



### **List of contents**

The year in brief

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CEO comments	3
Karolinska Development's business strategy	ć
The path to market for life science products	7
Key components to understand the value of Karolinska Development	Ç
Key events in 2018	10
Financial position – summary	12
The portfolio companies	13
The share and shareholders	23
Board of Directors	24
Employees	25
Directors' report	27
Financial statements	37
Notes	45
Auditor's report	74
Corporate Governance Report	77
Auditor's report on the corporate governance statement	82
Definitions	82
Publication dates for financial information	84

## **About Karolinska Development**

Karolinska Development (Nasdaq Stockholm: KDEV) is an investment company which offers a unique opportunity to share in the growth in value of a number of Nordic life sciences companies with high commercial potential, nine of which have projects in the clinical development or early launch phase. Clinical phase II results are expected for presentation by three of the portfolio companies' projects in 2019, offering the potential for substantially increased opportunities for attractive divestments or licensing deals. Comparable candidate drugs for our active holdings in the portiolio have, in recent years, been out-licensed or sold for contract values of between SEK 1.8 and 7.7 billion for the individual projects. The portfolio companies have been strengthened in the past year through the recruitment of senior executives with a documented ability to close international business deals in the life sciences sector.

www.karolinskadevelopment.com Twitter: @Karolinska\_Dev

#### **KEY EVENTS IN 2018**

31 MSEK Positive full-year result **952** MSEK

The total fair value of the portfolio increased by 33% to 952 MSEK

125 MSEK was invested

37%

The equity/assets ratio

#### **FINANCIAL SUMMARY**

SEKm	2018	2017	
Net profit/loss	30.5	179.6	
Cash, cash equivalents and short-term investments	85.8	169.6	
Earnings per share (SEK)	0.5	2.9	
Net asset value per share (SEK)	3.8	4.3	
Equity per share (SEK)	4.6	4.2	
Share price at year end (SEK)	6.2	5.8	
Investments in portfolio companies	124.6	91.9	
Total portfolio fair value	952.3	714.0	
Net portfolio fair value	618.9	447.8	

#### **OUR STARTING POINT FOR 2019**

- KD's portfolio companies have three projects where phase II data is expected in 2019;
- Based on available data, the potential for positive phase II data from the projects in question is between 27 and 50%, depending on therapeutic indication area;<sup>1</sup>
- A number of deals have been completed for comparable candidate drugs to our active holdings in the portfolio where the contract values of the individual projects totalled between SEK 1.8 and 7.7 billion.<sup>2</sup>
- The work of finding a solution to the convertible loan that matures in December is prioritized and intensified
- 1) Phase II success rates per disease area. Source: Hay, Michael, et al. "Clinical development success rates for investigational drugs." Nature biotechnology 32.1 (2014): 40.
- 2) Deal information obtained from BCIQ: BioCentury Online Intelligence.

### **CEO** comments



MY FIRST FULL calendar year as CEO was exciting and eventful, and that applies to both Karolinska Development and our portfolio companies. During the year, we saw several of the portfolio companies, such as Aprea Therapeutics, Modus Therapeutics, Forendo Pharma and OssDsign, take important steps forward. We also welcomed long-term, respected investors, such as HealthCap, as co-investors in our companies. And I am seeing increased confidence in us and our unique life science expertise.

We are determined to continue combining business acumen with professional development of innovative life science projects. Major progress in our portfolio companies' projects under our active ownership again resulted in a significant increase in the aggregate value of Karolinska Development's investments in 2018. At the end of December 2018, the Total Portfolio Fair Value amounted to SEK 952 million, an increase of 33% from SEK 714 million a year earlier. Largely because of this, along with effective cost control, we were also able, for the second consecutive year, to report a positive full-year result. Net profit for the full-year amounted to SEK 31 million.

Our work to bolster Karolinska Development's financial position, including finding a solution for the convertible loan that falls due in December 2019, was also a priority during the year and will be further intensified in 2019. We will present a solution to our owners as soon as the work is completed.

#### A strategy focused on spreading risk

Karolinska Development's progress in 2018 reflects our overall strategy. Most of our portfolio companies have projects in clinical development, with all the potential and risk that entails. Our strategy is to spread the risk through a broad portfolio, at the same time that each project is driven forward as effectively and qualitatively as possible to reach its full potential. Investing in life science companies is complex. In addition to expertise in the areas our portfolio companies work in, we have to understand the world in which they operate. This includes market mechanisms, how certification processes work and how they are best carried out.

The challenge for private investors without in-depth knowledge of the life sciences is to broaden their portfolio while also mitigating risk. We at Karolinska Development mainly invest in companies with a drug or a product or method that is considered "first-in-class," or which has orphan drug status. Beyond the biological risk, i.e. the risk associated with the level of invention, there is an executive risk in our portfolio companies. By assisting our portfolio companies in evaluating multiple indications, i.e., broadening their market by identifying more applications for their candidate drugs or products, we spread the development risks and thereby reduce the biological risk. In terms of the executive risk, our goal at Karolinska Development is to reduce it as far as possible. As an investment company, our role is to exercise active ownership and through our board role help and support our portfolio companies with all the knowledge and experience we have. We help them to build up their organizations and assist in recruiting and appointing professional boards. We then recruit individuals to management and the board who earlier in their careers have accomplished exactly what we want to achieve with the portfolio company in question.

#### More advances Continued progress in our portfolio companies

The pace of development in our portfolio companies remained very high during the year. Several projects have made major progress. Aprea Therapeutics, for example, reported positive initial results in a study in patients with the blood cancer myelodysplastic syndrome (MDS), Forendo Pharma initiated a phase 1a study of the candidate drug FOR-6219 for the treatment of endometriosis, Modus' application to initiate a phase 1 study in the US was approved, and OssDsign received 510(k) clearance from the FDA for its product, Cranioplug. In 2018, we received positive news from several of our portfolio companies.

#### Aprea Therapeutics

The positive initial results during the year from Aprea Therapeutics' ongoing phase 1b/2 study of APR 246 for the treatment of TP53 mutated myelodysplastic syndrome (MDS) strengthen our belief that APR 246 could become one of the world's first TP53 targeted drugs. Mutations in the TP53 gene occur in 50% of all human tumors and are often associated with resistance to cancer drugs. Despite the central role this gene plays in tumor biology, it has proven extremely difficult to develop targeted therapies for TP53. Aprea's APR 246 reactivates mutated TP53 protein and is currently one of the most advanced TP53-targeted candidate

"We continue determined to combine business acumen with professional development of innovative life science projects"

drugs in the world. As a result of the promising development in MDS, Aprea initiated in January 2019 a pivotal phase 3 study in patients with TP53 mutated MDS, the results of which are anticipated in 2020.

#### Forendo Pharma

Another of our portfolio companies is Forendo Pharma, which has developed the candidate drug FOR-6219 for eliminating endometriosis while at the same time maintaining normal hormonal cycles. After clinical trial authorization (CTA) was received from the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, a phase 1a study commenced in July 2018. Positive results from the study presented in March 2019 found FOR-6219 to be safe and well tolerated, with good pharmacokinetics at the doses tested. The positive results are an important milestone for Forendo Pharma and support the initiation of a phase Ib clinical study in healthy postmenopausal women with the aim to demonstrate Proof of Mechanism.

#### OssDsign

OssDsign had also good news to report during the year when it announced that its latest product, Cranioplug, received 510(k) clearance by the FDA, which allows marketing and sales of the product in the US. The implant is the first of its kind in the US market.

#### **Modus Therapeutics**

In late 2018, the FDA approved Modus Therapeutics' Investigational New Drug (IND) application to initiate a phase 1 clinical study in the US with subcutaneous sevuparin for treatment of sickle cell disease. The first patient cohort in the study was dosed in early 2019 and the results are expected in the first half of 2019. In addition, the company reported that its phase 2 study with sevuparin in Europe and the Middle East is fully recruited and that the results are expected in the first half of 2019.

#### Dilafor

But of course things do not always go according to plan. In October 2018, our portfolio company Dilafor announced that its phase 2b study of the candidate drug tafoxiparin did not achieve its primary goals. The

candidate drug, for treatment of protracted labor, was well tolerated by both women and children, but no statistically significant efficacy was observed in any of the dose levels studied. While, of course, it is always a disappointment when a hypothesis does not work out, it is a natural part of the drug development process, and we have taken this into consideration in our general investment strategy. The company is now evaluating the possibility of further clinical development in the indication labor induction.

#### **Umecrine Cognition**

When Umecrine Cognition completed its analysis of the results of a phase 2a study of GR3027 for idiopathic hypersomnia in late January 2019, it stated that the candidate drug's pharmacokinetics and safety profile remained good and that there is preliminary evidence of clinical efficacy in a subset of patients. Altogether, Umecrine Cognition deems it is motivated to further evaluate GR3027 for treatment of hypersomnia and other sleep disorders. At the same time, the clinical development of GR3027 for treatment of hepatic encephalopathy continues.

#### **External capital facilitates long-term development**

The external investments made in several of our portfolio companies offer excellent potential for them to develop their projects in a sustainable, high quality, and value-generating way. The fact that other international and highly regarded specialist investors are engaging in the companies also confirms our assessment of their potential.

The biggest external investment in 2018 came from an investment consortium headed by the US firm Redmile Group, which invested SEK 512 million in Aprea Therapeutics. The investment consortium also includes Rock Springs Capital, which, like Redmile Group, entered as a new owner. In early 2019, another investor, Janus Henderson Investors, joined the consortium by investing approximately SEK 51 million.

The venture capital firm Vesalius Biocapital III Partner, which specializes in investing in later stage European life science companies, invested EUR 4 million in Forendo Pharma during the year, while HealthCap is investing SEK 60 million in Modus Therapeutics.

In January 2019, OssDsign announced the closing of a private placement of SEK 64 million. Swedish private investors and the French invest-



ment company Alto Invest participated in the investment. OssDsign is now beginning the process towards a listing on Nasdaq First North in 2019.

#### 2019 - a year of opportunities

We expect 2019 to be just as newsworthy as 2018 for Karolinska Development. The results from three phase 2 studies from Aprea Therapeutics and Modus Therapeutics are expected in first half of 2019.

- Aprea Therapeutics will present the full results of a phase 2 study of myelodysplastic syndrome (MDS). Interim data presented in December 2018 shows an Overall Response Rate of 95% and a Complete Remission (CR) rate of 70%. Results from a phase 2 study of APR 246 in patients with platinum-sensitive high-grade serous ovarian cancer (HGSOC) will also be presented. Karolinska Development owns 2% of the company directly and a further 11% through KDev Investments (fully diluted). A few years ago, a licensing deal was signed for a similar pharmaceutical project with a contract value of more than SEK 4 billion. The average probabilities of positive phase 2 data for projects addressing ovarian cancer and MDS are 27% and 33%, respectively.
- Modus Therapeutics is expected to present the results from a phase 2 study of its candidate drug sevuparin for treatment of the heritable sickle cell disease in the first half of 2019. Karolinska Development owns 49% of Modus through Kdev Invest (fully diluted). In recent years, two partnership agreements have been signed on pharmaceutical projects in the same developmental phase for treatment of sickle cell disease. One has a contract value of approximately SEK 6 billion and the other nearly SEK 3 billion. The average probability of positive phase II data for the project is 50%.

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

We are also focused on our own financing situation since our convertible loan falls due for payment on December 31, 2019, if it is not converted to shares by then. If not converted, Karolinska Development will need to obtain financing before the end of the fourth quarter of 2019 for repayment of the convertible and to secure our continuing operations. A top priority for the Board of Directors and the company is to find a solution that includes discussions with convertible holders and financing institutions. We are confident of our ability to identify a solution and will make an announcement as soon as we can present one.

Lastly, we can again report that Karolinska Development for the second consecutive year delivered a positive full-year financial result. The high pace of development in our portfolio companies, coupled with the external investments we saw in 2018, also laid a solid foundation for our continued efforts in 2019. With additional results in the pipeline and constantly ongoing discussions with external parties, we look forward to a year of events that could, potentially, generate substantial increases in value.

Solna, April 30, 2019

#### **Viktor Drvota**

Chief Executive Officer

## Karolinska Development's business strategy



**EVALUATING THE QUALITY** and level of innovation of a research project is difficult for investors without in-depth knowledge of the life science sphere. Furthermore, opportunities for investment in unlisted companies tend to be limited.

An investment in Karolinska Development consequently offers a unique opportunity to share in the growth in value of a number of highly innovative Nordic life-science companies with substantial commercial potential, nine of which are currently in the clinical development or early launch phase. The majority of Karolinska Development's portfolio companies are unlisted.

#### Investments in ground-breaking medical innovations

Innovation level is an important parameter in evaluating the commercial potential of life science projects. Some are designed to make marginal improvements to existing treatments, whilst others are based on radically new types of compounds or technologies with the potential to dramatically improve patients' quality of life and maybe even increase the chances of a cure and survival. Karolinska Development only invests in the latter project category.

#### **Focusing on commercialisation**

Evaluating the companies' ability to commercialise the projects is equally important. Karolinska Development focuses on optimising the portfolio companies' potential for commercialising their projects, and the past year has seen the portfolio companies strengthened through the recruitment of people with a documented ability to close international business deals in the life sciences sector.

#### Reduced risk development strategies

Karolinska Development has long-established processes for minimising the risk that the results of clinical trials fail to live up to justifiable expectations. The portfolio companies receive professional support throughout the process of optimising the design of their clinical studies, and the potential for spreading the risk by expanding therapeutic indications is subject to continuous assessment. The development strategies for the individual projects are structured in close cooperation with world-leading scientific and clinical experts.

**Annual Report 2018** 

#### Financing and exit model

Karolinska Development invests in portfolio companies via syndication with other professional life science investors.

The investments in pharmaceutical projects continue until proof-ofconcept is demonstrated in phase II studies, at which point the potential for entering into cash-flow generating licensing deals, trade sales, or IPOs will be examined. The reasoning here is that positive phase II data markedly increases the potential for attractive business deals. It is only when this data has been generated that it is possible to demonstrate that a candidate drug has the anticipated biological effect, thereby substantially reducing the ongoing development risk and significantly increasing the value of the project. Karolinska Development's objective for the holdings in portfolio companies within medtech is to divest at the point when the companies have launched their first product and have become cash flow-positive.

## The path to market for life science products

# The various stages of pharmaceutical development

Developing a new pharmaceutical product takes a long time and demands substantial investments. It takes an average of 12 years to translate a new scientific theory into a registered pharmaceutical. The risk of an individual product failing to make it to market is high – only around 10% of the projects that start phase I trials make it to market. Commercialising the project can also prove difficult, whether the intention is to achieve this via out-licensing during development or through an in-house launch. The enormous potential

for growth in value in those companies that achieve success is, of course, the reason why there is, nonetheless, considerable interest in investing in smaller life science companies. A number of licensing agreements with contract values of between SEK 1.8 and SEK 7.7 billion<sup>3</sup> have been signed in recent years for project that are comparable with those being conducted by Karolinska Development's portfolio companies.

- 1) https://www.fass.se/LIF/menydokument?userType=2&menyrubrikId=3204
- 2) https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf
- Phase II success rates per disease area. Source: Hay, Michael, et al. "Clinical development success rates for investigational drugs." Nature biotechnology 32.1 (2014): 40.















## Preclinical research

Research and development activities carried out in a laboratory setting. Potential target structures for new pharmaceuticals are identified. Chemical or biological compounds with the ability to influence these target structures are characterised, produced on a small scale, and tested in a range of experimental models. The objective is to designate one or more candidate drugs with the desired properties for further development.

## Preclinical development

Officially regulated preclinical trials to ensure that a candidate drug has the properties required for it to be suitable for progression to clinical trials on humans. Ensuring that the compound has a good safety profile is an important component of this process.

### Phase I studies

Conducted on healthy test subjects to determine whether the candidate drug behaves in the same way in the body as that indicated in preclinical trials. Documentation of the safety profile of the compound is, once again, the focus of this phase.

### **Phase II studies**

Conducted on a limited number of patients with the disease that the candidate drug is intended to alleviate or cure. The focus is on studying efficacy and safety, and on establishing data for determining the doses to be used in the phase III studies.

### Phase III studies

Studies involving a substantially larger number of patients, sometimes numbering in the thousands. The results of the phase III studies form an important element of the source data required to obtain market approval from the pharmaceutical regulatory authorities.

## Registration process

An application, which can comprise 100,000s of pages of documentation, is submitted to one or more pharmaceutical regulatory authorities. Processing an application normally takes around one year.

### Market launch

If the pharmaceutical regulatory authority has approved the application, the product launch can begin. Price negotiations with the organisations that will pay for the drug must, however, be conducted first in the majority of countries.



## The path to market for life science products



## Market introduction of medtech products

Medtech products comprise everything from sticking plasters to radiotherapy equipment, and the commercialisation processes naturally differ in line with the type of product. One of the key differences between the development of medtech and pharmaceutical products is that medtech products do not usually undergo the formal clinical development phases (phase I-III studies) described in the section on the previous page. Another difference lies in the fact that the development risk is generally lower while the commercialisation risk is higher. Fewer projects fall by the wayside, but the market launch process is often more drawn out than for pharmaceuticals.

The official approval requirements for medtech products depend on the control level required to determine the product's safety and efficacy, or its similarity to previously approved products.

## Approval process in the USA

IIn the USA, the products are divided into three categories. Class I products require no formal approval, class II product are only required to show that they are equivalent to a previously approved product, while class III products must obtain Pre-Market Approval (PMA) before launch. In the latter case, clinical studies supervised by the US regulatory authority, the FDA, are required.

## Approval process in the EU

In the EU, the majority of products must be CE-labelled before sales may commence. The CE-labelling (Conformité Européenne) system requires the manufacturer to confirm that the product meets regulatory requirements. A product that achieves CE-labelling in one country has access to the entire EEA market. In many cases, the manufacturer can carry out all of the tests and investigations required to demonstrate the product's regulatory compliance. If the products are associated with specific risks, the manufacturer is required to engage an independent certification organisation, known as a "notified body".

### **Subsidies**

Once it has been approved, the product can be marketed and used, but a strong sales performance will usually require the health care provider to receive subsidies from government bodies or private insurance companies. The process of obtaining the go-ahead from the payers can be both complicated and drawn out. Health economic evaluations have become an increasingly important factor in obtaining payment for medtech products.

# Key components to understand the value of Karolinska Development

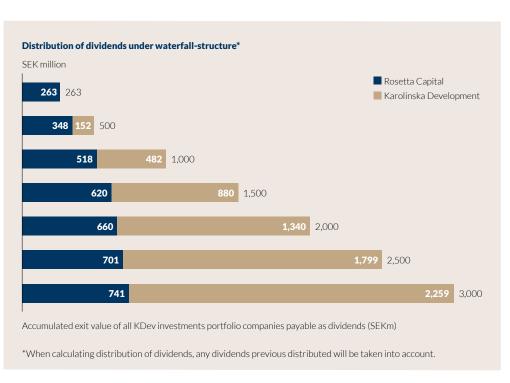
# What does "fair value" mean?

- Calculations of the fair value f the portfolio are based on the provisions of IFRS 13 and the International Private Equity and Venture Capital Valuation Guidelines (IPEV Valuation Guidelines), which were adopted by IPEV and represent current best practice on the valuation of private equity investments. The fair value of the portfolio is divided into "Total portfolio fair value" and "Net portfolio fair value".
- Total portfolio fair value is the aggregate return that would be obtained by Karolinska Development and KDev Investment if the shares in the portfolio companies were to be divested in an orderly transaction between market operators at the year-end.
- Net portfolio fair value is the aggregate dividend that Karolinska Development will receive after KDev Investment's dividend payment to Rosetta Capital.

## The Rosetta Capital deal

In December 2012, Karolinska Development entered into partnership with the international specialist investor, Rosetta Capital, which invested SEK 220 million in a number of portfolio companies in return for a share of the future profits from these companies. The shareholdings in the portfolio companies comprised by the agreement with Rosetta are invested in the jointly owned company, **KDev Investments AB**, which today comprises six companies: Aprea, Modus, Dilafor, Promimic, Asarina Pharma

and Biosergen. The return, including Rosetta Capitals investment of SEK 43 million, from KDev Investments' holding will be distributed in accordance with a "waterfall structure", as illustrated in the graph below. With its current shareholding, Karolinska Development's proportion of dividends will be 0% for accumulated dividends up to SEK 220 million, 65% for accumulated dividends between SEK 220 million and SEK 880 million, 75% for accumulated dividends between SEK 880 million and SEK 1,320 million, and 92% for accumulated dividends above SEK 1,320 million.

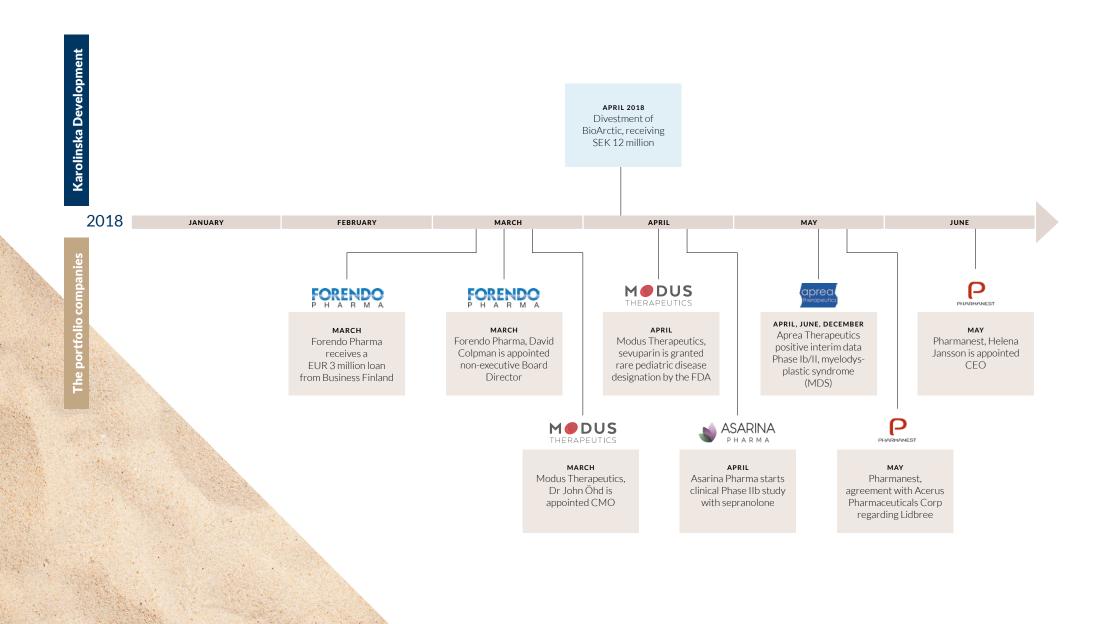


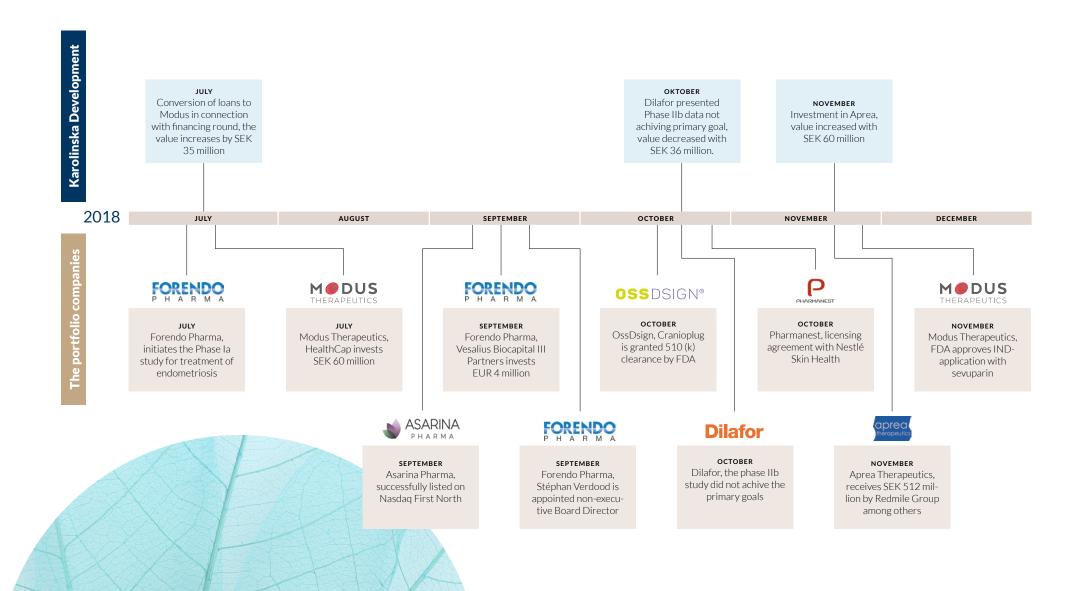
## Convertible loan

In January 2015, Karolinska Development issued convertibles with a nominal value of SEK 387 million which carry a nominal interest rate of 8%. The nominal value was reduced by SEK 58 million to SEK 329 million after a set-off issue in March 2017. The convertible falls due for payment on 31 December 2019 at the repayment amount of SEK 484 million (the interest is cumulative), or can be converted any time to shares at the request of the holder at a price of SEK 22 per class B share.

If not converted, Karolinska Development will need to obtain financing before the end of the fourth quarter of 2019 for repayment of the convertible and to secure our continuing operations. A top priority for the Board of Directors and the company is to find a solution that includes discussions with convertible holders and financing institutions.

## Key events in 2018





#### **Investments: January - December 2018:**

Karolinska Development's investments in the portfolio companies during the period January–December 2018 totalled SEK 124.6 million (SEK 91.9 million in 2017), of which SEK 117.3 million comprised cash investments and SEK 7.3 million comprised non-cash investments (interest on outstanding loans). Investments from external stakeholders totalled SEK 666.0 million.

#### The portfolio fair value

The total fair value of portfolio companies owned both directly by Karolinska Development and indirectly via KDev Investments increased by SEK 238.3 million in 2018 to SEK 952.3 million. The primary reason for the increase was the increase in the fair value and the investments in Aprea Therapeutics and Modus Therapeutics. The IPO listing of Asarina Pharma on Nasdaq First North also increased Fair Value. The result from Dilafors phase IIb-study in the drug candidate tafoxiparin to decrease the incident of slow progress of spontaneous onset of labor did not achive its primary goals, so a downgrade was made of the holding's fair value.

The increase in the fair value of the part of the portfolio owned via KDev Investments resulted in an increase in the potential dividend to Rosetta Capital by SEK 67.2 million to SEK 333.4 million. This, in turn, resulted in a net increase in the fair value of the portfolio by SEK 171.1 million in 2018 to SEK 618.9 million.

## Effect on the profit/loss of the increase in portfolio value, January-December 2018

The total result of the Changes in portfolio fair value, via the Income Statement, was SEK 58.5 million (252.1).

### The Investment Entity's revenues and profit/loss

Revenues totalled SEK 3.1 million during the year, compared to SEK 2.5 million in 2017 and primarily comprised income from services provided to portfolio companies.

The Investment Entity's operating profit/loss totalled SEK 74.0 million compared to SEK 220.5 million in 2017.

The Investment Entity's profit/loss for the full year of 2018 totalled SEK 30.5 million compered to SEK 179.6 million in 2017, or SEK 0.5 per share in 2018 compared to SEK 2.9 per share in 2017.

#### **Financial position**

The Investment Entity's equity totalled SEK 296.0 million on 31 December 2018 compared to SEK 267.1 million on 31 December 2017. The increase was due to the profit/loss for the full year of 2018 of SEK 30.5 million.

During 2018, the company signed an agreement with Den Norske Bank on a one-year credit facility totaling SEK 50 million. Interest-bearing liabilities therefore consist of a convertible loan and a one-year credit facility, and on 31 December 2018 amounted to SEK 478.3 million compared to SEK 379.2 million 31 December 2017.

On 31 December 2018, after payment of the operating expenses and investments, cash and bank balances, together with short-term investments totalled SEK 85.8 million compared to SEK 169.6 million at the end of 2017. The net debt thus amounted to SEK 392.5 million on 31 December 2018. Total assets amounted to SEK 794.4 million (SEK 663.3 million in 2017).

By the end of 2018, the majority of the portfolio companies were financed up to the next value-generating milestone and Karolinska Development is consequently of the opinion that the current cash equivalents and short-term investments are sufficient to cover follow-up investments in the existing portfolio companies, ongoing costs, and new investments.

See the section on Financial risk below for the Board of Directors' view of the company's financial situation taking into account the convertible loan, which falls due for payment on 31 December 2019.

#### Equity/assets ratio and net asset value

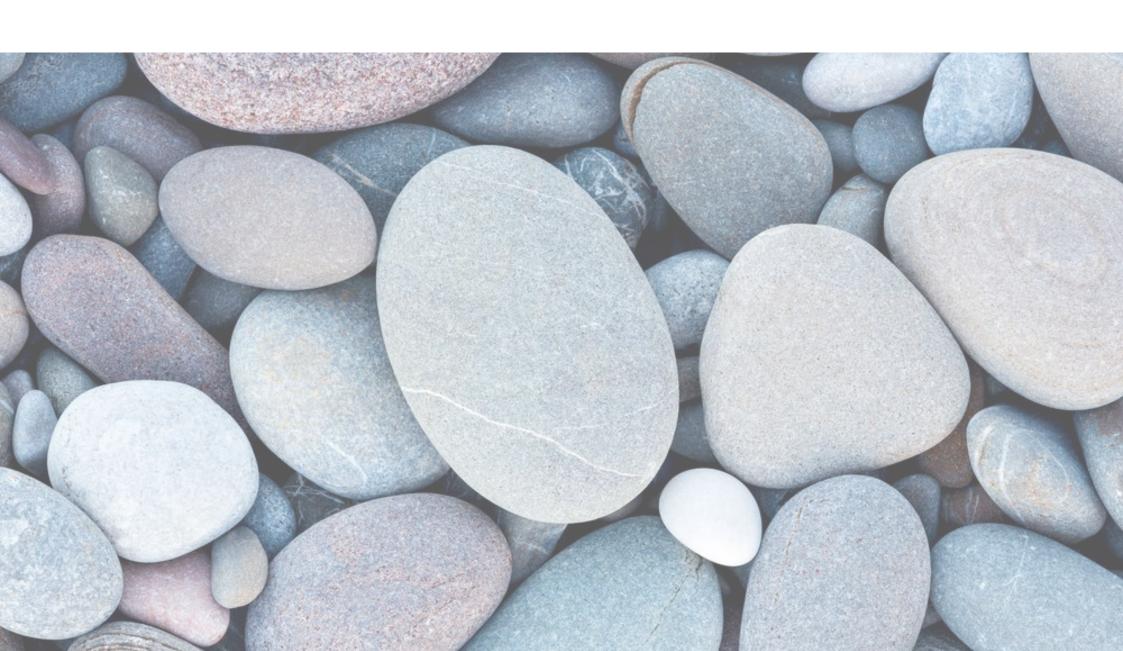
The equity/assets ratio of the Investment Entity amounted to 37% by 31 December 2018 compared to 40% on 31 December 2017. The net asset value amounted to SEK 3.8 per share at the end of 2018, compared to SEK 4.3 per share at the end of 2017.

#### **Accounting principles**

Karolinska Development is an Investment Entity as defined in IFRS 10, Consolidated Financial Statements, which affects financial years commencing 1 January 2014 or later.



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

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

Phase III

Phase II

Phase II

Preclinical

Phase III

#### Our current portfolio - significant value-inflection during 2019/2020 THERAPEUTICS Net Ownership\* Preclinical Phase I Phase II Phase III 2nd indication(s) ongoing/planned 2019 Ovarian cancer Platinum-resistent ovarian cancer KD 2%\*\* Myelodysplastic syndrome (MDS) 2019 KDev Invest 11% 2020 Myelodysplastic syndrome (MDS) **M** DUS KDev Invest 49% Sickle cell disease 2019 At-home setting with subcutaneous injection **Dilafor** KDev Invest 30% Labor induction 2020 Hepatic encephalopathy Umecrine KD 72% Idiopathic hypersomnia KD 12%\*\* 2019 **FORENDO** Endometriosis P KD 10%\*\* Pain relief during intrauterine device placement 2020 Passive investment ASARINA Premenstrual dysphoric disorder 2019 KDev Invest 1% Passive investment Systemic fungal Biosergen 2019 KDev Invest 4% Passive investment infections **MEDTECH** Prototyp Development PMA/510k Market Net Ownership\* **OSS**DSIGN® KD 25%\*\* Patient-specific craniofacial implants Expansion in the EU and the US 2019 KDev Invest 30% Medical implant coatings Expansion in the EU and the US 2019 Promimic Current phase KD: Karolinska Development - KDev Invest: KDev Investments Progress and expected results \* Fully diluted ownership based on current investment plans \*\* Includes indirect holdings through KCIP Co-Investment Fund **Earn-out agreements** athera Axelar oncopeptides lipidor Clanotech



#### Project (First-in class) APR-246

Primary indication MDS

#### **Development Phase**

Phase III

#### Holding in company\*

Karolinska Development 2%\*\* KDev Investments 11%

#### Other investors

Redmile Group Rock Springs Capital Versant Ventures 5AM Ventures HealthCap Sectoral Asset Management

#### Origin

Karolinska Institutet

#### More information

aprea.com

## **Aprea Therapeutics AB** Unique approach to treating

a broad range of cancers

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

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

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

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



#### THE MARKET

APR-246 has the potential to be used in many cancers as mutations in p53 are found in around 50% of all diagnosed cancers. The lead target indications thus far include blood tumors as MDS and AML. MDS is an orphan disease and represents a spectrum of hematopoietic stem cell malignancies. Approximately 30-40% of MDS patients progress to AML and mutations in p53 are found in up to 20% of MDS and AML patients, which is associated with poor overall prognosis.

#### **DEAL VALUES FOR SIMILAR PROJECTS**

- USD 469 million MEI Pharma (licensor) & Helsinn Group (licensee) 2016
- USD 483 million Calithera Biosciences (licensor) & Incyte (licensee) 2017

#### RECENT PROGRESS

new investors Redmile

Group and Rock Springs

Capital, with parti-

cipation by existing

investors.

Janus Henderson Investors joined the financing round announced in Dec 2019 and invested FUR 5 million.

**FEB** 

FDA granted APR-246 Fast Track designation and Orphan Drug designation for treatment of patients with TP53 mutated MDS

**APRIL** 

Results from Phase II expected in 2019.

Final results from Phase Ib/II study in MDS expected in 2019.

SEK 512 millon (EUR 50 million) raised from an investment consortium including

First patient included in pivotal Phase III

**EXPECTED MILESTONES** 

study in platinumsensitive HGSOC

<sup>\*</sup> Fully-diluted ownership based on current investment plans.

<sup>\*\*</sup> Includes indirect holdings through KCIF Co-Investment Fund



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

**Primary indication**Sickle cell disease (SCD)

## **Development Phase**Phase II

Holding in company\*

KDev Investments 49%

#### 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**

# Targeting relief for sickle cell disease patients

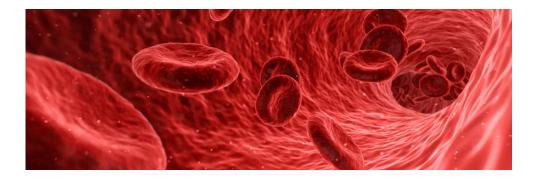
Modus Therapeutics (Stockholm, Sweden) is developing sevuparin, an innovative drug which has the potential to become a first-in-class treatment for sickle cell disease (SCD).

Sevuparin's anti-adhesive mechanism means it has the potential to prevent and resolve the microvascular obstructions experienced by SCD patients. These obstructions cause the severe pain experienced by patients during Vaso Occlusive Crisis (VOC) and result in high morbidity through organ damage as well the risk of premature death.

Modus has completed patient enrollment in a Phase II study of sevuparin in hospitalized SCD patients, and the results are expected in mid 2019. The randomized, double blinded study contains 140 SCD-patients with acute VOC. It compares intravenously administered sevuparin with placebo. The primary endpoint of the study is the demonstration of a reduced time to resolution of patient's VOC. Clinical sites across Europe and the Middle East took part in the study that was conducted in conjunction with Modus Therapeutics' co development partner Ergomed.

Modus is also developing subcutaneously administered sevuparin that has the potential to become a home-based, self-administered therapeutic option for SCD patients to prevent and treat VOC. A Phase I study is currently ongoing.

**APR** 



#### THE MARKET

SCD is an orphan disease with approximately 100,000 patients in the US and 35,000 patients in Europe. In addition, there is a large patient pool in the Middle East, India, South America and Africa. Lifetime medical care costs can exceed USD 1 million per patient with an estimated USD 1 billion spent annually in the U.S. The average number of VOC episodes per patient seeking hospital care is in the order of one VOC per year. The commercial impact of a SCD treatment that reduces hospital stay and the use of opioid analgesics is expected to be substantial. A label

2019

expansion to also include preventive treatment at home would expand the market size significantly.

#### **DEAL VALUES FOR SIMILAR PROJECTS**

- USD 665 million Novartis AG (buyer) & Selexys Pharmaceuticals (seller) 2016
- USD 340 million GlycoMimetics (licensor) & Pfizer (licensee) 2011

#### **RECENT PROGRESS**

2018

Sevuparin granted Rare Pediatric Disease Designation by the FDA

for the treatment of

children with SCD.

SEK 140 million raised in a financing led by new investor Health-Cap, which will invest SEK 60 million.

JUL

FDA approved IND application to initiate a Phase I clinical trial with subcutaneous sevuparin for the treatment of SCD.

NOV

Patient enrollment completed in Phase II study in SCD.

JAN

First cohort dosed in Phase I study with subcutaneously administered sevuparin.

**FEB** 

EXPECTED MILESTONES

Results from Phase II trial expected in mid 2019.

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



#### Project (First-in-class) GR3027

#### **Primary indications**

Hepatic encephalopathy Idiopathic hypersomnia

### **Development Phase**

Phase IIa

#### Holding in company\*

Karolinska Development 72%

#### Other investors

Norrlandsfonden Fort Knox Förvaring AB PartnerInvest

#### Origin

Umeå University

#### More information

umecrinecognition.com

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

## **Umecrine Cognition AB**

# Unique treatment approach for CNS-related disorders

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

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

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

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



#### THE MARKET

HE is a severe disorder with a large unmet need. In total, liver cirrhosis affects up to 1% of US and EU populations. Between 180,000 and 290,000 patients with cirrhosis in the US are hospitalized due to complications of HE. Once HE develops, mortality reaches 22-35% after five years. HE is also associated with large societal and individual costs.

There are no approved treatments for IH but several wake-promoting agents are used off-label. However, they are inadequate to alleviate

symptoms in most patients, and refractory or intolerance symptoms occur in one-quarter of patients.

#### **DEAL VALUES FOR SIMILAR PROJECTS**

- USD 397 million Aerial Biopharma (licensor)
   & Jazz Pharmaceuticals (licensee) 2014
- USD 201 million Vernalis (licensor) & Corvus Pharmaceuticals (licensee) 2015

#### **RECENT PROGRESS**

2019

JAN

Results from Phase IIa study in IH presented.

#### **EXPECTED MILESTONES**

2020

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



## **Project (First-in-class)** FOR-6219

### Primary indication

Endometriosis

#### **Development Phase**

Phase la

#### Holding in company\*

Karolinska Development 12%\*\*

#### Other investors

Novo Seeds Novartis Venture Fund Merck Ventures Vesalius Biocapital Innovestor

#### Origin

University of Turku

#### More information

forendo.com

\* Fully-diluted ownership based on current investment plans \*\* Includes indirect holdings through KCIF Co-Investment Fund

### 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 la 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.

#### **DEAL VALUES FOR SIMILAR PROJECTS**

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

#### **RECENT PROGRESS**

FOR-6219.

2018 JUL

Initiated clinical Edevelopment of ra

EUR 4 million raised from new investor Vesalius Biocapital III Partners.

**SEP** 

2019 MAR

Positive Phase Ia results presented.

**EXPECTED MILESTONES** 

Phase Ib study start in 2019.

## **OSS**DSIGN®

#### Project

OSSDSIGN® Cranial and OSSDSIGN® Facial

#### Primary indication

Cranial implants

#### **Development Phase**

Marketed

#### Holding in company\*

Karolinska Development 25%\*\*

#### Other investors

SEB Venture Capital Fouriertransform

#### Origin

Karolinska University Hospital Uppsala University

#### More information

ossdsign.com

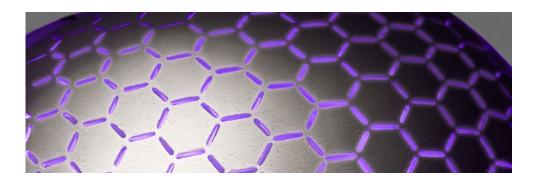
## OssDsign AB

# Commercializing the best craniofacial implants

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

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

OssDsign's personalized bone regeneration technology provides improved healing properties that are clinically proven to enhance patient outcomes. By combining a regenerative ceramic material reinforced with titanium, with tailored patient-specific designs enabled by state-of-the-art computeraided 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 cranio-maxillofacial (CMF) implants. The total market size was estimated to USD 1,8 billon in 2016 and is expected to grow at an CAGR of 5-9% worldwide over the next five years. The market for OssDsign's lead product in cranioplasty alone is estimated to approximately USD 200 million. OssDsign pursues a focused business strategy on a well-defined patient population. The advantages are that the targeted procedures are carried out in a limited number of easily identifiable hospitals around the world.

The indications are relatively price insensitive and easy to access on many markets from a regulatory perspective.

#### **DEAL VALUES FOR SIMILAR PROJECTS**

- USD 330 million Baxter International (buyer)
   & ApaTech (seller) 2010
- USD 360 million Royal DSM (buyer) & Kensey Nash (seller) 2012

#### RECENT PROGRESS

2018

ОСТ

2019

FEB

SEK 64 million raised from Swedish private investors and the French investment management company Alto Invest. **EXPECTED MILESTONES** 

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

510(k) clearance granted by US FDA to market OssDsign's latest product Cranioplug in the US.

<sup>\*</sup> Fully-diluted ownership based on current investment plans \*\* Includes indirect holdings through KCIF Co-Investment Fund



#### Project

HAnano Surface

### Primary indication

Implant surface coatings

#### **Development Phase**

Marketed

#### Holding in company\*

KDev Investments 30%

#### Other investors

ALMI Invest K-Svets Ventures Chalmers Ventures

#### Origin

Chalmers University of Technology

#### More information

promimic.com

### **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 commercialising dental implants coated with HA<sup>nano</sup> Surface in USA, amongst other countries. A manufacturing facility for HA<sup>nano</sup> coated implants to supply the US and Chinese markets has also been established by the Promimic's partner, Danco Anodizing.



#### 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.

#### **DEAL VALUES FOR SIMILAR PROJECTS**

- USD 95 million Nobel Biocare (buyer)
   & AlphaBioTec (seller) 2008
- USD 120 million MAKO surgical (buyer)
   & Pipeline Biomedical (seller) 2013

#### RECENT PROGRESS

2017

DEC

2019

MAR

510(k) clearance granted by US FDA to market dental implants coated with HA<sup>nano</sup> Surface. Entered into partnership with the US company Onkos Surgical **EXPECTED MILESTONES** 

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

<sup>\*</sup> Fully-diluted ownership based on current investment plans





#### Project (First-in-class)

Sepranolone

#### **Primary indication**

Premenstrual dysphoric disorder

#### **Development Phase**

Phase IIb

#### Holding in company\*

KDev Investments 1%

#### Major owners

Kurma Biofund The Foundation for Baltic and East European Studies Rosetta Capital Idinvest Patrimonie Sectoral Asset Management

#### Origin

Umeå University

#### More information

asarinapharma.com

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

### **Asarina Pharma AB**

Asarina Pharma (Solna, Sweden and Copenhagen, Denmark) is developing innovative and targeted products to treat women with severe symptoms associated with the menstrual cycle such as premenstrual dysphoric disorder (PMDD).

The company's most advanced drug candidate, sepranolone, is the first therapy specifically being developed for PMDD. Sepranolone is a non-hormonally active compound that inhibits the disease provoking effect of the progesterone metabolite, allopregnanolone, in women suffering from PMDD. A clinical phase IIb study in PMDD is ongoing. A Phase IIa trial of sepranolone for the treatment of menstrual migraine will begin mid 2019.

Asarina Pharma is listed on Nasdaq First North.



#### Project

Lidbree™

#### Primary indication

Pain relief during intrauterine device placement

#### **Development Phase**

Pivotal study in EU completed

#### Holding in company\*

Karolinska Development 10%\*\*

#### Other major owners

The Foundation for Baltic and East European Studies Recipharm Venture Fund Praktikerinvest

#### Origin

Karolinska Institutet

#### More information

pharmanest.se

\* Fully-diluted ownership based on current investment plans. \*\* Includes indirect holdings through KCIF Co-Investment Fund



### **Pharmanest AB**

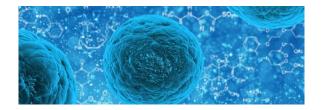
Pharmanest (Sweden and USA) offers product in urology and urogynecology disorders, colorectal conditions, radiotherapy, and interventional oncology procedures.

The company's portfolio presently consists of Deflux®, Solesta®, Barrigel™, and Lidbree™. Worldwide development and commercialization rights for the three products Deflux®, Solesta®, Barrigel™ have been obtained under a licensing agreement with Nestlé Skin Health. The products are all based on the Nestlé Skin Health's well-known and widely utilized NASHA™ (Non-Animal Stabilized Hyaluronic Acid) technology.

Pharmanest is also developing Lidbree™, a proprietary novel delivery technology that provides short-acting mucosal topical pain relief during placement of an intrauterine device (IUD). The product has additional potential applicability to other important medical procedures including certain types of hysteroscopies. Lidbree™ will be submitted for European regulatory review, and it will also be further developed for market introduction in the US.

Gedeon Richter has marketing and sales rights to commercialize Lidbree™ in Europe, Latin America and other specific geographies. In 2018, Pharmanest announced an exclusive agreement with Acerus Pharmaceuticals Corporation pertaining to the commercialization of Lidbree™ in Canada.





#### **Project** BSG005

#### **Primary indication**

Systemic fungal infections

### **Development Phase**

Preclinical

## Holding in company\* KDev Investments 4%

#### Other major owners

The Foundation for Baltic and East European Studies Sintef Venture II AS Rosetta Capital

#### Origin

SINTEF and Norweigan University of Science and Technology

#### More information

biosergen.se

## **Biosergen AS**

Based on the expertise in biosynthetic engineering Biosergen (Trondheim, Norway) is currently running a development program for systemic fungal infections where a candidate drug has been selected, BSG005. The candidate drug BSG005 is in preclinical development and has demonstrated a broad spectrum of antifungal activity.

Patients most susceptible to systemic fungal infections are those whose immune systems are compromised by diseases such as cancer and those who are receiving immunosuppressive therapy. While effective treatments are available, their use is usually limited by serious side-effects or an increasing incidence of drug resistance.

Biosergen's BSG005 has in preclinical models and experiments demonstrated a wide antifungal efficacy spectrum. BSG005 has so far shown superior properties compared to conventional treatment in terms of efficacy, toxicity and pharmacokinetics. Clinical development is expected to begin in 2019.

## **Dilafor**



**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.



## **Dilafor AB**

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.

<sup>\*</sup> Fully-diluted ownership based on current investment plans.

#### **Ownership structure**

On 31 December 2018, Karolinska Development had 3,931 shareholders. International investors controlled approximately 48,6% of the share capital and approximately 57,5% of the votes. All class A shares (each of which carries 10 votes, compared to 1 vote for each class B share) are held by Karolinska Institutet Holding AB.

#### **Share performance**

The closing price on the first day of trading in 2018 was SEK 6.00, and at the year end, the share traded at SEK 6.22, an increase of 4%. No dividends have been paid in 2018.

#### Share capital

At year-end 2018, the share capital amounted to SEK 0.6 million distributed among 64 418 737 shares. The nominal value is SEK 0.01 per share.

#### **Ticker symbol and listing**

Karolinska Development's share trades under the ticker symbol, KDEV. The share is listed on the NASDAQ Stockholm Exchange's Small Cap Index. The ISIN code is SE0002190926.

#### The convertible

Karolinska Development's outstanding convertible debt totalled SEK 329 million on 31 December 2018. As of 31 December 2018 the repayable amount (which is the amount payable on the due date 31 December 2019) was SEK 484 million. The convertible is traded under the ticker symbol, KDEV KV1, and is listed on the NASDAQ Stockholm Exchange with the ISIN code, SE0006510103.

SUM ALL SHAREHOLDERS	1,503,098	62,915,639	100.00%	100.00%
Sum Other Shareholders	0	34,584,345	53.69%	44.37%
Sum Top 10 Shareholders	1,503,098	28,331,294	46.31%	55.63%
Friheden Invest A/S	0	1,000,000	1.55%	1.28%
Försäkringsaktiebolaget Avanza Pension	0	1,219,665	1.89%	1.56%
Stift För Främjande&Utveckling	0	1,397,354	2.17%	1.79%
Ribbskottet AB	0	1,700,000	2.64%	2.18%
OTK Holding A/S	0	2,300,000	3.57%	2.95%
Costal Investment Management LLC	0	3,470,466	5.39%	4.45%
Östersjöstiftelsen	0	3,889,166	6.04%	4.99%
Sino Biopharmaceutical Limited	0	4,853,141	7.53%	6.23%
Tredje AP-Fonden	0	6,374,600	9.90%	8.18%
Karolinska Institutet Holding AB	1,503,098	2,126,902	5.64%	22.01%
Shareholders	A-Shares	B-Shares	Cap %	Vote %



### Hans Wigzell

Chairman since 2018. Board member since 2006. Born 1938. Professor Emeritus of Immunology and MD.

Other appointments: Chairman of Rhenman & Partner Asset Management AB. Board member of Sarepta Therapeutics Inc. and RaySearch Laboratories AB. Member of The Royal Swedish Academy of Engineering Sciences and of the Royal Swedish Academy of Sciences.

#### Previous assignments

include, among others, the President of Karolinska Institutet's Nobel Committee, and President of Karolinska Institutet and Director General of Smittskyddsinstitutet.

Holdings in Karolinska Development: 36,491 shares and SEK 39,992 convertible loan.



### Tse Ping

Vice Chairman and Board member since 2015. Born 1952. Honorary Doctorate, Fil Dr hc.

#### Other appointments:

Founder and CEO of Sino Biopharmaceutical Limited, Chairman and executive director of Hong Kong listed Lamtex Holdings Ltd, Vice Chairman of Charoen Pokphand Group (CP Group), where he has extensive experience of major merger and acquisition activity including Ping An Insurance, CITIC Group, China Mobile, ITOCHU Corporation, and Marko Group.

Previous appointments include Member of the Ninth, Tenth, and Eleventh National Committee of the Chinese People's Political Consultative Conference.

Holdings in Karolinska Development: 4,853,141 shares and SEK 272,858,294 in convertible bonds (by related legal person).



### Vlad Artamonov

Board member since 2012. Born 1978. MBA, B.Sc.

Other appointments: Board Member of Redbank Energy Ltd. and of Coastal Capital International Ltd., Managing Partner at Coastal Capital International Ltd.

Previous appointments include Investment Analyst at Greenlight Capital Inc., position in the Global Merger & Acquisition Group at Merrill Lynch in New York.

Holdings in Karolinska Development: 3,470,541 shares (by related legal person).



### Anders Härfstrand

Board member since 2017. Born 1956. MD, PhD.

#### Other assignments:

Chairman of Härfstrand Consulting, Board member Prothena Plc

Previous assignments: Chief Executive Officer of BBB Therapeutics BV, President and Chief Executive Officer Europe of Makhteshim Agan Industries Ltd; President and Chief Executive Officer of Humabs BioMed SA; Chief Executive Officer of Nitec Pharma AG, Various executive and management roles at Serono, Pfizer and Pharmacia.

Holdings in Karolinska Development: No holdings in Karolinska Development.



### Magnus Persson

Board member since 2017. Born 1960. MD PhD Assoc Prof. Educated at Karolinska Institutet.

#### Previous assignments:

CEO Karolinska Institutet Holding AB, Managing Partner The Column Group, Partner HealthCap, Clinical Research Physician Sanofi. Current board assignments include Galecto Biotech AS (Chairman), SLS Invest AB (Chairman) Health Innovation Platform AB (Chairman), Inititator Pharma (Chairman), Albumedix AS, Immunicum AB and Medical Prognosis Institute AS.

Holdings in Karolinska Development: No holdings in Karolinska Development.



### Theresa Tse

Board Member since 2017. Born 1992. Bachelor Degree of Science in Economics from the Wharton School of University of Pennsylvania.

#### Other appointments:

Executive Director, the Chairlady of the Board and the Chairlady of the Executive Board Committee and the Nomination Committee, respectively, of Sino Biopharmaceutical Ltd (listed in Hong Kong).

Holdings in Karolinska Development: 4,853,141 shares and SEK 272,858,294 in convertible bonds (by related legal person).

#### **MANAGEMENT**



### Viktor Drvota

CEO

Appointed as CEO on June 1, 2017, and previously CIO since 2016. Born 1965 M.D, Ph.D. Associate Prof. In Cardiology. Viktor Drvota has over 16 years of Venture Capital experience with several investments, significant fundraisings, IPOs and exits. He was responsible for Life science at SEB Venture Capital 2002-2016. During his appointment at SEB VC he also served as a Board member in several biotech and Medtech companies such as Arexis AB, SBL Vaccin AB, Nuevolution AS, Index Pharma AB, Scibase AB, Airsonett AB among others. Before joining SEB. Dr Drvota worked as Senior Consultant and Associate Professor in Cardiology at the Karolinska Institutet/hospital, Stockholm. Dr Drvota has experience from preclinical as well as clinical research in drug development and medical devices. Dr Drvota has 29 published research articles.

Holdings in Karolinska Development: 24,000 shares, 1,608,418 warrants.



### Fredrik Järrsten

Chief Financial Officer

Appointed 2017, Born 1967, MSc in Business and Economics. Fredrik Järrsten has more than 20 years of experience within investments and business development, including 12 years in the Life Science sector, Between 2014-2017. Fredrik was CFO and Business Development Director at Bactiguard, a Swedish Medtech company, where he among other things lead the company's IPO on Nasdag Stockholm, In 2006, Fredrik was appointed Director Business Development, including M&A, at Aleris, one of Scandinavia's leading private healthcare companies. While there, he led the work for eight years to generate growth through concluding some thirty acquisitions as well as through coordinating tender-driven organic growth. Fredrik has also worked as Investment Manager at the private equity company, Litorina Kapital 1999-2006 as well as the investment banks SEB Enskilda and Lazard 1992-1999 advising clients in M&A, fund raisings and IPO's.

Holdings in Karolinska Development: 40,000 shares, 402,105 warrants.

#### THE TEAM



## Ulf Richenberg

General Counsel

Appointed in 2008. Born 1955. Master of Laws. Ulf Richenberg has 25 years experience in business law, including positions as legal counsel of KIHAB, Esselte AB and Vattenfall, General Counsel of AB Stokab and Scribona AB and business law consultant at FOI.

Other appointments: Chairman of KCIF Fund Management AB. Board member of KD Incentive AB.

Holdings in Karolinska Development: 39,872 shares, 402,105 warrants.



## Elisabet Gimbringer

Financial Manager

Employed since November 2015. Born 1965. Economics and Business education from Stockholm University. Elisabet has worked as an approved public accountant for 10 years, and as a financial manager, business controller and financial controller for a number of different companies and fields for the last 15 years.

Other appointments: Board member of KD Incentive AB.

Holdings in Karolinska Development: 10,000 shares, 107,228 warrants.



## Eva Montgomerie

Head of Accounting

Employed since october 2013, Employed within the group since 2007. Born 1958. MSc in Business and economics. Eva Montgomerie has worked within the bank and finance sector for 12 years, 10 years within the food and clothing sector and 7 years within life science.

Other appointments: Finance manager in Dilafor AB and Pharmanest AB.

Holdings in Karolinska Development: 6,834 shares, 107,228 warrants.



### Felicia Rittemar

Analyst

Employed since 2016. Born 1990. MSc in medical science with a major in Bioentrepreneurship from Karolinska Institutet.

Holdings in Karolinska Development: 107,228 warrants.

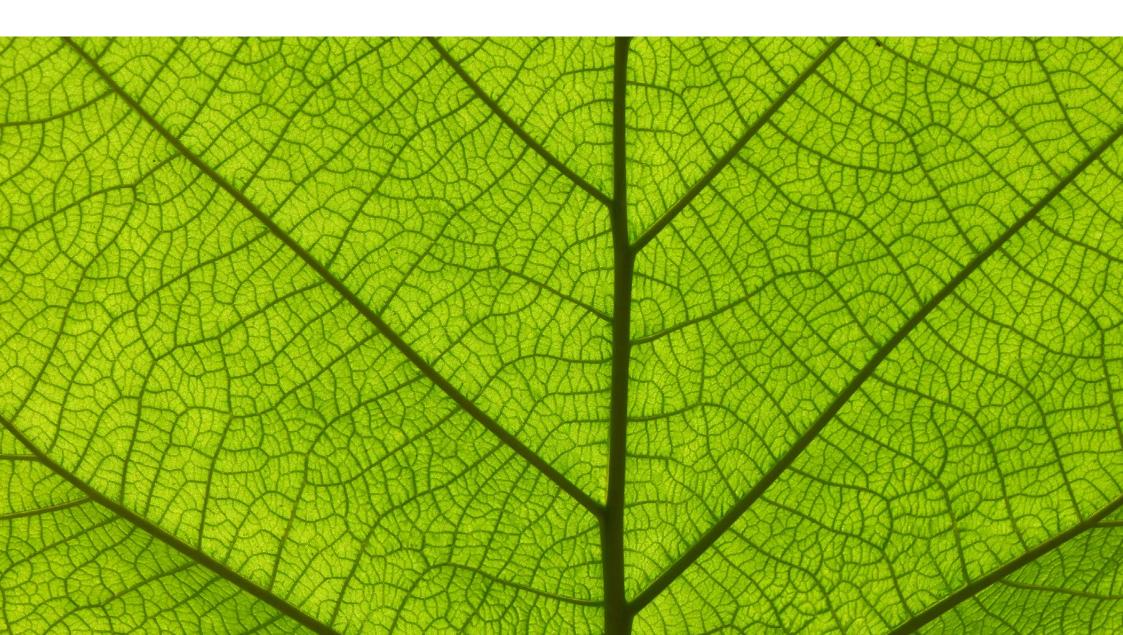


### Esther Miralles Simó

Analyst

Employed since 2018. Born 1990. MSc in medical science with a major in Bioentrepreneurship from Karolinska Institutet.

Holdings in Karolinska Development: No holdings in Karolinska Development.



The Board of Directors and the CEO of Karolinska Development AB (publ), corporate identity number 556707-5048, hereby present their annual report for the Parent Company and the financial report for the Investment Entity regarding the financial year 2018.

Karolinska Development AB (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 science companies with high commercial potential. Nine of the portfolio companies have projects in the clinical development or early launch phase. The investments in pharmaceutical companies are made through syndication with other professional life science investors.

Karolinska Development's objective is for the portfolio companies operating in the pharmaceutical development sector to continue until proof-of-concept is demonstrated in phase II studies, at which point the potential for entering into cash-flow generating licensing deals, trade sales, or IPOs is increased. The reasoning is that this is an attractive point in time for doing business. It is only then that it is possible to demonstrate that a candidate drug has the anticipated biological effect, thereby substantially reducing the ongoing development risk and significantly increasing the value of the project. Karolinska Development's objective for the holdings in portfolio companies within medtech is to divest at the point when the companies have launched their first product and become cash flow-positive.

Karolinska Development has access to world-class medical innovations at leading

universities and research institutions in the Nordic region, including Karolinska Institutet. The company's management comprises individuals with extensive experience of investment operations, research and development, and entrepreneurship, all of whom have access to extensive global networks in the pharmaceutical industry and/or the scientific sector.

## Important events during the financial year

#### Important events for Karolinska Development

- Hans Wigzell, Tse Ping, Vlad Artamonov, Anders Härfstrand, Magnus Persson and Theresa Tse were reelected as board members at the company's annual general meeting. Hans Wigzell was reelected Chairman of the Board (April 2018).
- The number of class B shares increased by 57,531 as a result of the allotment to the participant in the performance-based share incentive program (PSP 2015), adopted at the general meeting 2015 (June 2015).
- In connection with HealthCap investing SEK 60 million in Modus Therapeutics, loans from current shareholders were converted. The transaction resulted in an increase in Karolinska Development's book value of its holdings in Modus Therapeutics and a positive effect on earnings of approximately SEK 35 million (July 2018).
- The results of Dilafor's phase II b study affected the value of Karolinska Development's holdings in Dilafor and negatively impacted earnings by approximately SEK 36 million (October 2018).

 An investment in Aprea Therapeutics by Karolinska Development and an investment consortium, increased the book value of Karolinska Development's holding in Aprea Therapeutics. The positive earnings effect amounted to approximately SEK 60 million (November 2018).

## Important events for the portfolio companies Aprea

- Aprea Therapeutics presented positive interim data results from its ongoing Phase Ib/II clinical study of APR-246 in patients with myelodysplastic syndrome. The results strengthen APR-246's position as one of the world's most advanced TP53-targeted candidate drugs. (April, June and December 2018).
- An investment consortium headed by the American firm, Redmile Group, invested SEK 512 million in Aprea Therapeutics. The new capital will be used to finance further clinical development of APR-246 (November 2018).

#### Dilafor

 Dilafor announced that the company's phase Ilb study of its candidate drug, tafoxiparin, did not achieve its primary goals. Possibly continued clinical development in the indication labor induction is now being evaluated in the company (October 2018).

#### Forendo

- Forendo Pharma announced a EUR 3 million loan grant decision by Business Finland, to support the development of a novel drug for endometriosis treatment (March 2018).
- David Colpman was appointed non-executive Board Director. (March 2018).

- A clinical phase I trial of its candidate drug, FOR 6219, for the treatment of endometriosis was initiated (July 2018).
- The venture capital company, Vesalius Biocapital III Partners, which specialises in investing in later stage European life science companies, invested EUR 4 million (September 2018).

#### Modus

- Modus Therapeutics announced that Dr.
   John Öhd has been appointed to a position as Chief Medical Officer (CMO). (March 2018).
- Modus Therapeutics candidate drug sevuparin was granted rare pediatric disease designation by the US Food & Drug Administration (FDA) for the treatment of children with sickle cell disease (April 2018).
- HealthCap invests at total of SEK 60 million in Modus Therapeutics, making it one of the company's largest shareholders. The investment coincided with the conversion of convertible notes held by current shareholders. The new investment, together with the conversion, totalled just over SEK 140 million (July 2018).
- Modus Therapeutics announced that the FDA has approved the company's Investigational New Drug (IND) application to initiate a phase I clinical trial of sevuparin for the treatment of sickle cell disease (November 2018).

#### OssDsign

 OssDsign announced that its latest product, Cranioplug, had received 510 (k) clearance by the U.S Food and Drug Administration (FDA), allowing marketing and sales of the product in the USA. The implant is the first product of its kind in the US market (October 2018).

## Passive Investments (not active ownership through board representation)

#### Asarina Pharma

- Asarina Pharma announced the start of a clinical Phase IIb study with the drug candidate sepranolone. The study will be conducted in patients with premenstrual dysphoric disorder (April 2018).
- An oversubscribed new share issue was conducted and the company was successfully listed on the NASDAQ First North exchange in Stockholm. Karolinska Development's holding in the company totals 1.2% (September 2018).

#### Pharmanest

- Pharmanest announced the appointment of Helena Jansson as new Chief Executive Officer (May 2018).
- The company entered into an exclusive agreement with Acerus Pharmaceuticals Corporation pertaining to the commercialization of Pharmanest's gynecological pain relief product Lidbree in Canada (May 2018).
- The company entered into a licensing agreement with Nestlé Skin Health, giving Pharmanest the worldwide commercialisation and development rights for three products: Deflux®, Solesta® and Barrigel™ (October 2018).

#### **Earn-out agreement**

#### Oncopeptides

 The Oncopeptides share is listed on Nasdaq Stockholm. Karolinska Development is entitled to a 5% earn-out payment, according to an agreement with Industrifonden, when Industrifonden divests its holding in Oncopeptides. Part of the earn-out was realized during the third quarter, providing SEK 8.7 million to Karolinska Development.

#### **Divestments**

 By divesting the remaining holdings in Bio-Arctic, Karolinska Development followed up the partial exit of BioArctic which was made during the fourth quarter in 2017. Karolinska Development received SEK 12 million (April 2018).

## The Investment Entity and the Parent Company

The financial reporting is divided into financial reporting for the Parent Company and for the Investment Entity. The Parent Company and the Investment Entity are the same legal entity, but the reporting is divided up in order to meet legal reporting requirements.

The Parent Company reports in accordance with the Swedish Annual Accounts Act and Swedish Financial Accounting Standards Council's recommendation RFR 2. The Investment Entity is required to meet the requirements for a listed company and reports in accordance with IFRS, as adopted by the EU, and the Swedish Annual Accounts Act

## Financial Development for the Investment Entity in 2018 (SEK million)

#### Investments

As indicated above, Karolinska Development's investment strategy is to finance its portfolio companies to their next significant value inflection point, when the companies can be exited. Karolinska Development also focuses on attracting external specialized life science investors to secure a broad investor base to support the development of the portfolio companies and manage risks as well as maximize the chances of success.

During 2018, investments from external investors and Karolinska Development totaled SEK 790.6 million. In 2015, 2016 and 2017, total investments in portfolio companies

amounted to SEK 206 million, SEK 368 million and SEK 397 million respectively, giving a total investment amount of SEK 1,762 million in the four-year period 2015-2018.

Karolinska Development's investments in portfolio companies amounted to SEK 124.6 million, of which SEK 117.3 million was cash investments and SEK 7.3 million was non-cash investments (accrued interest on outstanding loans).

Karolinska Development invested in seven companies: Aprea Therapeutics (SEK 42.0 million), Modus Therapeutics (SEK 33.7 million), Umecrine Cognition (SEK 16.5 million), Dilafor (SEK 13.1 million), OssDsign (SEK 9.9 million), Forendo Pharma (SEK 6.5 million) and Promimic (SEK 2.9 million).

### $Investments\ in\ Karolinska\ Development's\ portfolio\ companies\ in\ 2018$

SEK million	Karolinska Development	External Investors	Total invested 2018
Aprea Therapeutics	42.0	476.6	518.6
Modus Therapeutics	33.7	44.5	78.2
Umecrine Cognition	16.5	3.9	20.4
Dilafor	13.1	16.0	29.1
OssDsign	9.9	41.3	51.2
Forendo Pharma	6.5	71.3	77.8
Promimic	2.9	7.2	10.1
Biosergen	0.0	5.2	5.2
Total	124.6	666.0	790.6

Biosergen is 100% financed by external investors.

#### Portfolio Fair Value

Fair Value of the portfolio companies owned directly via Karolinska Development increased by SEK 64.7 million in 2018. The main reasons for the change were increased fair values as well as the investments in Apreas Therapeutics, Umecrine Cognitions, Forendo Pharma and OssDsign. The remaining holding in BioArctic was divested.

Fair Value of the portfolio companies owned indirectly via KDev Investments increased by SEK 173.6 million in 2018. The main reasons were the increased Fair Value and investments in Aprea Therapeutics and Modus Therapeutics. The IPO listing of Asarina Pharma on Nasdaq First North also increased Fair Value. The

result from Dilafors phase IIb-study in the drug candidate tafoxiparin to decrease the incident of slow progress of spontaneous onset of labor did not achieve its primary goals, so a downgrade was made of the holding's fair value.

Total Fair Value of portfolio companies owned directly by Karolinska Development as well as indirectly via KDev Investments increased by SEK 238.3 million in 2018.

As a consequence of the increase in Fair Value of the portfolio owned via KDev Investments, the potential distribution to Rosetta Capital was raised by SEK 67.2 million, resulting in a net increase in Net Portfolio Fair Value of SEK 171.1 million in 2018.

SEK million	31 Dec 2018	31 Dec 2017	2018 vs 2017
Fair value in Karolinska Development portfolio (unlisted companies)	492.6	413.8	78.8
Fair value in Karolinska Development portfolio (listed companies)	0.0	14.1	-14.1
Fair value in KDev Investments portfolio	459.7	286.1	173.6
Total Portfolio Fair Value	952.3	714.0	238.3
Potential distribution to Rosetta Capital of fair value in KDev Investments	333.4	266.2	67.2
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	618.9	447.8	171.1

Total Portfolio Fair Value at 31 December 2018 amounted to SEK 952.3 million. Because the potential distribution to Rosetta Capital was SEK 333.4 million, Net Portfolio Fair Value at 31 December 2018 amounted to SEK 618.9 million.

## Results 2018 (comparable figures refer to 2017)

Karolinska Development's revenues consist primarily of services provided to portfolio companies, which amounted to SEK 3.1 million in 2018 (SEK 2.5 million).

The result of Changes in Portfolio Fair Value through profit or loss amounted to SEK 58.5 million in 2018 (SEK 252.1 million). Other financial assets, an earn-out agreement, increased in fair value by SEK 41.5 million in 2018 (SEK 2.5 million).

Other external expenses increased to SEK 14.0 million (SEK 13.0 million).

Personnel costs decreased in 2018 to SEK 15.0 million (SEK 23.5 million), mainly due to a workforce reduction and lower outcome from the bonus program.

Operating profit was SEK 74.0 million (SEK 220.5 million) in 2018.

A number of portfolio companies were financed via loans in 2018, and interest income amounted to SEK 7.3 million (SEK 4.5 million). The interest on the convertible is cumulative, because of which the interest expense increased to SEK 49.1 million in 2018 (SEK 43.5 million). Net financial costs amounted to SEK -43.5 million (SEK -40.9 million).

The Investment Entity's profit before tax amounted to SEK 30.5 million (SEK 179.6 million) in 2018. The main reason for the positive result was the increase in the value of several portfolio companies as well as increase in the value of earn-out payments.

#### Financial position

Retained earnings increased by SEK 30.5 million (increased SEK 177.0 million) and equity at 31 December 2018 amounted to SEK 296.0 million (SEK 267.1 million). Total assets amounted to SEK 794.4 million at 31 December 2018 (SEK 663.3 million) and the equity to total assets ratio in the Investment Entity was 37% (40%).

During 2018, the company signed an agreement with Den Norske Bank on a one-year credit facility totaling SEK 50 million. Interest-bearing liabilities therefore consist of a convertible loan and a one-year credit facility, and on 31 December 2018 amounted to SEK 478.3 million (SEK 379.2 million).

At 31 December 2018, cash and cash equivalents and short-term investments amounted to SEK 85.5 million (SEK 169.6 million).

See the section on Financial risk below for the Board of Directors' view of the company's financial situation taking into account the convertible loan, which falls due for payment on 31 December 2019.

#### Cash flow

Cash flow from operating activities before changes in working capital and operating investments amounted to SEK -29.0 million (SEK -34.4 million) in 2018, an improved cash flow of SEK 5.4 million compared to 2017.

During 2018, Karolinska Development invested SEK 117.2 million (SEK 89.8 million) in cash in its portfolio companies and, together with changes in working capital, cash from operating activities amounted to SEK -3.4 million (SEK 11.3 million). Net cash decreased by SEK 3.4 million (increased by SEK 8.7 million) in 2018.

## Information on risks and uncertainties

## **Investment Entity and Parent Company**Financial risk

As of December 31, 2018, Karolinska Development had an outstanding convertible loan of nominally SEK 329 million with an annual nominal interest rate of 8 percent. The convertible loan matures on December 31, 2019 with a repayment amount of approximately SEK 484 million (the interest rate is cumulative) if it is not converted to shares before then. The company also has an outstanding credit facility of SEK 50 million, which matures in November 2019. The company is in need of additional financing before the end of the last quarter of 2019 in order to finance the repayment of the convertible loan, the outstanding credit facility and secure the continued operation. The Board of Directors has taken steps to ensure the business's need for financing and is in discussions with the company's major convertible holder, Sino Biopharmaceutical Limited, also a major shareholder in the company, holding convertibles in the company with a nominal value of approximately SEK 273 million, regarding a set-off of Sino Biopharmaceutical Limited's convertibles, together with accrued interest, against shares in the company. In the discussions, Sino Biopharmaceutical Limited has stated in writing:

"We, Sino Biopharmaceutical Limited and Chia Tai Resource Limited (a wholly-owned subsidiary of Sino Biopharmaceutical Limited) (collectively referred to as "Sino Biopharmaceutical"), hereby express that Sino Biopharmaceutical, holding convertible loan in Karolinska Development of

nominal value of SEK 272,858,294 in total, have received the proposal from Karolinska Development for a full conversion of Sino Biopharmaceutical's holding of the convertible loan in Karolinska Development and are now sincerely considering the proposal and working out the implementation details with Karolinska Development. The proposal and our final decision regarding settlement of the convertible loan shall be subject to approval by the board of directors of Sino Biopharmaceutical."

Karolinska Development is also planning for a rights issue of shares to the company's shareholders, which is intended to be effectuated during the second half of 2019, and has appointed DNB Markets to assist with such rights issue. The company also works with other alternative solutions together with financial institutions. Should the Board of Directors not succeed with its plans to secure financing, there is a risk that conditions for going concern would not apply. However, the Board of Directors works actively with solutions to solve the financing situation and sees good opportunities for success in the near future and therefore judges that the company continues to have the possibility to implement the company's communicated business plan. The company's financial reports have been prepared based on a going concern assumption.

For more information on other financial risks, see Note 17.

### Risk of losing invested capital

Karolinska Development invests, for instance, in companies with projects at early stages, before beneficial effects have been proven, in animal testing or human testing, so-called proof

of principle and proof of concept, respectively. Accordingly, the business is associated with a great amount of risk. Karolinska Development invests primarily in unlisted companies, which means that Karolinska Development may not be able to find suitable exit alternatives for its investments within the time frame expected by Karolinska Development, or at all. If Karolinska Development is unsuccessful in finding suitable exit opportunities for its investments, the Company's business, results, financial condition, and growth could be adversely affected.

#### Future financing requirements

In order to secure financing for investments in current and new portfolio companies, Karolinska Development may seek additional financing in the future. Such additional financing may not be available to Karolinska Development on acceptable terms, or at all. If Karolinska Development is unable to obtain funding on time, the Company may be required to significantly curtail its investments, implying that the Company's business, results, financial condition, and growth could be adversely affected.

In addition, loan financing, if available, may be expensive and may involve restrictive covenants or may otherwise constrain the Company's financial flexibility, which could adversely affect the Company's business, results, financial condition, and growth.

#### Future capital needs

Future investments in new and existing portfolio companies will require capital. There is no guarantee that capital can be obtained on favorable terms or in sufficient amounts to finance the operations in accordance with

the business plan, or that such capital can be obtained at all

## Key employees at Karolinska Development and in the portfolio companies

It is vital that Karolinska Development succeeds in retaining its key employees and is able to recruit new employees when needed. Therefore, high demands will be placed on the Company's professional leadership, that Karolinska Development's distinctive profile is preserved, and that the forecasted development is met. Karolinska Development faces competition for personnel from other companies, investment funds, universities, public and private research centers as well as government entities and other organizations. If Karolinska Development would be unsuccessful in its efforts to retain and recruit relevant personnel, the Company's business, results, financial condition, and growth could be adversely affected.

Furthermore, a key factor for the portfolio companies is to succeed in retaining and recruiting individuals with experience in fundraising, company development and exits, and/or expertise in research and technology on which these companies are built. Equally important is a skillful leadership and that the staff considers the workplace stimulating. To achieve this, high demands will be placed on the portfolio companies' leadership. In addition to an interesting work environment, attractive employment conditions are important. The portfolio companies may fail in their efforts to retain and recruit staff with the appropriate skills, which may adversely affect the portfolio companies and the Company's business, results, financial position, and growth.

## Cooperation with the portfolio companies and co-investors

Karolinska Development usually has a representative on the board of directors of its portfolio companies. The aim on a strategic level is to be able to assist these portfolio companies in matters concerning their development. The boards of directors of the portfolio companies are also composed of representatives of other investors as well as independent directors. Cooperation on these boards is dependent on effective communication and good relationships between the directors, and with the management of the portfolio companies. Karolinska Development's board representatives are in a minority position on the boards of the portfolio companies and their influence on board meetings may be limited. Moreover, it is necessary for Karolinska Development and its executive management to succeed in reaching agreements with other investors which could contribute to the portfolio companies' further development. Karolinska Development also often holds a minority position in the portfolio companies. Karolinska Development and its board representatives may not be able to meet these requirements, which could adversely affect the portfolio companies' further development and the Company's business, results, financial condition, and growth.

#### Access to new investment opportunities

Karolinska Development has a non-exclusive deal flow agreement with Karolinska Institutet Holding AB ("KIHAB"), wholly owned by Karolinska Institutet ("KI"), and Karolinska Institutet Innovations AB ("KIAB"). As part of the agreement, there are plans to establish

a new incubator fund focused on identifying potentially valuable new medical innovations at KI and other Swedish universities at an early preseed stage. Karolinska Development may not be able to secure access to the deal flow coming from such an incubator fund or the fund may not be established.

Apart from its agreement with KIHAB and KIAB, Karolinska Development is also dependent on its relationships with universities, tech transfer offices, entrepreneurs, and investors to get access to additional deal flow. Karolinska Development may not be able to identify suitable deals to invest in.

## Complicated ownership structures in the portfolio companies

Karolinska Development's holdings in the portfolio companies are in some cases direct, in others indirect via, for example, KDev Investments AB and/or KCIF Co-Investment Fund KB, and sometimes the Company has a combination of direct and indirect holdings. The Company makes investments in the portfolio companies on a regular basis, normally through new issues of shares in the portfolio companies, but also through loans or other financing instruments. This means that the ownership structures of the portfolio companies are changing regularly. Furthermore, from time to time transfers of ownership are made in connection with exits, partial exits or due to restructurings. There is a risk that necessary waivers from pre-emption or preferential rights according to portfolio companies' articles of association or according to shareholders' agreements regarding the portfolio companies are not obtained, or not documented in the correct order. If anyone

were to dispute the Company's holdings in the portfolio companies and succeed with such a claim in a legal proceeding, it could result in an unexpected decrease in the value of the Company's holdings in portfolio companies, which could adversely affect the Company's operations, results, financial position, and growth.

## The development work of the portfolio companies

The majority of the portfolio companies' projects are in phase II stages of development and further research and development work is required before the innovations and technologies of the companies can be commercialized. Examples of such work are testing of drugs on patients to assess the candidate drugs' effect and safety. Problems or delays may occur and the development work may not be able to be conducted successfully, or at all. Future product development of the portfolio companies is subject to the risk of failure, inherent in the development of pharmaceutical, other biotechnological products or techniques, and medical devices. This includes, among others, the possibility that any or all of the portfolio companies' product candidates will show a lack of effect, be toxic or otherwise fail to either meet applicable regulatory standards, fail to receive necessary regulatory approvals or clearances, or turn out to be difficult to develop into commercially viable products.

Cash flow from the exit or licensing of projects is subject to the objectives of the portfolio companies' projects being achieved. Each outcome has a direct impact on the potential value of a portfolio company. Other factors that may have an impact on the cash flow from

the portfolio companies are competitors' successes and demand from potential buyers at a given point in time.

Annual Report 2018
Karolinska Development

Most of the portfolio companies' projects may not be commercialized to the extent necessary in order for Karolinska Development's investment in the project to be profitable, or even for Karolinska Development to recover the capital invested from the portfolio company in question. Karolinska Development has after the strategic reorganization a relatively narrow portfolio, limiting the potential that one or more projects that can be commercialized successfully enough to cause significant dividends or exit proceeds to Karolinska Development. If none of the portfolio companies are able to achieve such commercial success, it could adversely affect the portfolio companies' and the Company's business, results, financial condition, and growth.

#### The challenge of innovation

The markets for pharmaceuticals, diagnostics, biotechnology, and medical devices are characterized, inter alia, by long periods of research and development, rapid technological development, regulatory challenges, and a large number of competing product launches. The existing and potential customers of the portfolio companies often work within established reference models and standard practices. The portfolio companies conduct business with highly advanced research and pioneering technologies. If the portfolio companies cannot successfully, and within set time frames, break into these markets and establish their products and technologies, the portfolio companies' and the Company's business, results, financial condition, and growth could be adversely affected.

#### Long time before marketing of products

The time it takes before a product candidate has completed the entire research and development process, established a strong patent protection, satisfied all regulatory requirements, and found strong marketing and distribution partners, is often underestimated. Moreover, the market introduction of new products and technologies often starts slowly. Introducing new products and technologies, which are not previously known and accepted, or have predetermined reimbursement models, takes time. This could lead to delays in milestone payments and royalty income, or that they lapse entirely, which could adversely affect the portfolio companies' and the Company's business, results, financial condition, and growth.

#### Competition for the portfolio companies

The markets for the product candidates and new technologies of the portfolio companies are exposed to fierce competition. The portfolio companies' direct and indirect competitors are in many cases major international companies. Such actors are already established in the markets of the portfolio companies and may hold competitive advantages. Furthermore, they can normally react rapidly to new research and development or new market requirements. They may also, compared to the portfolio companies, have greater financial resources and expertise in research and development, clinical trials, better opportunities in obtaining regulatory approvals, and superior marketing.

Competitors may develop more effective, more affordable and more suitable products,

or may achieve patent protection earlier or be able to commercialize their products earlier than Karolinska Development's portfolio companies. These competing products may render the portfolio companies' product candidates obsolete or otherwise limit the ability of the portfolio companies to generate revenues from their product candidates, which could adversely affect the portfolio companies' and the Company's business, results, financial condition, and growth.

#### Market and technology development

The portfolio companies frequently operate in markets characterized by rapid development. New and competing products and technologies may pose a threat to the products developed by the portfolio companies. Moreover, new products and actors result in increased competition, which may negatively impact both price and market penetration. The future prospects of the portfolio companies will to a large extent depend on their ability to develop their business and to produce high-quality products and technologies. The portfolio companies' development work may not proceed without problems. Problems in the development work may lead to delays in set timetables and that products and techniques, once they are fully developed, will not satisfy the market requirements and demands and/or will not achieve broad market acceptance. Changes in pricing principles may impair the value of the products, technologies, and services developed by the portfolio companies, which in turn could adversely affect the portfolio companies' and Karolinska Development's business, results, financial condition, and growth.

#### Product liability for the portfolio companies

The portfolio companies are in many cases exposed to the risk of product liability claims that may be inherent due to flaws in manufacturing, studies, or marketing of certain pharmaceuticals or diagnostics, biotechnology, and medical devices. The portfolio companies may not be able to obtain or maintain insurance protection for such claims on acceptable terms, or at all. Moreover, insurance that the portfolio companies do obtain may not provide adequate protection against a potential claim. This could adversely affect the portfolio companies' and the Company's business, results, financial condition, and growth.

#### Need for strategic partners

Most of the portfolio companies have a great need to enter into partnerships or ally themselves with major international companies to market their products. The portfolio companies may not be successful in attracting third parties to enter into such partnerships, and, if such partnerships are entered into, they may not develop as planned. If a strategic partner does not fulfill its contractual obligations or commitments or fails to keep to expected time limits, or if a partner has to be replaced or if the clinical information that the partner receives for some reason appears to be of poor quality or incorrect, planned clinical trials may be extended, delayed, or terminated, which could have a negative impact on the business of the portfolio company and its ability to license or commercialize its products, which in turn could adversely affect the portfolio companies' and the Company's business, results, financial condition, and growth.

## Intellectual property rights of the portfolio companies

The success of the portfolio companies is to a large extent dependent on the portfolio companies' ability to protect methods and technologies that they develop with patent protection and other intellectual property rights in order to prevent competitors from using their innovations and other protected information. Since patent applications in general are confidential for 18 months from the date of the application, third parties may have filed patent applications for methods and technologies covered by a portfolio company's pending patent applications without the portfolio company being aware of such applications. Consequently, the portfolio company's patent application may not have priority, which in turn could result in the patent protection being considerably less extensive than applied for. The fact that a patent has been granted does not provide absolute protection during the term of the patent. Patents may later be declared invalid by court or an authority, which leads to insufficient patent protection vis-à-vis other innovations. In addition, granted patents must be properly transferred from the inventor/inventors to the portfolio company in question. Moreover, the extent of the patent protection is dependent on patent category and the wording of the patent application. The different patent categories and the wording of the patent application are of importance to the strength of a patent and may vary from case to case.

Because of the formulation of the patent legislation, the application of an innovation in accordance with a portfolio company's patent may be governed by the technology in another

## **Directors' report**

Annual Report 2018 Karolinska Development

patent on which the portfolio company's patent is dependent. In such a situation, the portfolio company may not be able to ensure the right to use such technology at reasonable conditions to the portfolio company, or at all.

A third party may sue a portfolio company for infringing its patent rights. Likewise, a portfolio company may need to resort to litigation against a third party to enforce a patent granted to the portfolio company or to determine the scope and invalidity of third-party proprietary rights. Patent litigations often take several years and the issue may, depending on the rules of the country in question, be tried in several courts. The cost of pursuing intellectual property litigation, even if resolved in the portfolio company's favor, could be substantial. Litigation could also divert the portfolio company's focus from the portfolio company's ordinary business. Uncertainty resulting from pursuing litigation could limit a portfolio company's ability to continue its operations. If any party should claim that a portfolio company's creation or use of methods or technologies infringes upon such party's intellectual property rights, the portfolio company may be forced to pay damages and cease the infringing activity.

In many countries, prohibitory injunctions may be announced at an early stage of legal proceedings. As prohibitory injunctions often require that security is provided, the portfolio companies may not have sufficient financial resources to pursue prohibitory injunctions.

It is not certain that the patents of the portfolio companies entail sufficient legal or commercial protection against financially strong competitors that, despite the patent, may use the portfolio company's methods and techno-

logies. Furthermore, the patents of the portfolio companies may not entail sufficient legal or commercial protection against similar products which the market assesses to be replaceable with the portfolio company's product. Only a few of the portfolio companies may have registered trademarks. Without accurate registration, it might be difficult, or at least time and resource consuming, to prevent a third party from using the respective portfolio company's trade name or brands, as applicable. If any of the risks related to the intellectual property of the portfolio companies were to materialize, it could adversely affect the portfolio companies' and the Company's business, results, financial condition, and growth.

#### Trade secrets of the portfolio companies

Each portfolio company may be dependent on trade secrets, which are not protected by patents or other intellectual property, being safeguarded. Such trade secrets could include, but are not limited to, information in relation to inventions for which patent protection has not been sought yet or to information in relation to manufacturing processes or methods for which patent protection cannot be sought. Employees and collaboration partners of the respective portfolio company do generally have an obligation of confidentiality towards the portfolio company. However, it can happen that someone, having access to information of great value for the portfolio company in question, discloses or uses the information in a manner that impairs the portfolio company's position on the market, which could adversely affect the relevant portfolio company's and the Company's business, results, financial condition, and growth.

## Future financing requirements of the portfolio companies

Research and development activities and marketing efforts in the life science industry are capital-intensive. The portfolio companies may not be able to obtain further capital on advantageous terms, and the capital which may be obtained may not be sufficient to finance the activities in accordance with the portfolio companies' respective business plans. Any inability of Karolinska Development to participate in future investment rounds in a portfolio company could lead to the portfolio company having to curtail its business and/or to Karolinska Development's holding in the company being diluted by other investors. Even in situations where Karolinska Development would be able and willing to participate, co-investors may not be willing to participate on the same terms and conditions. If any of these risks were to materialize, it could adversely affect the portfolio companies' and the Company's business, results, financial condition, and growth.

## Dependency on obtaining regulatory approvals

In order to obtain regulatory approvals for commercial sale of the portfolio companies' products, the portfolio companies and their collaborating partners will be required to complete clinical trials to demonstrate the safety and efficacy of the products. The portfolio companies and their collaborating partners may fail in obtaining approvals from regulatory authorities to commence or complete such clinical trials. If approval is obtained, such clinical trials may prove that the products are not safe or effective to the extent necessary to obtain

marketing authorizations from regulatory authorities. Positive results demonstrated in development studies and clinical trials that the portfolio companies and their collaborating partners finalize may not be confirmed in results obtained in future clinical trials.

The portfolio companies and their collaborating partners will not be able to market any of their products without first obtaining the requisite authorizations from the appropriate regulatory authorities. The regulatory process to obtain marketing authorization for a new pharmaceutical product may take many years and usually requires significant financial and other resources. If the portfolio companies and their collaborating partners do not obtain the requisite authorizations to market their product candidates, it could adversely affect the portfolio companies' and the Company's business, results, financial condition, and growth.

#### **Environmental regulations**

Because of the chemical ingredients in pharmaceutical products and the nature of their manufacturing process, the pharmaceutical industry is subject to extensive environmental regulation and the portfolio companies are subject to the risk of incurring liability for damages or costs of remediation, renovation or control of environmental problems. The portfolio companies may not be able to obtain the operating licenses necessary to conduct their business. In addition, if the portfolio companies fail to comply with environmental regulations relating to the proper use or disposal of hazardous materials or otherwise fail to comply with conditions attached to operating licenses, such licenses could be revoked. The

portfolio companies can also be subject to legal sanctions and substantial liability and costs, or could be required to suspend or modify their operations, which could adversely affect the portfolio companies' and the Company's business, results, financial condition, and growth.

#### Financial risks

Financial risks are described in Note 17.

## Financial Development for the Parent Company in 2018

(Amounts in SEK million, comparable figures refer to 2017)

During 2018, the Parent Company's operating profit amounted to SEK 74.0 million (SEK 220.5 million), a decrease of SEK 146.5 million compared to 2017. The Parent Company's net profit for the year amounted to SEK 30.5 million (SEK 179.6 million).

The positive result for 2018 led to an increase in equity from SEK 267.1 million at 31 December 2017 to SEK 296.0 million at 31 December 2018.

### Corporate governance report

The Corporate Governance Report is in the end of the annual report.

# Guidelines for Remuneration to the CEO and other Executive Management as well as other conditions

The Guidelines for Remuneration to Executive Management are prepared by the Board of Directors for adoption by the Annual General Meeting. For the 2018 guidelines, see Note 5.

# The main features of the Board of Directors' proposal for Guidelines for Remuneration to Executive Management to the Annual General Meeting 2019

Karolinska Development shall maintain remuneration levels and terms required to recruit and retain senior executives with the competence and experience needed to achieve the Company's operational goals. Total remuneration to executive management must be competitive, reasonable and appropriate. Fixed base salary is determined based on the individual's area of responsibility and experience. Variable salary (i) is formulated with the aim of encouraging Karolinska Development's longterm value creation; (ii) is based upon criteria that are predetermined, clear, measurable and can be influenced; (iii) has established limits for the maximum outcome; and (iv) is not pensionable income. If terminated by the Company, the term of notice for the CEO is twelve months and for other senior executives six months.

#### Share capital and owner

Karolinska Development's share capital at the end of the financial year amounted to SEK 0.6 million, distributed among 64,418,737 shares with a par value of SEK 0.01, of which 1,503,098 were A shares (with 10 votes each) and 62,915,639 were B shares (with one vote each). The largest shareholders were Tredje AP-Fonden, with a total of 6,374,600 B shares representing 9.90% of the capital and 8.18% of the votes; Sino Biopharmaceutical Limited, with 4,853,141 B shares representing 7.53% of the capital and 6.23% of the votes; and Karolinska Institutet Holding AB, with

1,503,098 A shares and 2,126,902 B shares representing 5.64% of the capital and 22.01% of the votes.

#### **Holding of treasury shares**

At year-end, the company held 244,285 treasury shares, corresponding to SEK 2,443 of the share capital, and the consideration paid totaled SEK 4.7 million. Share repurchases were made in the previous financial year for the purpose of covering social security costs related to the PSP incentive programs. No repurchases or transfers occurred during the year.

## The Annual General Meeting's authorization to the Board

The Annual General Meeting 2018 authorized the Board, for the period up until the next annual general meeting, to decide, whether on one or several occasions without pre-emption rights for the shareholders, to issue new series B shares up to a maximum of ten percent of the share capital.

The Annual General Meeting also authorized the Board to decide on the transfer of 244,285 previously acquired series B shares to cover social security costs in PSP 2015.

#### **Future development**

Karolinska Development has a portfolio of exciting companies that are funded to deliver key value-generating milestones. The portfolio companies have three projects where phase II data is expected in 2019. Based on available data, the potential for positive phase II data from the projects in question is between 27 and 50%, depending on therapeutic indication area.

A number of deals have been completed for comparable projects where the contract values of the individual projects totalled between SEK 1.8 and 7.7 billion. Karolinska Development does not provide any forecasts with regard to the divestment of portfolio companies.

The work of finding a solution to the convertible loan that matures in December is prioritized and intensified.

#### **Environment and responsibilities**

Karolinska Development's operations do not involve any special environmental risks and do not require any special environmentally related permits or authorizations from authorities. Karolinska Development undertakes its operations according to applicable health and safety regulations and offers its employees a safe and sound working environment.

35

## Multi-year summary

SEKm	2018	2017	2016	2015	2014 (restated)	2013 (restated)	2012 (restated)
Income statement							
Revenue	3	2	5	3	5	5	4
Result from change in fair value	100	255	-147	-976	-304	-533	121
Operating expenses	-29	-37	-33	-47	-69	-64	-60
Operating profit/loss	74	221	-174	-1,020	-368	-592	65
Financial net	-44	-41	-43	-34	-4	41	-22
Profit/loss after financial items	31	180	-217	-1,055	-372	-550	43
Balance sheet							
Tangible non-current assets	-	-	-	-	1	1	-
Shares in portfolio companies	619	448	149	268	1,113	1,336	1,827
Loans receivable from portfolio companies	5	3	1	-	12	6	13
Other financial assets	27	41	38	38	38	38	9
Total non-current assets	651	492	188	306	1,164	1,381	1,849
Other current assets	58	2	2	10	17	5	6
Short-term investments	70	150	238	278	128	165	174
Cash and cash equivalents	16	19	11	20	13	35	109
Total current assets	143	171	250	308	157	205	288
Total assets	794	663	438	614	1,321	1,587	2,137
Equity	296	267	30	248	1,257	1,565	2,116
Long-term liabilities	11	384	399	355	35	9	11
Current liabilities	487	12	9	12	30	12	11
Total liabilities and equity	794	663	438	614	1,322	1,586	2,137
Cash flow							
Cash flow from operating activities	-3	11	-9	-325	-109	-71	43
Cash flow from financing activities	0	-3	0	332	86	-2	-2
Cash flow for the year	-3	9	-9	7	-22	-73	40

## Multi-year summary continued

SEKm	2018	2017	2016	2015	2014 (restated)	2013 (restated)	2012 (restated)
Key ratios <sup>1</sup>			'				
Net asset value	247	277	33	244	1,257	1,562	2,110
Net debt	393	210	150	57	106	191	272
Capital employed	307	651	429	603	1,292	1,574	2,116
Return on equity	10%	66%	-729%	-425%	-30%	-35%	2%
Return on capital employed	10%	27%	-51%	-175%	-29%	-35%	2%
Equity to total assets ratio	37%	40%	7%	40%	95%	99%	99%
Average number of employees	7	7	6	12	13	14	16
Data per share							
Profit/loss after tax, SEK, after dilution	0.48	2.93	-4.08	-19.84	-7.64	-11.38	0.89
Profit/loss after tax, SEK, before dilution	0.48	2.93	-4.08	-19.84	-7.64	-11.38	0.89
Equity, SEK	4.6	4.2	0.6	4.6	23.6	32.4	43.6
Net asset value, SEK	3.8	4.3	0.7	4.7	23.7	32.5	43.7
Share price at year-end, SEK	6.2	5.8	6.0	9.6	13.30	30.90	15.30
Dividend, SEK	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Share price/Equity per share	135%	139%	1,076%	207%	56%	95%	35%
Share price/Net asset value per share	162%	133%	854%	205%	56%	95%	35%
Number of shares at year-end	64,361,206	64,361,206	53,464,998	53,449,640	53,384,558	48,531,417	48,531,417
Weighted average number of shares before dilution	64,136,941	61,243,234	53,210,223	53,151,328	48,606,243	48,350,016	48,529,767
Weighted average number of shares after dilution	64,136,941	61,300,516	53,210,223	53,151,328	48,606,243	48,350,016	48,529,767

<sup>1)</sup> Definitions of key ratios, see page 82

# Proposed appropriation of the profit of the parent company (SEK).

The following earnings are available for appropriation by the Annual General Meeting:

SEK	31 Dec 2018
Retained loss	-1,704,275,211
Share premium reserve	1,970,751,616
Net profit for the year	30,510,052
Total	296,986,457

The Board of Directors proposes that profits brought forward be appropriated as follows:

SEK	31 Dec 2018
Share premium	1,970,751,616
Retained loss	-1,673,765,159
To be carried forward	296,986,457

For information regarding the operating results and financial position of the Investment Entity and the Parent Company, refer to the following income statements, balance sheets, statements of cash flow and accompanying notes. Unless otherwise stated, all amounts are reported in thousands of Swedish kronor (SEK 000).

Annual Report 2018 Karolinska Development

37

## **Income statement for the Investment Entity**

SEK 000	Note	2018	2017
Revenue	2	3,073	2,464
Change in fair value of shares in portfolio companies	17	58,499	252,072
Change in fair value of other financial assets	17	41,481	2,483
Other expenses	3, 4	-14,017	-12,996
Personnel costs	5	-14,993	-23,513
Operating profit		74,043	220,510
Interest income		7,318	4,549
Interest expenses	6	-49,464	-43,495
Other financial gains and losses	6	-1,387	-1,969
Financial net		-43,533	-40,915
Profit before tax		30,510	179,595
Taxes	7	-	-
NET PROFIT FOR THE YEAR		30,510	179,595

## Statement of comprehensive income for the Investment Entity

SEK 000	Note	2018	2017
Net profit for the year		30,510	179,595
Total comprehensive income for the year		30,510	179,595

## Earnings per share

SEK 000	Note	2018	2017
Earnings per share, weighted average, before dilution		0.48	2.93
Number of shares, weighted average before dilution	12	64,136,941	61,243,234
Earnings per share, weighted average, after dilution		0.48	2.93
Number of shares, weighted average after dilution	12	64,136,941	61,300,516

## **Statement of financial position for the Investment Entity**

SEK 000	Note	31 Dec 2018	31 Dec 2017
Assets	<u> </u>		
Financial non-current assets			
Shares in portfolio companies at fair value through profit or loss	8	618,927	447,783
Loans receivable from portfolio companies	9	5,098	3,436
Other financial assets	17	26,970	40,596
Total non-current assets		650,995	491,815
Current assets			
Receivables from portfolio companies		473	611
Other financial assets	17	53,060	-
Other current receivables	10	3,432	531
Prepaid expenses and accrued income	11	632	666
Short-term investments at fair value through profit or loss	17	69,949	150,329
Cash and cash equivalents	17	15,843	19,305
Total current assets		143,389	171,442
TOTAL ASSETS		794,384	663,257
Equity and liabilities			
Equity	12		
Share capital		644	644
Share premium		1,970,752	1,970,752
Accumulated losses including net profit for the year		-1,675,389	-1,704,275
Total equity		296,007	267,121
Long-term liabilities			
Convertible loan	13	-	379,184
Other financial liabilities	14, 17	11,423	4,807
Total long-term liabilities		11,423	383,991
Current liabilities			
Convertible loan	13	428,303	-
Current interest-bearing liabilities	15	50,000	-
Accounts payable		1,373	1,155
Other current liabilities		831	1,627
Accrued expenses and prepaid income	16	6,447	9,363
Total current liabilities		486,954	12,145
Total liabilities		498,377	396,136
TOTAL EQUITY AND LIABILITIES		794,384	663,257

39

## Statement of changes in the Investment Entity's equity

SEK 000	Note	Share capital	Share premium	Accumulated losses	Total
Opening equity at 1 Jan 2018	12	644	1,970,752	-1,704,275	267,121
Net profit for the year				30,510	30,510
Total comprehensive income for the year				30,510	30,510
Effect of incentive programs				-1,624	-1,624
Share issue					0
Closing equity at 31 Dec 2018		644	1,970,752	-1,675,389	296,007
Opening equity at 1 Jan 2017 (restated)	12	26,732	1,884,310	-1,881,227	29,815
Net profit for the year				179,595	179,595
Total comprehensive income for the year				179,595	179,595
Reduction in share capital		-31,525	31,525		0
Effect of incentive programs				-15	-15
Set-off share issue		5,436	54,905	-2,628	57,713
Share issue		1	12		13
Closing equity at 31 Dec 2017		644	1,970,752	-1,704,275	267,121

## Statement of cash flows for the Investment Entity

SEK 000	Not	2018	2017
Operating activities			
Operating profit		74,043	220,510
Adjustments for non-cash items			
Result of fair value change		-99,980	-254,555
Other items		-2,134	18
Proceeds from short-term investments		-570	-405
Interest received/paid		-343	2
Cash flow from operating activities before changes in working capital and operating investmen	ts	-28,984	-34,430
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables		-4,368	348
Increase (+)/Decrease (-) in operating liabilities		46,506	2,876
Cash flow from operating activities		13,154	-31,206
Investment activities			
Payment from earn-out agreement		8,663	-
Sale of shares in portfolio companies	34	11,911	45,565
Acquisitions of shares in portfolio companies, loans to portfolio companies	33, 34, 36	-117,237	-89,775
Proceeds from sale of short-term investments <sup>1</sup>		80,047	86,747
Cash flow from investment activities		-16,616	42,537
Financing activities			
lssue costs		-	-2,628
Cash flow from financing activities		0	-2,628
Cash flow for the year		-3,462	8,703
Cash and cash equivalents at the beginning of the year	17	19,305	10,602
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR	17	15,843	19,305
Supplemental disclosure <sup>1</sup>			
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR		15,843	19,305
Short-term investments, market value at closing date		69,949	150,329
CASH AND CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS AT THE END OF THE YE	AR	85,792	169,634

<sup>1)</sup> Surplus liquidity in the Investment Entity is invested in fixed income funds 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 funds, including cash, cash equivalents and short-term investments.

## **Income statement for the Parent Company**

SEK 000	Note	2018	2017
Net sales	23	3,073	2,464
Revenue		3,073	2,464
Change in fair value of shares in portfolio companies	24	58,499	252,072
Change in fair value of other financial assets	25	41,481	2,483
Other external costs	26, 27	-14,017	-12,996
Personnel costs	28	-14,993	-23,513
Operating profit		74,043	220,510
Interest income and similar income	29	7,318	4,549
Interest expenses and similar expenses	30	-50,851	-45,464
Financial net		-43,533	-40,915
Taxes	31		-
NET PROFIT FOR THE YEAR		30,510	179,595

## Statement of comprehensive income for the Parent Company

SEK 000	Note	2018	2017
Net profit for the year		30,510	179,595
Total comprehensive income for the year		30,510	179,595

## **Balance sheet for the Parent Company**

SEK 000	Note	31 Dec 2018	31 Dec 2017
Assets			
Financial non-current assets			
Shares in subsidiaries	32	0	0
Shares in joint ventures	33	470,172	335,139
Shares in associated companies	33	138,665	88,471
Other long-term securities holdings	34	10,090	24,173
Loans receivable from portfolio companies	36	5,098	3,436
Other financial assets	37	26,970	40,596
Total non-current assets		650,995	491,815
Current assets			
Receivables from subsidiaries		473	611
Other financial assets	38	53,060	-
Other receivables	39	3,432	531
Prepaid expenses and accrued income	40	632	666
Short-term investments	17	69,949	150,329
Cash and cash equivalents		15,843	19,305
Total current assets		143,389	171,442
TOTAL ASSETS		794,384	663,257
Equity and liabilities			
Equity			
Restricted equity			
Share capital	12	644	644
Unrestricted equity	41		
Share premium		1,970,752	1,970,752
Accumulated losses		-1,705,899	-1,883,870
Net profit for the year		30,510	179,595
Total equity		296,007	267,121
Long-term liabilities			
Convertible loan	13	-	379,184
Other financial liabilities	42	11,423	4,807
Total long-term liabilities		11,423	383,991
Current liabilities			
Convertible loan	13	428,303	-
Short-term interest-bearing liabilities	43	50,000	-
Accounts payable		1,373	1,155
Other current liabilities		831	1,627
Accrued expenses and prepaid income	44	6,447	9,363
Total current liabilities		486,954	12,145
Total liabilities		498,377	396,136
TOTAL EQUITY AND LIABILITIES		794,384	663,257

## Statement of changes in equity for the Parent Company

	Restric	ted equity	Unrestricted equity				
SEK 000	Note	Share capital	Share premium reserve	Accumulated losses	Net profit for the period	Total equity	
Opening equity at 1 Jan 2018	12	644	1,970,752	-1,883,870	179,595	267,121	
Appropriation of profit				179,595	-179,595	0	
Net profit for the year					30,510	30,510	
Total		644	1,970,752	-1,704,275	30,510	297,631	
Effect of incentive programs				-1,624		-1,624	
Share issue						0	
Closing equity at 31 Dec 2018		644	1,970,752	-1,705,899	30,510	296,007	
Opening equity at 1 Jan 2017 (restated)	12	26,732	1,884,310	-1,664,395	-216,832	29,815	
Appropriation of loss				-216,832	216,832	0	
Net profit for the year					179,595	179,595	
Total		26,732	1,884,310	-1,881,227	179,595	209,410	
Effect of incentive programs				-15		-15	
Share issue		1	12			13	
Set-off share issue		5,436	54,905	-2,628		57,713	
Reduction in share capital		-31,525	31,525			0	
Closing equity at 31 Dec 2017		644	1,970,752	-1,883,870	179,595	267,121	

## **Statement of cash flows for the Parent Company**

SEK 000	Note	2018	2017
Operating activities	'		
Operating profit		74,043	220,510
Adjustments for non-cash items			
Result of fair value change	24, 25	-99,980	-254,555
Other items		-2,134	18
Realized change in value of short-term investments		-570	-405
Interest received/paid		-343	2
Cash flow from operating activities before changes in working capital and operating investments		-28,984	-34,430
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables		-4,368	348
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CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR		15,843	19,305
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<sup>1)</sup> Surplus liquidity in the Parent Company is invested in fixed income funds 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 Parent Company's available funds, including cash, cash equivalents and short-term investments.

## Note 1 Accounting policies

### **Operations in general**

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 ("portfolio companies") that develop these assets into differentiated products that will make a difference to patients' lives and provide an attractive return on investment to its shareholders. The Company's shares of series B is traded on Nasdag Stockholm.

# Compliance with generally accepted accounting policies and law

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and the interpretations of the IFRS Interpretations Committee, as adopted by the EU. Furthermore, recommendation RFR 1 Supplementary Accounting Regulations for Groups and statements UFR 7 and 9 from the Swedish Financial Reporting Board have been applied.

### Conditions when preparing the financial statements

This is an English translation of the Swedish annual report. In the event of any discrepancy between the content of the two versions, the Swedish version shall prevail.

The Company's functional currency is Swedish kronor, which is also the reporting currency of the Investment Entity. This means that the financial statements are presented in Swedish kronor. All figures, unless otherwise indicated, are rounded to the nearest thousand. Assets and liabilities are recognized at historical cost, except for certain financial assets and liabilities measured at fair value. Financial assets and liabilities measured at fair value consist of holdings in subsidiaries, joint ventures and associated companies, other securities holdings, other financial assets and liabilities, and short-term investments classified as financial assets held for sale.

The preparation of the financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the application of accounting policies and carrying amounts of assets, liabilities, revenue and expenses. The estimates and assumptions are based on historical experience and various other factors which are considered appropriate under prevailing conditions. The results of these estimates and assumptions are then used to assess the carrying amounts of assets and liabilities that are not otherwise evident from other sources. The actual result may differ from these estimates and assessments.

Estimates and assumptions are reviewed periodically. Changes in estimates are recognized in the period the change is made if the change only affects that period or in the period the change is made and future periods if the change affects both the current period and future periods.

The following accounting policies for the Investment Entity have been applied consequently to all periods presented in the financial statements, unless otherwise stated below.

# New and amended standards applied by the Investment Entity

New or amended IFRS standards and interpretations from the IFRS Interpretations Committee have not had an impact on the Investment Entity. Two new standards apply as of 1 Jan 2018: IFRS 9 "Financial Instruments" and IFRS 15 "Revenue from Contracts with Customers".

IFRS 9 "Financial Instruments" covers the recognition of financial assets and liabilities and replaced IAS 39 "Financial Instruments: Recognition and Measurement". IFRS 9 requires financial assets to be classified in different categories and that the measurement is made at fair value or amortized cost. The classification is determined upon initial recognition based on

### Classification of financial assets and liabilities under IFRS9

SEK 000	Booked value <sup>1</sup>	Category due to IAS 39 2017-12-31	Category due to IFRS 9 2018-12-31
Assets			
Shares in portfolio companies	618,927	Fair value through profit or loss	Fair value through profit or loss
Loans receivable from portfolio campanies	5,098	Loans and receivables	Amortized costs
Other financial assets, non-current	26,970	Fair value through profit or loss	Fair value through profit or loss
Receivables from portfolio companies	473	Loans and receivables	Amortized costs
Other financial assets, current	53,060	Fair value through profit or loss	Fair value through profit or loss
Short-term investments	69,949	Fair value through profit or loss	Fair value through profit or loss
Cash and cash equivalents	15,843	Fair value through profit or loss	Fair value through profit or loss
Total assets	790,320		
Liabilities			
Other financial liabilities	11,423	Other financial liabilities	Other financial liabilities
Convertible loan	428,303	Other financial liabilities	Other financial liabilities
Current interest-bearing liabilities	50,000	Other financial liabilities	Other financial liabilities
Accounts payable	1,373	Other financial liabilities	Other financial liabilities
Total liabilities	491,099		

<sup>1)</sup> The classification due to IFRS 9 has not caused changes in book value compared to IAS 39.

the Company's business model and the characteristics of contractual cash flows. The portfolio companies will continue to be measured at fair value through profit or loss, which also applies to financial assets and short-term investments. Karolinska Development has no predicted credit losses. For financial liabilities, there were no changes compared to IAS 39. The introduction of IFRS 9 has been made with full retrospective calculation and has not changed the impact compared to previous reporting, due to the fact that the valuation guidelines of Karolinska Development already were in line with IFRS 9 "Financial Instruments".

See table above "Classification of financial assets and liabilities under IFRS 9".

IFRS 15 Revenue from Contracts with Customers specifies how and when revenue is recognized, but also contains rules on providing more informative, relevant disclosures in the financial statements. Karolinska Development does not have any contracts with customers that are changed by the introduction of IFRS 15, because of which the introduction has not changed the impact compared to previous reporting.

## New and amended IFRS and interpretations that enter into force in 2019

The Investment Entity applies as of 1 January 2019 the following new and amended IFRS and interpretations that have issued but not yet entered into force on the closing date:

IFRS 16 Leases specifies how leases are calculated, measured and recognized. The standard requires lessees to calculate the asset and liability for all leases unless the lease term is 12 months or less or the asset is of low value. IFRS 16 Leases replaces IAS 17 Leases. The Investment Entity will apply the simplified transition period. The introduction of IFRS 16 has little impact on the Investment Entity's reporting (below 1% of total assets) relative to current reporting. Karolinska Development has only one lease, on office space.

None of the other IFRS or interpretations that have not yet been adopted are expected to a have a material impact on the Investment Entity.

### Significant accounting policies

#### Classification

The Investment Entity's non-current assets and long-term liabilities are essentially limited to amounts that are expected to be recovered or settled more than twelve months after the closing date. Current assets and current liabilities of the Investment Entity comprise amounts that are expected to be recovered or settled within twelve months of the closing date.

### Operating segments

An operating segment is a component of a company engaged in a business activity from which it may earn revenue and incur expenses, whose operating income is regularly reviewed by the Company's chief operating decision maker, and for which there is separate financial information. The Investment Entity's reporting of operating segments complies with the internal reporting to the chief operating decision maker. The chief operating decision maker has the function of assessing the profit/loss of the operating segments and determining the allocation of resources. In the Investment Entity's assessment, the management constitutes the chief operating decision maker. In internal reporting, the management evaluates the Investment Entity's result, but does not analyze the results for various parts of the Investment Entity. Consequently, the Investment Entity is considered a single reportable operating segment.

### Consolidating policies

Karolinska Development has determined that it meets the definition of an investment entity. An investment entity does not consolidate its subsidiaries, IFRS 10 Consolidated Financial Statements, or apply IFRS 3 Business Combinations when it obtains control over another company, with the exception of subsidiaries that provide services associated with the investment entity's investing operations. An investment entity instead measures its holdings in portfolio companies at fair value through profit or loss in accordance with IFRS 9 "Financial Instruments".

Karolinska Development does not have any holdings in other investment entities that will be consolidated in any reporting period.

### **Subsidiaries**

Subsidiaries are companies under the control of the Investment Entity. Consequently, an investor controls an investee only if the investor has:

- a) power over the investee;
- b) exposure, or rights, to variable returns from its involvement with the investee; and
- c) the ability to use its power over the investee to affect the amount of the investor's returns.

Karolinska Development considers all the facts and circumstances in assessing whether it controls an investee. The Company reassesses whether control exists if the facts and circumstances suggest that one or more of the controlling factors have changed.

### Associated companies

An associated company is an entity over which the Investment Entity exercises significant influence through the ability to participate in decisions related to the financial and operational strategies of the business. This situation normally occurs when the Investment Entity, directly or indirectly, owns shares representing 20–50% of the votes, or receives significant influence through agreements.

Karolinska Development is an investment entity in accordance with IAS 28 Investments in Associates and Joint Ventures and has chosen to recognize its holdings in associated companies at fair value with changes in value through profit or loss in accordance with IFRS 9 "Financial Instruments". The accounting policy for financial assets at fair value through profit or loss is described in the section on financial instruments below.

### Joint ventures

A joint venture is a joint arrangement whereby two or more parties that share joint control of the arrangement have the rights to its net assets. Joint control means contractually agreed sharing of control of an arrangement, which exists only when decisions about the relevant activities require the unanimous consent of the parties sharing control. Karolinska Development

Annual Report 2018 Karolinska Development

47

Note 1 continued

has chosen to recognize its holdings in joint ventures at fair value with changes in value through profit or loss, which is permitted in accordance with IAS 28 Investments in Associates and Joint Ventures.

# Significant assessments in the application of the accounting policies

The following section describes the most significant assessments, besides those containing estimates (see below), which management has made in the application of the Investment Entity's accounting policies and which have the most significant impact on the amounts recognized in the financial statements.

### Qualification as an investment entity

In Karolinska Development's assessment, the Company meets the criteria for an investment entity. An investment entity is a company that meets the following criteria:

- a) it obtains funds from one or more investors for the purpose of providing the investor(s) with investment management services;
- b) it commits to its investor(s) that its business purpose is investing funds solely for returns from capital appreciation, investment income, or both; and
- c) it measures and evaluates the performance of substantially all its investments on a fair value basis.

In Karolinska Development's assessment, the Company also has the following typical characteristics to qualify as an investment entity:
a) it has more than one investment:

- b) it has more than one investor:
- b) it has more than one investor,
- c) it has investors that are not related parties of the entity; and/or
- d) it has ownership interests in the form of equity or similar interests.

Karolinska Development has investments in several portfolio companies, has several investors that are not related parties to the Company and the investments are in equities.

The following significant assessments have been made in determining whether the Company qualifies as an investment entity:

- Karolinska Development invests in portfolio companies for the purpose of generating a return in the form of capital appreciation and investment income. Karolinska Development does not receive, nor does it have as its aim to receive, benefits from the Company's investments that are not available to other parties not related to the investee. The commercial purpose is not to develop medical products as such, but rather to invest to create and maximize the return. An important factor in the assessment is Karolinska Development's involvement in the investments' operations, since the Company provides certain services to support the development projects in the portfolio investments. Because of its influence as a shareholder, Karolinska Development normally appoints one or more board members of the portfolio companies. Despite that it provides certain services to the portfolio companies, Karolinska Development has reached the conclusion that it meets the criteria for an investment entity.
- Moreover, the primary metric to evaluate the portfolio companies is based on fair value. Although Karolinska Development also monitors the portfolio companies through studies and clinical trials, for instance, the primary purpose of monitoring these key indicators is to better understand changes in fair value and assess the need for additional future investments.
- The Company has a documented exit strategy for all its portfolio companies. Karolinska Development's investment strategy is to retain investments for a limited period. In every decision whether to invest in a company, the company and/ or development project in question must have clear potential for a final exit, e.g., through a sale to an outside party, that the asset can be transferred or that there is a potential that the project (portfolio company) will be licensed to an outside party with a high return to global partners. The exit strategies are taken into consideration in the valuations.

### Going concern assumption

As of signing this annual report, the company has no new contracted financing to cover the financing need arising in 2019 in connection with the payment of the current convertible loan, 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. For more information see Directors report.

### Influence over the portfolio companies

Karolinska Development's ownership interests in its portfolio companies range from a few percent up to 74%. A relatively large proportion of Karolinska Development's share of the portfolio companies lies within the range of 25-74% and in some cases fluctuates over time through investments that increase or dilute Karolinska Development's holdings.

Karolinska Development normally enters into shareholder agreements with other shareholders in the portfolio companies. Where shareholder agreements assure other investors or founders of influence, Karolinska Development is not considered to have control, even if its ownership interest formally exceeds 50%. Karolinska Development has therefore chosen to recognize its holdings at fair value through profit or loss as holdings in associated companies or joint ventures depending on the degree of control.

### Valuation of portfolio companies

The calculation of the Portfolio Fair Value is based on IFRS 13 standards of deciding and reporting fair value and the International Private Equity and Venture Capital Valuation Guidelines (IPEV Valuation Guidelines) established by the IPEV, which represent the current best practice on the valuation of private equity investments.

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 and is designated in the Investment Entity's balance sheet as Shares in portfolio companies at fair value through profit or loss.

A detailed description of the impact of the portfolio valuation of the agreement with Rosetta Capital is provided in Note 17.

### Important sources of uncertainty in estimates

Following are the most important future assumptions and other important sources of uncertainty at the end of the reporting period that entail a significant risk of material adjustments in the carrying amounts of assets and liabilities during the next financial year.

### Valuation method for portfolio companies

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

DCFs of the underlying business consider all of the cash flows of a portfolio company, which are then discounted with

an appropriate rate and also risk-adjusted to take the development risks in pharmaceutical development into consideration. Revenue streams are approximated from epidemiological data on the intended therapeutic indication and a number of assumptions such as pricing per patient and year, market share and market exclusivity (from IPR and regulatory market protection). As described in the IPEV Valuation Guidelines, the inputs in the DCF models are constructed with a high level of subjectivity. Hence, this method is only suitable for late-stage assets, either pharmaceutical companies with lead projects in late-stage (phase III) development or technology projects with an established market presence and where revenues can be projected with a higher degree of confidence than in products in earlier stages of development. As of 31 December 2018, there are no portfolio companies valued by DCF.

Companies with an established revenue stream may be valued by sales multiples. The multiples should be derived from current market-based multiples for comparable companies. As with DCF valuations, this method requires that the company has a mature market presence and its sales forecasts can be made with sufficient certainty. Furthermore, as this method only considers revenue streams, the IPEV Valuation Guidelines stipulate that non-operating assets or liabilities need to be taken into account when applying this method. As of 31 December 2018, no companies were valued according to sales multiples.

Early-stage companies, defined as pharmaceutical assets prior to phase III development and technology assets prior to establishing targeted and sustainable sales revenues, which have not recently been financed by a transaction involving a third-party investor, are valued at the price of the most recent investment, corresponding to the last post-money valuation of the portfolio company. Companies in such early stages of development typically show relatively flat value appreciation through the financing rounds as they complete preclinical and early clinical milestones. Significant value appreciation is unlikely during this period and the post-money valuation, despite not being validated by an external investor, is considered a good approximation of fair value.

Such situations arise when Karolinska Development, alone or with other investors that have participated in previous investment rounds, reinvests in portfolio companies. Should a new investor join an investment round, the valuation method will fall under a higher valuation priority, although the actual metric – post-money valuation – is the same as if only existing owners participate.

Should Karolinska Development opt out of an investment round with no intention to participate in later rounds, the price in the most recent investment may still be a valid valuation method, provided that these circumstances lead to a disproportionate post-money valuation because of the loss of negotiating power over pricing (and Karolinska Development's ownership may be drastically diluted). However, as Karolinska Development's unwillingness to invest likely reflects a lower perceived value compared to previous post-money valuations, a lowering of value is often a good indication of fair value in such cases.

As the share price of internal financing rounds is decided by existing investors, caution is taken to ensure that the share price is not artificially deflated or inflated. In each quarterly fair value assessment the post-money valuation by internal investment rounds is benchmarked against portfolio company progress (e.g., met or failed milestones), comparable values for peer companies, bids from external investors and other applicable valuation methods to ensure that the post-money valuation is at an appropriate level to be considered fair value.

The cautious approach is particularly applied if an investment round is followed by a round that included a then third-party investor. An increase in fair value may be merited if, e.g., milestones have been reached during the time between investments, although in certain cases a large increase may not be considered. In these cases, the total amount invested since the investment round with third-party investors corresponds to the appreciation in value, while additional increases in value are not be included until the valuation is validated by new third-party investors.

Net asset value, defined as a portfolio company's assets minus its liabilities, is used as the fair value of portfolio companies without current operations. This typically occurs in companies

49

Note 1 continued

considered financial assets as a consequence of discontinued development projects or withdrawn products. In essence, these companies are valued by their liquidation value.

#### Revenue

Revenue consists of dividends on shares in portfolio companies and invoiced services rendered to portfolio companies for management, communication, finance and administration, including legal and analytical operations. Revenue for services rendered is recognized in the period in which the service is rendered and recognized as the fair value of the consideration that has been or will be received, less value-added tax.

### Operating expenses and financial income and expenses

### Financial income and expenses

Financial income and expenses consist of interest income on bank deposits, receivables and interest-bearing securities, interest on loans, dividend income, foreign exchange differences, and unrealized and realized gains on financial deposits.

Interest income on receivables and interest on debt are recognized over their term to maturity using the effective interest method. The effective interest rate is the rate that makes the present value of all estimated future cash payments and disbursements over the expected interest rate duration equal to the carrying amount of the receivable or liability.

Interest income includes accrued transaction costs and any discounts, premiums and other differences between the original value of the claim and the amount received at maturity.

Direct transaction costs for raising loans are distributed over the term of the loan.

Dividend income is recognized when the shareholder's right to receive payment is established.

### **Earnings per share**

Earnings per share before dilution are calculated by dividing the net profit for the year attributable to Karolinska Development's shareholders by a weighted average number of shares outstanding during the period.

The weighted average number of outstanding shares is calculated by adjusting the number of shares outstanding at the beginning of the period for share issues and repurchases made during the period, multiplied by the number of days that the shares were outstanding in relation to the total number of days in the period. For diluted earnings per share, the number of shares is adjusted for all dilutive potential shares, which include warrants. The warrants are dilutive if the exercise price is less than the estimated fair value of the Investment Entity's shares and this reduces earnings per share after dilution.

### **Recognition and measurement of financial instruments**

Financial instruments recognized in the balance sheet include, on the asset side, shares and participations, other financial assets, loans, accounts receivable, short-term investments, cash and cash equivalents. The liability side consists of borrowings, other financial liabilities and accounts payable.

Financial instruments that are not derivatives are initially recognized at amortized cost, corresponding to the instrument's fair value plus transaction costs for all financial instruments except those belonging to the category financial assets at fair value through profit or loss, which are measured at fair value, net of transaction costs. Subsequent measurement depends on how they are classified as below.

A financial asset or financial liability is recognized in the balance sheet when the Investment Entity becomes a party according to the instrument's contractual terms. Accounts receivable are recognized in the balance sheet once the invoice has been sent. Liabilities are recognized when the counterparty has performed and a contractual obligation to pay exists, even if the invoice has not yet been received. Accounts payable are recognized when the invoice is received.

A financial asset is derecognized from the balance sheet when the contractual rights are realized, expire or the Investment Entity loses control over them. The same applies to part of a financial asset. A financial liability is derecognized from the balance sheet when the contractual obligation is fulfilled or otherwise extinguished. The same applies to part of a financial liability. The acquisition and disposal of financial assets are recognized on the trade date, i.e., the date when the Investment Entity pledges to acquire or dispose of the asset, except in the cases where the Investment Entity acquires or disposes of listed securities, in which case settlement date accounting applies.

The fair value of listed financial assets corresponds to the asset's quoted purchase price on the closing date.

### Classification of financial instruments

IFRS 9 classifies and measures financial instruments. The classification depends on the purpose of the acquisition of the financial instrument. Management determines the classification at the original purchase date. The classification determines how the financial instrument is measured after initial recognition.

#### **Financial assets**

The following three measurement categories apply to financial assets:

- Amortized cost
- Fair value through other comprehensive income (FVTOCI)
- Fair value through profit or loss (FVTPL)

### A financial asset is measured at amortized cost if:

- The financial asset is held within a business model whose objective is to realize the financial asset's cash flows by collecting contractual cash flows, and
- The contractual cash flows consist solely of repayments of principal and interest on the principal amount outstanding

Karolinska Development has assessed the following assets as belonging to this category:

### Financial assets held for trading

A financial asset is classified as held for trading if it:

 has been acquired principally for the purpose of selling it or buying back in the near term;

50

Note 1 continued

- on initial recognition is part of a portfolio of identified financial instruments that are managed together and has a recent actual pattern of short-term profit-taking; or
- is a derivative that is not designated as an effective hedging instrument.

Short-term investments, fixed income funds, have been assessed as belonging to this category.

### Loans receivable and receivables from subsidiaries

Loans receivable and receivables from subsidiaries are financial assets that are not derivatives, have fixed or determinable payments and are not quoted on an active market. Assets in this category are measured at amortized cost. Amortized cost is determined from the effective interest rate calculated on the acquisition date. Receivables from subsidiaries are recognized at the amount that is expected to be received after an allowance for impaired receivables. As the expected duration is short, the nominal value is recognized without discounting. Loans receivable from portfolio companies and receivables from subsidiaries have been assessed as belonging to this category.

### Cash and cash equivalents

Cash and cash equivalents include cash and bank balances and other short-term liquid investments that are readily convertible to cash and are subject to an insignificant risk of changes in value. To be classified as cash and cash equivalents, the duration may not exceed three months from the date of acquisition. Cash and bank balances are categorized as "Loans receivable and accounts receivable," which are measured at amortized cost. Because the bank balances are payable upon demand, amortized cost corresponds to the nominal amount.

Financial assets at fair value through other comprehensive income (FVTOCI)  $\,$ 

 The financial asset is held within a business model whose objective is to realize the financial asset's cash flows by both collecting contractual cash flows and selling the asset, and  The contractual cash flows consist solely of repayments of principal and interest on the principal amount outstanding

Karolinska Development has no financial assets in this category.

### Financial assets at fair value through profit or loss (FVTPL)

All other financial assets are measured at fair value with the changes recognized in profit or loss. This category consists of two subgroups: held for trading and financial assets designated at FVTPL.

This category includes shares in portfolio companies and other financial assets.

### **Financial liabilities**

Financial liabilities are measured at either amortized cost or at fair value through profit or loss.

### Financial liabilities at amortized cost

This category includes loans and other financial liabilities, e.g., convertible loans, short-term interest-bearing liabilities and accounts payable. Loans are measured at amortized cost. Amortized cost is based on the effective interest rate calculated when the liability was incurred. As the expected duration of accounts payable is short, the nominal value is recognized without discounting.

### Financial liabilities at fair value through profit or loss (FVTPL)

This category comprises financial liabilities held for trading and derivatives that are not used for hedge accounting. Liabilities in this category are measured at fair value with changes in value recognized through profit or loss. Other financial liabilities have been assessed as belonging to this category. For the present, there are no liabilities in this category.

### Impairment testing of financial assets

Impairment is calculated and recognized for financial assets at amortized cost and for financial assets at fair value with changes in value recognized in other comprehensive income. An allowance for

impaired receivables is recognized and calculated as needed. Karolinska Development has no allowance for impaired receivables.

### Share capital

### Dividends

Dividends are recognized as a liability after the AGM has approved the dividend.

### **Employee benefits**

### Defined contribution pension plans

Obligations stemming from defined contribution pension plans are expensed through profit or loss as incurred.

Certain individual pension undertakings have been guaranteed in the form of Company-owned endowment insurance policies. The Investment Entity has no further obligation to cover possible shortfalls in the endowment insurance or to pay any amount in excess of deposited premiums, which is why these pension plans are accounted for as defined contribution pension plans. Accordingly, the payment of premiums corresponds to a final settlement of the undertaking vis-à-vis the employee. In accordance with IAS 19 and the regulations for defined contribution pension plans, the Investment Entity therefore reports no assets or liabilities, with the exception of specific payroll taxes related to these endowment insurance policies.

### Share-based payment

The Matching Share Rights allotted to senior executives in the previous PSP programs are measured at fair value on the allotment date. The value of Matching Shares on the allotment date has been established by the Black-Scholes pricing model. For more information on the valuation, see Note 5.

The fair value set on the allotment date is expensed with a corresponding adjustment in equity distributed over the vesting period, based on the Investment Entity's estimate of the number of Matching Share Rights it expects to be vested. On each closing date, the Investment Entity reevaluates its estimate of

the number of Matching Share Rights it expects to be vested. If a previous estimate is revised, the effect is recognized in income with a corresponding adjustment in equity.

Social security costs attributable to share-based payments are expensed over the vesting period.

### **Taxation**

Income tax comprises current and deferred taxes. Income taxes are recognized through profit or loss except when the underlying transaction is recognized through other comprehensive income against equity or directly against equity, whereby the associated tax effect is recognized through other comprehensive income or directly against equity.

Current tax is tax to be paid or received for the current year, applying the tax rates enacted or substantively enacted by the closing date. This includes adjustments to current tax attributable to prior periods.

Deferred tax is calculated on the difference between recognized tax and tax values of the Investment Entity's assets and liabilities. Deferred tax is accounted for using the balance sheet liability method. Deferred tax liabilities are generally recognized for all taxable temporary differences, while deferred tax assets

are recognized to the extent it is probable that the amounts can be offset against future taxable profits.

Deferred tax assets for deductible temporary differences and tax losses carried forward are recognized only to the extent it is probable that they will be utilized. The value of deferred tax assets is reduced when it is no longer considered probable that they can be utilized. The carrying amount of deferred tax assets is tested at each closing date and reduced to the extent it is no longer probable that sufficient taxable profit will be available to allow all or part of the asset to be recovered.

Deferred tax assets and liabilities are offset when they relate to income taxes levied by the same authority and the Investment Entity intends to settle the tax on a net basis.

### **Contingent liabilities**

A contingent liability is recognized when there is a possible obligation as a result of past events and whose existence is confirmed only by one or more uncertain future events, or when there is a commitment that is not recognized as a liability or provision because it is not probable that an outflow of resources will be required.

### Note 2 Revenue distribution

Services rendered are comprised of invoiced services provided to portfolio companies in Sweden. These services consist of management, communication, finance and administration, including legal and analytical operations.

### Revenue per significant source

SEK 000	2018	2017
Invoiced services	3,073	2,464
Total revenue	3,073	2,464

### **Note 3** Other external expenses

### Fees and remuneration to the Investment Entity's auditors

SEK 000	2018	2017
EY		
Audit services	1,196	1,167
Audit related services	467	550
Tax consulting	211	234
Total	1,874	1,951

The audit fee refers to the auditor's reimbursement for execution of the statutory audit. This work includes the audit of the annual report and annual accounts, the administration of the Board of Directors and the CEO, and fees for advice offered in connection with the audit assignment. Audit related services primarily involve quality assurance services other than the statutory audit.

## **Note 4** Operating leases

The Investment Entity has chosen to finance premises and equipment through leases. Only operating leases have been signed. Expensed leasing payments and future contractual leasing payments are indicated below.

SEK 000	2018	2017
Expensed leasing payments during the period	714	1,086
Future leasing payments		
Within one year	729	713
Between one year and five years	745	2
Total future leasing payments	1,474	715

The table below shows the Investment Entity's impact on the balance sheet in connection with the introduction of IFRS 16 "Leases" on 1 January 2019. The effect is minimal on the reporting (below 1% of total assets) relative to 2018, and is marginal as well on the cash flow statement. The Company, which has only two leases (property lease and a lease of low value), uses the simplified transition method. The Company does not use any simplifications. The property lease is for one year with a one-year extension.

SEK 000	1 Jan 2019
Obligations for operating leases 31 December 2018	1,474
Discount applying the Investment Entity's discount rate 4%	-64
Lease liability 31 December 2018	1,410

## Note 5 Employees and personnel costs

### Average number of employees

Full-time equivalent	2018	Of whom women	Of whom men	2017	Of whom women	Of whom men
Investment Entity	7	57%	43%	7	43%	57%
Total	7	57%	43%	7	43%	57%

### Remuneration expenses for employees

### Salaries, other remuneration and social security costs

	2017			
SEK 000	Salaries and remuneration	remunera- security		Social security costs
Investment Entity	16,277	5,049	20,580	4,424
(of which pension expenses)	2,438	591	2,203	534

### **Defined contribution pension plans**

The Investment Entity has defined contribution pension plans. Payments to these plans are made on an ongoing basis according to the rules of each plan.

## Remuneration to executive management and the board of directors

### The Guidelines for Remuneration to Executive Management

### 1 APPLICABILITY

The Guidelines shall be in force until the Annual General Meeting 2019.

The Guidelines applies on salary and other forms of remuneration to the CEO and other management personnel (executive management) decided after the 2018 Annual General Meeting. They apply to all categories of remunerations and benefits, whether paid in cash, or paid now or in the future, or if certain or uncertain. Compensation and issues of securities covered by Chapter 16 of the Swedish Companies Act are not covered by these Guidelines.

### 2 GUIDELINES FOR REMUNERATION

### 2.1 General

Remuneration to executive management comprises fixed salary, variable remuneration, pension and customary other benefits.

Karolinska Development shall maintain compensation levels and terms required to recruit and keep an executive management with the competence and experience necessary to meet the company's operational goals. The total remuneration to executive management shall be competitive, reasonable and appropriate.

Market term consultancy fee may be paid to board directors that perform services to the company outside the scope of the directorship.

### 2.2 Fixed salary

Fixed salaries shall be based on each individual's experience and field of responsibility. Fixed salary shall be revised annually for each calendar year.

#### 2.3 Variable remuneration

Variable remunerations shall be formed to promote Karolinska Development's long term value creation; be based upon criteria that are predetermined, clear, measurable and that can be influenced; if in form of variable salary, have a fixed cap; not be included when calculating pension insurance premiums.

CEO and other executive management are entitled to bonus based on exits in the portfolio. The total maximum payment for the exit related bonus, shall be limited to MSEK 50 per exit and financial year.

Annual short-term incentive programs (STI) based on set objectives are proposed by the Remuneration Committee and resolved by the Board of Directors for each calendar year. The payment to an employee under a STI program shall be limited to an amount corresponding to six months' salaries. The cost for the company at maximum outcome of STI 2018 amounts 3.6 MSEK.

The company has five annual long-term incentive programs (LTI) for the year 2018-2010, 2015 and 2017, each resolved by the respective Annual General Meeting.

Information about the exit bonus and about the STI and LTI programs will be found in the Annual report for 2017, note 5. Information is also available on the Company's web site in the Corporate Governance section.

### 2.4 Pension

The company's costs for pension for an employee shall be paid during the period when the employee is active in the company. Pension insurance premiums shall not be paid when an employee has retired. In addition to what is required under Swedish law, premiums shall be paid in accordance with an adopted pension premium plan.

### 2.5 Customary other benefits

Executive management are entitled to such customary other benefits that are applied for all employees at Karolinska Development, such as sick pay, health care and wellness program. The number of paid holidays is thirty.

Executive management are not allowed to receive fees for serving as directors of board of directors, when related to the employment at Karolinska Development. The company does not provide company cars.

The termination period at termination by the company shall not exceed six months for the executive management. Severance

pay may be paid only to the CEO. Fixed salary during a period of notice and severance pay aggregated are not to exceed an amount equivalent to the individual's fixed salary for two years.

### 2.6 Preparations and decisions

The company's Remuneration Committee is to prepare decisions related to salaries and other remuneration to executive management. The board of directors is to decide regarding salary to the CEO and principles for remuneration to other executive management.

### 3 EXCEPTIONS

The board of directors may case by case decide on exceptions if there are special reasons. Circumstances known to the board of directors when the Guidelines where decided are normally not reason enough for an exception. Exceptions (if any) shall be commented on at the following Annual General Meeting.

#### **4 DEVIATIONS**

There has been one deviation during the year. Severance was paid to the former CFO. There was special reasons for the deviation. At the shift of CFO, it was of great importance to ensure a smooth transition period. These circumstances were not known when the 2017 Guidelines were adopted by the AGM.

## 5 PREVIOUSLY DECIDED REMUNERATIONS NOT YET DUE FOR PAYMENT

At the time of the 2018 AGM there are no decided remunerations to executive management not due for payment.

## Remuneration to the Chief Executive Officer, other senior executives and the Board of Directors

The executive management includes the Chief Executive Officer, Chief Financial Officer and General Counsel.

The table below shows the remuneration to the CEO, other senior executives and the Board of Directors during the financial year.

### 2018

CEN 000	Base salary/	Variable	Other benefits	Danaian acata	DCD was aways?	Tatal vanavnavation
SEK 000	Board fee <sup>1</sup>	remuneration	and remuneration	Pension costs	PSP program <sup>2</sup>	Total remuneration
Viktor Drvota, CEO	2,563	1,568	1	668		4,800
Jim Van heusden, former CEO		335			450	785
Other senior executives (2 persons)	2,877	1,779	2	792		5,450
Other senior executives, former CFO	381	295	34	67		777
Total management	5,821	3,977	37	1,527	450	11,812
Hans Wigsell, Chairman	383					383
Vlad Artamonov, Board member	200					200
Tse Ping, Board member, Board member	200					200
Anders Härfstrand, Board member	200					200
Magnus Modée Persson, Board member	200					200
Theresa Tse, Board member	200					200
Niclas Adler, former Board member	17					17
Summa styrelsen	1,400	-	-	-		1,400
Summa	7,221	3,977	37	1,527	450	13,212

<sup>1)</sup> Since AGM 2018 the entire Board fee is paid out after the AGM and is based on meeting attendance.

### 2017

SEK 000	Base salary/ Board fee	Variable remuneration	Other benefits and remuneration	Pension costs	PSP program <sup>2</sup>	Total remuneration
Viktor Drvota, CEO from 1 June 2017	1,451	1,635	0	391		3,477
Jim Van heusden, CEO through 31 May 2017, employed through 18 Oct 2017	2,227	1,053	168	485	586	4,519
Other senior executives (3 persons)	5,091	1,844	157	937		8,056
Total, management	8,769	4,532	325	1,813	586	16,025
Hans Wigzell, Chairman from 29 Dec, former Board member	200					200
Niclas Adler, Chairman 24 May-29 Dec 2017, former Board member	300					300
Bo Jesper Hansen, fee as consultant <sup>1</sup>	539					539
Bo Jesper Hansen, Chairman through 24 May 2017	219					219
Henrijette Richter, Board member through 24 May 2017	131					131
Vlad Artamonov, Board member	200					200
Tse Ping, Board member	200					200
Khalid Islam, Board member through 24 May 2017	131					131
Carl-Johan Sundberg, Board member through 24 May 2017	100					100
Anders Härfstrand, Board member from 24 May 2017	100					100
Magnus Modée Persson, Board member from 24 May 2017	100					100
Hans-Olov Olsson, Board member 24 May - 31 Oct 2017	83					83
Total, Board of Directors	2,303	-	-	-	-	2,303
Total	11,072	4,532	325	1,813	586	18,329

 $<sup>1) \,</sup> Refers \, to \, assignment \, as \, consultant \, over \, and \, above \, his \, role \, as \, Chairmen \, of \, the \, Board; \, see \, below. \, 2017 \, covers \, 5 \, months.$ 

<sup>2)</sup> PSP program refers to the benefit in the form of shares received from PSP 2015, excluding social security costs, for PSP 2015 in 2018. For a description of the program, see below.

<sup>2)</sup> PSP program refers to recognized costs, excluding social security costs, for PSP 2014 and PSP 2015 in 2017.

## Gender distribution of senior executives and Board of Directors

Information as of closing date

	2018	2017
Board of Directors		
Men	5	5
Women	1	1
Total	6	6
CEO and senior executives		
Men	3	4
Women	0	0
Total	3	4

### **Compensation to the CEO**

### Pension terms

The contractual pension amounts to 26% of gross salary and consists of premium-based compensation.

### Variable remuneration to the CEO

The CEO is entitled to a bonus based on exits in the portfolio. The remuneration amounts to 1/3 of 4% of the net proceeds paid to the company upon the exit. The remuneration includes all of the company's costs in relation to the payment. The maximum payment, together with the payment to other senior executives reported in the first paragraph of the section "Variable remuneration to other executive managers", is limited to SEK 50 million per exit and calendar year. The CEO is also eligible for STI 2018 and LTI 2017, which are reported in the section "Annual incentive programs" below.

### Severance, other executive managers

No senior executives are entitled to severance. According to the Guidelines for Remuneration to Executive Management, severance may only be paid to the CEO.

### Variable remuneration

### Variable remuneration to other executive managers

Other executive managers are entitled to a bonus based on exits in the portfolio. The remuneration to other senior executives totals 2/3 of 4% of the net proceeds paid to the company upon the exit. The remuneration includes all of the company's costs in relation to the payment. The maximum payment, together with the payment to the CEO reported in the section "Variable remuneration to the CEO," is limited to SEK 50 million per exit and calendar year. Other senior executives and (partially) the former CEO are eligible for STI 2018 in the section "Incentive programs" below.

### Annual incentive programs

Karolinska Development's annual long-term incentive programs (LTI) for the years 2008-2010, 2015 and 2017 and the Company's annual short-term incentive programs (STI) for the years 2017 and 2018 are described below.

### Incentive programs 2008–2010

No current employees of the Company are covered by the program.

The program was designed as a combined warrant and profit-sharing program consisting of three annual stages for the years 2008-2010. The warrants have expired.

Each profit-sharing plan is related to appreciation in the value of the portfolio companies and extends 15 years. The 2008 profit-sharing program is related to the Company's investment portfolio as of 31 December 2007, while the 2009 and 2010 programs refer to investments that the Company made in the calendar year before the sub-plan.

Each sub-plan provides entitlement to a cash payment equivalent to a total of 5% of the portion of the return on the investments encompassed by the sub-plan, in excess of a threshold rate. The threshold rate consists of the initial value of the investments encompassed by a specific sub-plan, to the extent they have been exited, adjusted by an annual rate of 6% for the years 2008–2012 and 8% thereafter. On the "plus side" are the proceeds received from exits.

To the extent that returns exceed an annual return of 35%, the portion that exceeds the returns is halved to 2.5%. To the extent that returns exceed 50%, the amount in excess of 50% will be further halved to 1.25%. Excess returns above 60% are not eligible for profit-sharing.

In addition to the portion of excess returns as stated above, the sub-plan 2010 also provides entitlement to a total of 37.5% of KDAB Carried Interest, according to the limited partnership agreement the Company has entered into with the European Investment Fund ("EIF") related to KCIF Co-Investment Fund KB ("KCIF"). KDAB Carried Interest can be summarized as 20% of any return exceeding an annual threshold rate of 6% of - and after repayment of - the amounts that the Company and EIF have committed to KCIF. According to the agreement with EIF, Karolinska Development is entitled to the current portion of the KDAB Carried Interest only if it is included in the Company's profit-sharing plan. As a result, this portion of the profit-sharing plan essentially means that the Company, despite accounting costs that arise, is not foregoing any amount it otherwise would have had available, with the exception of the additional social security costs that this profit-sharing entails for the Company.

Outcome: No payments have been made as part of the program.

### Performance-based share incentive program 2015 (PSP 2015)

The 2015 Annual General Meeting adopted a performance-based share incentive program for employees where participants acquire shares ("Savings Shares") on the open market. Under certain conditions participants may receive, free of charge, a maximum of five Performance Shares and one Matching Share Right from the company for each Savings Share they purchase. Matching Share Rights and Performance Shares are allotted after three years. The maximum number of Performance Shares and Matching Share Rights was 1,078,410. The program comprises a maximum of ten participants.

To receive Matching Share Rights, a participant must still be employed during the vesting period. The Performance Shares have a target related to Karolinska Development's share price performance and a comparison between the so-called Start

Price and End Price. The Start Price, measured as an average over ten trading days from 21 May 2015 through 3 June 2015, was SEK 11.39. The End Price is measured as the average over ten trading days beginning on 2 May 2018. For an allotment, the share price must rise by a total of 15% above the Start Price. For a maximum allotment (five Performance Shares per Savings Share), the share price must rise by 100% above the Start Price. Within this span, allotments are made proportionately. Allotments are capped at 35 times the Start Price, after which the number of allotted Performance Shares is reduced. Participants will be compensated in cash for dividends paid during the period.

The Company intends to cover social security costs related to the program by acquiring and transferring a maximum of 338,840 of its own shares. As of 30 September 2015, 74,850 Savings Shares had been acquired, which are related to previous share based programs, however.

An expense reduction of SEK 1.6 million (SEK 0.6 million) was recognized for PSP 2015 in 2018.

The program concluded in 2018, at which point a total of 57,531 Matching Share Rights valued at SEK 0.5 million were allotted to former CEO Jim Van heusden, who was the only participant in the program. No Performance Shares were allotted. The value of the benefit amounted to SEK 0.5 million and is included in the table above on remuneration to the CEO, other senior executives and the Board of Directors.

### LTI 2017

The Annual General Meeting 2017 resolved on a Long Term Incentive program, "Warrant Program 2017/2020," for all Company employees, according to the following terms. A maximum of 3,216,836 warrants will be issued. Each warrant entitles the holder to subscribe for one (1) series B share in the company. Subscription of shares by virtue of the warrants may be effected during the period 30 June 2020 - 31 August 2020.

The subscription price per share will correspond to 250% of the volume weighted mean value according to Nasdaq Stockholm's official price list for shares of series B in the Company during the ten (10) trading days immediately following the Annual General Meeting 2017.

The warrants were allocated as follows: to the CEO, 1,608,418; to other senior executives, 402,105 each; and to other employees, 107,228 each. In total, 3,136,416 warrants were subscribed; 80,420 were reserved for new recruitments but never subscribed.

### Short Term Incentive Program 2017 (STI 2017)

In 2017, the Board of Directors decided on a Short Term Incentive Program, STI 2017, for senior executives based on a number of specific corporate goals established by the Board for 2017. The goals are designed to promote Karolinska Development's long-term value appreciation. The remuneration is dependent on whether one or more goals are met and has a fixed cap corresponding to six months' base salary for each participant. Goals were partly met, which rendered an accrual of SEK 3.4 million (SEK 3.4 million including social security costs). The expense is included as variable remuneration in the above table in 2017.

### Short Term Incentive Program 2018 (STI 2018)

In 2018, the Board of Directors decided on a Short Term Incentive Program, STI 2018, for senior executives based on a number of specific corporate goals established by the Board for 2018. The goals are designed to promote Karolinska Development's long-term value appreciation. The remuneration is dependent on whether one or more goals are met and has a fixed cap corresponding to six months' base salary for each participant. Goals were partly met, which rendered an accrual of SEK 3.0 million. The expense is included as variable remuneration in the above table in 2018.

# Note 6 Interest expenses and other financial gains and losses

### Interest expenses

SEK 000	2018	2017
Accrued interest convertible loan	-49,119	-43,494
Interest expenses	-345	-1
Total	-49,464	-43,495

### Other financial gains and losses

SEK 000	2018	2017
Change in value of short-term investments	-400	-243
Exchange rate gains and losses	-237	-24
Other financial expenses	-750	-1,702
Total	-1,387	-1,969

### Note 7 Taxes

### Reconciliation of effective tax rate

SEK 000	%	2018	%	2017
Profit before tax		30,510		179,595
Income tax expense calculated at applicable rate in the Parent Company	22.0%	-6,712	22.0%	-39,511
Tax effect of				
Non-deductible expenses		-29		-2,130
Tax-exempt revenue		787		2,889
Issue costs		-		578
Changes in fair value, non-taxable		21,996		56,002
Increase in tax losses carried forward without corresponding capitalization of deferred taxes		-16,041		-17,829
Recognized current tax	0.0%	0	0.0%	0
Change in deferred tax	0.0%	-	0.0%	-
Recognized deferred tax	0.0%	-	0.0%	-
Total recognized tax	0.0%	-	0.0%	-

### Unrecognized deferred tax assets

Deductible temporary differences and tax losses carried forward for which deferred tax assets have not been recognized through profit or loss and the balance sheet primarily relate to losses generated by the Parent Company. Any future gains on the sale of business-related shares and participations in the portfolio companies are non-taxable profits. Deferred tax assets have therefore not been recognized for these losses, since it is unlikely that Karolinska Development AB will be able to utilize the tax losses carried forward to offset future taxable profits, despite that there is no time limit on these tax losses carried forward. Unrecognized deferred tax assets for Karolinska Development amounted to SEK 154,352 thousand (SEK 143,549 thousand) at 31 December 2018, and SEK 0 thousand (SEK 54,552 thousand) relates to deficits that are restricted by Group contributions and mergers.

# Note 8 Shares in portfolio companies at fair value through profit or loss

SEK 000	31 Dec 2018	31 Dec 2017
Accumulated acquisition cost		
At the beginning of the year	447,783	149,408
Investments during the year	124,556	91,869
Sales during the year	-11,911	-45,566
Changes in fair value in net profit for the year	58,499	252,072
Closing balance	618,927	447,783

## Note 9 Loans receivable from portfolio companies

SEK 000	31 Dec 2018	31 Dec 2017
Loans receivable from portfolio companies		
At the beginning of the year	3,436	957
Loans provided	1,620	25,347
Conversions	-	-22,896
Foreign exchange difference	42	28
Total	5,098	3,436

## Note 10 Other current receivables

SEK 000	31 Dec 2018	31 Dec 2017
Receivable European Investment Fund, EIF	2,795	-
Tax assets	630	483
Other	7	48
Total	3,432	531

## Note 11 Prepaid expenses and accrued income

SEK 000	31 Dec 2018	31 Dec 2017
Prepaid rental expenses	-	186
Accrued interest income	23	50
Insurance premiums	184	198
Other	425	232
Total	632	666

## Note 12 Equity

## Changes in share capital

Year	Transaction	Number of shares	Share capital	Number of A shares	Number of B shares	Subscription price	Par value
Total per 1 Jan 2011		33,331,417	16,665,709	1,503,098	31,828,319		0.5
April 2011	Share issue	15,200,000	7,600,000	0	15,200,000	40	0.5
Total per 31 Dec 2011		48,531,417	24,265,709	1,503,098	47,028,319		0.5
Total per 31 Dec 2012		48,531,417	24,265,709	1,503,098	47,028,319		0.5
Total per 31 Dec 2013		48,531,417	24,265,709	1,503,098	47,028,319		0.5
December 2014	Share issue	4,853,141	2,426,570		4,853,141	13	0.5
Total per 31 Dec 2014		53,384,558	26,692,279	1,503,098	51,881,460		0.5
December 2015	Share issue	65,082	32,541		65,082		0.5
Total per 31 Dec 2015		53,449,640	26,724,820	1,503,098	51,946,542		0.5
September 2016	Share issue	15,358	7,679		15,358		0.5
Total per 31 Dec 2016		53,464,998	26,732,499	1,503,098	51,961,900		0.5
April 2017	Share issue	10,871,698	5,435,849		10,871,698		0.5
June 2017	Reduction in share capital	0	-31,524,981		-		0.01
July 2017	Share issue	564	6		564		0.01
August 2017	Share issue	23,840	238		23,840		0.01
October 2017	Share issue	106	1		106		0.01
Total per 31 Dec 2017		64,361,206	643,612	1,503,098	62,858,108		0.01
June 2018	Share issue	57,531	575		57,531		0.01
Total per 31 Dec 2018		64,418,737	644,187	1,503,098	62,915,639		0,01

### Net asset value per share

	Investmen	t Entity	
SEK 000	31 Dec 2018	31 Dec 2017	
Net assets			
Cash and cash equivalents	15,843	19,305	
Short-term investments	69,949	150,329	
Loans receivable from portfolio companies	5,098	3,436	
Net financial assets and liabilities	15,547	35,789	
Convertible loan and short-term interest-bearing liabilities	-478 303	-379,184	
Total net assets	-371,866	-170,325	
Estimated fair value of portfolio companies	618 927	447 783	
Total net asset value	247,061	277,458	
Number of shares	64,174,452	64,116,921	
Net asset value per share	3.85	4.33	

#### **Share structure**

The number of shares amounts to 64,418,737, of which 1,503,098 are series A shares and 62,915,639 are series B shares. Series A shares carry ten votes per share and series B shares carry one vote per share. All shares have an equal right

to the Company's assets in the case of liquidation and profit distributions. All series B shares have been listed for trading on the main list of Nasdaq OMX since 15 April 2011.

In 2012 and 2013, a total of 244,285 shares with a par value of SEK 0.01, corresponding to SEK 2,443 in share capital, were repurchased for SEK 4,726,904 in consideration. The shares were repurchased to cover the social security costs in the PSP incentive programs.

### Other contributed capital

Relates to capital contributed by the owners.

### Retained earnings incl. net profit for the year

Retained earnings including current year results include retained earnings of the Parent Company. Previous allocations to the statutory reserve are included in this equity item.

### Earnings per share basic and diluted

SEK 000	2018	2017
Net profit for the year	30,510	179,595
Weighted average number of shares before dilution	64,136,941	61,243,234
Earnings per share, SEK, before dilution	0.48	2.93
Weighted average number of shares after dilution	64,136,941	61,300,516
Earnings per share, SEK, after dilution	0.48	2.93

### Note 13 Convertible loan

Karolinska Development has issued convertibles, so-called compound financial instruments, in which the holder has right to convert to shares and where the number of shares that are issued is not affected by changes in the fair value of the shares.

The liability component of a compound financial instrument is initially recognized at fair value for a similar liability without a conversion right to shares. The equity component is initially recognized as the difference between the total fair value of the compound financial instrument and the fair value of the liability component. Directly attributable transaction costs are allocated to the liability and equity components in proportion to their initial carrying amounts.

After acquisition, the liability component of the compound financial instrument is valued at amortized cost using the effective interest method. The equity component of a compound financial instrument is not revalued after acquisition, except upon conversion or redemption.

Karolinska Development issued convertibles with a nominal amount of SEK 386,859 thousand on 2 January 2015 which carry a nominal interest rate of 8%. The nominal amount decreased to SEK 329,258 thousand after the set off issue in March 2017. The convertible falls due for payment on 31 December 2019 at its nominal amount of SEK 483,788 thousand (the interest is cumulative) or can at any time be converted to shares on the request of the holder at a price of SEK 22 per B share. The value of the liability and equity components (conversion right) was determined on the date of issuance.

The convertibles are recognized in the balance sheet according to the following table.

	31 Dec 2	2018	31 Dec 20	017
SEK 000	Current liabilities	Of which affect cash flow	Long-term liabilities	Of which affect cash flow
Nominal value of convertible debenture issued on 2 January 2015	329,337		386,859	
Less issue costs	-23,982		-28,171	
Share of equity	-42,164		-49,528	
Remaining liability after issuance 2 January 2015	263 191	0	309,160	0
Accrued interest expenses	165,112		128,766	
Converted nominal liability	-		-57,522	
Converted share of issue costs	-		4,189	
Converted share of equity	-		7,364	
Converted accrued interest	-		-12,680	
Redemption of convertible	-	-	-93	-93
Total	428,303	0	379,184	-93

## **Note 14** Other financial liabilities

	31 Dec	31 Dec 2018		31 Dec 2017	
SEK 000		Of which affect cash flow		Of which affect cash flow	
Accumulated acquisition cost					
At the beginning of the year	4,807		4,798		
Fair value change in net profit for the year	6,616	-	9	-	
Closing balance	11,423	0	4,807	0	

## Note 15 Short-term interest-bearing liabilities

SEK 000	31 Dec 2018	31 Dec 2017
Short-term loan debt	50,000	-
Total	50,000	-

## Note 16 Accrued expenses and prepaid income

SEK 000	31 Dec 2018	31 Dec 2017
Salaries and remuneration to personnel	3,031	5,079
Remuneration to Board of Directors	1,011	171
Auditor and consulting fees	402	585
Payroll tax and accrued pension costs	1,243	1,618
Social security costs	723	1,895
Other	37	15
Total	6,447	9,363

## Notes

## Note 17 Financial assets and liabilities

### Financial assets and liabilities by category

### 2018

	Financial assets desi	gnated at:	Finacial liabilities desi	gnated at:		
SEK 000	Fair value through profit or loss	Amortizaiced costs	Fair value through profit or loss	Amortiziced costs	Total carrying amount	Fair value
Shares in portfolio companies at fair value through profit or loss	618,927				618,927	618,927
Loans receivable from portfolio companies		5,098			5,098	5,098
Other financial assets	80,030				80,030	80,030
Receivables from portfolio companies		473			473	473
Short-term investments at fair value through profit or loss	69,949				69,949	69,949
Cash and cash equivalents		15,843			15,843	15,843
Total	768,906	21,414			790,320	790,320
Convertible loan			428,303		428,303	428,303
Short-term interest-bearing liabilities				50,000	50,000	50,000
Other financial liabilities			11,423		11,423	11,423
Accounts payable				1,373	1,373	1,373
Total			439,726	51,373	491,099	491,099

### 2017

SEK 000	Financial assets designated at fair value through profit or loss	Loans and receivables	Other financial liabilities	Total carrying amount	Fair value
Shares in portfolio companies at fair value through profit or loss	447,783			447,783	447,783
Loans receivable from portfolio companies		3,436		3,436	3,436
Other financial assets	40,596			40,596	40,596
Receivables from portfolio companies		611		611	611
Short-term investments at fair value through profit or loss	150,329			150,329	150,329
Cash and cash equivalents		19,305		19,305	19,305
Total	638,708	23,352	0	662,060	662,060
Convertible loan			379,184	379,184	379,184
Other financial liabilities			4,807	4,807	4,807
Accounts payable			1,155	1,155	1,155
Total			385,146	385,146	385,146

### **Short-term investments**

Surplus liquidity that may temporarily arise in Karolinska Development is placed in fixed income funds or interest-bearing instruments and is recognized as short-term investments with a remaining duration exceeding 3 months.

### Fair value measurement

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, directly or indirectly
- **Level 3** Fair value determined based on valuation models where significant inputs are based on non-observable data

The carrying amounts of financial assets and liabilities measured at amortized cost approximate their fair value.

## Investment Entity's assets and liabilities at fair value as of 31 December 2018

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies at fair value through profit or loss			618,927	618,927
Loans receivable from portfolio companies		5,098		5,098
Other financial receivables			80,030	80,030
Receivables from portfolio companies		473		473
Cash and cash equivalents and short-term investments	85,792			85,792
Total	85,792	5,571	698,957	790,320
Financial liabilities				
Other financial liabilities			11,423	11,423
Short-term interest-bearing liabilities			50,000	50,000
Accounts payable		1,373		1,373
Total		1,373	61,423	62,796

## Investment Entity's assets and liabilities at fair value as of 31 December 2017

**6**=17.000

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies at fair value through profit or loss	14,083		433,700	447,783
Loans receivable from portfolio companies		3,436		3,436
Other financial receivables			40,596	40,596
Receivables from portfolio companies		611		611
Cash and cash equivalents and short-term investments	169,634			169,634
Total	183,717	4,047	474,296	662,060
Financial liabilities				
Other financial liabilities			4,807	4,807
Accounts payable		1,155		1,155
Total		1,155	4,807	5,962

The following describes the main methods and assumptions used to determine the fair value of financial assets and liabilities in the tables above.

# Shares in associated companies and other long-term holdings (unlisted holdings)

The valuation of unlisted holdings is based on the International Private Equity and Venture Capital Valuation Guidelines. For a further description, see Note 1 Accounting policies, "Valuation of portfolio companies."

### Financial assets and liabilities at fair value

A fair value estimate is made based on discounted future cash flows, where a discount rate reflecting the counterparty's credit risk is the most significant input. For financial assets in Level 2, a discount rate of 7% has been used. For financial liabilities, there is no significant difference compared to the carrying amounts included in Level 2, so the carrying amounts are considered a good approximation of fair value.

### Changes in financial assets and liabilities on Level 3 in 2018

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At the beginning of the year	433,700	40,596	4,807
Acquisitions	124,557	-	-
Disposals/compensation	-	-8,663	-
Gains and losses realized in profit or loss	60 670	48,097	6,616
Carrying amount at year-end	618,927	80,030	11,423
Realized gains and losses for the period included in profit or loss	1,789	0	0
Unrealized gains and losses for the period included in profit or loss	58,881	48,097	-6,616

There were no transfers between Level 1 and 2 in 2018.

### Changes in financial assets and liabilities on Level 3 in 2017

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At the beginning of the year	149,408	38,113	4,798
Transfers to and from Level 3	-14,083	-	-
Acquisitions	91,869	-	-
Disposals	-45,566	-	-
Gains and losses realized in profit or loss	252 072	2,483	9
Carrying amount at year-end	433,700	40,596	4,807
Realized gains and losses for the period included in profit or loss	45,820	0	0
Unrealized gains and losses for the period included in profit or loss	206,252	2,483	-9

There were no transfers between Level 1 and 2 in 2017.

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 on the portfolio's fair value of the agreement with Rosetta Capital

"Potential distribution to Rosetta Capital" is the amount of SEK 333.4 million 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 dividends on Rosetta Capital's preference and common shares. The distribution to Rosetta Capital will take place only when KDev Investments distributes a dividend. KDev Investments will only distribute dividends after all accounts payable and outstanding liabilities have been repaid.

## Expanded fair value calculations taking into consideration the portfolio valuation and potential distribution to Rosetta Capital

SEK 000	31 Dec 2018	31 Dec 2017
Fair value of Karolinska Development portfolio (unlisted companies)	492,600	413,844
Fair value of Karolinska Development portfolio (listed companies)	0	14,083
Fair value of KDev Investments portfolio	459,740	286,070
Total Portfolio Fair Value <sup>1</sup>	952,340	713,997
Potential distribution to Rosetta Capital of fair value in KDev Investments <sup>2</sup>	333,413	266,214
Net Portfolio Fair Value (after potential distribution to Rosetta Capital) <sup>3</sup>	618,927	447,783

<sup>1)</sup> Total Portfolio Fair Value" is indicated in Note 1.

<sup>2)</sup> SEK 43.3 million repayment of Rosetta Capital's investments in KDev Investments and SEK 290.1 million distribution of dividends on common and preference shares.

<sup>3)</sup> Net Portfolio Fair Value (after potential distribution to Rosetta Capital)" is indicated in Note 1.

64

Note 17 continued

#### 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. See Note 1 Accounting policies, Valuation methods.

### Financial risks

Through its activities, the Investment Entity is exposed to various financial risks. Financial risks refer to fluctuations in operating results and cash flow as a result of changes in exchange rates, interest rates, refinancing and credit risks. Responsibility for the Investment Entity's financial transactions and risks rests with both the Parent Company's finance department and the local subsidiaries. The overarching objective of the finance function is to provide cost-effective financing and to minimize adverse effects on the Investment Entity's earnings from market fluctuations.

### Currency risk

Currency risk is the risk that changes in exchange rates will negatively impact the Investment Entity. The Investment Entity's foreign exchange exposure consists of transaction exposure resulting in exposure in foreign currency linked to the contractual cash flows and balance sheet items where changes in exchange rates affect the results and cash flows. The Investment Entity's exposure to currency risk is not significant.

### Credit risk

Credit risk is the risk that the counterparty to a transaction fails to fulfill its obligations under the contract and that any guarantee does not cover the Investment Entity's claim. Maximum credit risk exposure is equivalent to the book value of financial assets.

The credit risk in cash, cash equivalents and short-term investments is limited as the Investment Entity's counterparties are banks with high credit ratings.

### Assets exposed to credit risk

SEK 000	31 Dec 2018	31 Dec 2017
Loans receivable from portfolio companies	5,098	3,436
Other financial assets	80,030	40,596
Receivables from portfolio companies	473	611
Other current receivables	3,432	531
Short-term investments	69,949	150,329
Cash and cash equivalents	15,843	19,305
Maximum exposure to credit risk	174,825	214,808

#### Price risk

The Investment Entity is exposed to share price risk on the Investment Entity's holdings in portfolio companies measured at fair value (shares in associated companies, joint ventures and other long-term securities holdings). The Investment Entity otherwise is not exposed to valuation risk.

#### Interest risk

Interest risk is the risk that changes in market interest rates affect cash flow or the fair value of financial assets or liabilities. The Investment Entity's investment guideline is to invest in fixed income funds or interest-bearing instruments with low risk, because of which the risk associated with interest rate changes is low.

### Liquidity risk

Liquidity risk is the risk that the Investment Entity cannot meet its short-term payment obligations. The Investment Entity's guidelines state that the liquidity reserve must remain at such a level that it meets the Investment Entity's ongoing liquidity requirements and requirements for investments in portfolio companies for the following 12-month period. The convertible loan which falls due for payment on December 31, 2019 is disregarded from here since it requires a separate solution.

### 2018

SEK 000	Within 3 months	3-12 months	1-5 years	Over 5 years	Total
Convertible loan <sup>1</sup>	-	483,788	-	-	483,788
Short-term interest-bearing liabilities	-	50,000	-	-	50,000
Accounts payable	1,373	-	-	-	1,373
Other current liabilities	831	-	-	-	831
Total	2,204	533,788	0	0	535,992

1) See Note 13 Convertible loan

#### 2017

SEK 000	Within 3 months	3-12 months	1-5 years	Over 5 years	Total
Convertible loan	-	-	483,788	-	483,788
Accounts payable	1,155	-	-	-	1,155
Other short-term liabilities	1,627	-	-	-	1,627
Total	2,782	-	483,788	-	486,570

### Management of capital risks

The Investment Entity's capital management objective is to ensure the Investment Entity's capacity to continue operations, generate reasonable returns for shareholders and provide benefits to other stakeholders. The Investment Entity's policy is to minimize the risks in capital management. In accordance with the Investment Entity's investment guidelines, surplus liquidity is managed by an external manager. The portfolio will maintain an average term of no longer than 1.5 years and invest in fixed income funds or interest-bearing instruments. år och investeras i räntefonder eller räntebärande instrument.

## Note 18 Pledged assets and contingent liabilities

SEK 000	31 Dec 2018	31 Dec 2017
Pledged assets		
Right to earn-out payments for transferred Oncopeptides shares <sup>1</sup>	53,060	-
Contingent liabilities		
Investment commitment in portfolio companies	10,265	-
Total pledged assets	63,325	-

<sup>1)</sup> The right to earn-out payments for the divested shares in Athera and Lipidor are also pledge assets.

### **Endowment insurance**

Individual pension undertakings have been guaranteed in the form of Company-owned endowment insurance policies covering two former employees. The Investment Entity (which includes the Parent Company) has no further obligation to cover possible shortfalls in the endowment insurance or to pay any amount in excess of the premiums paid, due to which the Investment Entity considers these pension plans to be defined contribution pension plans. Accordingly, payment of premiums

corresponds to final settlement of the undertaking vis-à-vis the employee.

In accordance with IAS 19 and the regulations for defined contribution pension plans, the Investment Entity and the Parent Company therefore report neither assets nor liabilities, with the exception of special payroll contributions, related to these endowment insurance policies.

## Note 19 Related parties

### **Affiliates**

The Investment Entity has a related party relationship with its subsidiaries, joint ventures, associated companies and the companies in the Karolinska Institutet Holding AB Group.

Karolinska Development has a non-exclusive deal flow agreement with Karolinska Institutet Holding AB ("KIHAB") and Karolinska Institutet Innovations AB ("KIAB"), a wholly owned subsidiary of KIHAB, including inter alia, a new incubator fund with a focus on identifying potentially valuable new medical innovations at Karolinska Institutet at an early stage.

Furthermore, Karolinska Development has rendered services to the portfolio companies in the areas of management, communication, finance and administration, including legal and analytical operations. Fees for services rendered have been market based.

In November 2009 Karolinska Development and the European Investment Fund ("EIF") entered into an agreement whereby EIF invests in parallel with Karolinska Development in portfolio companies. The investments are made through KCIF Co-Investment KB ("KCIF"). KCIF invests in parallel with Karolinska Development at a ratio of 27:73 (KCIF: Karolinska Development) on the condition that certain stated investment criteria are fulfilled. The investors and limited partners in KCIF are EIF, which has committed EUR 12.9 million, and Karolinska Development, which has committed EUR 4.5 million. The amounts are

paid to KCIF as needed to make investments, to cover KCIF's expenses, and to pay an annual management fee to KCIF Fund Management AB ("FMAB"), a limited partner responsible for the operation of KCIF. The management fee for the financial year 2018 amounted to SEK 582 thousand (541).

FMAB is currently 75% owned by Karolinska Development and 25% by KIAB. The parties have entered into a shareholder agreement regarding FMAB.

### **Compensation and profit distribution**

FMAB is entitled to an annual management fee corresponding to 2.5% of the capital committed to KCIF during the investment period and 1% of invested capital thereafter. In practice, FMAB fulfills its obligations to manage the operations of KCIF by purchasing services from Karolinska Development according to a service agreement. The service agreement entitles Karolinska Development to annual compensation equivalent to what remains of the management fee after deducting FMAB's other expenses and a certain buffer for future expenses in FMAB. Any dividends from KCIF will essentially be distributed as follows. First, EIF and Karolinska Development will receive an amount corresponding to the portion of the committed capital paid to KCIF at the time of the dividend payment and annual interest of 6% on this amount. Secondly, 80% of the remaining funds will be distributed to EIF and Karolinska Development in proportion to their capital investment. The remaining 20% will be distributed to Karolinska Development on the condition that 25% of the amount is redistributed to KIAB and at least 37.5% is redistributed to the investment managers through Karolinska Development's profit-sharing program (which comprises only former

Through its ownership and managerial role, Karolinska Development has concluded that it controls FMAB and therefore considers FMAB to be a subsidiary. The indirect ownership in the portfolio companies through KCIF holding has been included in Karolinska Development's share of the portfolio companies, Note 33.

	2018			2017		
SEK 000	Sale of services	Interest income	Purchase of services	Sale of services	Interest income	Purchase of services
Associate relationship						
Owner: Karolinska Institutet Holding Group			957			1,151
(of which rental cost)			(935)			(1,028)
Portfolio companies	3,072	7,318	14	2,482	4,549	21
Total	3,072	7,318	971	2,482	4,549	1,172

	31 Dec	2018	31 Dec 2	31 Dec 2017	
SEK 000	Liability to associates	Receivable from associates	Liability to associates	Receivable from associates	
Associate relationship					
Karolinska Institutet Holding Group	7	-	186	-	
Portfolio companies	-	473	21	99,802	
Total	7	473	208	99,802	

## Note 20 Significant events after the closing date

### The portfolio companies

- Modus Therapeutics announced that patient enrolment for the phase II study of sevuparin in patients with sickle cell disease (SCD) has been completed. The results of the study are expected in mid-2019 (January 2019).
- Umecrine Cognition announced the analysed results of its phase IIa study of the GR3027 candidate drug in patients with idiopathic hypersomnia. The primary study objectives were met in regard to safety and pharmacokinetics. The study also showed preliminary evidence of clinical efficacy in a subset of patients. Umecrine Cognition will analyze the data further before a decision to potentially move forward with the development of GR3027 in idiopathic hypersomnia or other sleep disorders. In parallel, Umecrine Cognition will continue the clinical development in hepatic encephalopathy (January 2019).
- OssDsign announced the closing of a private placement of SEK 64 million. Swedish private investors and the French investment company Alto Invest took part in the private placement. OssDsign will now begin the process towards a listing on Nasdaq First North in 2019 (February 2019).
- Modus Therapeutics announced the successfully dosed first cohort in phase I study of subcutaneously administered sevuparin (February 2019).
- Aprea Therapeutics announced that a new investor, Janus Henderson Investors, joins Series C financing of the company, raising the total amount of the financing from EUR 50 million to EUR 55 million (February 2019).
- Forendo Pharma announced positive results from a Phase la study with the drug candidate FOR 6219 for the treatment of endometriosis. The results found FOR 6219 to be safe and well tolerated, with good pharmacokinetics at the doses tested (March 2019).
- Aprea Therapeutics announced that FDA received an Orphan Drug Designation for APR-246 for the treatment of patients with Myelodysplastic Syndromes (MDS) having a TP53 mutation. In addition, FDA has also granted Fast Track Designation to APR-246 for treatment of MDS (April 2019).

 Dilafor announced completion of a capital raising and plans to start a new Phase 2b study of tafoxiparin to soften the cervix prior to labor induction. The transaction will increase the value of Karolinska Development's holding in Dilafor and gives a positive effect on earnings by approximately SEK 16.8 million (April 2019).

## Note 21 Parent Company's accounting policies

### Parent Company's accounting policies

The Parent Company's annual report has been prepared in accordance with the Swedish Annual Accounts Act (1995:1554) and recommendation RFR 2 Accounting for Legal Entities from the Swedish Financial Reporting Board. Statements UFR 7 and 9 from the Swedish Financial Reporting Board have been applied as well. Application of RFR 2 means that the Parent Company will apply all EU-approved IFRS as far as possible within the framework of the Annual Accounts Act and the Pension Obligations Vesting Act and take into consideration the relationship between reporting and taxation. The policies described in Note 1 regarding the Investment Entity also apply to the Parent Company unless otherwise indicated below.

The following accounting policies for the Parent Company have been applied consistently to all periods presented in the Parent Company's financial statements.

#### **Subsidiaries**

Shares in subsidiaries are recognized at fair value through profit or loss in the Parent Company's financial statements.

### **Associated companies and joint ventures**

Shares in associated companies and joint ventures are recognized at fair value through profit or loss in the Parent Company's financial statements. Dividends are recognized as revenue when they are adopted by the Annual General Meeting.

### Other long-term securities holdings

Shares in other long-term securities holdings are recognized at  $% \left( 1\right) =\left( 1\right) \left( 1\right) +\left( 1\right) \left( 1\right) \left( 1\right) +\left( 1\right) \left( 1\right) \left( 1\right) \left( 1\right) +\left( 1\right) \left( 1\right)$ 

fair value through profit or loss in the Parent Company's financial statements.

### Change in fair value of shares in portfolio companies

The Company recognizes its holdings in subsidiaries, joint ventures, associated companies and other long-term securities holdings at fair value through profit or loss. If the value of a holding in subsidiaries, joint ventures, associated companies or other long-term securities holdings is lower or higher than its acquisition cost on the closing date, the holding is valued at fair value.

## Note 22 Information on the Parent Company

Karolinska Development AB (publ), Corporate Identity Number 556707-5048, is a Swedish limited liability company with its registered office in Solna.

Subsequent notes relate to the Parent Company.

### Note 23 Revenue distribution

SEK 000	2018	2017
Invocied services	3,073	2,464
Total revenue	3,073	2,464

# Note 24 Change in fair value of shares in portfolio companies

SEK 000	2018	2017
Change in fair value of shares in subsidiaries	0	0
Change in fair value of shares in joint ventures and associated companies	60,671	183,073
Change in fair value of other long-term securities holdings	-2,172	68,999
Total	58,499	252,072

# Note 25 Change in fair value of other financial assets

SEK 000	2018	2017
Change in fair value of other financial assets and liabilities	41,481	2,483
Total	41,481	2,483

## Note 26 Other external expenses

#### **Auditor fees**

SEK 000	2018	2017
EY		
Audit services	1,196	1,167
Audit related services	467	550
Tax consulting	211	234
Total	1,874	1,951

Auditor fees refer to the auditor's remuneration for the statutory audit. The work includes the examination of the annual report and accounting records, the administration by the Board and the CEO, and fees for auditing advice in connection with the audit assignment. Audit related services primarily relate to quality assurance services other than the statutory audit.

## Note 27 Operating leases

The Parent Company has chosen to finance premises and equipment through leases. Only operating leases have been signed. Expensed leasing payments and future contractual leasing payments are indicated below.

SEK 000	2018	2017
Expensed leasing payments during the period	714	1,086
Future leasing payments		
Within one year	729	713
Between one year and five years	745	2
Total future leasing payments	2,188	715

## Note 28 Employees and personnel costs

See Note 5 for further information.

### Average number of employees

		2018		2017		
Full-time equivalent	Number	Of whom women	Of whom men	Number	Of whom women	Of whom men
Parent Company	7	57%	43%	7	43%	57%
Total	7	57%	43%	7	43%	57%

### **Employee benefits**

SEK 000	2018	2017
Salaries and remuneration	13,839	18,377
Social security costs/payroll tax	5 049	4,424
Pension costs	2,438	2,203
Total	21,326	25,003

## Salaries and other remuneration distributed between Board members, etc. and other employees

	2018		2017		
SEK 000	Board and CEO	Other employees	Board and CEO	Other employees	
Salaries and remuneration	11,972	1,867	16,516	1,861	
Pension costs	1,527	911	1,813	390	
Total	13,212	2,778	18,329	2,251	

### Note 29 Interest income and similar income

SEK 000	2018	2017
Interest income	7,318	4,549
Total	7,318	4,549

## Note 30 Interest expenses and similar expenses

SEK 000	2018	2017
Interest expenses	-345	-1
Accrued interest convertibles	-49,119	-43,494
Change in value of short-term investments	-399	-243
Exchange rate losses	-238	-24
Other financial expenses	-750	-1702
Total	-50,851	-45,464

### Note 31 Taxes

SEK 000	%	2018	%	2017
Profit/loss before tax		30,510		179,595
Income tax expense calculated at applicable rate in the Parent Company	22.0%	-6,712	22.0%	-39,511
Tax effect of	22.070	0,7 12	22.070	07,011
Non-deductible expenses		-29		-2,130
Tax-exempt income		787		2,889
Issue costs		-		578
Fair value change, non-taxable		21,996		56,002
Increase in tax losses carried forward without corresponding capitalization of deferred tax		-16,041		-17,829
Recognized tax	0.0%	0	0.0%	0

## Unrecognized deferred tax assets

Deductible temporary differences and tax losses carried forward for which deferred tax assets have not been recognized through profit or loss or the balance sheet mainly refer to the deficits incurred in the Parent Company. Any future gains on the sale of business-related shares and participations in the portfolio companies are non-taxable profits. Deferred tax assets have not been recognized for these deficits as it is unlikely that Karolinska Development AB will be able to offset the amounts against future taxable profits, despite that there is no time limit on the tax losses carried forward. Unrecognized deferred tax assets for Karolinska Development as of 31 December 2018 amounted to SEK 154,352 thousand (SEK 143,549 thousand), and SEK 0 thousand (SEK 54,552 thousand) refers to the tax effect of deficits that are restricted by Group contributions and mergers.

## Note 32 Shares in subsidiaries

SEK 000	2018	2017
Accumulated book value		
At the beginning of the year	0	0
Sales during the year	-	-
Closing balance, book value	0	0

No investments in subsidiaries were made in 2018 or 2017.

### Specification of holdings in subsidiaries

	Total holding <sup>1</sup>			alue in Company
SEK 000	31 Dec 2018	31 Dec 2017	31 Dec 2018	31 Dec 2017
KCIF Fund Management AB	75.00%	37.50%	-	-
KD Incentive AB	100.00%	100.00%	-	_
Total book value			0	0

Including indirect ownership interest through portfolio company. Ownership interest corresponds to formal voting rights according to the participating interest. In addition, a shareholder agreement has been entered into in some cases giving Karolinska Development tontrolling interest.

# Note 33 Shares in joint ventures and associated companies

SEK 000	2018	2017
Accumulated book value		
At the beginning of the year	423,610	148,808
Investments during the year	124,556	91,729
Fair value measurement through profit or loss	60,671	183,073
Closing balance, book value	608,837	423,610

### Specification of holdings in joint ventures

	Total holding	Total holding Fully diluted <sup>1</sup>		Book value in Parent Company	
SEK 000	31 De	2018	31 Dec 2017	31 Dec 2018	31 Dec 2017
Karolinska Development portföljen		'	"		
Umecrine Cognition AB	74.48%	72.00%	58.40%	343,845	315,283
KDev Investments AB	88.18%²		87.75%	126,327	19,856
Aprea Therapeutics AB	11.69%	11.69%	19.54%	-	-
Asarina Pharma AB	1.10%	1.10%	2.48%	-	-
Biosergen AS	4.10%	4.10%	5.35%	-	-
Dilafor AB	38.87%	30.00%	35.25%	-	-
Modus Therapeutics Holding AB	62.76%	49.00%	72.61%	-	-
Modus Therapeutics AB	62.76%	49.00%	72.61%	-	-
Promimic AB	32.00%	32.00%	32.00%	-	-
Total book value				470,172	335,139

<sup>1)</sup> Ownership with full dilution according to current investment plans.

### Specification of holdings in associated companies

	Total holding Fully diluted <sup>1</sup>		Total holding	Book value in Parent Company	
SEK 000	31 Dec	2018	31 Dec 2017	31 Dec 2018	31 Dec 2017
Aprea Therapeutics AB	1.66%	1.66%	1.35%	31,220	6,868
Forendo Pharma Oy	11.13%	10.30%	15.53%	25,193	14,582
OssDsign AB	27.67%	26.50%	27.40%	70,944	59 479
KCIF Co-Investment Fund KB	26.00%		26.00%	11,308	7,542
Aprea Therapeutics AB	0.99%	0.99%	1.49%	-	-
Asarina Pharma AB	0.08%	0.08%	0.19.%	-	-
Forendo Pharma Oy	4.11%	3.00%	5.74%	-	-
OssDsign AB	4.25%	4.10%	5.47%	-	-
Total book value				138,665	88,471

<sup>1)</sup> Ownership with full dilution according to current investment plans.

<sup>2)</sup> Karolinska Development owns 88.18% (87.75%) of KDev Investments, which in turn owns the shares in the portfolio companies.

## **Notes**

Note 33 continued

### Investments in joint ventures and associated companies

SEK 000	2018	2017
Aprea Therapeutics AB	17,889	-
Forendo Pharma Oy	5,947	-
KCIF Co-Investment Fund KB	1,509	-
KDev Investments AB	72,768	22,896
OssDsign AB	9,866	23,595
Umecrine Cognition AB	16,577	45,238
Total investments in joint ventures		
and associated companies	124,556	91,729

### Non-cash investments in joint ventures and associated companies

SEK 000	2018	2017
Accrued interest		
OssDsign AB	1,823	692
Umecrine Cognition AB	5,497	3,855
Total non-cash investments	7,320	4,547

## Note 34 Other long-term securities holdings

SEK 000	2018	2017
Accumulated book value		
At the beginning of the year	24,173	600
Acquisition during the year	-	140
Divestments	-11,911	-45,566
Fair value measurement	-2,172	68,999
Closing balance, book value	10,090	24,173

### Specification of holdings in other long-term securities

	Total h	olding	Book value in Parent Company	
Name	31 Dec 2018	31 Dec 2017	31 Dec 2018	31 Dec 2017
BioArctic AB	0.00%	0.74%	-	14,083
Pharmanest AB	9.58%	9.58%	10,090	10,090
Total book value			10,090	24,173

### Non-cash investments in other long-term securities holdings

SEK 000	2018	2017
Fair value measurement	-2,172	68,999
Total non-cash investments	-2,172	68,999

Annual Report 2018 Karolinska Development

70

## Note 35 Parent Company's holdings in subsidiaries, joint ventures and associated companies

Company	Registered office	Corporate Identity Number	Number of shares	Equity, SEK 000	Profit/loss, SEK 000
Karolinska Development					
Aprea Therapeutics AB	Stockholm	556631-2285	176,812	545,925	-137,575
Forendo Pharma Oy	Turku	FI 2520329-3	1,343	68,475	-63,649
KD Incentive AB	Solna	556745-7675	100,000	149	-
KCIF Fund Management AB	Solna	556777-9219	75,000	220	-
OssDsign AB	Uppsala	556841-7546	187,682	40,712	-61,170
Umecrine Cognition AB	Umeå	556698-3655	9,145,186	6,230	-25,941
KCIF Co-Investment Fund KB	Solna	969744-8810	26	34,432	6,880
Aprea Therapeutics AB	Stockholm	556631-2285	105,052	545,925	-137,575
Asarina Pharma AB¹	Umeå	556698-0750	13,622	139,910	-44,025
Forendo Pharma Oy	Turku	FI 2520329-3	496	68,475	-63,649
OssDsign AB	Uppsala	556841-7546	28,824	40,712	-61,170
KDev Investments AB	Solna	556880-1608	1,770,330	453,356	94,240
Aprea Therapeutics AB	Stockholm	556631-2285	1,241,878	545,925	-137,575
Asarina Pharma AB¹	Umeå	556698-0750	176,423	139,910	-44,025
Biosergen AS	Trondheim	NO 687622075	4,506,669	5,625	-2,836
Dilafor AB	Stockholm	556642-1045	357,921	13,077	-30,033
Modus Therapeutics Holding AB	Stockholm	556851-9523	12,328,233	212,737	-4,905
Modus Therapeutics AB	Stockholm	556669-2199	100,000	17,646	-41,823
Promimic AB	Göteborg	556657-7754	252,392	17,222	-14,987

<sup>1)</sup> Listed on Nasdag Stockholm First North

# Note 36 Loans receivable from joint ventures and associated companies

SEK 000	31 Dec 2018	31 Dec 2017
Loans receivable from portfolio companies		
At the beginning of the year	3,436	957
Loans provided	1,620	25,347
Conversions	-	-22,896
Foreign exchange difference	42	28
Total	5,098	3,436

# Non-cash investments in loans receivable from joint ventures and associated companies

SEK 000	31 Dec 2018	31 Dec 2017
Loans provided (For 2017: included in investments in KDev Investments, Note 34)	-	22,896
Conversions	-	-22,896
Foreign exchange difference	42	28
Total non-cash investments	42	28

## Note 37 Other financial assets, non-current

SEK 000	31 Dec 2018	31 Dec 2017
Other financial assets, non-current		
Receivable Rosetta Capital	26,970	25,118
Receivable earn-out payment (classified as current in 2018)	-	15,478
Total	26,970	40,596

# Note 38 Other financial assets, current

SEK 000	31 Dec 2018	31 Dec 2017	
Other financial assets, current			
Receivable earn-out payment (classified as non-current in 2017)	53,060	-	
Total	53,060	-	

# Note 39 Other current receivables

SEK 000	31 Dec 2018	31 Dec 2017
Receivable European Investment Fund, EIF	2,795	
Tax assets	630	483
Other	7	48
Total	3,432	531

# Note 40 Prepaid expenses and accrued income

SEK 000	31 Dec 2018	31 Dec 2017
Prepaid rental expenses	-	186
Accrued interest income	23	50
Insurance premiums	184	198
Other	425	232
Total	632	666

# **Note 41** Proposed appropriation of profit

SEK 000	2018-12-31
Retained loss	-1,704,275,211
Share premium reserve	1,970,751,616
Net profit for the year	30,510,052
Total	296,986,457

The Board of Directors proposes that profits brought forward be appropriated as follows:

To be carried forward	296,986,457
Retained loss	-1,673,765,159
Share premium reserve	1,970,751,616

# **Note 42** Other financial liabilities

31 Dec 2018	31 Dec 2017	
11,423	4,807	
11,423	4,807	
	11,423	

# Note 43 Current interest-bearing liabilities

SEK 000	31 Dec 2018	31 Dec 2017
Short term loan debt	50,000	-
Total	50,000	0

# Note 44 Accrued expenses and prepaid income

SEK 000	31 Dec 2018	31 Dec 2017
Salaries and remuneration to personnel	3,031	5,079
Remuneration to Board of Directors	1,011	171
Auditor and consulting fees	402	585
Payroll tax and accrued pension costs	1,243	1,618
Social security costs	723	1,895
Other	37	15
Total	6,447	9,363

# Note 45 Related parties

### **Affiliates**

The Parent Company has a related party relationship with its subsidiaries, joint ventures, associated companies and the companies in the Karolinska Institutet Holding AB Group.

Karolinska Development has signed a deal flow agreement with KIAB and its parent company, KIHAB, one of Karolinska Development's largest shareholders, to ensure Karolinska Development's access to research projects through KIAB's flow of innovations from cutting-edge research at Karolinska Institutet and other academic institutions across the Nordic region. Furthermore, Karolinska Development has rendered services to portfolio companies on technical studies and administration. The fees for these services rendered are market based.

# **Notes**

Note 45 continued

	2018					
SEK 000	Sale of services	Interest income	Purchase of services	Sale of services	Interest income	Purchase of services
Associate relationship						
Karolinska Institutet Holding Group		-	957		-	1,151
(of which rental cost)			(935)			(1,028)
Subsidiaries	443		14	415	-	21
Joint ventures and associated companies	2,628	7,318	0	2,067	4,549	0
Total	3,072	7,318	971	2,482	4,549	1,172

	31 Dec 2018  Liability to Receivable associate from associate		31 Dec	2017
SEK 000			Liability to associate	Receivable from associate
Associate relationship				
Owner: Karolinska Institutet Holding Group	7	-	186	-
Subsidiaries	-	177	21	480
Joint ventures and associated companies	-	296	-	99,321
Total	7	473	208	99,802

# Annual Report 2018 Karolinska Development

73

# Signing of the annual financial statements

The Board of Directors and CEO hereby certify that the annual report has been prepared according to the Annual Accounts Act and RFR 2 and provides a true and fair view of the Company's financial position and results and that the administration report provides a true and fair overview of the Company's operations, financial position and results, and that it describes significant risks and uncertainties facing the Company. The Board of Directors and CEO hereby certify that the Investment Entity report has been prepared according to the International Financial Reporting Standards (IFRS), as adopted by the EU, and provides a true and fair overview of the Investment Entity's financial position and results, and that the administration report for the Investment Entity provides a true and fair overview of the Investment Entity's operations, financial position and results, and that it describes significant risks and uncertainties facing the Investment Entity.

The annual report and the Investment Entity report have been approved for presentation by the Board on 30 April 2019. The Investment Entity's and Parent Company's income statements and balance sheets will be presented for adoption by the Annual General Meeting of shareholders on 26 June 2019.

Hans Wigzell	Tse Ping	Vlad Artamonov
Chairman	Board member	Board member
Anders Härfstrand	Magnus Modée Persson	Theresa Tse
Board member	Board member	Board member

Viktor Drvota CEO

Our Auditor's Report was presented on 30 April 2019

Ernst & Young AB

Björn Ohlsson Authorized Public Accountant

# **Auditor's report**

# **Auditor's report**

To the general meeting of the shareholders of Karolinska Development AB (publ), corporate identity number 556707-5048

# Report on the annual accounts for the parent company and the financial statements for the investment entity

## **Opinions**

We have audited the annual accounts for the parent company and the financial statements for the investment entity of Karolinska Development AB (publ) for the year 2018. The annual accounts for the parent company and the financial statements for the investment entity are included on pages 26–73 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company as of 31 December 2018 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The financial statement for the investment entity have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the investment entity as of 31 December 2018 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and the financial statement.

We therefore recommend that the general meeting of shareholders adopts the income

statement and balance sheet for the parent company and the investment entity.
Our opinions in this report on the annual accounts for the parent company and the financial statement for the investment entity are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

# Considerable uncertainty relating to the going concern assumption

We want to draw attention to the board's information in the directors' report on page 30 and 34 and note 1 in the financial statement. which states that the cash equivalents as per December 31, 2018 is not sufficient to repay the outstanding credit facility and convertible loan which matures in November 2019 and December 2019. In the directors' report it is presented that the company is in need of additional financing in the next 12 month in order to finance the repayment of the convertible loan, the outstanding credit facility and secure the continued operation. Should sufficient financing not be obtained, there is a risk that the requirement for adopting going concern is not met. The Board of Directors has taken steps to ensure the business's need for financing and is in negotiations with the company's major convertible holder, including a proposal from the company for a conversion of the convertible loan.

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.

## **Basis for Opinions**

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the investment entity in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

# **Key Audit Matters**

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and financial statements of the current period. In addition to the matter described in the material uncertainty related to going concern section, we have determined the matters described below to be the key audit matters to be communicated in our report. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and financial statements as a whole, but we do not provide a separate opinion on

these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial statements.

# Valuation of shares in portfolio companies

## Description

Carrying value for shares in portfolio companies, amounted to 619 MSEK as per 31 December 2018, corresponding to 78 % of the Investment entity and parent entity's (hereafter collectively mentioned as Company) total assets.

The valuation of shares in portfolio companies is based on the International Private Equity, Venture Capital Valuation Guidelines (IPEV) and IFRS 13 Fair Value Measurement.

The Company has classified its shares in portfolio companies to fair value level 3 as defined

by IFRS 13, which means that fair value is based on models where significant data is based on non-observable data.

The process of valuation of unlisted shares in portfolio companies requires management assessment, changes in ownership strategy, the development of the portfolio companies and ownership shares have consequences for the method of valuing these shares and thus the carrying amount. As changes in these judgements affects the carrying amount, we have considered this as a particular important area in the audit.

# How our audit addressed this key audit matter

In our audit we have gained an understanding of the valuation process and the key controls in this process. We have verified the Company's ownership in the portfolio companies, reviewed internal models regarding calculation of fair value and tested that the methodology is in accordance

with the International Private Equity, Venture Capital Valuation Guidelines (IPEV) and IFRS 13 Fair Value Measurement.

Refer to note 1 on the page 45 and note 17 on page 61 for description and specification of accounting principles regarding valuation of portfolio companies.

# Other Information than the annual accounts for the parent company and the financial statement for the investment entity

This document also contains other information than the annual accounts and financial statement and is found on pages 1–25. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts for the parent company and the financial statement for the investment entity accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts for the parent company and the financial statement for the investment entity, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts for the parent company and the financial statement for the investment entity. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

# Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts for the parent company and the financial statement for the investment

entity and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the financial statements, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts for the parent company and the financial statement for the investment entity and that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts for the parent company and financial statement for the investment entity, The Board of Directors and the Managing Director are responsible for the assessment of the parent company's and the investment entity's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

# Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts for the parent company and the financial statement for the investment entity as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable

# **Auditor's report**

assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts for the parent company and the financial statement for the investment entity.

A further description of our responsibilities for the audit of the annual accounts for the parent company and the financial statement for the investment entity is located at Revisors-inspektionen's (the Swedish Inspectorate of Auditors) website at: http://www.revisorsinspektionen.se/rn/showdocument/documents/rev\_dok/revisors\_ansvar.pdf. This description forms part of our auditor's report.

# Report on other legal and regulatory requirements

### **Opinions**

In addition to our audit of the annual accounts for the parent company and the financial statement for the investment entity, we have also audited the administration of the Board of Directors and the Managing Director of Karolinska Development AB (publ) for the year 2018 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated (loss be dealt with) in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

# **Basis for opinions**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the investment entity in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

# Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the investment entity's type of operations, size and risks place on the size of the parent company's and the investment entity's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the investment entity's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

# Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board

of Directors or the Managing Director in any material respect:

Annual Report 2018
Karolinska Development

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

A further description of our responsibilities for the audit of the administration is located at Revisorsinspektionen's (the Swedish Inspectorate of Auditors) website at: http://www.revisorsinspektionen.se/rn/showdocument/documents/rev\_dok/revisors\_ansvar.pdf. This description forms part of our auditor's report.

Stockholm 30 April 2019 Ernst & Young AB

Björn Ohlsson Authorized Public Accountant

This Corporate Governance Report has been prepared in accordance with the Swedish Code of Corporate Governance and the Swedish Annual Accounts Act.

# Corporate Governance at Karolinska Development

# Application of the Swedish Code of Corporate Governance

Karolinska Development complies with the Swedish Code of Corporate Governance (the Code), without deviations.

## Information on the Company's website

On its website, the Company has a special section for corporate governance issues under the section Corporate Governance, https://www.karolinskadevelopment.com/en/corporate-governance

# **General meetings**

Under the Swedish Companies Act, the general meeting is the Company's highest decisionmaking body. The general meeting may resolve upon every issue for the Company, which is not specifically reserved for another company body's exclusive competence. At the annual general meeting, which shall be held within six months from the end of the financial year, shareholders exercise their voting rights on issues such as the adoption of income statements and balance sheets, appropriation of the Company's profits or losses, resolutions to release the members of the board of directors and the chief executive officer from liability for the preceding financial year, the appointment of members of the board of directors and auditor and remuneration for the board of directors and the auditor. Besides the annual general meeting, extraordinary general meetings may be convened. In accordance with the articles of association, all general meetings shall be convened through announcements in the Swedish Official Gazette (Sw. Post- och Inrikes Tidningar) and by posting the notice to the meeting on the Company's website. An announcement shall simultaneously be placed in Svenska Dagladet with information that the meeting has been convened. Minutes from the general meetings are published on

Karolinska Development's web page.

All shareholders who are directly registered in the share register kept by Euroclear five weekdays prior to the general meeting and who notify the Company of their intention to attend the general meeting at the latest by the date specified in the notice convening the meeting, shall be entitled to attend the general meeting and vote according to the number of shares they hold. Shareholders may attend general meetings in person or through a proxy and may also be accompanied by up to two assistants.

### Composition of the Board and functions, etc.

The board of directors is the highest decision making body after the general meeting. The board of directors' responsibility is regulated in the Swedish Companies Act, the Swedish Annual Accounts Act, the Company's articles of association, directions given by the general meeting and the procedure for the board of directors of the Company adopted by the board of directors. In addition, the board of directors shall comply with the Swedish Corporate Governance Code and Nasdaq Stockholm's Rule Book for Issuers, as well as other Swedish and foreign laws and regulations, as applicable.

Pursuant to the Swedish Companies Act, the board of directors is responsible for the Com-

pany's organization and the administration of the Company's affairs. Furthermore, the board of directors shall continuously assess the Company's and the group's financial situation, as well as see to that the Company's organization is formed in a way that the accounting, management of funds and the Company's financial conditions are controlled in a secure manner.

The assignments of the board of directors include, inter alia, to set objectives and strategies, see to that there are effective systems for follow-up and control of the Company's operations, and see to that there is a satisfactory control of the Company's compliance with laws and other regulations applicable to the Company's operations. The assignments of the board of directors also include to see to that required ethical guidelines are set for the Company's behavior and to see to that the Company's disclosure of information is characterized by transparency and is correct, relevant and reliable. In addition, the assignments of the board of directors include appointing, evaluating and if necessary, removing the chief executive officer.

Members of the board of directors are appointed annually by the annual general meeting for the period until the end of the next annual general meeting.

According to the Articles of Association, the Board shall consist of not less than three and not more than nine directors. Deputies shall not be appointed. At the Annual General Meeting 2018, six directors and no deputies were elected.

# Regulations regarding the appointment and dismissal of directors and amendments to the Articles of Association

The Articles of Association contain no special regulations regarding the appointment and

dismissal of directors and no special regulations regarding amendments to the Articles of Association

# Authorization to the Board to issue new shares or acquire its own shares

The Annual General Meeting on April 26, 2018 authorized the board of directors to issue on one or several occasions without pre-emption rights for the shareholders new shares of series B up to a maximum of ten percent of the share capital.

The Annual General Meeting also authorized the Board to decide on transfer of earlier acquired shares of series B amounting to 244,285, to cover social security fees in PSP 2015.

# Holdings of ten percent or more of the votes

There is one holding that represents more than one tenth of the voting rights for all shares in Karolinska Development, Karolinska Institutet Holding AB (the only holder of non-listed series A shares) with 22.01 percent of the votes (5.64 percent of the shares).

### The chief executive officer

The chief executive officer reports to the board of directors. The chief executive officer's responsibility is governed by the Swedish Companies Act, the Swedish Annual Accounts Act, the Company's articles of association, directions given by the general meeting, the instruction for the chief executive officer and other internal directions and guiding principles adopted by the board of directors. In addition, the chief executive officer shall comply with the Swedish Corporate Governance Code and Nasdaq Stockholm's Rule Book for Issuers, as well as other Swedish and foreign laws and regulations, as applicable.

According to the Swedish Companies Act,

the chief executive officer shall handle the day-to-day management pursuant to the board of directors' guidelines and instructions. In addition, the chief executive officer shall take any measures necessary in order for the Company's accounts to be maintained pursuant to law and that the management of funds is conducted in an appropriate manner. The division of work between the board of directors and the chief executive officer is described in the instruction for the chief executive officer.

The chief executive officer shall administrate the operative management and execute the resolutions passed by the board of directors. The chief executive officer shall control and supervise that the matters to be dealt with by the board of directors according to applicable legislation, the articles of association and internal instructions are presented to the board of directors, and shall continuously keep the chairman of the board of directors informed about the performance of the Company's operations, its earnings and financial position, as well as any other event, circumstances or condition that cannot be assumed to be irrelevant to the board of directors or the share-holders.

## **Nomination Committee**

The nomination committee shall carry out its duties in accordance with the Swedish Corporate Governance Code. The nomination committee's main duties are to propose candidates for the positions as chairman of the board of directors and other members of the board of directors, as well as propose fees and other remuneration to each members of the board of directors. The nomination committee is also to make proposals on the election of and remuneration to the auditor.

The five largest owners (as set forth in the

share register kept by Euroclear Sweden AB as of August 31, 2018) have a right each to appoint one member of the Nomination Committee for the Annual General Meeting 2018. The members of the Nomination Committee have elected the chairman among themselves. The Nomination Committee consists of Peter Lundkvist (Chairman) representing Tredje AP-fonden, Hans Möller representing KIHAB, Yan Cheng representing Sino Biopharmaceutical, Todd Plutsky representing Coastal Capital and Anders Bladh representing Ribbskottet AB.

If a member of the Nomination Committee resigns or is prevented from pursuing his/her assignment, the shareholder that has appointed such member shall appoint a new member. In the event that the shareholding in the Company is materially changed, before the Nomination Committee has completed its assignment, the Nomination Committee may decide to change the composition of the Nomination Committee, as determined by the Nomination Committee (considering the principles applicable for the appointment of the Nomination Committee). No fees shall be paid to the members of the Nomination Committee. Out of pocket expenses shall be reimbursed by the Company.

# **Board of Directors**

# **Composition of the Board**

The Company's Board consists of six directors, Hans Wigzell (Chairman), Tse Ping (vice Chairman), Vlad Artamonov, Anders Härfstrand, Magnus Persson and Theresa Tse. None of the directors is employed by the company.

Information on remuneration to Board as determined by the Annual General Meeting, can be found in the annual report under the note 5 "Employees and costs for employees".

## **Elected directors**

Hans Wigzell. Chairman since 2018 Board member since 2006. Born 1938. Professor Emeritus of Immunology and MD. Other appointments Chairman of Rhenman & Partner Asset Management AB. Board member of Sarepta Therapeutics Inc. and RaySearch Laboratories AB. Member of The Royal Swedish Academy of Engineering Sciences and of the Royal Swedish Achademy of Sciences. Previous assignments include, among others, the President of Karolinska Institutet's Nobel Committee. and President of Karolinska Institutet and Director General of Smittskyddsinstitutet, Holdings in Karolinska Development 36.491 shares and SEK 39.992 convertible loan.

**Tse Ping.** Vice Chairman and Board member since 2015, Born 1952. Honorary Doctorate, Fil Dr hc. Other appointments Founder and CEO of Sino Biopharmaceutical Limited, Chairman and executive director of Hong Kong listed Lamtex Holdings Ltd, Vice Chairman of Charoen Pokphand Group (CP Group), where he has extensive experience of major merger and acquisition activity including Ping An Insurance, CITIC Group, China Mobile, ITO-CHU Corporation, and Marko Group. Previous appointments

include Member of the Ninth, Tenth, and Eleventh National Committee of the Chinese People's Political Consultative Conference. Holdings in Karolinska Development 4,853,141 shares and SEK 272,858,294 in convertible bonds (by related legal person).

Viad Artamonov. Board member since 2012. Born 1978. MBA, B.Sc. Other appointments Board Member of Redbank Energy Ltd. and of Coastal Capital International Ltd., Managing Partner at Coastal Capital International Ltd. Previous appointments include Investment Analyst at Greenlight Capital Inc., position in the Global Merger & Acquisition Group at Merrill Lynch in New York. Holdings in Karolinska Development 3,470,541 shares (by related legal person).

Anders Härfstrand. Board member since 2017. Born 1956. MD, PhD. Other assignments; Chairman of Härfstrand Consulting, Board member Prothena Plc. Earlier assignments; Chief Executive Officer of BBB Therapeutics BV, President and Chief Executive Officer Europe of Makhteshim Agan Industries Ltd; President and Chief Executive Officer of Humabs BioMed SA; Chief Executive Officer of Nitec Pharma AG, Various executive and management roles at Serono,

Pfizer and Pharmacia. No holdings in Karolinska Development.

Magnus Persson. Board member since 2017. Born 1960. MD PhD Assoc Prof. Educated at Karolinska Institutet, Previous assignments CEO Karolinska Institutet Holding AB, Managing Partner The Column Group, Partner HealthCap, Clinical Research Physician Sanofi. Current board assignments include Galecto Biotech AS (Chairman), SLS Invest AB (Chairman) Health Innovation Platform AB (Chairman), Cantargia AB (Chairman), Inititator Pharma (Chairman), Albumedix AS, Immunicum AB and Medical Prognosis Institute AS. No holdings in Karolinska Development.

Theresa Tse. Board Member since 2017, Born 1992, Bachelor Degree of Science in Economics from the Wharton School of University of Pennsylvania. Other appointments, Executive Director, the Chairlady of the Board and the Chairlady of the **Executive Board Committee** and the Nomination Committee. respectively, of Sino Biopharmaceutical Ltd (listed in Hong Kong). Holdings in Karolinska Development 4,853,141 shares and SEK 272.858.294 in convertible bonds (by related legal person).

## **Independence requirements**

The table below shows which elected directors are considered independent in relation to the Company and its management as well as in relation to the Company's major shareholders, as definitions in the Code.

			Indepen	dent of:		
Name	Function	Elected	Company/ Mgmt.	Major holders		
Hans Wigzell	Chairman	2006	yes	yes		
Tse Ping	director	2015	yes	yes		
Vlad Artamonov	director	2012	yes	yes		
Anders Härfstrand	director	2017	yes	yes		
Magnus Persson	director	2017	yes	yes		
Teresa Tse	director	2017	ves	ves		

A major holder means a holder controlling, directly or indirectly, at least ten per cent of the shares or votes.

The Company meets the Code requirement that a majority of the elected directors must be independent in relation to the Company and its management, and that a minimum of two of these must be independent in relation to major shareholders.

### The Board's work etc.

According to the Rules of procedure, the Board shall normally meet six times per year. During 2018 the Board held 15 meetings, of which 4 meetings were per capsulam. Of the other 11 meetings Hans Wigzell attended 11, Tse Ping 1, Anders Härfstrand 11, Magnus Person 11, Vlad Artamonov 10 and Theresa Tse 2.

The General Counsel of the company, Ulf Richenberg is the secretary at the board meetings.

The Board annually adopts rules of procedure, an instruction on the delegation of work between the Board and the CEO, and an instruction on financial reporting to the Board.

The Board also adopts policies, which constitute a foundation for the Company's internal control systems. These are the Information and Insider Policy, IT Security Policy, Gender Equality Policy, Environmental Policy, HR Policy, Ethics Policy, Investment Policy and Dividend Policy.

The board evaluation of the board work has been conducted through a questionnaire distributed to all directors. The aggregated result of the questionnaire has been distributed to the directors and been subject to internal discussion. The full result of the evaluation has been submitted to the Nomination Committee.

The board has three committees, an Audit Committee, a Remuneration Committee and an Investment Committee.

#### **Audit Committee**

Karolinska Development's Audit Committee consists of three members: Hans Wigzell (Chairman), Magnus Persson and Vlad Artamonov, each being independent in relation to the Company's major shareholders and in relation to the Company and its management.

The audit committee shall, without any other

impact on the tasks and responsibilities of the board of directors:

- monitor the Company's financial reporting;
- in respect of the financial reporting, monitor the effectiveness of the Company's internal control, internal audit, and risk management;
- remain informed regarding the auditing of the group reporting and financial statements;
- inform the board about the result of the audit and about how the audit contributed to the accuracy of the financial reporting and about the function of the Audit Committee;
- review and monitor the impartiality and independence of the auditor, and in that respect, pay particular attention to non-audit services provided by the auditor; and
- assist in the preparation of proposals to the annual general meeting's resolution regarding election of auditor.

The Audit Committee met 5 times during 2018. Hans Wigzell attended 5, Magnus Persson 5 and Vlad Artamonov 4.

### **Remuneration Committee**

Karolinska Development's Remuneration Committee consists of three members: Hans Wigzell (Chairman), Anders Härfstrand and Vlad Artamonov, each being independent in relation to the Company and its management.

The remunerations committee's main tasks are to:

- prepare the board of directors' decisions on issues concerning principles for salary, remuneration and other terms of employment for the executive management;
- monitor and evaluate programs for variable remuneration for the executive manage-

- ment, both ongoing and those terminated during the year; and
- monitor and evaluate the application of the guidelines for remuneration to the management that the annual general meeting is legally obliged to decide on, as well as the current remuneration structures and levels in the Company.

The Remuneration Committee met 6 times during 2018, of which 4 where per capsulam. All members participated in the remaining 2 meetings.

### **Investment Committee**

Karolinska Development's Investment Committee consists of three members: Hans Wigzell (chairman), Magnus Person and Anders Härfstrand.

The main tasks of the Investment Committee are to prepare and analyze investment proposals and submit recommendations to the Board of Directors.

The Investment Committee met 7 times during 2018 of which 2 where per capsulam. All members attended the remaining 5 meetings.

## **Chief Executive Officer**

Viktor Drvota. Appointed as CEO on June 1, 2017, and previously CIO since 2016. Born 1965 M.D, Ph.D. Associate Prof. In Cardiology. Viktor Drvota has over 16 years of Venture Capital experience with several investments, significant fundraisings, IPOs and exits. He was responsible for Life science at SEB Venture Capital 2002 –2016. During his appointment at SEB VC he also served as a Board member in several biotech and Medtech companies such as Arexis AB, SBL Vaccin AB, Nuevolution AS, Index Pharma AB.

Scibase AB, Airsonett AB among others. Before joining SEB, Dr Drvota worked as Senior Consultant and Associate Professor in Cardiology at the Karolinska Institutet/hospital, Stockholm. Dr Drvota has experience from preclinical as well as clinical research in drug development and medical devices. Dr Drvota has 29 published research

articles. Holdings in Karolinska Development:

24,000 shares, 1,608,418 warrants.

# The main components of the Company's system for internal control and risk management in relation to financial reporting

# Internal control and risk management at Karolinska Development

Internal control is designed to provide reasonable assurance as to the reliability of external financial reporting and compliance with the law, generally accepted accounting principles and rules for listed companies.

The key elements of the Company's system for internal control and risk management related to financial reporting are presented below. The Company's internal control comprises mainly the areas of Control Environment, Risk Assessment, Control Activities, Communications and Monitoring.

Control environment. The control environment constitutes the basis for the internal control. Karolinska Development has a flat organizational structure with a clear division of responsibilities and rights. There is an established system of governing documents in the form of Policies adopted by the board and Instructions adopted by the CEO. Within the framework of overarching policies, they govern decisions, au-

thorization and processes involving purchases, payments and investments. Among these documents, the Valuation Guidelines, governing methods and processes for valuation of the portfolio, should be mentioned. The documentation is centrally accessible to all employees through the Company's internal IT network. The Company has employed personnel responsible for controlling and legal functions, who jointly work towards a well-functioning control environment as one of their specifically stated goals. These governing documents form the basis for how transactions should be handled, recorded and reported.

Risk assessment. The Company works continuously with a structured risk assessment with regard to issues which have an impact on the Company's financial position and result. Special attention is paid to the risk of irregularities and favoritism at the Company's expense. Risk assessment includes inter alia: (i) the existence, at a given date, of an asset or liability, (ii) that a business transaction or an event has occurred during the period and relates to the Company, (iii) that there are no assets, liabilities or business transactions which are not recorded or items for which the necessary information is missing, (iv) that each asset and liability is recorded and valued in accordance with law, generally accepted accounting principles and internal valuation rules; (v) that the business transactions are recorded at the correct amount and that profit and expenses are attributable to the correct period, (vi) that an asset or liability relates to the Company on a specified date and, (vii) that an item is classified and described in accordance with law, generally accepted accounting principles and listing rules.

Control Activities. The financial reporting is subject to control activities aimed at preventing, detecting and correcting errors and discrepancies. These consist of a specified allocation of work, documented and clearly described rules for how business transactions are to be approved as well as their traceability, the application of accounting and valuation principles, analytical monitoring, account reconciliation, monitoring of agreements, board resolutions, policies and certification procedures.

As relates to the portfolio, regular follow-ups are made of planned and implemented investments in terms of whether the companies have met the stipulated targets for further investments. Furthermore, evaluations are made, and priorities set among the companies' projects. Scientific results and business opportunities are both monitored. This is done continuously both in regularly meetings in the R&D Team and in regularly management meetings.

There is also a monthly analysis of how different activities in portfolio companies affect the valuation of these in the parent company and the consolidated financial statements. Valuation effects are reported to and finally approved by the CFO and the CEO.

**Communications.** The internal financial reporting complies with stipulated reporting plans. The Company's rules of procedure and the instruction on reporting to the Board include detailed descriptions as to when and what should be reported to and handled by the Board. The Company's CFO, with the support of controllers, is responsible for the financial reporting to the Board, which includes information on the Company's results and financial

position. Reporting plans are aimed at ensuring complete, accurate and timely information to the Company's management and the Board.

The Company has quite few employees, all active at the same workplace. Aside from the above-mentioned Management Meetings, regular information meetings are held, which enables quick and accurate internal communication and information.

Monitoring. Internal rules on internal control and risk management are updated at least annually and when necessary. Assessment of compliance is performed on a detailed level. The Audit Committee meets prior to Board meetings where interim reports are to be discussed. The auditors are present at the meetings of the Audit Committee and meet annually with the directors without anyone from management present.

# Specific assessment of the need for internal audit

Karolinska Development has no internal audit function. The Board is of the opinion that there is no need for an internal audit function at present. The reasons are that the Company has relatively few employees, its business is established in only one location, the majority of significant transactions are similar in character and relatively straightforward, and there is a clear internal accountability within the Company.

Solna, February 2019

Board of Directors of Karolinska Development AB

# Auditor's report on the corporate governance statement

To the general meeting of the shareholders of Karolinska Development AB (publ), org nr 556707-5048

# **Engagement and responsibility**

It is the Board of Directors who is responsible for the corporate governance statement for the year 2018 on pages 77–80 and that it has been prepared in accordance with the Annual Accounts Act.

# The scope of the audit

Our examination has been conducted in accordance with FAR's auditing standard RevU 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

# **Opinions**

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2–6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Stockholm April 30, 2019 Ernst & Young AB

Björn Ohlsson Authorized Public Accountant Annual Report 2018 Karolinska Development

81

## **Definitions of Key Terms**

### After-tax earnings per share

Profit/loss after tax attributable to the Parent Company's shareholders divided by the weighted average number of shares before and after dilution

### Equity per share

Equity divided by the number of shares outstanding at year-end

# Net Portfolio Fair Value (after potential distribution to Rosetta Capital)

The net aggregated proceeds that Karolinska Development will receive after KDev Investments' distribution of proceed to Rosetta Capital

### **Alternative Performance Measures**

The Company presents certain financial measures in the annual 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 operating in life science and are wholly or partially owned by Karolinska Development.

### 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 year-end.

## Capital employed

Total equity and interest-bearing liabilities

### Equity to total assets ratio

Equity divided by total assets

# Net asset value and net asset value per share

Net Portfolio Fair Value of the total portfolio (SEK 618.9 million), loans receivable from portfolio companies (SEK 5.1 million), short-term investments (SEK 70.0 million), cash and cash equivalents (SEK 15.8 million), and the net of financial assets and financial liabilities less interest-bearing liabilities (SEK 68.9 million minus SEK 478.3 million). Net asset value per share: the net asset value in relation to the number of shares outstanding, excluded repurchased shares (64 174 452) on the closing date (31 December 2018).

### Return on equity

Profit/loss after financial items divided by equity.

### Return on capital employed

Profit/loss after financial items divided by capital employed.

# Other definitions

# Deal flow agreement

Agreement between Karolinska Development and KIAB aiming to grant Karolinska Development access to research projects through KIABs evaluation of innovations from research Karolinska Institutet.

### Fair value

The NASDAQ Stockholm regulations for issuers require companies listed on NASDAQ Stockholm to apply the International Financial Reporting Standards, IFRS, in their consolidated financial statements. The application of the standards allows groups of an investment company nature to apply so-called fair value in the calculation of the carrying amount of certain assets. These calculations are made on the basis of established principles and are not included in the opening accounts of the Group's legal entity, nor do they affect cash flows.

Karolinska Development applies the accounting principles of fair value according to the International Private Equity and Venture Capital Valuation Guidelines and adheres to the guidance of 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. If there is no valuation available based on a similar transaction, risk adjusted net present value (rNPV) calculations are made of the portfolio companies whose projects are suitable for this type of calculation. In other cases, Karolinska Development's total investment is used as the best estimation of fair value. In one other case, the valuation at the time of the last capital contribution is used.

The part of the Fair Value that is related to the value of Karolinska Development's portfolio companies is named Portfolio Fair Value or Fair Value of the portfolio. The calculation of the Portfolio Fair Value is based on IFRS 13 standards of deciding and reporting fair value and the International Private Equity and

Venture Capital Valuation Guidelines (IPEV Valuation Guidelines) decided by the IPEV board that represent the current best practice, on the valuation of private equity investments.

The Portfolio Fair Value is divided into *Total Portfolio Fair Value* and *Net Portfolio Fair Value* (after potential distribution to Rosetta Capital).

### Karolinska Development

Karolinska Development AB (publ.), Corporate Identity Number 556707-5048

#### Karolinska Institutet

Karolinska Institutet, Corporate Identity Number 202100-2973

Karolinska Institutet is one of the world's leading medical universities and awards the Nobel Prize in Physiology or Medicine.

### KIAB

Karolinska Institutet Innovations AB, Corporate Identity Number 556528-3909
KIAB, which is owned (indirectly via KIHAB) by Karolinska Institutet, identifies projects with high commercial potential at an early stage by actively seeking new ideas from Karolinska Institutet and other Nordic universities. KIAB leads and also finances the project development in early phases, where the objective is to establish a licensing agreement or a start-up company.

#### **KIHAB**

Karolinska Institutet Holding AB, Corporate Identity Number 556525-6053
KIHAB is owned by Karolinska Institutet. KIHAB is the Parent Company of a group of five wholly owned subsidiaries, including Karolinska Institutet Innovations AB (KIAB).

# **Glossary**

### Amino acids

Amino acids are the chemical building blocks that can be combined in chains, or sequences, to form proteins and peptides.

### CNS

Central Nervous System (CNS), including the brain and spinal cord

## Double-blind (study)

A double-blind study is one in which both the subject and investigator are unaware of the assigned treatment.

## Chemotherapy

See Cytotoxics.

### Cohort (in medical research)

A group of individuals with defined characteristics who are followed for a period of time to examine the effect of one or several exposures.

## Complete remission (CR)

Disappearance of all clinical evidence of disease in response to treatment.

### Cytotoxics

Pharmaceuticals that target fast growing cells, for example cancer cells. These compounds usually work by halting the cell division process. The treatment with cytotoxics is referred to as chemotherapy.

## Overall Response Rate (ORR)

The proportion of patients who respond to treatment.

## Orphan disease

A rare disease that affects a small percentage of the population.

## Programmed cell death

A suicide mechanism a cell may go through if it is somehow damaged.

### **Proof of Mechanism**

Relates to early clinical development and typically refers to the demonstration of a drug candidate's mechanism by, for instance, showing that the drug reaches the target organ, interacts with the intended molecules, and affects cell biochemistry and biology in the desired direction.

### Protein

Large molecules built from sequences of amino acids. Proteins are used in many different ways in an organism; they provide structure for cells and tissues, they catalyze chemical reactions in the form of enzymes and they are involved in the signalling in and between cells.

# Randomized (study)

A study in which the trial participants are randomly allocated into two or more treatment groups that are prescribed a specific treatment or placebo.

### Receptor

A large molecule, usually a protein, which is attached to cell membranes and binds to a target molecule. The target molecule can be a hormone that has a certain effect on the cell to which it binds to.

### **Steroids**

Type of organic molecules that among other things include natural hormones.

# Publication dates for financial information

Interim Report January - March 2019 Interim Report January - June 2019 Interim Report January - September 2019 Year-end Report January - December 2019 Annual Report 2019 21 May 2019 21 August 2019 7 November 2019 February 2020 March 2020



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