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## Karolinska Development

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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. Three of the portfolio companies are expected to present clinical phase II and phase III project results during 2020, offering the potential for substantially increased opportunities for attractive divestments or licensing deals. Comparable candidate drugs have, in recent years, been out-licensed or sold for contract values of billions for the individual projects.

For further information, see [www.karolinskadevelopment.com](http://www.karolinskadevelopment.com)

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## Financial Update

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### Fourth quarter

- The net profit/loss for the fourth quarter was SEK 328.8 million (SEK 14.9 million in the fourth quarter of 2018). Earnings per share totalled SEK 3.20 (SEK 0.2 million in the fourth quarter of 2018).
- The result of the Change in fair value of shares in portfolio companies amounted to SEK 383,0 million. The result is largely due to the result of the change in fair value regarding the listed holding in Aprea Therapeutics.
- The total fair value of the portfolio was SEK 1,553.4 million at the end of December 2019, corresponding to an increase of SEK 540,9 million from SEK 1,012.5 million at the end of the previous quarter. The net portfolio fair value at the end of December 2019 was SEK 1,047.6 million, corresponding to an increase of SEK 377.9 million from SEK 669.7 million at the end of the previous quarter.
- Net sales totalled SEK 0.7 million during the fourth quarter of 2019 (SEK 0.9 million during the fourth quarter of 2018).
- Karolinska Development invested a total of SEK 6.8 million in portfolio companies during the fourth quarter. Fourth quarter investments in portfolio companies by Karolinska Development and other specialised life sciences investors totalled SEK 35.6 million.
- Cash and cash equivalents increased by SEK 31.3 million during the fourth quarter, totalling SEK 52.1 million on 31 December 2019.
- The Parent Company's equity on 31 December 2019 was SEK 1,007.8 million.

### Full year

- The full-year net profit was SEK 303.0 million (SEK 30.5 million in 2018). Earnings per share totalled SEK 4.10 (SEK 0.48 in 2018).

- The full-year result for the change in the fair value of the portfolio amounted to SEK 415.1 million (SEK 58.5 million during 2018).
- The total fair value of the portfolio was SEK 1,553.4 million at the end of December 2019, an increase from SEK 952.3 million at the corresponding date in 2018. The net portfolio fair value was SEK 1,047.6 million, an increase from SEK 668.9 million at the corresponding date in 2018.
- Revenue totalled SEK 3.4 million for the full year of 2019 (SEK 3.1 million in 2018).
- Karolinska Development invested a total of SEK 48.9 million in its portfolio companies during the full year. Full-year investments in the portfolio companies by Karolinska Development and other specialised life sciences investors totalled SEK 445.7 million.
- Cash and cash equivalents decreased by SEK 33.7 million during the full year, totalling SEK 52.1 million on 31 December 2019.
- The Parent Company's equity on 31 December 2019 was SEK 1,007.8 million.
- The Board will not propose any dividend for the financial year 2019.

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## Significant events during the fourth quarter

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- Aprea Therapeutics completed its IPO on Nasdaq Global Select Market in the US. The Company received a total gross amount, before deductions for the guarantors' discounts and commissions and other transaction costs, of approximately USD 97.75 million (October 2019).
- OssDsign announced that the company has been granted 510(k) clearance by the US Food and Drug Administration (FDA) to market OssDsign Cranial PSI Accessories in the US. The products are a set of 3D-printed patient specific surgical accessories designed to support and expand the use of the company's cranioplasty implants that have previously been approved in the United States. (October 2019).
- The subscription period for the directed issue to the Company's convertible bond holders was extended in several steps during the fourth quarter until December 16 (October–December 2019).
- Karolinska Development divested its indirect holding of 1 % in the portfolio company Asarina Pharma. The divestment had only a limited impact on Karolinska Development's net earnings (October 2019).
- Karolinska Development announced that unconditional subscription- and repurchase commitments corresponding to set-off and repurchase of 94.2 per cent of the Company's convertible loan, corresponding to SEK 438.4 million including accrued interest at June 30, 2019, had been entered in the then ongoing directed new share issue.
- Karolinska Development published a prospectus supplement for the then ongoing directed new share issue to the holders of the Company's convertible loan (November 2019).
- OssDsign released updated outcome data which revealed that the rate of infections leading to implant removal of OSSDSIGN Cranial PSI remained low (2.4%) after a median follow-up time of 17 months. (November 2019).

- The result of the first partial registration in the then ongoing directed new share issue showed that holders of the convertible had subscribed for shares corresponding to an amount of SEK 208 million of the convertible loan in nominal terms or 63.3% of the remaining convertible loan at the time of the announcement of the Directed Issue (November 2019).
- Karolinska Development announced a change of number of shares and votes in the Company. As a result of the first a partial registration of the then ongoing directed share issue there were 143,189,323 shares, representing a total of 156,717,205 votes outstanding in the Company, with 15,030,980 votes for shares of series A and 141,686,225 votes for shares of series B (November 2019).
- Aprea Therapeutics presented results from two Phase Ib/II clinical which evaluated the safety and efficacy of APR-246 in combination with azacitidine for the treatment of TP53 mutated Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) (December 2019)
- Forendo Pharma has entered a license and collaboration agreement with the global pharmaceutical company Novartis to develop new drugs for the treatment of chronic liver diseases (December 2019).
- Sino Biopharmaceutical and Chia Tai Resources divested their remaining convertibles equivalent to SEK 85 million in nominal terms, corresponding to SEK 121 million including accrued interest until 30 June 2019, to Worldwide International Investments Limited. Worldwide also committed to set-off its convertibles by subscribing for shares in the then ongoing directed share issue (December 2019).
- Umecrine Cognition announced that the enrollment was completed in its Phase 2a study in patients with liver cirrhosis and hepatic encephalopathy (December 2019).
- Karolinska Development announced that the share price in Aprea as of 12 December of USD 39.37 would mean a net profit effect for Karolinska Development of approx. SEK 422 million in the fourth quarter. At the same time, it was announced that a prospectus supplement had been published relating to the then ongoing directed share to the holders of the Company's convertible loan (December 2019).
- The result of the final partial registration in the directed share issue to the holders of the Company's convertible loan was published. Holders of the convertible had subscribed for shares equivalent to an additional SEK 85.9 million of the Company's convertible loan in nominal terms. Following the final partial registration, SEK 13.6 million of the Company's convertible loan in nominal terms or SEK 20.0 million including accrued interest until December 31, was outstanding (December 2019).
- The Company's short-term financing needs were secured through a loan from Sino Biopharmaceutical amounting to SEK 70 million (December 2019).
- Umecrine Cognition announced Notice of Allowance from USPTO for a patent protecting lead compound golexanolone (December 2019).
- The number of series B shares increased by 32,476,086 shares as a result of the final partial registration of the directed share issue, The total number of shares in the Company now amounts to 175,665,409 shares, distributed among 1,503,098 shares of series A and 174,162,311 shares of series B (December 2019).

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## Significant post-period events

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- Karolinska Development announced that the Company has repaid SEK 20.0 million of the convertible loan that was outstanding, including accrued interest until December 31, 2019. With that the whole convertible loan which was issued by Karolinska Development in January 2015 and was due for payment on December 31, 2019, was resolved (January 2020).
- Aprea Therapeutics was granted Breakthrough Therapy Designation for APR-246 in combination with azacitidine for the treatment of myelodysplastic syndrome (MDS) with a TP53 mutation (January 2020).

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

"Karolinska Development's financial situation over the past year has been extremely strained but we have now, after extensive and strenuous efforts, solved the company's substantial indebtedness, secured our short-term financing needs, and reported the company's best ever results. And while we achieved all this, the development rate in our portfolio companies continued to be very high throughout the year. Significant progress was recently also made by several of the companies, including Aprea Therapeutics' IPO in the USA and Forendo Pharma's licence and collaboration agreement with Novartis. Coverage of Karolinska Development's progress in these areas has, however, been somewhat overshadowed by the substantial financial challenges we have faced, and it is very satisfying to be able to report that we are now in a position where we can once again focus fully on our investments and on the further development of our business model."

### Contact information

For further information, please contact:

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

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

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## Chief Executive's Report

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### **Substantial progress by the portfolio companies overshadowed**

Karolinska Development's financial situation over the past year has been extremely strained. Our cash position at the end of the second quarter was SEK 36 million and liabilities totalled SEK 506 million – figures that should be viewed in the light of a market value which, in May 2019, hit a low of SEK 177 million. Intensive efforts during the year enabled us to turn the situation around, however, and the convertible loan has now been repaid in full and the market value was consequently improved. We have also secured our short-term financing needs by means of a bridge loan for SEK 70 million, and the value of the company's realisable assets has increased significantly over the past six months. We have also noted, however, that coverage of the significant progress made recently by several of our portfolio companies and which contributed to the massive SEK 303 million profit reported for 2019, as a whole by Karolinska Development, has been overshadowed by the substantial financial challenges we have faced.

### **Successful IPO by Aprea in New York**

Aprea Therapeutics conducted a successful initial public offering on the USA's Nasdaq Global Select Market in October. The company's share price has since risen sharply, and the increased value of the holding made a major contribution to Karolinska Development's record profit for 2019. Aprea's candidate drug, APR 246, reactivates mutant TP53 protein and is currently one of the world's leading TP53-targeting candidate drugs. The company intends, given a positive outcome of an ongoing pivotal phase 3 study, to submit a registration application in the USA for the myelodysplastic syndrome indication by late 2020/early 2021. The candidate drug also has the potential to treat a number of other types of cancer and an oral treatment form is under development in order to facilitate patient treatment. Aprea's IPO is by far the biggest in Karolinska Development's history and proof of the value that can be generated through early investments in outstanding Nordic life science innovations.

### **The first significant licence agreement with a leading pharma company**

In December, Forendo Pharma announced that they had entered into a licence and collaboration agreement with Novartis – one of the world's biggest pharmaceutical companies – to develop new drugs for the treatment of chronic liver disease. Forendo received an upfront payment and is entitled to milestone payments and sales-based royalties on products emanating from the research collaboration, which will be entirely funded by Novartis. In conjunction with the initiation of the collaboration, Novartis will make an equity investment in Forendo.

This is one of the most significant milestones in Karolinska Development's development – none of our portfolio companies have ever entered into a licence and collaboration agreement of this importance before. The value of the agreement has not been disclosed, but in general terms, a licence and collaboration agreement of this kind has the potential to create enormous value for the licensing company, provided that the project develops well. Karolinska Development has a ca. 10% holding in Forendo Pharma.

### **Promising development at OssDsign, Umecrine Cognition and Modus**

In October, OssDsign received 510(k) clearance for 3D-printed, patient-specific surgical accessory devices from the US Food and Drug Administration (FDA), enabling the marketing and sale of the products in the USA. The products are designed to support and expand clinical use of OssDsign's patient-specific cranioplasty implant, which has already been cleared in the USA. OssDsign also reported favourable

outcome data during the quarter, revealing that the rate of infections leading to removal of the cranial implant remained low (2.4%) after a median follow-up time of 17 months. OssDsign was listed in the summer of 2019 and at the turn of the year, had a market value of ca. SEK 305 million. Karolinska Development owns 13% of the company.

Umecrine Cognition, in which Karolinska Development has a 74% holding, also reported positive news during the quarter. Enrolment of patients with liver cirrhosis and hepatic encephalopathy in its ongoing phase 2a study was completed and the company received a Notice of Allowance for an important patent in the USA, protecting its candidate drug, golexanolone.

Modus Therapeutics, which reported in 2019 that the company's phase 2b study of sevuparin in patients with sickle cell disease had failed to achieve its primary goals, has evaluated and begun planning work and financing activities with the goal of developing its sevuparin candidate drug for a completely different indication. Published information on this potential new project is still thin on the ground for patent-strategic and competitive reasons, but we are very hopeful with regard to the potential favourable development of our investment in Modus in the longer term. Until such time as the results of Modus' financing activities for this new indication are known, however, Karolinska Development has elected to write down its holding in the year-end accounts to a valuation level that corresponds to that discussed with potential investors at the end of 2019.

## **The road ahead**

After extensive and strenuous efforts, our financial situation is stable, our short-term financing needs are secured, and we have posted the company's best ever results. Our focus can, therefore, now return to the development of our portfolio companies and we expect important news on a number of fronts over the year ahead:

- Forendo Pharma is expected to present the results of a phase 1b study of its FOR-6219 candidate drug by the end of this quarter.
- The results of Umecrine Cognition's phase 2 study of the golexanolone (GR3027) candidate drug in patients with hepatic encephalopathy are expected in the spring.
- Dilafor is planning to present the results of its new phase 2 study this summer, evaluating the tafoxiparin candidate drug as a treatment for reducing protracted labour in conjunction with induced deliveries.
- Aprea Therapeutics is expected to present the results of its ongoing pivotal phase 3 study of patients with myelodysplastic syndrome in the autumn, and provided that the results are favourable, to submit an application for marketing approval of its candidate drug in the USA shortly thereafter.

Preparations are now beginning, in parallel with our energetic work with the portfolio companies and our continued investment activities in the Nordic life sciences sphere, for Karolinska Development's programme that will see Nordic innovations launched in Asia in collaboration with our nowadays majority shareholder, Sino Biopharmaceutical. We also already have an organisation with personnel who have extensive experience of the Asian pharmaceutical and medtech market, and with an extensive network of contacts among the leading regional companies and investors. We look forward to presenting our plans in detail later this year.

Solna, 13 February 2020

Viktor Drvota  
Chief Executive Officer

## Portfolio Companies

### A Focused Portfolio with High Commercial Potential

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

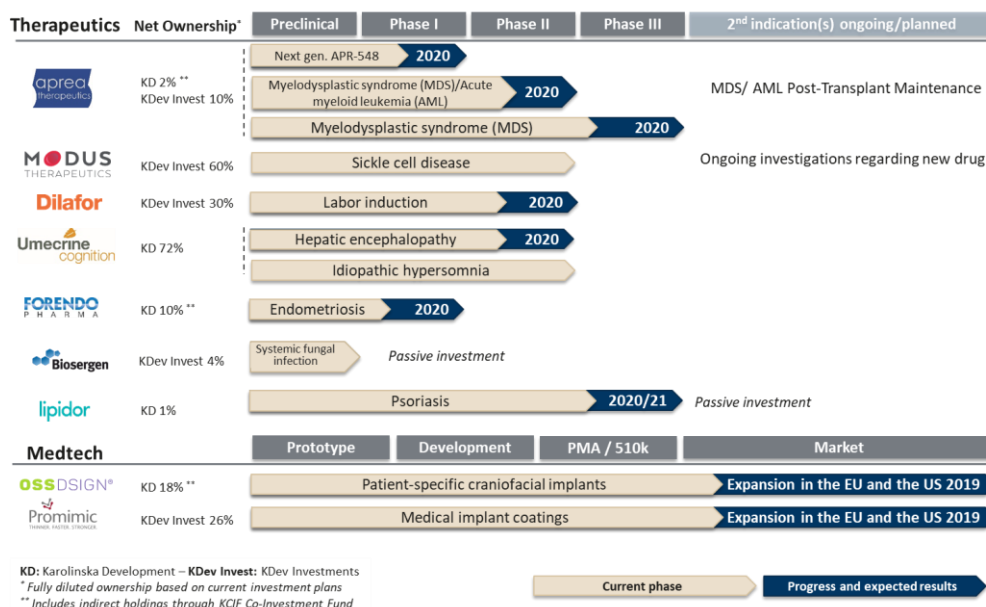
Karolinska Development has a focused portfolio of therapeutic and medtech companies with significant value-generating potential. The portfolio companies are developing highly differentiated and commercially attractive products that have the potential to deliver compelling clinical and health economic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

During the past years, Karolinska Development has optimized the clinical programs of the portfolio companies to reach clinically meaningful value-inflection points 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 2020, when several of the companies are supposed to present Phase II proof-of-concept data and Phase III data. The medtech companies OssDesign and Promimic are revenue generating and have significant milestones mapped out in 2020 regarding execution of their commercial strategies.

In addition to its active value creation in 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 three life science companies.

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



### Earn-out agreements

		
Phase III	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](http://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 phase Ib/II interim data during 2019.

Aprea has initiated a pivotal Phase III study in patients with TP53 mutated MDS from which results are anticipated during third quarter 2020. The company also aims to start a study in non-Hodgkin's lymphoma as well as a study in solid tumors in combination with anti-PD1 therapy. In addition, the company intends to initiate Phase I studies with the next generation oral P53 reactivator.

#### 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)
- FDA granted Breakthrough Therapy Designation for APR-246 in combination with azacitidine (January 2020).

#### Expected milestones

- Final results from Phase Ib/IIa study in MDS expected in 2019.
- Result from Phase III study expected in the third quarter 2020.

**Project (First-in-class)**

Sevuparin

**Primary indication**


Sickle cell disease (SCD)

**Development Phase**

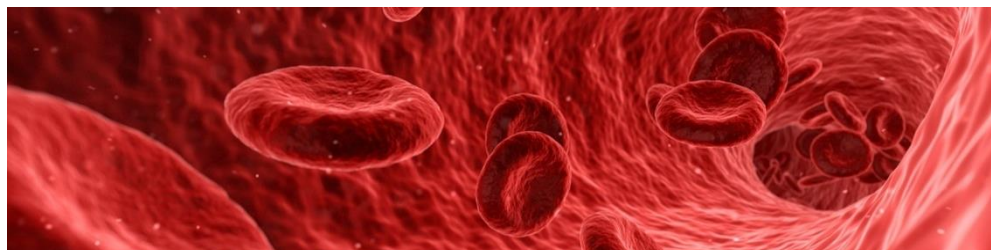
Phase II

**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.

#### 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

- Results from Phase II trial in SCD presented and no significant efficacy was observed (May 2019).
- Modus is now considering a new indication for further development of sevuparin.

## Dilafor

### Project (First-in-class)

Tafoxiparin

### Primary indication

Labor induction

### Development Phase

Phase IIb

### Holding in company\*

KDev Investments 30%


### Other investors

The Foundation for Baltic and East European Studies, Opocrin, Praktikerinvest, Rosetta Capital, Lee's Pharmaceutical

### Origin

Karolinska Institutet

### More information

 dilafor.com

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

### Deal values for similar projects

- USD 397 million Velo Bio (seller) & AMAG Pharmaceuticals (buyer) 2018
- USD 465 million Palatin Technologies (licensor) & AMAG Pharmaceuticals (licensee) 2017

## Dilafor AB



## Reducing complications with childbirth

Dilafor (Solna, Sweden) is developing tafoxiparin for obstetric indications. 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 per cent 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 second quarter 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](http://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

- 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 during the second quarter 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, Novartis

**Origin**  
University of Turku, Finland

**More information**  
 forendo.com

\* Fully-diluted ownership based on  
current investment plans

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

#### Deal values for similar projects

- USD 853 million Astellas (buyer) & Ogeda (seller) 2017
- USD 595 million Neurocrine Biosciences (licensor) & AbbVie (licensee) 2010

## Forendo Pharma Ltd



### Novel therapies for women's health.

Forendo (Turku and Oulu, Finland) is developing a new treatment for eliminating endometriosis while at the same time maintaining normal hormonal cycles.

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 5 million raised from new investor Sunstone Life Science Ventures (July 2019).
- Start of the Phase 1b study of its lead endometriosis program, FOR-6219 (August 2019).
- Novartis enters into license and collaboration agreement and invests in Forendo (December 2019).

#### Expected milestones

- Result from the Phase 1b study in first quarter 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 the Japanese market during 2020.



**Project**

HA<sup>nano</sup> 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**

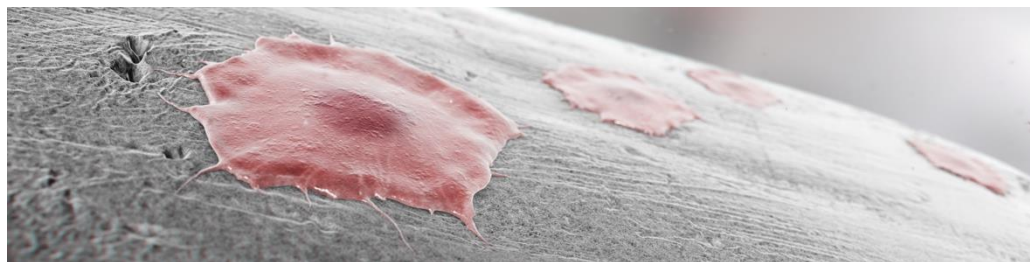
 promimic.com

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

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

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

#### The market

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

#### Recent progress

- Entered into partnership with the US company Onkos Surgical (March 2019).
- The company's first spinal device utilizing HA<sup>nano</sup> Surface to improve osseointegration has been 510(k) approved by the FDA (August 2019).

#### Expected milestones

- Further product launches and license agreements with major manufacturers during 2020.

## 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 Oct-Dec	2018 Oct-Dec	2019 Full-year	2018 Full-year
<b>Condensed income statement</b>				
Change in fair value of shares in portfolio companies	383.0	36.4	415.1	58.5
Net profit/loss	328.8	14.9	303.0	30.5
<b>Balance sheet information</b>				
Cash, cash equivalents and short-term investments	52.1	85.8	52.1	85.8
Net asset value (Note 1)	1,027.3	300.1	1,027.3	300.1
Net debt (Note 1)	-37.8	-392.5	-37.8	-392.5
<b>Share information</b>				
Earnings per share, weighted average before dilution (SEK)	3.2	0.2	4.1	0.5
Earnings per share, weighted average after dilution (SEK)	3.2	0.2	4.1	0.5
Net asset value per share (SEK) (Note 1)	5.9	4.7	5.9	4.7
Equity per share (SEK) (Note 1)	5.7	4.6	5.7	4.6
Share price, last trading day in the reporting period (SEK)	3.5	6.2	3.5	6.2
<b>Portfolio information</b>				
Investments in portfolio companies	6.8	43.4	48.9	124.6
Of which investments not affecting cash flow	0.8	0.8	1.9	7.3
Portfolio companies at fair value through profit or loss	1,047.6	618.9	1,047.6	618.9

### Financial Development for the Investment Entity in 2019

#### *Investments (comparable numbers 2018)*

Investments in the portfolio in the fourth quarter 2019 by external investors and Karolinska Development amounted to SEK 35.6 (553.4) million, whereof 81% (92%) by external investors.

Karolinska Development invested SEK 6.8 (43.4) million, of which SEK 6.0 (42.4) million was cash investments. Investments were made in Umecline Cognition with SEK 4.8 million and in Modus Therapeutics with SEK 2.0 million. Non-cash investments (accrued interest on loans) amounted to 0.8 (0.8) million.

Investments by external investors in the portfolio companies amounted to SEK 28.8 (509.9) million. Investments were made in Forendo Pharma SEK 28.3 million and Modus Therapeutics SEK 0.5 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-Q4 2019
Umecrine Cognition	34.4	2.5	36.9
Forendo Pharma	6.6	133.1	139.7
OssDsign	5.5	145.8	151.3
Modus Therapeutics	2.0	0.5	2.5
Dilafor	0.4	11.5	11.8
Aprea Therapeutics	-	51.4	51.4
Lipidor	-	25.2	25.2
Promimic	-	20.0	20.0
Asarina Pharma	-	6.8	6.8
<b>Total</b>	<b>48.9</b>	<b>396.8</b>	<b>445.7</b>

### **Portfolio Fair Value**

Fair Value of the portfolio companies owned directly by Karolinska Development increased by SEK 81.1 million during the fourth quarter 2019. Fair value increased mainly as a result of the rise in the share price of the listed holding Aprea but also by the rise in the share price of the listed holding Lipidor, the increased fair value of Forendo Pharma (in connection with another investment round from third parties) and loans (including accrued interest) to the portfolio company Umecrine Cognition. Fair value of the listed holding OssDsign decreased as a result of a partial divestment of the holding but also by a decline in the share price.

Fair Value of the portfolio companies owned indirectly via KDev Investments increased by SEK 459.7 million during the fourth quarter 2019. The main reason for the increase was the rise in the share price of the listed holding Aprea but decreased as a result of mainly an adjustment of the value of the holding in Modus Therapeutics to a valuation level that corresponds to what was discussed at the end of 2019 with potential investors for the development of a new indication. Fair value also decreased as a result of the divestment 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 540.9 million in the fourth 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 163.0 million, resulting in Net Portfolio Fair Value increasing by SEK 377.9 million in the fourth quarter 2019.

SEKm	31 Dec 2019	30 Sep 2019	Q4 2019 vs Q3 2019
Karolinska Development Portfolio Fair Value (unlisted companies)	446.7	456.9	-10.2
Karolinska Development Portfolio Fair Value (listed companies)	162.8	71.4	91.4
KDev Investments Portfolio Fair Value	943.9	484.2	459.7
<b>Total Portfolio Fair Value</b>	<b>1,553.4</b>	<b>1,012.5</b>	<b>540.9</b>
Potential distribution to Rosetta Capital of fair value of KDev Investments	505.8	342.8	163.0
<b>Net Portfolio Fair Value (after potential distribution to Rosetta Capital)</b>	<b>1,047.6</b>	<b>669.7</b>	<b>377.9</b>

Total Portfolio Fair Value on 31 December 2019 amounted to SEK 1,553.4 million and the potential distribution to Rosetta Capital amounted to SEK 505.8 million. Net Portfolio Fair Value on 31 December 2019 amounted to SEK 1,047.6 million. Compared to 31 December 2018, the Total Portfolio Fair Value increased with SEK 601.0 million and the Net Portfolio Fair Value increased with SEK 428.7 million.

***Profit development 2019 (comparable numbers 2018)***

During the fourth quarter 2019, Karolinska Development's revenue amounted to SEK 0.7 (0.9) million and consists primarily of services provided to portfolio companies. The revenue for the full year 2019, amounted to SEK 3.4 (3.1) million.

Change in fair value of shares in portfolio companies of in total SEK 377.9 (36.4) million includes the difference between the increase in Net Portfolio Fair Value during the fourth quarter 2019 with SEK 383.0 million and the net of investments in the portfolio companies of SEK 6.8 million as well as the partial divestment of the holding in OssDesign and the divestment of the holding in Asarina Pharma, in total amounting to SEK 17.8 million. Change in fair value of other financial assets amounted to SEK -37.0 (-3.2) million and are the consequence of a partial divestment and realization of an earn-out deal but also due to changes in valuation of earn-out deals. For the full year 2019, the change in fair value of shares in portfolio companies amounted to SEK 416.6 (58.5) million and the change in fair value of other financial assets and liabilities amounted to SEK -28.2 (41.5) million.

During the fourth quarter 2019 other expenses amounted to SEK 8.8 (3.6) million and personnel costs amounted to SEK 6.2 (2.7) million. The difference in other expenses compared to the fourth quarter 2018 is caused by costs in relation to the completed set-off issue of the convertible loan. The difference in personnel costs compared to the fourth quarter of 2018 is mainly due to the outcome of bonus schemes in 2019. For the full year 2019 other expenses amounted to SEK 18.2 (14.0) million and personnel cost amounted to 23.5 (15.0) million. The difference in personnel costs compared to the fourth 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 of bonus schemes to the employees which increased comparable costs in 2019.

The operating profit/loss in the fourth quarter 2019 amounted to SEK 331.5 million compared to SEK 27.8 million in the fourth quarter 2018. The operating profit/loss for the full year 2019 amounted to 347.9 (74.0) million.

Financial net increased during the fourth quarter 2019 compared to the fourth quarter 2018 and amounted to SEK -2.8 (-12.9) million, which is primarily related to that the majority of the convertible loan was converted at the set-off issue during the quarter. For the full year 2019 the financial net amounted to SEK -45.0 (-43.5) million.

The Investment Entity's Net profit/loss amounted to SEK 328.8 (14.8) million in the fourth quarter 2019. Net profit/loss for the full year 2019 amounted to SEK 303.0 (30.5) million.

***Financial position***

The Investment Entity's equity to total assets ratio amounted to 86% on 31 December 2019, compared to 34% on 30 September 2019.

The set-off issue directed towards the holders of the convertible loan was completed during the fourth quarter. This in combination with a net profit of SEK 328.8 million in the fourth quarter resulted in the equity on 31 December 2019 increasing to SEK 1,007.7 million compared to SEK 270.2 million on 30 September 2019.

Interest-bearing liabilities after the completed set-off issue, consisted of the remaining part of the convertible loan and a bridge loan amounting to SEK 70 million, in total amounting to SEK 90 million on 31 December 2019, compared to SEK 505.0 million on 31 December 2018. The remaining part of the convertible loan was repaid in January 2020.

After paying operational costs and investments in the fourth quarter 2019, cash and cash equivalents amounted to SEK 52.1 million on 31 December 2019 compared to SEK 85.8 million on 31 December 2018. Net debt amounted to SEK 37.8 million on 31 December 2019 compared to SEK 392.5 million on 31 December 2018.

***Financial situation***

See section "Financial risks" for the Board's view of the company's financial situation

## Financial Development – Parent Company

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

During the fourth quarter 2019, the Parent Company's Net profit/loss amounted to SEK 328.8 million (SEK 14.8 million).

Due to the positive result for the fourth quarter 2019, the equity increased from SEK 270.2 million 30 September 2019 to SEK 1,007.8 million 31 December 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 31 December 2019 was SEK 3.53, and the market capitalization amounted to SEK 620 million.

The share capital of Karolinska Development on 31 December 2019 amounted to SEK 1.8 million divided into 1,503,098 A shares, each with ten votes (15,030,980 votes) and 174,162,311 B shares, each with one vote (174,162,311 votes). The total number of shares and votes in Karolinska Development on 31 December 2019 amounted to 175,665,409 shares and 189,193,291 votes.

### Ownership

On December 31, 2019, Karolinska Development had 3,925 shareholders.

Shareholder	A-Shares	B-Shares	Cap %	Vote %
Sino Biopharmaceutical Limited	0	75,727,285	43.11%	40.03%
Worldwide International Investments Ltd	0	32,276,620	18.37%	17.06%
Karolinska Institutet Holding AB	1,503,098	2,126,902	2.07%	9.07%
Tredje AP-Fonden	0	6,256,600	3.56%	3.31%
Östersjöstiftelsen	0	3,889,166	2.21%	2.06%
OTK Holding A/S	0	2,900,000	1.65%	1.53%
Stift För Främjande & Utveckling	0	2,641,389	1.50%	1.40%
Coastal Investment Management LLC	0	2,470,541	1.41%	1.31%
Ribbskottet AB	0	2,000,000	1.14%	1.06%
Försäkringsaktiebolaget Avanza Pension	0	1,228,771	0.70%	0.65%
Sum Top 10 Shareholders	1,503,098	131,517,274	75.72%	77.46%
Sum Other Shareholders	0	42,645,037	24.28%	22.54%
<b>Sum All Shareholders</b>	<b>1,503,098</b>	<b>174,162,311</b>	<b>100.00%</b>	<b>100.00%</b>

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## Information on Risks and Uncertainties

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### Investment Entity and Parent Company

#### Financial risks

On December 18, 2019, the final outcome was announced in the directed new share issue addressed to the Company's convertible bond holders. In total, convertible holders had subscribed for shares in the directed share issue corresponding to SEK 294 million in nominal value of the Company's convertible loan. The remaining SEK 13.6 million in nominal value of the convertible loan was then repaid in January 2020. At the end of 2019 it was also announced that the short-term capital requirement had been secured by a bridge loan of SEK 70 million, which expires on December 31, 2020, and where repayment can be made by cash, payment and / or through set-off in connection with a new issue of B shares.

The Board can note that the successful directed share issue to the convertible holders, which enabled a reduction of the entire convertible loan, a favorable development of listed assets in the portfolio as well as the secured loan, means that conditions for a going concern exists.

The management is also working on a number of financing options to refinance the bridge loan and increase the degree of strategic and operational headroom for the future.

For a detailed description of other risks and uncertainties, see the Annual report 2018 as well as prospectus and the prospectus supplements "Invitation to subscribe for shares in Karolinska Development AB (publ)".

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## Signing of the report

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Solna, 13 February 2020

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.

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## Dates for Publication of Financial Information

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Annual Report 2019	26 March 2020
Interim Report January – March 2020	30 April 2020
Annual General Meeting	7 Maj 2020
Interim Report January – June 2020	20 August 2020
Interim Report January – September 2020	11 November 2020

Karolinska Development is required by law to publish the information in this interim report. The information was published on 13 February 2020.

This interim report, together with additional information, is available on Karolinska Development's website: [www.karolinskadevelopment.com](http://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 Oct-Dec	2018 Oct-Dec	2019 Full-year	2018 Full-year
Revenue		728	853	3,384	3,073
Change in fair value of shares in portfolio companies	2	383,010	36,370	415,136	58,499
Change in fair value of other financial assets and liabilities		-37,023	-3,173	-28,215	41,481
Other expenses		-8,830	-3,554	-18,186	-14,017
Personnel costs		-6,173	-2,705	-23,474	-14,993
Depreciation of right-of- use assets		-176	0	-704	0
<b>Operating profit/loss</b>		<b>331,536</b>	<b>27,791</b>	<b>347,941</b>	<b>74,043</b>
Financial net		-2,749	-12,937	-44,964	-43,533
<b>Profit/loss before tax</b>		<b>328,787</b>	<b>14,854</b>	<b>302,977</b>	<b>30,510</b>
Taxes		-	-	-	-
<b>NET PROFIT/LOSS FOR THE PERIOD</b>		<b>328,787</b>	<b>14,854</b>	<b>302,977</b>	<b>30,510</b>

### Condensed statement of comprehensive income for the Investment Entity

SEK 000	Note	2019 Oct-Dec	2018 Oct-Dec	2019 Full-year	2018 Full-year
Net/profit loss for the period		328,787	14,854	302,977	30,510
<b>Total comprehensive income/loss for the period</b>		<b>328,787</b>	<b>14,854</b>	<b>302,977</b>	<b>30,510</b>

### Earnings per share for the Investment Entity

SEK	Note	2019 Oct-Dec	2018 Oct-Dec	2019 Full-year	2018 Full-year
Earnings per share, weighted average before dilution		3.20	0.23	4.10	0.48
Number of shares, weighted average before dilution		102,658,544	64,174,452	73,874,552	64,136,941
Earnings per share, weighted average after dilution		3.20	0.23	4.10	0.48
Number of shares, weighted average after dilution		102,658,544	64,174,452	73,874,552	64,136,941

### Condensed balance sheet for the Investment Entity

SEK 000	Note	31 Dec 2019	31 Dec 2018
<b>ASSETS</b>			
<b>Tangible assets</b>			
Right-of-use assets		704	-
<b>Financial assets</b>			
Shares in portfolio companies at fair value through profit or loss	2	1,047,600	618,927
Loans receivable from portfolio companies		1,768	5,098
Other financial assets		-	26,970
<b>Total non-current assets</b>		<b>1,050,072</b>	<b>650,995</b>
<b>Current assets</b>			
Accounts receivable		39	-
Receivables from portfolio companies		322	473
Other financial assets		62,620	53,060
Other current receivables		787	3,432
Prepaid expenses and accrued income		732	632
Short-term investments, at fair value through profit or loss		0	69,949
Cash and cash equivalents		52,132	15,843
<b>Total current assets</b>		<b>116,632</b>	<b>143,389</b>
<b>TOTAL ASSETS</b>		<b>1,166,704</b>	<b>794,384</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Total equity</b>		<b>1,007,732</b>	<b>296,007</b>
<b>Long-term liabilities</b>			
Other financial liabilities		-	11,423
<b>Total long-term liabilities</b>		<b>0</b>	<b>11,423</b>
<b>Current liabilities</b>			
Convertible loan	3	19,964	428,303
Current interest liabilities		70,000	50,000
Other financial liabilities		46,851	-
Accounts payable		11,484	1,373
Liability to make lease payment		726	-
Other current liabilities		2,991	831
Accrued expenses and prepaid income		6,956	6,447
<b>Total current liabilities</b>		<b>158,972</b>	<b>486,954</b>
<b>Total liabilities</b>		<b>158,972</b>	<b>498,377</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>1,166,704</b>	<b>794,384</b>

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

SEK 000	Note	2019-12-31	2018-12-31
<b>Opening balance, equity</b>		<b>296,007</b>	<b>267,121</b>
Net profit/ loss for the period		302,977	30,510
Effect of incentive programs etc		14	-1,624
Share capital		1,113	-
Prospectus costs		-13,545	-
Share premium		421,166	-
<b>Closing balance, equity</b>		<b>1,007,732</b>	<b>296,007</b>

**Condensed statement of cash flows for the Investment Entity**

SEK 000	Note	2019 Full-year	2018 Jan-Dec
<b>Operating activities</b>			
Operating profit/loss		347,941	74,043
<b>Adjustments for items not affecting cash flow</b>			
Depreciation		704	0
Change in fair value	2	-386,921	-99,980
Other items		-716	-2,134
Proceeds from short-term investments		783	-570
Interest paid/received		-1,765	-343
<b>Cash flow from operating activities before changes in working capital and operating investments</b>		<b>-39,974</b>	<b>-28,984</b>
<b>Cash flow from changes in working capital</b>			
Increase (-)/Decrease (+) in operating receivables		-215	-4,368
Increase (+)/Decrease (-) in operating liabilities		32,780	46,506
<b>Cash flow from operating activities</b>		<b>-7,409</b>	<b>13,154</b>
<b>Investment activities</b>			
Part payment from earn-out deal		11,617	8,663
Proceeds from sale of shares in portfolio companies		23,444	11,911
Acquisitions of shares in portfolio companies		-46,958	-117,237
Proceeds from sale of short-term investments <sup>1</sup>		69,140	80,047
<b>Cash flow from operating activities</b>		<b>57,243</b>	<b>-16,616</b>
<b>Financing activities</b>			
Convertible debentures issue		-13,545	-
<b>Cash flow from financing activities</b>		<b>-13,545</b>	<b>0</b>
<b>Cash flow for the period</b>		<b>36,289</b>	<b>-3,462</b>
Cash and cash equivalents at the beginning of the year		15,843	19,305
<b>CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD</b>		<b>52,132</b>	<b>15,843</b>
<b>Supplemental disclosure<sup>1</sup></b>			
<b>CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD</b>		<b>52,132</b>	<b>15,843</b>
Short-term investments, market value at closing date		0	69,949
<b>CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS AT THE END OF THE PERIOD</b>		<b>52,132</b>	<b>85,792</b>

<sup>1</sup>Surplus liquidity in the Investment Entity was invested in interest-bearing instruments and is recognized as short-term investments with a maturity exceeding three months. These investments were consequently not reported as cash and cash equivalents and were therefore included in the statement of cash flows from operating activities. The supplemental disclosure was presented to provide a total overview of the Investment Entity's available fund including cash, cash equivalents and short-term investments described here. As of December 31, 2019, there is no short-term investments.

### Condensed income statement for the Parent Company

SEK 000	Note	2019 Oct-Dec	2018 Oct-Dec	2019 Full-year	2018 Full-year
Revenue		728	853	3,384	3,073
Change in fair value of shares in portfolio companies		383,010	36,370	415,136	58,499
Change in fair value of other financial assets		-37,023	-3,173	-28,215	41,481
Other expenses		-9,009	-3,554	-18,901	-14,017
Personnel costs		-6,173	-2,705	-23,474	-14,993
<b>Operating profit/loss</b>		<b>331,533</b>	<b>27,791</b>	<b>347,930</b>	<b>74,043</b>
Financial net		-2,739	-12,937	-44,917	-43,533
<b>Profit/loss before tax</b>		<b>328,794</b>	<b>14,854</b>	<b>303,013</b>	<b>30,510</b>
Tax		-	-	-	-
<b>NET PROFIT/LOSS FOR THE PERIOD</b>		<b>328,794</b>	<b>14,854</b>	<b>303,013</b>	<b>30,510</b>

### Condensed statement of comprehensive income for the Parent Company

SEK 000	Note	2019 Oct-Dec	2018 Oct-Dec	2019 Full-year	2018 Full-year
Net profit/loss for the period		328,794	14,854	303,013	30,510
<b>Total comprehensive income/loss for the period</b>		<b>328,794</b>	<b>14,854</b>	<b>303,013</b>	<b>30,510</b>

### Condensed balance sheet for the Parent Company

SEK 000	Note	31 Dec 2019	31 Dec 2018
<b>ASSETS</b>			
<b>Financial assets</b>			
Shares in portfolio companies at fair value through profit or loss	2	1,047,600	618,927
Loans receivable from portfolio companies		1,768	5,098
Other financial assets		-	26,970
<b>Total non-current assets</b>		<b>1,049,368</b>	<b>650,995</b>
<b>Current assets</b>			
Accounts receivable		39	-
Receivables from portfolio companies		322	473
Other financial assets		62,620	53,060
Other current receivables		787	3,432
Prepaid expenses and accrued income		732	632
Short-term investments at fair value through profit or loss		-	69,949
Cash and cash equivalents		52,132	15,843
<b>Total current assets</b>		<b>116,632</b>	<b>143,389</b>
<b>TOTAL ASSETS</b>		<b>1,166,000</b>	<b>794,384</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Total equity</b>		<b>1,007,754</b>	<b>296,007</b>
<b>Long-term liabilities</b>			
Other financial liabilities		-	11,423
<b>Total long-term liabilities</b>		<b>0</b>	<b>11,423</b>
<b>Current liabilities</b>			
Convertible loan	3	19,964	428,303
Current interest liabilities		70,000	50,000
Other financial liabilities		46,851	-
Accounts payable		11,484	1,373
Other current liabilities		2,991	831
Accrued expenses and prepaid income		6,956	6,447
<b>Total current liabilities</b>		<b>158,246</b>	<b>486,954</b>
<b>Total liabilities</b>		<b>158,246</b>	<b>498,377</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>1,166,000</b>	<b>794,384</b>

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

SEK 000	Note	31 Dec 2019	31 Dec 2018
<b>Opening balance, equity</b>		<b>296,007</b>	<b>267,121</b>
Net profit/ loss for the period		303,013	30,510
Effect of incentive programs		-	-1,624
Share capital		1,113	-
Prospectus costs direct issue 2019		-13,545	-
Share premium reserve		421,166	-
<b>Closing balance, equity</b>		<b>1,007,754</b>	<b>296,007</b>

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## Notes to the Financial Statements

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### 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 per cent) without having an impact on equity.

#### Related party transactions

In addition to remuneration to the Board of Directors and senior executives in the normal course of business, the following transactions took place in 2019: Sino Biopharmaceutical Limited, the largest shareholder in the company, has provided a bridge loan of SEK 70 million ending December 31, 2020 with an annual interest rate of 8.0%. Repayment can be made through cash payment and / or through set-off in connection with a new issue of B shares.

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

##### Going concern assumption

Based on financing received and the reduction in debt, this year-end report has been prepared based on an going concern assumption.

##### 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 – December 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 1,047.8 million), loans receivable from portfolio companies (SEK 1.8 million), cash and cash equivalents (SEK 52.1 million), and net of financial assets and liabilities minus interest-bearing liabilities (SEK 15.8 million minus SEK 90.0 million), in relation to the number of shares outstanding (175,421,124) on the closing date (31 December 2019).

**Net debt:** Interest-bearing liabilities (SEK 90.0 million) reduced with cash and cash equivalents (SEK 52.1 million).

## NOTE 2 Fair value

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

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

### Fair value as of 31 December 2019

SEK 000	Level 1	Level 2	Level 3	Total
<b>Financial assets</b>				
Shares in portfolio companies, at fair value through profit or loss	162,771	-	884,829	1,047,600
Loans receivable from portfolio companies	-	1,768	-	1,768
Other financial assets	-	-	62,620	62,620
Accounts receivable	-	39	-	39
Receivables from portfolio companies	-	322	-	322
Cash, cash equivalents and short-term investments	52,132	-	-	52,132
<b>Total</b>	<b>214,903</b>	<b>2,090</b>	<b>947,449</b>	<b>1,164,481</b>
<b>Financial liabilities</b>				
Other financial liabilities	-	-	46,851	46,851
Accounts payable	-	11,484	-	11,484
Liability to make lease payment	-	726	-	726
<b>Total</b>	<b>-</b>	<b>12,210</b>	<b>46,851</b>	<b>59,061</b>

#### Fair value as of 31 December 2018

SEK 000	Level 1	Level 2	Level 3	Total
<b>Financial assets</b>				
Shares in portfolio companies, at fair value through profit or loss	0	-	618,927	618,927
Loans receivable from portfolio companies	-	5,098	-	5,098
Other financial assets	-	-	80,030	80,030
Receivables from portfolio companies	-	473	-	473
Cash, cash equivalents and short-term investments	85,792	-	-	85,792
<b>Total</b>	<b>85,792</b>	<b>5,571</b>	<b>698,957</b>	<b>790,320</b>
<b>Financial liabilities</b>				
Other financial liabilities	-	-	11,423	11,423
Accounts payable	-	1,373	-	1,373
<b>Total</b>	<b>-</b>	<b>1,373</b>	<b>11,423</b>	<b>12,796</b>

#### Fair value (level 3) as of 31 December 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	-97,355	-	0
Acquisitions	48,909	-	-
Disposals	-21,725	-24,623	-
Gains and losses recognized through profit or loss	336,073	7,213	35,428
<b>Closing balance 31 December 2019</b>	<b>884,829</b>	<b>62,620</b>	<b>46,851</b>
Realized gains and losses for the period included in profit or loss	12,747	0	0
Unrealized gains and losses in profit or loss for the period included in profit or loss	323,326	7,213	-35,428

#### Fair value (level 3) as of 31 December 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	124,557	-	-
Disposals	-	-8,663	-
Gains and losses recognized through profit or loss	60,670	48,097	6,616
<b>Closing balance 31 December 2018</b>	<b>618,927</b>	<b>80,030</b>	<b>11,423</b>
Realized gains and losses for the period included in profit or loss	1,789	-	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	58,881	48,097	-6,616

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 505.8 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 p

SEK 000	31 Dec 2019	31 Dec 2018
Karolinska Development Portfolio Fair Value (unlisted companies)	446,658	492,600
Karolinska Development Portfolio Fair Value (listed companies)	162,771	0
KDev Investments Portfolio Fair Value	943,946	459,740
<b>Total Portfolio Fair Value</b>	<b>1,553,375</b>	<b>952,340</b>
Potential distribution to Rosetta Capital of fair value of KDev Investments	505,775	333,413
<b>Net Portfolio Fair Value (after potential distribution to Rosetta Capital)</b>	<b>1,047,600</b>	<b>618,927</b>

### Potential distribution to Rosetta Capital in consideration

\* SEK 43.3 million repayment of investments in KDev Investments made by Rosetta Capital and SEK 462.5 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 per cent. The nominal amount was reduced to SEK 329 million

after the set-off issue in March 2017. The convertible debentures were due for payment on 31 December 2019. Through a set-off issue in 2019, a total of SEK 294.3 million in nominal value was converted and SEK 21.4 million in nominal value was reduced through repurchases. At year-end, SEK 13.6 million, in nominal value, thus remained equivalent to SEK 20.0 million, including accrued interest until 31 December 2019.

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	2019-12-31	2018-12-31
Nominal amount of convertible debentures issued on 2 January 2015	329,257	329,337
Issue costs	-23,982	-23,982
Equity portion	-42,164	-42,164
<b>Debt at issuance date 2 January 2015</b>	<b>263,111</b>	<b>263,191</b>
Accrued interest costs prior years	165,192	115,993
<b>Opening balance 1 January 2019</b>	<b>428,303</b>	<b>379,184</b>
<b>Set-off share issue 2019</b>		
Converted nominal amount	-315,670	-
Converted part of issue costs	23,982	-
Converted part of equity portion	42,164	-
Converted part of accrued interest costs	-138,898	-
Redemption of convertible 2019	-21,396	-
<b>Debt prior this year's interest</b>	<b>18,485</b>	<b>379,184</b>
Accrued interest costs this year	1,479	49,119
<b>Total</b>	<b>19,964</b>	<b>428,303</b>

#### NOTE 4      Pledge assets and contingent liabilities

SEK 000	2019-12-31	2018-12-31
<b>Pledge assets</b>		
The right to payment under Earn-out agreement regarding Oncopeptides shares <sup>1</sup>	-	53,060
<b>Contingent liabilities</b>		
Investment agreement in portfolio company	2,000	-
<b>Summa</b>	<b>2,000</b>	<b>53,060</b>

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