,911
Acquisitions of shares in portfolio companies		-40,958	-74,640
Proceeds from sale of short-term investments ¹		51,836	79,677
Cash flow from operating activities		34,322	25,611
Financing activities			
Convertible debentures issue		-	-
Cash flow from financing activities		0	0
Cash flow for the period		-12,216	-1,403
Cash and cash equivalents at the beginning of the year		15,843	19,305
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		3,627	17,902
Supplemental disclosure¹			
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		3,627	17,902
Short-term investments, market value at closing date		17,156	70,123
CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS AT THE END OF THE PERIOD		20,783	88,025

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 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Full-year
Revenue		713	728	2,656	2,220	3,073
Change in fair value of shares in portfolio companies		10,359	979	32,126	22,129	58,499
Change in fair value of other financial assets		-4,758	19,134	8,808	44,654	41,481
Other expenses		-2,476	-2,790	-9,892	-10,463	-14,017
Personnel costs		-4,802	-4,100	-17,301	-12,288	-14,993
Operating profit/loss		-964	13,951	16,397	46,252	74,043
Financial net		-13,682	-9,878	-42,178	-30,596	-43,533
Profit/loss before tax		-14,646	4,073	-25,781	15,656	30,510
Tax		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		-14,646	4,073	-25,781	15,656	30,510

Condensed statement of comprehensive income for the Parent Company

SEK 000	Note	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Full-year
Net profit/loss for the period		-14,646	4,073	-25,781	15,656	30,510
Total comprehensive income/loss for the period		-14,646	4,073	-25,781	15,656	30,510

Condensed balance sheet for the Parent Company

SEK 000	Note	30 Sep 2019	30 Sep 2018	31 Dec 2018
ASSETS				
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2	669,710	539,114	618,927
Loans receivable from portfolio companies		7,664	5,100	5,098
Other financial assets		27,928	76,587	26,970
Total non-current assets		705,302	620,801	650,995
Current assets				
Accounts receivable		150	-	-
Receivables from portfolio companies		258	637	473
Other financial assets		60,909	-	53,060
Other current receivables		1,291	976	3,432
Prepaid expenses and accrued income		6,134	843	632
Short-term investments at fair value through profit or loss		17,156	70,123	69,949
Cash and cash equivalents		3,627	17,902	15,843
Total current assets		89,525	90,481	143,389
TOTAL ASSETS		794,827	711,282	794,384
EQUITY AND LIABILITIES				
Total equity		270,226	281,153	296,007
Long-term liabilities				
Convertible loan	3	-	416,023	-
Other financial liabilities		11,423	4,807	11,423
Total long-term liabilities		11,423	420,830	11,423
Current liabilities				
Convertible loan	3	469,914	-	428,303
Current interest liabilities		35,000	-	50,000
Accounts payable		1,341	1,030	1,373
Other current liabilities		2,213	1,328	831
Accrued expenses and prepaid income		4,710	6,941	6,447
Total current liabilities		513,178	9,299	486,954
Total liabilities		524,601	430,129	498,377
TOTAL EQUITY AND LIABILITIES		794,827	711,282	794,384

Condensed statement of changes in equity for the Parent Company

SEK 000	Note	30 Sep 2019	30 Sep 2018	31 Dec 2018
Opening balance, equity		296,007	267,121	267,121
Net profit/ loss for the period		-25,781	15,656	30,510
Effect of incentive programs		0	-1,624	-1,624
Closing balance, equity		270,226	281,153	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 remaining 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 – September 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 669.7 million), loans receivable from portfolio companies (SEK 7.7 million), short-term investments (SEK 17.2 million), cash and cash equivalents (SEK 3.6 million), and net of financial assets and liabilities minus interest-bearing liabilities (SEK 77.4 million minus SEK 504.9 million), in relation to the number of shares outstanding (64 174 452) on the closing date (30 September 2019).

Net debt: Interest-bearing liabilities (SEK 504.9 million) reduced with short-term investments (SEK 17.2 million) and cash and cash equivalents (SEK 3.6 million).

NOTE 2 Fair value

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

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

Fair value as of 30 September 2019

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

Fair value as of 30 September 2018

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	0	-	539,114	539,114
Loans receivable from portfolio companies	-	5,100	-	5,100
Other financial assets	-	-	76,587	76,587
Receivables from portfolio companies	-	637	-	637
Cash, cash equivalents and short-term investments	88,025	-	-	88,025
Total	88,025	5,737	615,701	709,463
Financial liabilities				
Other financial liabilities	-	-	4,807	4,807
Accounts payable	-	1,030	-	1,030
Total	-	1,030	4,807	5,837

Fair value (level 3) as of 30 September 2019

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

Fair value (level 3) as of 30 September 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	81,113	-	-
Gains and losses recognized through profit or loss	24,302	44,654	-
Closing balance 30 September 2018	539,115	85,250	4,807
Realized gains and losses for the period included in profit or loss	-26	-	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	24,328	44,654	-

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

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

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

SEK 000	30 Sep 2019	30 Sep 2018	31 Dec 2018
Karolinska Development Portfolio Fair Value (unlisted companies)	456,882	450,913	492,600
Karolinska Development Portfolio Fair Value (listed companies)	71,360	0	0
KDev Investments Portfolio Fair Value	484,220	397,832	459,740
Total Portfolio Fair Value	1,012,462	848,745	952,340
Potential distribution to Rosetta Capital of fair value of KDev Investments	342,752	309,632	333,413
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	669,710	539,113	618,927

* SEK 43.3 million repayment of investments in KDev Investments made by Rosetta Capital and SEK 299.5 million distribution of dividends to preference shares and common shares.

Information on fair value measurement in level 3

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

For detailed description, see the annual report 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	329,337	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	41,611	36,839	49,119
Total	469,914	416,023	428,303

NOTE 4 Pledge assets and contingent liabilities

SEK 000	2019-09-30	2018-09-30	2018-12-31
Pledge assets			
The right to payment under Earn-out agreement regarding Oncopeptides shares ¹	163,490	-	53,060
Contingent liabilities			
Investment agreement in portfolio company	6,000	-	10,265
Summa	169,490	0	63,325

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