# KAROLINSKA DEVELOPMENT



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Karolinska Development's mission is to create value for researchers, patients, society, and investors through the development of new innovative treatments by:

- investing in companies that develop specialty care products and orphan drugs for patients suffering from life-threatening or serious debilitating conditions where there exist well-defined unmet medical needs;
- incentivize and empower strong leadership and accountability in our strategic portfolio companies with a focus on clinical development, raising capital and business development towards significant value inflection points;
- proactively seeking syndication with other professional investors within the life science sector to further expand the company's access to capital, expertise, network and new innovations; and
- applying an investment strategy, where the investments in existing and future portfolio companies are gated and linked to achievement of well-defined value inflection points to reach an exit which is optimal for each portfolio company.

# Key events in 2014 and the start of 2015

#### **Karolinska Development**

#### **NEW STRATEGY**

Karolinska Development's new strategy includes focus on the strategic portfolio, clear emphasis on leadership in the portfolio companies, proactively syndicating investments and an investment strategy based on the portfolio companies' treatments under development, unique properties and possibilities.

#### **SEK 450 MILLION FINANCING FINALIZED**

A SEK 63 million directed share issue to Thai Charoen Pokphand Group (CP Group) was followed by a general meeting decision to issue two convertible loans.

In February 2015, a directed issue of convertibles of nominally approximately SEK 173 million to CP Group and rights issue of convertibles of nominally approximately SEK 214 million was completed.

#### **CHANGES IN BOARD AND MANAGEMENT**

Jim Van heusden was appointed new CEO in March 2015 with a strong background in venture capital and pharmaceutical research and development.

Three new Board Members with venture capital and medical research backgrounds were elected at the General Meeting in April 2014 – Robert Holland, Henrijette Richter and Carl Johan Sundberg.

Christian Tange was appointed new CFO in April 2014.

#### The Portfolio Companies

# LICENSE AGREEMENT AND FINANCING IN FORENDO PHARMA

Forendo out-licensed the US rights for fispemifene to Apricus Biosciences. In the agreement, Forendo received an upfront payment of USD 5 million, shares in Apricus and rights to milestone payments of up to USD 305 million and royalties on sales.

Forendo also finalized a EUR 12 million financing for the company's endometriosis program. Experienced life science investors Novartis Venture Fund, MS Ventures and Novo Seeds joined the new financing round, alongside the existing investors Karolinska Development, Novo Seeds and Finnvera.

#### **CLINICAL STUDIES INITIATED**

Aprea initiated dosing in a Phase I/II proof-of-concept clinical trial of APR-246 in combination with chemotherapy in patients that have relapsed with platinum-sensitive high-grade ovarian cancer.

Athera Biotechnologies started a Phase I clinical trial with fully human antibody PC-mAb for the use in acute coronary disease.

#### **REGULATORY PROGRESS**

OssDsign received 510(k) marketing approval in the US for Cranioplug – a follow-up product to Craniomosaic which is now being marketed in several European countries.

Clanotech, Aprea and Dilaforette all received Orphan Drug Designation by the EMA for their respective leading product candidate. Dilaforette and Clanotech also received Orphan Drug Designation designation by the US FDA.

#### **AGREEMENTS**

Dilafor entered into a license and partnership agreement with Lee's Pharmaceutical Holdings Ltd. for the development and commercialization of tafoxiparin for obstetrics and gynecological indications in China, Hong Kong, Macau, and Taiwan.

NovaSAID entered into a collaboration with Cadila Pharmaceuticals to develop new treatments for inflammation and pain in conditions such as rheumatoid arthritis.

Boehringer Ingelheim International decided not to exercise its option agreement to license Athera Biotechnologies' cardiovascular antibody due to re-evaluation of its strategy.

Dilaforette entered into a co-development agreement with Ergomed for the Phase II clinical development of sevuparin in patients with sickle-cell disease.

#### **CLINICAL RESULTS**

XSpray reported positive Phase I data for HyNap™ nilotinib, a reformulation of an established drug treatment for chronic leukemia.

Data from an exploratory study indicates that Pharmanest's pain relief SHACT may be used in women undergoing hysteroscopies.

Umecrine Mood presented data from its exploratory Phase I/II study with the company's drug candidate UC1010 in premenstrual dysphoric disorder. The study did not reach its primary end-point but generated important data for the continued development.

Dilaforette announced the results from an exploratory Phase I/II clinical trial in malaria with its candidate drug sevuparin. The study did not reach its primary end-point in uncomplicated malaria. However, sevuparin showed a good safety profile and important anti-adhesive effects were observed which warrants further development in Sickle Cell Disease.

# Message from the Chairman

During 2014, the Karolinska Development Board of Directors initiated far-reaching changes in the company's strategy as a consequence of the development of the company since the IPO. The need to revise how the company operates was evident. Now, the company is clearly oriented and to be set up as an investment vehicle. We therefore empower the portfolio companies with an independent leadership to finance and develop the projects towards well-defined value inflection points, and to find investors and/or industrial partners. Also, we seek syndication of our investments with other specialized investors, and we focus the investments in our mature, strategic portfolio to achieve optimal returns for each asset.

While the way the company operates moving forward into 2015 and beyond will be different from the previous years, the hard work that have laid the foundation for the portfolio and the innovations we have invested in, is now also starting to show results.

# Financing completed to implement the investment strategy

The financing completed in the first months of 2015 generated proceeds of approximately SEK 450 million. The SEK 63 million directed share issue to Thai Charoen Pokphand Group (CP Group) was followed by a rights issue of convertibles of nominally SEK 214 million and a directed issue of convertibles of SEK 173 million to CP Group. Karolinska Development now has the capital to execute on the new strategy while also securing a partnership with a major Asian life science investor.



#### Our Vision

Our vision for the future, our guiding star, is to offer a differentiated investment strategy through thorough selection of the best innovations from highly reputed academic institutions and biotech companies, and to manage those investments through strict project management and tangible, scientific and value creating milestone financing. We will focus our investments on the development of differentiated treatments for patients suffering from life-threatening or serious debilitating conditions where there exist a clear unmet medical need. Karolinska Development will engage actively in our existing and future portfolio companies and work with founders and management to shape the strategic direction of these companies towards well defined value inflection points. To assist us in achieving that, we will continuously seek to expand on a syndicate of sophisticated life science investors. Jointly, we will engage in the value creating developments with a view to create significant equity returns over the medium to long term. We are aware that value progression in the early stage of an investment cycle is modest. However, as the strategic portfolio companies assets mature there is likely a material value uplift, particularly if this can be unlocked through liquidity events.

#### Engaging the new strategy

Karolinska Development is advanced with the implementation of the new strategy. We have identified companies for our strategic portfolio that will be the main focus of our investments together with specialized, international, life science investors. The syndicate that jointly financed Forendo's endometriosis programme is an example of this. The investment strategy is based on each asset's optimal exit point and we are closely monitoring the unique properties of the portfolio companies' treatments under development and their environment to ensure future returns on our investments.

We will also continue to strengthen the leadership in the portfolio companies. This is achieved by additions to companies' management of serial entrepreneurs, and to bring in highly experienced life science professionals as independent board members and advisors into the portfolio companies. Karolinska Development has an important mission to continuously expand the professional network to ensure optimal performance of the investment entity and the portfolio. With Jim Van heusden's vast experience in biotech, pharmaceutical and medtech development, and a long successful background from venture capital, I am confident that Karolinska Development under Jim's leadership will develop successfully.

While we leave a year behind us with multiple challenges in Karolinska Development, we also experienced many positive events that will help trigger further important future milestones in respect of creating value for developing differentiated treatments for patients with unmet medical needs and for our investment community.

Bo Jesper Hansen, MD, PhD, Chairman of the Board

# Message from the CEO

During 2014 a new strategy was defined to transform Karolinska Development into an investment company dedicated exclusively to life sciences. The four cornerstones in this new strategy include: i) a clear focus within the portfolio, ii) an increased emphasis on leadership within our portfolio companies, both on the management as well as board level, iii) proactively syndicating our investments with experienced international life sciences investors and iv) an investment strategy based on each portfolio company's unique possibility to generate attractive returns.

While realizing that 2014 was a difficult year for Karolinska Development in many aspects, it is also very inspiring to see the top-notch high-quality science coming from Karolinska Institutet, which provides a strong basis to create and build new companies to bring high-quality science and new innovative treatments to patients, thereby creating value for all our stakeholders.

We will now focus on the implementation of the new strategy by further refining our investment focus, and strengthening our organisational structure and team.

#### Clear mission for 2015

A clear focus within the existing portfolio and attracting new investments from experienced international life sciences co-investors is an important priority for us now. The divestment of Axelar that was announced in March 2015 is a first step in the implementation of the new strategy. This enables a redistribution of resources to our core strategic portfolio, thereby building long term value for our shareholders.

It is also clear that we need to attract new co-investors to our strategic portfolio companies while exploring alternative funding for our opportunistic portfolio companies where needed.

Forendo Pharma's recent fundraising, thereby broadening the investor syndicate with several highly experienced life sciences investors alongside Karolinska Development is a good example of our new investment strategy.

Further focus will be on increasing the leadership within our portfolio companies, both on the management as well as board level, to ensure that our portfolio companies focus on value creating milestones with the over-arching goal to achieve successful exits with attractive returns for our shareholders.

The new focus will not guarantee immediate success but will form a solid basis to align our most important assets towards valuable exits. The Karolinska Development team's dedication to the new investment strategy will contribute to a clearer investment process that will be more transparent to our stakeholders.

#### Upcoming clinical development in the portfolio

During 2015, we have much to look forward to in terms of further clinical progress within our portfolio. Dilaforette will initiate a Phase II clinical proof-of-concept trial with sevuparin for the treatment of sickle-cell disease patients during the second quarter this year. The study will investigate sevuparin's ability to reduce pain and hospitalization among patients suffering from vaso-occlusive crises, where today there is a clear lack of treatment alternatives. Aprea's dose escalation trial in ovarian cancer patients is expected to progress into a Phase II trial during the first half of 2015. Aprea's lead candidate APR-246 will be administered in combination with chemotherapy to explore the potential of APR-246 to improve treatment regimens for relapsed patients. Furthermore, the preclinical programs in Forendo, Clanotech, and Umecrine Cognition are expected to progress into first in man clinical studies during 2015 and Akinion

will restart their clinical program with AKN-028 in acute myeloid leukemia. OssDsign is another company with exciting development ahead. Its lead products, Craniomosaic – a patient-specific implant for severe cases where cranioplasty is required – is being introduced to new European markets in 2015. In addition, OssDsign are planning for several follow-up products, including Cranioplug that has received marketing approval by the US FDA and further market expansion into personalized facial reconstruction surgery implants.

#### A portfolio focused on unmet medical needs

Karolinska Development's investment strategy is focused on innovative treatments that address unmet medical needs. We are pleased to note that Clanotech in glaucoma surgery with CLT-28643, Aprea in ovarian cancer with APR-46, and Dilaforette in sickle-cell disease with sevuparin all have received orphan drug designation for Europe by EMA. Dilaforette and Clanotech also recently received orphan drug designation from the US FDA.

Our mission is to bring high-quality science and new innovative treatments to patients, thereby creating value for all our stakeholders. As a dedicated life sciences investor our aim is to identify the most promising innovations from academia and the biotech sector using stringent investment criteria and together with strong investor syndicates. This leverages the high risks involved in this sector, but also allocates financial resources and know-how into therapeutic approaches that have the most potential to make a real impact into the life of patients and the healthcare system.

Jim Van heusden, PhD



# Financial position in brief

#### Investment Entity profit/loss

The Investment Entity's operating profit amounted to SEK -372 million which corresponds to an decrease of SEK -173 million compared to the previous year.

Loss for the period amounted to SEK -376 million compared to SEK -157 million for 2013 or SEK -7.7 per share for 2014 compared to SEK -3.2 per share for 2013.

Operating loss during the year was affected by a change in fair value of the holdings by KDev Investments AB in Axelar AB amounting to SEK -220 million due to the partnering progress not reaching expectations. The fair value change in Biosergen AS affected the operating loss by SEK -28 million, due to lack of financing for future development.

Revenues amounted to SEK 5 million during the year, which was unchanged compared to

#### Investments, cash and cash equivalents

Investments in the portfolio in the amount of SEK 84 million were made by Karolinska Development during 2014, compared to SEK 266 million during 2013.

At year-end total cash, cash equivalents and short-term investments amounted to SEK 141 million compared to SEK 201 million at year-end 2013. At the same time, total net cash from unconsolidated portfolio companies amounted to SEK 55 million compared to SEK 112 million at year-end 2013.

#### Portfolio valuation

The portfolio Fair Value amounted to SEK 1,502 million at the end of 2014, a decrease of 228 million compared to the corresponding period last year when the Fair Value amounted to SEK 1,730 million.

#### Equity ratio and net asset value

The Investment entity's equity ratio decreased during the fiscal year by 3 percentage points to 96 %. The net asset value amounted to SEK 30.8 per share at the year-end 2014, compared to SEK 40.7 per share the previous year.

#### Accounting principles

Karolinska Development is an investment entity according to IFRS 10 Consolidated Financial Statements, which affects financial years beginning 1 January 2014 or later. The difference versus the 2013 Annual Report is that all portfolio companies, including subsidiaries, are measured at fair value. It will therefore be easier to follow the Investment Entity's net asset value and how the total value development of the portfolio over time affects the recognized results (see Note 45).

Investment Entity loss for the period

SEK -372m

(2013: SEK -199m)

Loss per share

**SEK -7.7** 

(2013: SEK -3.2)

Investments in portfolio companies

**SEK 84** 

(2013: SEK 266m)

Total cash, cash equivalents and

**SEK 141m** (2013: SEK 201m)

Portfolio Fair Value

SEK 1,502m (2013: SEK 1,730m)

Net asset value per share

**SEK 30.8** (2013: SEK 40.7)

# Karolinska Development's financing

During the fourth quarter 2014 and the first quarter 2015, Karolinska Development finalized its financing in three steps that in total generates proceeds of approximately SEK 450 million.



#### **Private placement**

Sino Biopharmaceutical, a company in the CP Group, subscribed shares of series B, amounting to SEK 63 million in a directed share issue. The issue is performed within the scope of the mandate to the Board decided at the company's 2014 Annual General Meeting and thus introduced a new large shareholder into the company.

#### **Rights issue of convertibles**

The rights issue of convertibles was subscribed by 32 percent of the then existing shareholders. Additionally, CP Group, guaranteed an undertaking, to subscribe for 44 percent of the rights issue amount or SEK 100 million. During the first quarter 2015, the Board of Directors decided to extend the subscription period of the rights issue of convertibles to allow allotment of convertibles to two new investors, Paradigm Capital Value Fund SICAV och EMF Europäische Marketing und Finanzmanagement AG. Approximately 17 percent or SEK 39 million was subscribed by these two investors. Other subscriptions for convertibles without support of subscription rights corresponded to approximately 1 percent of the rights issue. Altogether, the rights issue with preferential rights for the company's shareholders was subscribed to approximately 94 percent.

#### **Directed issue of convertibles**

During December 2014 a directed issue of convertibles to CP Group was completed under the same terms as the rights issue of convertibles, which generated proceeds to Karolinska Development of SEK 173 million.

# A new major shareholder with a clear vision for Karolinska Development

After the completed financing of Karolinska Development, the company now has a new major shareholder in Thai Charoen Pokphand Group (CP Group). Here, Vice Chairman of CP Group, Mr. Tse Ping explains the reasons behind the investment and how he sees Karolinska Development's future growth.

#### How did CP Group discover Karolinska Development and what motivated you to become a major investor and supporter of the company?

Since innovation has historically played a vital role in CP Group's competitiveness and growth, and continues to be a prime driver of change in the modern economy, we are committed to accessing the latest scientific thinking and supporting its industrial implementation by leveraging our market expertise.

We became interested in Karolinska Development because of its close proximity and unique access to world-class scientific resources at the Karolinska Institutet, and the Swedish and European healthcare innovation systems, as well as the company's well-defined processes for utilizing its context for pharmaceutical research and development.

We believe CP Group's experience can help Karolinska Development set up a strategic process for selecting, developing, and bringing to market pharmaceutical and medical innovations relevant for the fast growing Asian market – which can create new expertise within the company and add value for its shareholders.

# What other industries does CP Group operate in and what other major investments have you made recently?

CP Group is Thailand's largest private corporation, and one of the largest industrial conglomerates in Asia, with annual revenues of USD 41 billion. We are diversified with major holdings within agro-industry and food, telecommunications, pharmaceuticals, insurance, ICT, and finance, among other holdings.

Regarding recent investments, most notably, during 2013, CP Group bought shares worth USD 9.4 billion from HSBC to become the largest shareholder of Ping An Insurance; one of the largest insurance companies in the world. During 2015, CP Group announced plans to invest USD 10.4 billion along with Japanese company Itochu to acquire the largest shareholding in CITIC, one of China's largest conglomerates. During the last two years, we have also made sizable investments with Itochu, Marko, and China Mobile.

# How can Karolinska Development explore possibilities within the emerging Asian market?

Karolinska Development should, with CP Group's support in its Board Asia Committee, undertake a systematic approach for establishing trust with the key stakeholders in Asia, including regulatory bodies, investors and capital markets, and the pharmaceutical industry.

This approach will allow for unique opportunities for syndication of investments, clinical and research collaborations, licensing and distribution partnerships, and financial exits in the Asian economies. Over time, Karolinska Development should position itself as the natural partner for EU and US developed innovations with competitive application potential in the Asian market.

# How do you envision the future of Karolinska Development?

Karolinska Development will continue to build a process of strategic partnership for accessing new technologies that can complement its existing portfolio, and add new areas of expertise, in order to strengthen the uniqueness of the Karolinska Development brand. The selection of technologies will mirror wider trends in the industry; such as personalized medicine, medical ICT and big data, advanced robotics, as well as other high impact innovations.

Most importantly, the company will also need to develop innovative financial and commercialization models for supporting R&D and bringing products to market through an accelerated process.



# Karolinska Development – value creation based on an innovative research and commercial approach

Many small research companies struggle to turn their medical innovations into commercial products. While their scientific know-how is often high, their access to capital and commercial expertise is limited. Karolinska Development works to increase the value of such companies by providing financing, expertise, a network of contacts and active corporate governance. At year-end 2014, Karolinska Development owned shares in around twenty research companies, divided into a strategic portfolio and an opportunistic portfolio. The company's investment focus is on developing new treatments for rare and life-threatening diseases.

# Focused investment portfolio and strict investment criteria

Prior to any new or follow-on investment, each project is evaluated against a number of stringent criteria. The path to a successful exit must be in place from the very first investment and the product must offer clear advantages over competing treatment alternatives. Since the risk in drug development is high, Karolinska Development focuses on companies that develop new treatments for rare and life-threatening diseases. In these segments, development costs are usually lower, the registration process is less complicated and the time to market is shorter than for new treatments for endemic diseases. Consequently, this type of project is attractive to large pharmaceutical companies, which creates opportunities to divest or license the projects as early as during the development process. Adequate intellectual property protection is another important cornerstone of Karolinska Development's investment criteria.

#### Strong leadership in portfolio companies

Karolinska Development works diligently to strengthen leadership in its portfolio companies, including by placing professional, independent directors on their boards and by better focusing their managements on the commercial aspects of drug development. Karolinska Development's team consists of individuals with many years of experience from major pharmaceutical companies, where they have successfully worked on drug development and commercialization. These individuals actively support the portfolio companies with commercial expertise in product and business development, including on M&A and financing issues, as well as with extensive R&D experience.

The portfolio companies are usually managed virtually by a few employees, especially in their early development. A large part of the development work is done through commissioned research and development. In these areas, Karolinska Development has signed a number of framework agreements with carefully selected and qualified providers of R&D services. The researchers who created the projects usually remain an important resource for the companies throughout the development work, normally as members of the board or scientific advisors.

#### Differentiated investment approach

Karolinska Development has a strict investment policy. Follow-on investments require a clear business plan to advance the company in question to the next value inflection point. Karolinska Development can support portfolio companies the whole way to the market if relevant from a value creation perspective, but in most cases an exit is sought earlier.

#### Proactive syndication strategy

Karolinska Development works to broaden its portfolio companies' access to capital by building strong investor relations and proactively seeking syndicated financing together with other specialized life sciences. This has resulted in, among other things, a private placement recently directed to the Asian life science investor CP Group. The partnership with CP Group is expected to improve contacts with the fast-growing Asian pharmaceutical industry, which will strengthen opportunities to bring innovations to Asia.

# Meeting the new CEO of Karolinska Development

Jim Van heusden was appointed CEO of Karolinska Development in March 2015. Below, he provides a flavor of his first impressions of the company and his view of the ongoing change process.

You have been deeply involved in the life science industry for more than 20 years. What particular element in your background do you think is most important for becoming successful in your new position?

I have really learned biotech venture capital investing from the best, through twelve years of hard work at the successful European investment company Gimv, which is listed on Euronext with a market capitalization of more than 1 billion euros. During my career at Gimv, I have invested in sixteen life sciences companies, most of which have been sold or introduced on the stock market. My scientific training and background in drug discovery and development of course helps to understand the scientific rationale of a new investment proposal, but it is clearly the translation of that science into a real business case with a differentiated product profile and a focus on capital efficiency which turns it into a real investment case. This is most important when generating superior returns on invested capital.

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# What's your first impression of Karolinska Development?

I am fully aware that Karolinska Development has had a rough ride, especially over the last year. For a long time, its strategy resembled that of a classical pharmaceutical company. Karolinska Development was often the sole significant investor and was strongly involved in the operational business of its portfolio companies. The approach has now changed towards becoming a professional investment company with an arms length's distance to its portfolio companies' and striving to syndicate with other professional life sciences investors. In my opinion, this is an absolutely necessary change, and I am convinced that it improves the potential for future success.

# What are your first steps to further develop the company?

We need to rebuild confidence with all our stakeholders and increase the awareness and knowledge of Karolinska Development in the capital markets. It will take time, there are no shortcuts—it's all down to face-to-face meetings with influential stakeholders around the world. Although we have a stable financial situation, we must focus our resources on those companies that have the greatest potential to generate attractive returns for our shareholders. A structured approach to our portfolio is an absolute prerequisite to accomplish this. That said, we will of course continue to support the portfolio companies in different ways. Here, I believe that the network I have built in the last twenty years—with international pharmaceutical and biotech companies, professional life science investors and investment banks—may come in handy.

# Karolinska Development's investment criteria – patient-focused innovation

To maximize opportunities for a favorable return on its capital, Karolinska Development invests strictly in existing portfolio companies and new opportunities that meet a number of well-defined criteria.

#### A product with clear advantages

The assets that the portfolio companies develop must be offering a clear differentiation and advantages compared with existing and/or future competing products.

#### Orphan drugs and specialty care products

Karolinska Development primarily invests in pharmaceutical projects with the potential to obtain orphan drug status and products used in specialty care.

#### Well-defined clinical and regulatory strategy

The portfolio companies must have a convincing plan how their asset will be taken through the clinical development path, the registration and market access process in a compelling way that maximizes its commercial value.

#### Exit strategy

Investments are limited to projects where we have defined how and when their commercial value can be realized through a licensing deal or sale.

#### Market exclusivity

A future product must be positioned to obtain market exclusivity based on intellectual rights (e.g., patents) and/or orphan drug status.

#### Right leadership and clear ties to leading researchers

The portfolio companies must have a professional management of serial entrepreneurs or next generation entrepreneurs in place, and close collaborations with leading researchers in their specialty.

#### Opportunities to syndicate the investment

The project must be able to attract additional professional life science investors that can contribute to further value creation with their expertise and networks.

# Sources of new innovations

#### Agreement with Karolinska Institutet

Most of Karolinska Development's current portfolio companies originated in preferential deal flow agreement with Karolinska Institutet Innovations AB. The agreement provides access to innovations from Karolinska Institutet, one of the world's most well-respected and highest ranking medical schools.

#### Other deal flow agreements

In recent years, Karolinska Development has entered into similar collaborations with a number of Nordic universities and highly respected academic research institutions in the US and Europe. Through the Mayo Clinic in the US, Ospedale San Raffaele in Italy and the Medical University of Graz, Austria, the company has access to innovations from around 7,000 other researchers and physicians.

# 2014 – A year in transition

During the year, Karolinska Development refined its investment strategy and strengthened its financial position at the same time that several portfolio companies reported significant success.

# Strategic changes lead to sharper investment focus and clearer commercial orientation

Karolinska Development worked at length in 2014 to refine its investment strategy — with the goal of maximizing opportunities to create significant value at an acceptable risk level. As a result of this work, the company's investments have been divided into a Strategic Portfolio and an Opportunistic Portfolio. In addition, strict criteria have been applied to future investment decisions. At the same time, the company's investment focus on treatments for severe and life-threatening diseases has been reinforced.

#### Stronger financial position

During the autumn of 2014, financing was initiated to facilitate implementation of Karolinska Development's new investment strategy. The financing has been obtained in three steps: a private placement to the company's new principal owner, CP Group, an issue of convertible bonds and a rights issue of convertibles to CP Group. In total, the company obtained proceeds of SEK 450 million before issue costs.

#### New cooperation agreements

Three portfolio companies signed new cooperation agreements during the year. NovaSAID initiated a partnership with Cadila Pharmaceuticals to develop new treatments for inflammation and pain, Dilafor entered into a licensing partnership with Lee's Pharmaceutical and Forendo Pharma licensed the US rights for fispemifene to Apricus Biosciences. The latter has a maximum potential value of USD 57.5 million up to market launch and an additional maximum of USD 260 million plus tiered double-digit royalties based on sales after launch.

#### Progress in project development

During the year, new clinical data were presented for several portfolio company projects, including Pharmanest's SHACT (pain relief in connection with gynecological procedures), Umecrine Mood's UC1010 (premenstrual dysphoric disorder, PMDD) and XSpray's HyNap™ nilotinib (improved version of approved cancer therapy). New studies were started with Aprea's APR-246 (ovarian cancer) and Athera's PC-mAb (complications from cardiovascular diseases). Clanotech was granted orphan drug status in the EU for its drug candidate used in glaucoma surgery and OssDsign's Cranioplug was approved for launch in the US.

#### **Difficult Decisions**

The development of medicinal products involves continuous risks, and sometimes difficult decisions. In 2014, we made decisions to adjust the fair value for our portfolio companies Axelar by SEK -221 million as the company did not find a partner for the further development of the company's anticancer agent, and Biosergen by SEK -28 million due to the company not securing external financing. Similarly. This development is of course not optimal, but it mirrors the significant risks linked to each step in the clinical development of pharmaceuticals. It also reminds us on how careful our investments should be done and linked to possible achievements of value inflection points, although we are well aware that we can never fully mitigate all risks.

# An introduction to drug development

From the time a researcher decides to develop a drug based on new theory, it takes between 10 and 15 years until it can be used in healthcare. But the majority of ideas fade along the way. A fairly optimistic rule of thumb is that of every 5,000 candidate drugs that are tested in early-stage research, five make it to clinical trials on humans and one all the way to market approval<sup>1</sup>.



After an arduous process to identify and optimize new molecules, the emphasis in this phase is on testing through the use of animal studies to determine if the candidate drug (CD) is sufficiently safe for testing in humans. The first indication that the CD should have its intended effect in the body at a dosage level that does not produce unwanted side effects is called proof-of-principle. Typically, this is shown using relevant animal models or in Phase I.

The first tests on humans are carried out. Normally, a small group of healthy volunteers (20–100 individuals) is selected. The CD is given in increasing doses in order to test its safety and how it is absorbed and broken down in the body.

Trials are performed to test the CD's effect on patients and to establish an appropriate dosage level. Study sizes vary greatly depending on the area of disease, from around ten up to several hundred patients. A positive outcome in a Phase II trial is usually called proof-of-concept.

The efficacy of the CD is compared to a placebo and/or existing therapies. Data from these studies form the basis for subsequent applications for market approval of the pharmaceutical. The clinical trials in Phase III are normally multicenter studies on large patient groups, around 300 to 3,000 or more, depending on the target indication.

The regulatory authorities in each market evaluate all the relevant data generated in the clinical trials. If approved, the authority will also decide on detailed prescription guidance. The process usually takes between 12 and 18 months. Before the pharmaceutical can be used in healthcare, an acceptable price for both the manufacturer and payer must be negotiated. To facilitate this often protracted process, pharmaceutical companies usually perform health economic calculations and studies as an integral part of the development process.

<sup>1)</sup> Source: Läkemedelsindustriföreningen (trade organization for the Swedish pharmaceutical research industry), www.lif.se

# Karolinska Development's investments

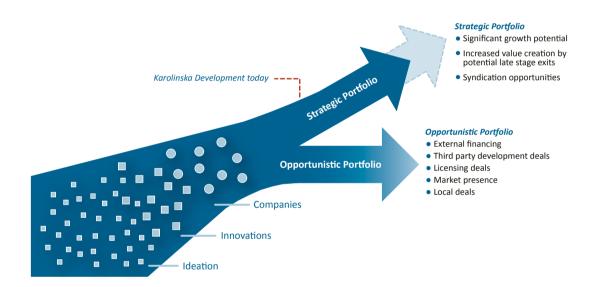
Karolinska Development had investments in 21 companies at year-end 2014. These companies are divided into a Strategic Portfolio and an Opportunistic Portfolio. The company tries to realize the value in the Opportunistic Portfolio in order to increase opportunities to invest in the Strategic Portfolio.

#### The Strategic Portfolio

The Strategic Portfolio contains nine companies, several of which have the potential to obtain orphan drug status for their products. Two companies have already received such approval. The portfolio companies in the Strategic Portfolio are engaged in scientifically and commercially promising projects that are expected to reach value inflection points in the short and medium term.

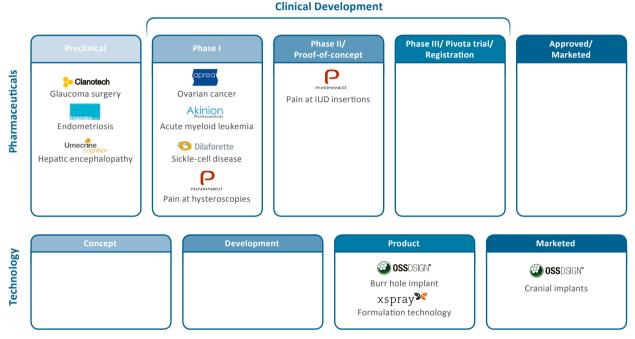
#### The Opportunistic Portfolio

The Opportunistic Portfolio contains twelve portfolio companies primarily focused on specialty drugs. The portfolio contains projects that have already been introduced on the market or where development agreements have been signed with third parties. Karolinska Development is planning in the short and medium term to realize the values in the Opportunistic Portfolio in order to increase opportunities to invest in the Strategic Portfolio.

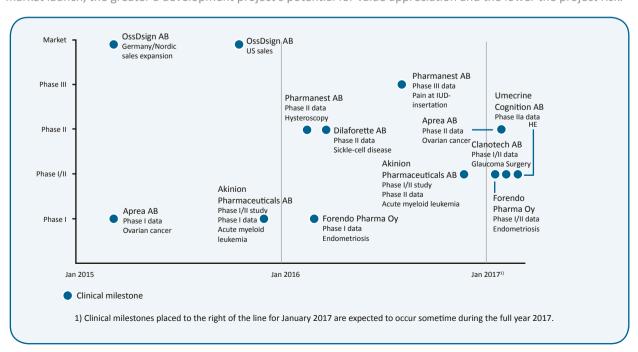


# Value development in the Strategic Portfolio

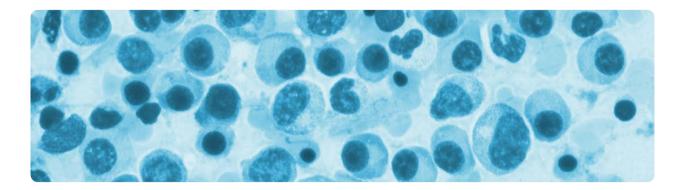
Most of the companies in the Strategic Portfolio are in a clinical phase and many are nearing new value inflection points or market introductions. A typical value inflection point is when the results of a clinical trial are reported. Study results and regulatory opinions are among the factors that affect the valuations of the companies which are reported quarterly, the so-called fair value of the portfolio. In the final analysis, it is naturally the portfolio companies' ability to sell their projects in various ways and on favorable terms that creates real value for Karolinska Development's shareholders.



The illustration below shows possible, related value inflection points in the Strategic Portfolio. The closer it is to market launch, the greater a development project's potential for value appreciation and the lower the project risk.



# Akinion Pharmaceuticals AB



Akinion develops novel pharmaceuticals for treating hematological cancer. The company's drug candidate AKN-028 inhibits a key growth factor in leukemia cells and preclinical data indicates efficacy against cancer cells in acute myeloid leukemia that have developed resistance against standard of care chemotherapy.

#### No targeted treatments available for AML

Acute Myeloid Leukemia (AML) is a haematological cancer caused by rapid growth of abnormal, leukemic white blood cells. As the leukemic cells outnumber normal white and red blood cells in the blood, an array of anaemic and immunologic deficiency symptoms ensues. The current treatment consists of chemotherapy and bone marrow transplantation and no targeted treatments have been approved. Because of the brief duration of complete remission, mainly due to chemotherapy resistance of the tumour cells, the five-year survival rate is 34 percent for patients aged below 65 and four percent for patients aged above 65.1

Akinion's pharmaceutical candidate AKN-028 is a small molecule kinase inhibitor developed for the treatment of AML. Preclinical studies of AKN-028 show a unique efficacy against all primary AML tumour samples tested, even chemotherapy-resistant AML tumours. AKN-028 inhibits an important molecular driver in AML, the indications from the Flt-3 receptor. Its unique preclinical efficacy profile² is believed to be the result of the inhibition of Flt-3 as well as one additional molecule which Akinion has chosen not to disclose to date. AKN-028 is orally administered and has, in the Company's view, clear potential to be first-in-class.

The unique competitive feature of AKN-028 is its efficacy on AML tumours resistant to chemotherapy. Since some of the AML patients are already chemotherapy-resistant at diagnosis and the majority develop chemotherapy resistance during therapy, a new pharmaceutical capable of overcoming this resistance would be of great medical importance. In addition, preclinical results indicate a synergistic effect of AKN-028 given in combination with current standard of care chemotherapy. Consequently it is expected that AKN-028 could be administered both as monotherapy and in combination with existing chemotherapy.

#### The market

Each year, around 30,000 new patients are diagnosed with AML in the seven major pharmaceutical markets.<sup>3</sup> Only 28 percent of the AML patients aged 60 or older receives treatment in the form of chemotherapy, the only available pharmaceutical treatment aimed at achieving disease remission as per today. 20 percent of the patients in this age group are only given palliative care, meaning that while these patients are spared from adverse effects of chemotherapy, survival time is very short. To further emphasize the need for new treatments in AML, a majority of patients treated across all age groups are recruited to clinical trials.<sup>4</sup>



#### **Pharmaceuticals**

Project:

Primary indication:

Acute Myeloid Leukemia

Development Phase: Phase I/II

Holding in company: **81** %\*

rigin:

Spin-out from industry

More information: www.akinion.com

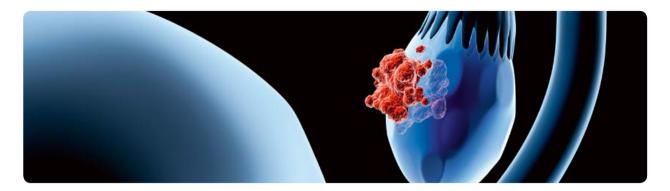
Includes indirect holdings through KDev Investments

#### **Current status**

- A phase I/II clinical study in AML patients relapsed or resistant to first line chemotherapy was halted due to the need to improve the pharmaceutical formulation regarding low and variable exposure.
- AKN-028 has potential of being granted orphan drug designation within AMI

- Resume the phase I/II study with improved formulation and complete the study (H2-2015).
- Complete the phase II proof-of-concept study (H2-2016).
- 1) Source: Surveillance, Epidemiology and End Results (SEER), program från 1996 till 2002.
- Source: Eriksson, A, et al: The novel tyrosine kinase inhibitor AKN-028 has significant antileukemic activity in cell lines and primary cultures of acute myeloid leukemia; Blood Cancer Journal, 2012 (2).
- 3) Source: Datamontor, Acute myeloid leukemia Epidemiology, 2014.
- 4) Source: Datamontor, Acute myeloid leukemia Treatment, 2014.

# Aprea AB



Aprea is focusing on the development of novel anticancer compounds targeting the tumor suppressor protein p53. The company has initiated a Phase I/II clinical trial with the lead candidate APR-246 in patients with ovarian cancer.

#### Targeting a key cancer driver

Cancers develop and spread due to malfunction of the cells' normal growth control mechanisms. One such growth mechanism is the p53 tumour suppressor gene. De-activation of p53 results in uncontrolled growth of the cell that may lead to cancer development. Moreover, de-activation of p53 is also strongly associated with resistance to chemotherapy.

Aprea has identified small molecules that reactivate p53. The company's first pharmaceutical candidate, APR-246, has been tested in a clinical phase I/ II trial with promising results, published in the Journal of Clinical Oncology.¹ In preclinical studies, APR-246 has been shown to induce cell death in many cell lines with varying p53 status. Aprea has also demonstrated that APR-246 has a very strong synergistic effect when used together with the platinum-based pharmaceuticals in ovarian cancer cells taken directly from patients.

The company is now performing a proof-of-concept study where platinum substances are reintroduced in combination with APR-246 in platinum sensitive ovarian cancer patients. In this disease, most patients will relapse in after completion of treatment and the likelihood that a patient will

respond to the reintroduction of a platinum-based regimen depends on the platinum-free interval (PFI). For example, among patients with a PFI of 6–12 months, only 20–30 percent respond to additional of platinum based chemotherapy, underlining the great need for improved treatment of relapse within ovarian cancer.

#### The market

The market potential in ovarian cancer alone is substantial. Currently, more than 225,000 women are living with ovarian cancer and approximately 67,000 new patients are diagnosed with the disease each year in the seven major markets.<sup>2</sup> The latter number is expected to increase to 75,000 annually overthe next ten years, and the number of prevalent cases is expected to reach close to 250,000. The ovarian cancer pharmaceutical market is by analysts expected to grow by more than 13 percent annually until 2020, when the total market value is expected to amount to approximately at USD 2.3 billion.<sup>3</sup>



#### **Pharmaceuticals**

Project: APR-246

Primary indication: Ovarian cancer

Development Phase: Phase I/II

Holding in company: **62** %\*

Origin:

Karolinska Institutet

More information: www.aprea.com

\* Includes indirect holdings through KDev Investments and KCIF co-inverstment fund

#### **Current status**

- Phase I/II dose-titration study completed.
- Phase I/II study in combination with platinum based standard treatment in platinum sensitive second line ovarian cancer patients is ongoing.
- Orphan drug designation granted by EMA.

- Complete part one (phase Ib) of proof-of-concept study in platinum sensitive ovarian cancer (Q2-2015).
- Complete part two (phase II) of proof-of-concept study in platinum sensitive ovarian cancer (2017).
- 1) Source: Lehmann et al., J Clin Oncol. 30(29):3633-3639, 2012.
- 2) Source: Datamonitor, Epidemiology: Ovarian Cancer, 2012.
- 3) Source: Global Data, Ovarian Cancer Therapeutics Global Drug Forecasts and Treatment Analysis 2020, 2012.

# Clanotech AB



Clanotech develops a treatment that may reduce the risk of complications in connection with glaucoma surgeries and in the treatment of wet age-related macular (wAMD) degeneration. Clanotech's candidate drug CLT-28643 is in preclinical development and has shown anti-inflammatory properties as well as and ability to inhibit growth of blood vessels and fibrosis.

# Improving current treatments for glaucoma and wAMD

Increase of intraocular pressure (IOP) and retinal neovascularization are the most common causes of blindness among an ageing population. Patients with severe glaucoma who are refractory to IOP lowering medications undergo surgical intervention that creates a flap helping the eye to drain liquid more effectively and lowers IOP. Correct healing of the flap is critical for the long term success of the procedure. A cytotoxic antimetabolite (Mitomycin-C) is therefore used today to prevent closure of the flap, but the treament is associated with significant side effects. The current treatments for wAMD are focused on neovascularisation based on inhibition of the vascular endothelial growth factor (VEGF). These treatments need to be administered by frequent injections in the eye to maintain the patients' vision.

Clanotech's  $\alpha 5\beta 1$ -integrin antagonist has shown to have favorable anti-angiogenic, anti-fibrotic and anti-inflammatory properties for the optimal balance in the healing process. Clanotech's aim is to develop a product that offers safe and efficacious adjuvant therapy in connection with glaucoma surgery in order to avoid intra- and postoperative problems experienced with the cytotoxic anti-metabolite used today. Moreover, Clanotech's pharmaceutical candidate has the potential to

be used as a complementary treatment with the current standard of care for wAMD patients to achieve a long lasting effect given in combination with anti-VEGF treatment.

#### The market

There are approximately 300,000 glaucoma surgeries performed each year in the US, Japan and Europe. This number is expected to grow considerably over the next decades with an aging population. The number of surgical procedures in these markets is estimated to reach approximately 350,000 during 2021.¹ At the same time, the failure rate of current treatment is high (28–51 percent).² A novel, safe and effective adjuvant treatment may therefore increase the success rate of the procedure which will further encourage patients to undergo this treatment, increasing the number of surgical procedures further. Since the orphan drug status is connected to this condition, it is possible to obtain registration early in the process.

The total global socioeconomic costs of the wet form of AMD amounts to approximately USD 350 billion each year³ and there are around 4 million people suffering from the wet form of AMD worldwide.⁴ Lucentis and Eylea, both anti-angiogenic products indicated for this disease, achieved combined sales of over USD 6 billion in 2012.⁵



#### **Pharmaceuticals**

# Project: CLT-28643

Primary indication: Adjuvant treatment to glaucoma surgery

Development Phase: **Preclinical** 

Holding in company: **80** %\*

Karolinska Institutet

More information:

 Includes indirect holdings through KDev Investments

#### **Current status**

 Orphan drug designation for glaucoma surgery has been granted by the EMA in Europe and the US FDA.

- Start of Phase I/II clinical study in glaucoma surgery (H2-2015)
- 1) Source: Willkins et al.: Intraoperative mitomycine c for glaucoma surgery; The
- 2) Source: Clanotechs egna marknadsundersökningar. 2013.
- 3) Source: Access Economics, The Global Economic Cost of Visual Impairment, 2010.
- 4) Source: AMD Alliance International, Increasing Understanding of Wet Age-Related Macular Degeneration (AMD) as a Chronic Disease, 2011.
- 5) Source: Global Data, 2014.

# Dilaforette AB



Dilaforette's drug candidate sevuparin is developed from the well-known pharmaceutical heparin. The substance may restore normal blood flow in patient with debilitating and life threatening sickle-cell disease.

## Unmet needs in treating acute pain attacks

Dilaforette focuses on sickle cell disease (SCD), which is a genetic disorder caused by mutation in the haemoglobin gene. This may cause red blood cells to assume an abnormal 'sickle' form. In SCD sickled red blood cells adhere to the lining of the blood vessels, restrict blood flow and results in episodes of severe pain. This leads to Vaso Occlusive Crisis (VOC), which are painful episodes and the clinical hallmark of the disease. These painful episodes occur on average during approximately 50 percent of the days of the affected patients and 90 percent of hospital admissions are for acute pain.1 On average, VOC causes around one hospitalization per patient and year.<sup>2</sup> Repeated episodes of VOC are accompanied by organ damages and the average life expectancy of males and females with SCD is only 42 and 48 years, respectively.3 Besides pain management, there is currently no therapy for treatment of acute VOC.

Preclinical studies have shown that sevuparin has the potential to reduce time to recovery from

the crisis, to reduce need of analgesics as well as hospitalization time. Dilaforette's treatment has therefore the potential to lower the pain that many SCD patients experience and also function as a health economics relief by contributing to reduced hospitalization.

#### The market

In the US and in Europe, SCD is an orphan disease with approximately 30,000 and 80,000 patients, respectively.<sup>4</sup> In addition, SCD is common in the Middle East and Africa where around 300,000–400,000 persons are born with the disease each year. By successfully limiting the incidence and intensity of crisis, sevuparin could potentially fill a therapeutic void that could decrease hospital stays and the use of analgesics. The commercial impact of such a treatment can therefore be expected to be substantial.



#### **Pharmaceuticals**

Project: **Sevuparin** 

Primary indication: Sickle-cell disease (SCD)

Development Phase: **Phase I** 

Holding in company: 64 %\*

Project origin: Karolinska Institutet, Uppsala University

More information: www.dilaforette.se

\* Includes indirect holdings through KDev Investments

#### Current status

- Safety documentation of sevuparin has been successfully completed in a Phase I clinical trial.
- Sevuparin has been granted Orphan Drug Designation in SCD by EMA in Europe and by FDA in the US.
- Dilaforette entered a collaboration agreement with the contract research organisation Ergomed for the Phase II study in SCD patients suffering from VOCs.

- Initiate phase II clinical studies of sevuparin in SCD (Q1-2015).
- Complete phase II studies in SCD (H1-2016).
- 1) Source: Orringer et. al., JAMA. 286(17):2099-2106, 2001.
- 2) Source: Brousseau et al., JAMA. 303(13):1288-1294, 2010.
- 3) Source: Platt et al., N Engl J Med 1991.
- 4) Source: WHO, 2001 and Hassel, Am J Prev Med. 3B (4 Suppl): S512-21, 2010.

# Forendo Pharma Oy



Endometriosis affects women in fertile age and is caused by cells normally lining the uterus growing outside the uttering causing pain. Forendo's development program is focused on eliminating endometriosis while at the same time maintaining normal hormonal cycles.

# Effective treatment without negative effect on hormonal balance

Endometriosis is caused by cells normally lining uterus being present outside of the uterine cavity, affecting women in reproductive age. Typically these endometrial cells can be found lining the outside of the womb, on the ovaries and in the fallopian tubes. The cell growths progress over time, and occur as larger tumorous lesions in the abdominal cavity. In many cases the disease causes infertility due to the adhesions and cysts formed on the reproductive organs.

Current treatments within endometriosis involve pharmaceuticals that suppress estrogen synthesis alongside pain and inflammatory control pharmaceuticals (NSAIDs). Oral contraceptives are moderately effective in milder cases of endometriosis. GnRH agonists inhibits the production of systemic estrogen and are effective, however resulting in severe menopausal like symptoms such as hot flashes and loss of libido, risk of osteoporosis as well as depression and cognitive events. Radical surgical treatments where the uterus, ovaries or fallopian tubes are removed, leads to infertility.

Forendo develops a treatment to inhibit the growth of endometrios cells. 17 $\beta$ HSD1 is an enzyme which converts the weak estrogen estrone to the much more potent estradiol during the menstrual cycle. By inhibiting 17 $\beta$ HSD1, the estrogenic influence on the endometriosis is reduced, while leaving the systemic estrogen levels intact. With this therapeutic method, menopausal like symptoms caused by systematic decreased levels of estrogen will be avoided. Forendo's 17 $\beta$ HSD inhibitors have been shown to effectively block formation of estrogen in human endometriosis lesions ex vivo and in a primate disease model cause regression of endometriosis and relief of the associated inflammatory pain while maintaining the normal hormonal cycle.

#### The market

It is estimated that ten percent of all fertile women are affected by endometriosis, corresponding to a total of 176 million women all over the world. Lack Endometriosis has a major impact on the well-being of the women affected and results in a socioeconomic burden, e.g. because of sick leaves due to the lack of safe and effective treatment. Forendo's method to treat endometriosis has therefore, in the Company's view, a high potential.



#### **Pharmaceuticals**

Project: **FP-5677** 

Primary indication: **Endometriosis** 

Development Phase: **Preclinical** 

Holding in company: 18 %\*

Origin:

University of Turku

More information: www.forendo.com

Includes indirect holdings through KCIF Co-investment Fund

#### **Current status**

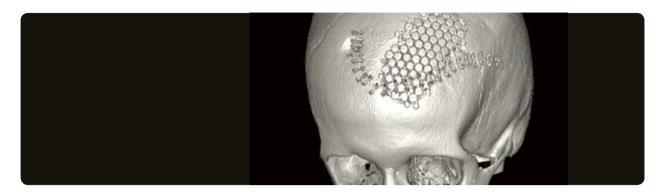
- Forendo's pharmaceutical candidate undergoes the preclinical development phase.
- The scientific rationale for treating endometriosis with  $17\beta HSD1$  inhibitors have been established ex vivo using human endometriosis tissues and in vivo in a primate endometriosis model.
- Forendo also develops Fispemifene for the treatment of secondary hypogonadism – the US development and commercialization rights have been licensed to Apricus Biosciences Inc. Through the license agreement, Forendo has received an upfront payment of USD 5 million as well as shares in Apricus Biosciences Inc. equivalent to approximately USD 7.5 million and Forendo is moreover entitled to milestone payments totaling up to USD 305 million and sales based royalties.

#### **Planned milestones**

- Start the phase I single dose study (H2-2015).
- Complete the three month phase I study in healthy women (H1-2016).
- Complete the of phase IIa in endometriosis patients (2017).

1) Surce: Rogers et. al., Reproductive Sciences. 16(4):335-346, 2001 2) Source: Endometriosis.org

# OssDsign AB



Trauma and surgical procedures may lead to the need for surgical repairs of patients' cranium. OssDsign has developed Craniomosaic, a bioceramical implant that is tailormade to fit into the cranial defect. The implant enables the flow of blood and tissue fluids that benefits the healing process. The product has so far shown excellent clinical results in difficult patients.

#### Cranial implant that improves quality of life

Currently used implants based on materials such as plastics, polymers and metals have shown limited tissue integration and causes lifetime risks for skin penetration and infection.¹ When such complications occur, treatment choices are few, failure rate increases and treatment costs are high. A recent study of 1,200 patients demonstrates that hospital costs are more than five times higher in patients with complications after advanced surgery than to complication-free surgery.²

A high percentage of cranioplasties treatments fail in case patients have large defects or due to other risk factors, such as poor blood circulation. OssDsign AB ("OssDsign") has developed Craniomosaic, a bio ceramic implant tailored to fit the patient's skull defect. The product is made of calcium phosphate bio ceramic tiles, interconnected by a thin titanium mesh. The implant is designed in a pattern that allows free circulation of blood and tissue fluids, while allowing bone healing. The product has so far shown excellent clinical results in complex patient cases.

#### The market

The market for biomaterials products in orthopaedics was estimated at EUR 1.5 billion in 2013.<sup>3</sup> The market for OssDsign's lead product in cranioplasty alone is expected to amount to approximately EUR 100 million in 2017.<sup>4</sup> In addition, OssDsign has several products in its portfolio, expanding the company's commercial potential. The market is attractive since it is concentrated, as these surgeries only are carried out at a limited number of hospitals and as the price sensitivity is moderate for products with proven efficacy.



#### Technology

Project:
Craniomosac, Cranioplug

Primary indication: Cranial implants

Development Phase: Marketed

Holding in company: **26** %

Origin:

Karolinska Univerity Hospital, Uppsala University

More information: www.ossdsign.com

\* Includes indirect holdings through KCIF Co-Investment Fund

#### **Current status**

- Lead product Craniomosaic has been launched in the markets within Germany, the Nordic countries and Spain.
- In house ISO 13485 certificated production.
- Cranioplug, a follow-up product to Caraniomosaic, received 510(k) clearance by FDA in the US.
- Documentation of bone growth on OssDsign bio ceramic material has been published.<sup>5</sup>
- Multi-centre clinical study is on-going.

- Regulatory applications in the US and Japan
- Widen the market launch of Craniomosaic during 2015
- 1) Source: Marchac & Greensmith, JPRAS. 61(7):744-752, 2008.
- 2) Source: von Lanthen et. al., Annals of Surgery. 254(6):907-913, 2011.
- 3) Source: Orthopedic Network News, 20 juli 2014. Based on US market numbers, extrapolated on the global market.
- 4) Source: OssDsigns egna estimat.
- 5) Source: Engstrand et. al., Journal of Neurosurgery 120: 273-277, 2014.

# Pharmanest AB



Pharmanest develops pharmaceuticals that gives fast pain relief in connection with gynecological procedures. The products are based on new unique formulations av well-documented pharmaceuticals and is applied locally in the cervix and uterus. No advanced instruments are used and the systemic exposure is minimal.

# Millions of women experience pain in gynecological procedures

Experience of pain in connection with gynaecological procedures and in childbirth is well documented. At the same time, supply of effective local pain relief in gynaecology and obstetrics is very limited. Millions of women undergo gynaecological procedures each year with no or insufficient pain relief.

Pharmanest is developing new unique formulations based on well documented active substances. The formulations are applied topically in the cervix and uterus using applicators developed by Pharmanest. The pain relief is obtained immediately, no advanced instrumentation is required and the systemic effect is minimal.

Pharmanest's first product candidate SHACT is developed to be used for pain relief in connection with gynaecological procedures. There are presently, to Pharmanest's knowledge, no similar local pain relief products with documented efficacy available on the market. Pharmanest's aim is to be able to provide effective local pain relief which is advantageous from both a patient and a health

economic perspective. The clinical data generated so far clearly demonstrates that SHACT may play an important role in pain management within the gynaecological procedure segment.

#### The market

Approximately 150 million women around the world have an IUD.¹ The medical need for local pain relief in connection with IUD insertions and outpatient hysteroscopies has been confirmed by recently conducted market surveys.² A majority of the surveyed physicians found the product to be very favourable and rated a high likelihood of use in their clinical practices. A previous study showed that around two-thirds of women with experience of IUDs who were interviewed would choose this type of product if it was available. Pharmanest's product candidates also offer potential in other indications such as pain relief in connection with dilation and curettages, abortions and obstetric pain.



#### Pharmaceuticals

Project: **SHACT** 

Primary indication:

Pain during gynecological procedures

Development Phase: **Phase II** 

Holding in company: **63** %\*

Origin:

Karolinska Institutet, Karolinska Univerity Hospital

More information: www.pharmanest.se

\* Includes indirect holdings through KCIF Co-Investment Fund

#### **Current status**

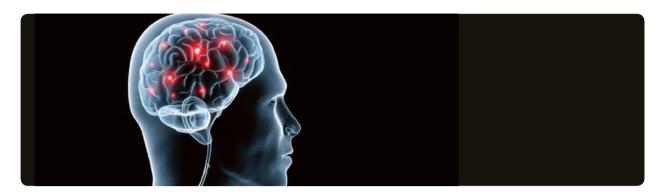
- A randomized, double-blind phase II study with SHACT which included 218 women undergoing IUD insertion has been finalized. The study showed that women receiving SHACT experienced less pain and discomfort compared to placebo. The effects were statistically significant and clinically meaningful, while no serious adverse events were reported in the study.
- A feasibility study in outpatient hysteroscopies has been completed and found no safety or tolerability issues recorded, nor did the study find that SHACT is interfering with the examination.

#### **Planned milestones**

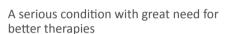
- Decide on strategy for registration in EU and US.
- Prepare for commercial production.
- Initiate phase II study in hysteroscopy.

1) Source: United Nations, World Contraceptive Use, 2011.
2) Source: Market research carried out by Pharmanest, 2013.

# **Umecrine Cognition AB**



Umecrine Cognition develops pharmaceuticals to reduce cognitive disorders and other serious symptoms in connection with hepatic encephalopathy.



In liver damage, for example as a consequence of cirrhosis, there is a risk for elevated ammonia levels in the resulting in brain damage. This condition, hepatic encephalopathy (HE) is characterized by impairments of the sleep-wake cycle, consciousness, cognition, memory, decreased energy levels, personality change and reduced motor skills. An increased activity in the inhibitory GABA system in the central nervous system is a plausible main driver for the clinical signs and symptoms of the disease.

Umecrine Cognition is developing pharmaceuticals to treat acute life-threatening HE and longterm maintenance in minimal HE caused by endogenous CNS active steroids (GABA-steroids). Certain neuroactive steroids increases the inhibited GABA signaling, causing cognitive impairment in the disease state. This makes neurosteroid antagonists a credible therapeutic class to explore for novel treatments in HE. The expected effects of such treatment include shortened hospital stay with less need for intensive care and improved and maintained cognitive functions.

Umecrine Cognition's therapy modulates GABA signalling. Currently, there are, to the Company's

knowledge, no treatments are based on available directly addressing the signs and symptoms of HE. This new treatment would be used when motivated by a worsening of these symptoms, whereas present treatments are based on prophylactic use to reduce the risk of recurrent episodes by aiming to indirectly control hyperammonemia. The treatment can therefore potentially be combined with present standard of care.

#### The market

HE is a severe disorder with a large unmet need. In total, liver cirrhosis affects up to one percent of the US and EU populations.¹ Between 125,000 and 200,000 patients with liver cirrhosis in the US are hospitalized due to complications associated with HE.² Once HE develops, mortality reaches 22–35 percent after five years.³ HE is also associated with large societal and individual costs. In the US, the total costs for hepatic encephalopathy has been estimated to be USD 4.6 billion in 2005 and USD 7.2 billion in 2009.⁴ Umecrine Cognition's strategy is to focus on short-term treatment in hospitalized patients with severe HE. An effective novel treatment within this indication is likely to make a major contribution for the treatment of this disorder.



#### **Pharmaceuticals**

Project: GABA modulator

Primary indication:

Hepatic encephalopathy

Development Phase: Preclinical

Holding in company: 69 %\*

Origin: Umeå University

More information: www.umecrine.se

 Includes indirect holdings through KCIF Co-Investment Fund and Umecrine AB

#### **Current status**

- A pharmaceutical candidate has been selected for preclinical development.
- Mechanism of action has been established regarding the GABA-steroid modulating approach to improving cognitive function.
- Proof-of-principle has been demonstrated by normalizing cognitive and motor function in validated experimental models of hepatic encephalopathy.

#### Planerade milstolpar

- Start phase I clinical trial (H2-2015).
- Complete the phase II study (2017)
- 1) Source: Schuppan and Afdhal, 2008. Lancet. 371: 838-851 och Blachier et. al., 2013. J. Hepatol. 58: 593-608.
- 2) Source: HCUPnet, Healthcare Cost and Utilization project, 2006.
- 3) Source: Yoneyama et. al, 2004. Dig. Dis. Sci. 49: 1174-1180 och Planas et. al., 2004. J. Hepatol. 40: 823-830.
- 4) Source: Stepanova et al., 2012. Clin. Gastroenterol. Hepatol. 10:1034-1041.

# XSpray Microparticles AB



Many promising pharmaceutical projects are halted due formulation issues of the active compound. Some approved drugs also have limitations of usage as a consequence of sub-optimal formulation. XSpray's technology may change that.

# Improved safety and quality of life in cancer treatments

An examples of a drug class with a great need for improved formulations is protein kinase inhibitors (PKIs), that are often used as a targeted therapy for many types of cancers. Due to low solubility, many of today's marketed PKI therapies suffer from low absorption and high risk of adverse events due to sudden increase of exposure. Cancer patients on the PKI treatments are in many cases required to abstain from eating during several hours before and after intake of the pharmaceutical to avoid safety concerns associated with the treatment. This infers a high impact on quality of life for the patients.

XSpray's patented HyNap™ technology is able to formulate challenging pharmaceutical substances with poorly water-soluble substances, inhaled substances and biopharmaceuticals, providing full control over particle properties in the nanometer to micrometer size range. XSpray has shown 26 times better solubility, eight times better bioavail ability and elimination of food interaction, with a reformulation of a marketed TKI using HyNap.¹ In a completed Phase I trial with the HyNap formulation, XSpray convincingly demonstrated that

bioavailability of nilotinib was improved and that the clinically important food effect on exposure of the pharmaceutical was eliminated. Currently no other formulation technology focusing on improvement of TKIs are known to Karolinska Development.

#### The market

The PKI class include a number of commercially successful brands such as Tasigna with sales of USD 1.3 billion during 2013.2 PKIs are the second sales leading class of targeted cancer therapies, having sales of USD 9 billion in 2011, equivalent to 30 percent of total oncology sales in the seven major pharmaceutical markets.3 Over the next five years it is estimated that more than USD 267 billion of branded pharmaceutical sales are at risk from generic competition.4 The pharmaceutical industry is experiencing difficulties in developing new pharmaceuticals at the same rate as the expiration rate of patents on many important pharmaceuticals. This increases the demand for effective life cycle management of successful products and access to external projects, resulting in more licensing deals and acquisitions.



#### Technology

Project: **HyNap™** 

Primary indication: Formulation technology

Development Phase:

Holding in company: **63** %\*

Origin: Start-up

More information: www.xspray.com

Includes indirect holdings through KCIF Co-Investment

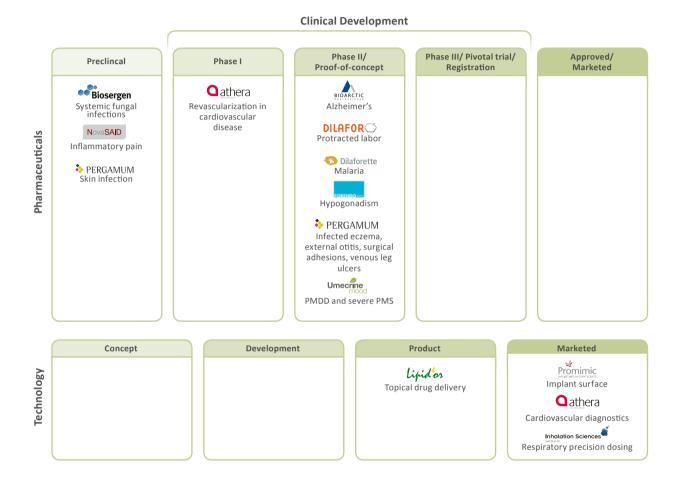
#### **Current status**

- GMP production facility supporting phase I and II clinical trials is validated and ready for production.
- Animal studies demonstrate significantly improved bioavailability of HyNap™ formulation.
- Stability for 14 months of HyNap™ formulation has been demonstrated.
- First phase I trial with the HyNap formulation of nilotinib was successfully completed.

- Start phase I clinical trial of second PKI (H2-2015).
- Complete phase I clinical trial of second PKI (H2-2016).
- 1) Source: Results from Clinical phase I study, performed by XSpray.
- 2) Source: EP Vantage, December 2012.
- 3) Source: Datamonitor, Market and Product Forecasts: Targeted Cancer Therapies 2011–21, 2012.
- 4) Source: Pharmaceutical Executive, Managing Product Lifecycle, June 2011.

# Karolinska Development's Opportunistic Portfolio

The Opportunistic Portfolio contains eleven companies that mainly focus on specialty care products. Some of the projects in the portfolio have already been launched to the market or are part of third party development agreements. Karolinska Development plans to realise the values of the Opportunistic Portfolio in near or mid term, in order to increase the investments in the Strategic Portfolio.



# Athera Biotechnologies AB



Athera's fully human monoclonal antibody PC-mAb is intended for the treatment of patients with acute cardiovascular diseases, who are at an increased risk of secondary events and death. Previously published studies have shown that low plasma levels of endogenous antibodies against phosphorylcholine (anti-PC) are linked to poor prognosis in acute heart attack patients, as well as in patients with peripheral arterial disease undergoing vein graft surgery. By treatment with PC-mAb, the inflammatory response may potentially be inhibited, reducing the risk of secondary events. A phase I clinical trial with healthy individuals is currently ongoing with PC-mAb. The development costs for Athera Biotechnologies AB's pharmaceutical product candidate are co-financed by the EU FP7 program, within the project CARDIMMUN.

#### **Pharmaceuticals**

Project: PC-mAb

Primary indication: Revascularization in cardiovascular

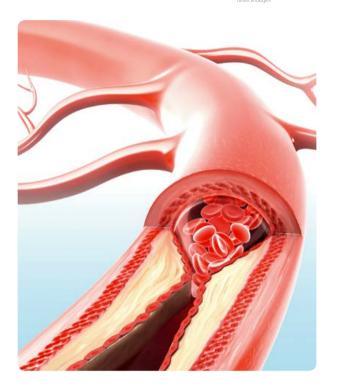
disease

Development Phase: Phase I

Ownership: 65%\*

Project origin: **Karolinska Institutet**More information: **www.athera.se** 

\*Includes indirect ownership through KCIF Co-investment Fund



# BioArctic Neuroscience AB

BioArctic develops pharmaceuticals, devices and diagnostic methods for diseases affecting the central nervous system. The company's most advanced program is BAN2401, a monoclonal antibody for the treatment of Alzheimer's disease, that has been developed together with Eisai. Currently, Phase II clinical trials of BAN2401 are ongoing.

#### Pharmaceuticals

Project: BAN2401

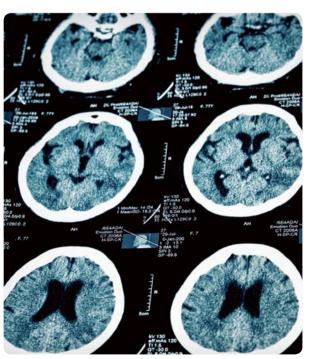
Primary indication: Alzheimer's disease

Development Phase: Phase II

Ownership: 3%

Project origin: **Karolinska Institutet**More information: **www.bioarctic.se** 





# Biosergen AS

BBiosergen AS is developing an innovative pharmaceutical candidate, BSG005, for treatment of life-threatening systemic fungal infections. This condition occurs in patients whose immune system is compromised, such as patients who receive immunosuppressive therapy. BSG005 is currently in preclinical development and the substance has a broad anti-fungal spectrum with excellent activity against Aspergillus and Candida, which are the two main invasive fungal infections. The safety profile of BSG005 is significantly better compared to existing treatments available on the market, such as amphotericin B, based on preclinical characterization.

#### **Pharmaceuticals**

Project: BSG005

Primary indication: Systemic fungal infection

Development Phase: Preclinical

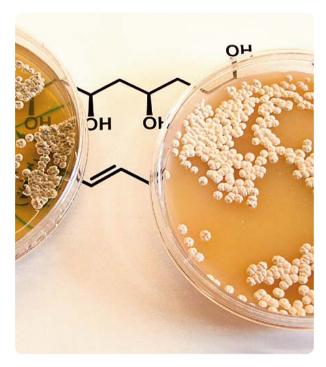
Ownership: 60%\*

Project origin: Norges teknisk-naturvitenskapelige

universitet, SINTEF

More information: www.biosergen.no
\*Includes indirect ownership through KDev Investments





# Dilafor AB

Protracted labor is the main cause of emergency surgical deliveries, such as caesarian section or vacuum extraction. The condition is often associated with several complications for both mother and child. Heparin has been shown to shorten labor time in pregnant women with risk for thrombosis, but is not appropriate for routine use in pregnant women due to the increased risk of bleeding. Dilafor AB's pharmaceutical candidate tafoxiparin is modified from heparin to eliminate the risk of bleeding and has been shown in preclinical studies to enhance ripening of the uterine cervix and to improve uterine contractility. Tafoxiparin therefore has the potential to provide an effective solution to the challenge of protracted labor. Subgroup analyses of a phase II clinical trial in 263 first-time mothers indicated that fewer women treated with tafoxiparin than placebo

#### **Pharmaceuticals**

Project: Tafoxiparin

Primary indication: Protracted labor

Development Phase: Phase II

Ownership: 47%\*

Project origin: Karolinska Institutet

More information: www.dilafor.com

\*Includes indirect ownership through KDev Investments



were in labor that lasted more than 12 hours and the results also indicated a trend towards shortening of labor time. These findings are now sought to be confirmed in a phase IIb- study, which will also identify the appropriate dose. The study is planned to start during 2015. Dilafor has a license agreement for the Chinese market with Lee's Pharmaceuticals.



# Lipidor AB



TThe use of topical pharmaceuticals is common in treatment of dermal diseases, such as psoriasis and eczema. In many cases, the formulations are inconvenient and results in reduced patient use. Lipidor has developed AKVANO, a water free lipid formulation that is sprayed on the skin. The formulation is safe, free from irritants, dries quickly and feels pleasant on the skin. AKVANO allows for fast and simple application and has excellent cosmetic qualities. Hence AKVANO addresses key issues behind the low usage rate seen with topical formulations.

Results from a clinical phase I/II study with calcipotriol formulated with AKVANO showed effect in patients with psoriasis compared to the marketed formulation of calcipotriol. Lipidor has signed a license agreement for cosmetic products with CCS Healthcare AB, one of the largest Nordic manufacturer of skin care products.

#### Technology

Project: AKVANO

Application: **Topical drug delivery**Development Phase: **Product** 

Ownership: **50%**Project origin: **Start-up** 

More information: www.lipidor.se



# Inhalation Sciences Sweden AB



Inhalation Sciences Sweden AB has developed a patented research and development platform which provides the possibility for companies developing inhaled pharmaceuticals to generate high quality data during the early development stage. The precision dosing system provides the possibility of examining respiratory aerosols prior to any formulation and inhaler device development. The business model includes sales of instrumentation and technology transfer of the platform to pharmaceutical companies as well services to companies without relevant research and development capabilities.

#### Technology

Projects: PreciseInhale

Application: Respiratory precision dosing

Development Phase: Marketed

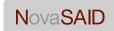
Ownership: 68%\*

Project origin: Karolinska Institutet

More information: www.inhalation.se
\*Includes indirect ownership through KDev Investments



#### NovaSAID AB



Inflammatory diseases, such as rheumatoid arthritis and osteoarthritis, are characterized by joint pain and swelling. These inflammatory symptoms are mediated by the signaling molecule prostaglandin E2 (PGE2). Some of current pharmaceuticals act by reducing prostaglandins, but are not selective for PGE2 but will also reduce other physiologically important prostaglandins. The long-term use of these treatments therefore leads to gastrointestinal and cardiovascular side effects. NovaSAID develops a selective inhibitor of microsomal prostaglandin E-synthase 1, the enzyme that is responsible for the formation of PGE2 during inflammation. The project is being developed together with Cadila Pharmaceuticals Ltd. According to the license agreement between the companies, all revenue generated from the sale and marketing in India, Middle East and Africa shall be retained by Cadila Pharmaceuticals Ltd. The revenue generated from sales in all other countries will be shared by the two companies. Cadila Pharmaceuticals will bear all costs associated with the program through phase II clinical development.

#### **Pharmaceuticals**

Project: Selective inhibitor of microsomal PGE-synthase 1

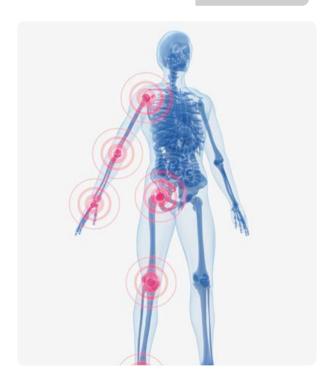
Primary indication: Inflammatory disease

Development Phase: Preclinical

Ownership: 77%

Project origin: Karolinska Institutet

\* Includes indirect ownership through KDev Investments



# Pergamum AB

Pergamum AB's development programs focus on peptides derived from human proteins and further optimized for their biopharmaceutical properties. These properties include broad antibacterial action, modulation of inflammation and restoration of functions that are essential for normal wound healing. The efficacy of the pharmaceutical products that are available on the market is considered very limited and there is a very high demand for products that can provide curative therapy.

A phase I/II clinical trial of Pergamum AB's peptide LL-37 in patients with venous leg ulcers has been completed. Safety and tolerability were excellent and LL-37 had a significantly improved healing rate compared to placebo. Pergamum AB's peptide PXL-01 has demonstrated to placebo.

#### Pharmaceuticals

Projects: LL-37, PXL01, DPK-060, PXL181

Primary indications: Venous leg ulcers, surgical adhesions, external otitis, infected eczema, skin infection

Development Phase: Phase II (PXL181 in preclinical phase)

Ownership: 56%\*

Project origin: Karolinska Institutet, Lund University, Uppsala University, Sahlgrenska University Hospital

More information: www.pergamum.com

\* Includes indirect ownership through KDev Investments



strated signs of efficacy in a clinical phase II trial for the prevention of post-surgical adhesion and the peptide DPK-060 has shown improvement in cure rate of outer ear infections. Pergamum AB has signed a co-development agreement with Cadila Pharmaceuticals Ltd. regarding PXL181, one of Pergamum's early stage development projects. The company is currently evaluating additional strategic partnering opportunities.



# **Promimic AB**



With its high growth, the implant industry is driven by a search for improved materials and new implant surfaces in order to improve clinical outcome and develop new products. Several new implant materials have recently been developed with very good mechanical properties. However, many materials have a limited ability to integrate with bone. Promimic AB develops a unique implant coating, HAnano Surface, that can be applied on all implant materials, including metals, ceramics, pyrocarbon and polymers, regardless of dimensions and structure of the implant. The 20 nanometer thin coating of hydroxyapatite accelerates integration with bone and increases the anchoring strength of the implants. The technology has been extensively evaluated both in vitro and in vivo demonstrating that HAnano Surface reduces healing time of

an implant. HAnano Surface has received FDA approval for use in connection with dental implants. Promimic AB aims to become the implant industry's preferred supplier of synthetic bone materials for the interface between implant and the human tissue.



#### Technology

Project: HAnano Surface
Application: Implant surface
Development Phase: Marketed

Ownership: 31%\*

Project origin: Chalmers University of Technology

More information: www.promimic.com
\* Includes indirect ownership through KDev Investments

# **Umecrine Mood AB**



Many women experience some form of discomfort and mood changes in the period before their menstruation. In about five percent of fertile aged women these symptoms are so debilitating that they affect normal social life. This condition is classified as the disease state premenstrual dysphoric disorder (PMDD). The symptoms cause significant suffering for the affected patients and confers huge costs on society. Umecrine Mood AB's pharmaceutical candidate UC1010 is a first-in-class therapy for PMDD. UC1010 is being developed specifically to target the atypical effects of progesterone metabolites on GABA-A receptor activity in the brain, believed to underlie key PMDD symptoms. In a phase II study, 120 patients with PMDD received subcutaneous injections with either

placebo or one of two doses of UC1010 during one menstrual cycle. The objectives of the trial were to study the safety and efficacy of UC1010. The primary efficacy objective was reduction in the typical symptoms of PMDD. There were no safety concern with UC1010 and it was well tolerated. While the primary efficacy objective of the study was not met, post hoc analysis revealed that correcting for certain confounding factors in the study, promising signs of activity were demonstrated. These data needs to be confirmed in additional clinical trials.

#### **Pharmaceuticals**

Project: UC1010

Primary indication: PMDD and severe PMS

Development Phase: Phase II

Ownership: 38%\*

Project origin: Umeå University

More information: www.umecrine.se/mood

\* Includes indirect ownership through KDev Investments and Umecrine AB



# Karolinska Development's share and shareholders in 2014

#### Ownership structure

On December 31, 2014, Karolinska Development had 3,014 share-holders. International investors owned 45% of the share capital and 36% of the votes. On the same date, institutional investors held 92% of the share capital and 94% of the votes. All series A shares (each of which carries 10 votes, compared with 1 vote for each B share) are held by Karolinska Institutet Holding AB.

#### Share performance

The closing price on the first trading day was SEK 31.0, and at year-end 2013 the share traded at SEK 13.3, a decrease of 57%. No dividend was paid in 2014.

#### Share capital

At year-end 2014, the share capital amounted to SEK 26.7m distributed among 53.4 million shares. The quota value is SEK 0.50 per share. The net asset value amounted to SEK 30.8 per share.

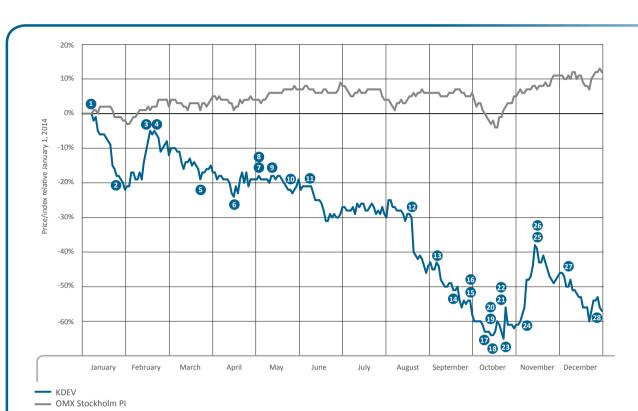
#### Ticker symbol and listing

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

#### Shareholder

	A-shares	B-shares	Cap %	Vote %
Thai Charoen Pokphand Group	0	4,853,141	9.1%	7.3%
Third Swedish National Pension Fund	0	4,678,500	8.8%	7.0%
Karolinska Institutet Holding AB	1,503,098	2,126,902	6.8%	25.6%
Coastal Investment Management LLC	0	3,470,541	6.5%	5.2%
The Foundation of Baltic and East European Studies	0	3,345,537	6.3%	5.0%
OTK Holding A/S	0	1,700,000	3.2%	2.5%
Insamlingsstiftelsen för främjande och utveckling av medicinsk forskning vid Karolinska Institutet	0	1,397,354	2.6%	2.1%
Foundation Asset Management AB	0	1,392,035	2.6%	2.1%
Jarla Investeringar AB	0	1,357,555	2.5%	2.0%
Ramsbury Invest AB	0	1,261,278	2.4%	1.9%
Sum top 10 shareholders	1,503,098	25,582,843	50.7%	60.7%
Sum other shareholders	0	26,298,617	49.3%	39.3%
Sum all shareholders	1,503,098	51,881,460	100.0%	100.0%

As at December 31, 2014 Source: Euroclear



#### Significant evens 2014

- 1 NovaSAID initiates partnership with Cadila Pharmaceuticals
- 2 Christian Tange appointed CFO
- 3 Year-end report 2013
- **4** Dilafor enters license agreement with Lee's Pharmaceuticals
- **5** Pharmanest show positive restuls from SHACT feasibility study in hysteroscopies
- **6** Apreas initiates Phase I/II study with APR-246 in ovarian cancer
- 7 January-March interim report
- 8 XSpray Announces Positive Phase I Data for HyNap Nilotinib
- **9** Karolinsk Development's Annual General Meeting New Board Directors elected

- 10 Dilaforette presents Phase I/II data in uncomplicated malaria
- 11 Umecrine Mood reports preliminary data from exploratory Phase II study in PMDD
- 12 January-June interim report
- 13 Bruno Lucidi new CEO in Karolinska Development oncology companies
- 14 Umecrine Mood presents final results from PMDD study
- 15 CEO Torbjörn Bjerke leaves Karolinska Development
- **16** Karolinska Development invites to a Capital Markets Day and brings the third quarter report forward
- 17 Bruno Lucidi appointed CEO of Karolinska Development
- 18 Forendo Pharma announces the US licensing of fispemifene to Apricus Biosciences
- 19 OssDsign's Cranioplug receives marketing approval in the US

- 20 Clanotech receives orphan drug designation in the EU
- **21** Athera initiates Phase I trial with PC-mAb
- 22 January-September interim report and new strategy presented
- 23 Forendo Pharma closes 12 million euro financing
- 24 Karolinska Development secures funding from CP Group initiates convertible bond issue preparations
- 25 Notice of Extraordinary General Meeting
- **26** Boehringer Ingelhiem opts out of Athera option rights for PC-mAb
- **27** Karolinska Development's Extraordinary General Meeting approves issues of convertibles
- 28 Karolinska Development announces preliminary outcome of the rights issue of convertibles

### **Board**

#### **BOARD**



#### **BO IESPER HANSEN**

Chairman and Board member since 2013.
Born 1958. MD. PhD. Other appointments
Chairman of Swedish Orphan Biovitrum AB and
Topotarget A/S. Board member of Hyperion
Therapeutics Inc., GenSpera Inc., Newron SA,
Ablynx NV, Orphazyme A/S and CMC Kontrast
AB. Previous appointments include various
positions in Swedish Orphan International AB
since 1993, including CEO 1998–2010. Medical
advisor for Synthélabo, Pfizer, Pharmacia and
Yamanouchi. Founder of Scandinavian Medical
Research. Holdings in Karolinska Development
SEK 400.000 convertible loan.



#### HENRIJETTE RICHTER

Board member since 2014. Born 1971. PhD MSc. Other appointments Partner at Sofinnova Partners, Paris. Previous positions include Investment Director at Novo Seeds, Novo A/S, (2007-2014) where she served on the boards of Cytoguide ApS, Avilex Pharma ApS, Affinicon ApS, Orphazyme A/S and EpiTherapeutics A/S. In addition she is on the Board of Directors for the Green Development and Demonstration Programme (GUDP) of the Danish Food, Agriculture and Fisheries Ministry. No holdings in Karolinska Development.



#### 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).



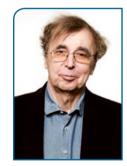
#### CARL JOHAN SUNDBERG

Board member since 2014. Born 1958. Professor of Physiology. Other appointments Board Director of Cobra Biologics AB, Coordinator Science and Society, the Vice-Chancellor's Office at KI, member of Karolinska Institutet Innovation Council, director of the Unit of Bioentrepreneurship, Fellow of the Royal Swedish Academy of Engineering Sciences, member of the Medical Commission of the International Olympic Committee, Inspector General of the Medical Association and Chairman of Research!Sweden. Previous assignments include Investment Director at Karolinska Investment Fund, Board Director of Global Genomics AB, AngioGenetics AB, NsGene AS, Cellectricon AB, Alfta Rehab Center Holding AB, Karolinska Education AB and Feelgood Swedish AB, Vice President of Euroscience and Chairman of the Swedish Professional Associations for Physical Activity and Sports Medicine. No holdings in Karolinska Development.



#### CHARLOTTE EDENIUS

Board member since 2012. Born 1958. PhD., Medical Degree. Other appointments Executive VP Development at Medivir AB. Previous appointments include Senior VP Preclinical & Clinical R&D at Orexo AB, CSO at Biolipox AB, several positions within Clinical R&D at Astra-Zeneca, academic research at Karolinska Institutet and Board Member of Karolinska Institutet Innovations AB and Qlucore AB. No holdings in Karolinska Development.



#### HANS WIGZELL

Board member since 2006. Born 1938. Professor Emeritus of Immunology and MD. Other appointments Chairman of Rhenman & Partner Asset Management AB. Board member of Swedish Orphan Biovitrum AB, Valneva SA, 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 8,491 shares.



#### ROBERT HOLLAND

Board member since 2014. Born 1955. MD, PhD. Other appointments Board director of Newron Pharmaceuticals SpA and Early Clinical Development Consulting Ltd. Medical Director and part of senior management at Oxford Gene Technology IP Ltd. Previous assignments include, leading position in AstraZeneca, including Head of Personalized Healthcare & Biomarkers and Head of Neuroscience, positions in clinical research at Wellcome, Solvay and Upjohn, Fellow of the Faculty of Pharmaceutical Medicine. No holdings in Karolinska Development.

#### The Team



JIM VAN HEUSDEN **Chief Executive Office** 

Appointed in 2015 Born 1971 PhD. Jim Van heusden has over 20 years of experience within venture capital, research and development within the pharmaceutical industry, including as Founder and Managing Director at bioskills (2013-2015) and as Partner at the European investment company Gimv (2001-2013). During his appointment at Gimy he also served as a Board member in several biotech companies including Multiplicom NV (as Chairman), Ablynx NV. ActoGeniX NV. Pronota NV and Prosensa. During 1993-2001, Jim Van heusden worked as Senior Scientist at Janssen Pharmaceuticals (Johnson & Johnson). No holdings in Karolinska Development.



TERJE KALLAND **Deputy CEO and Chief Scientific Officer** 

Appointed Deputy CEO in 2012 and as CSO in 2011. Born 1951. MD, PhD. Terje Kalland has over 20 years experience from senior positions in the pharmaceutical industry, including as Senior Vice President, Biopharmaceuticals Research at Novo Nordisk (2005-2011), CSO of Biovitrum (2002-2005) and Global Head of Oncology Research at Pharmacia Corporation (1988-2002). Terje Kalland is a member of the Royal Swedish Academy of Engineering Sciences. Other appointments Chairman of KDev Oncology AB and Axelar AB. Board member of Akinion Pharmaceuticals AB and ARTs Biologics A/S. Holdings in Karolinska Development 45,000 shares and SEK 164,850 convertible loan.



CHRISTIAN TANGE Chief Financial Officer

Appointed in 2014. Born 1966. MSc in Economics and Business Administration. Christian Tange has over 15 years' experience in international growth companies including 12 years within life science as global CFO for CMC Biologics from 2003-2012 and Business Controller for Warner Lambert Nordic from 1997-2000. Christian Tange has also acted as an industrial advisor and consultant for Private Equity Funds and Corporate Finance Advisors in M&A deals within life science. Other appointments Board member of Dilafor AB and KDev Investments AB. Holdings in Karolinska Development 34,333 shares.



LILE 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 4,967 shares and SEK 15,543 convertible loan.



**GUNILLA EKSTRÖM Vice President Operations** 

Appointed in June 2012. Born 1958. MD, PhD, Associate Professor at Karolinska Institutet. Gunilla Ekström has over 20 years of experience from senior positions in the pharmaceutical industry, including as Senior Vice President at Orexo AB and Global Product Director at AstraZeneca R&D. Other appointments Board member of Athera Biotechnologies AB, Biosergen AS Inhalation Sciences Sweden AB Lipidor AB, NovaSAID AB, Pharmanest AB, and CEO of Biosergen AS. Holdings in Karolinska Development 11.983 shares.



ANN-SOFIE STERNÅS **Vice President IPR** 

Appointed in June 2012. Born 1961. European Patent Attorney, MSc Chemical Engineering. Ann-Sofie Sternås has almost 20 years of IP experience from large pharmaceutical companies and has held senior IPR positions within Astra and AstraZeneca. During many years, Ann-Sofie was heavily involved in IP litigation of several block-buster drugs. Ann-Sofie is specialized in IP-strategic matters with a heavy focus on the US legislation, particularly IP in the interface between patent law and regulatory law. Other appointments Part of a number of management teams within the Karolinska Development portfolio companies. Holdings in Karolinska Development 9,600 shares.



DANIEL BOLANOWSKI Business Analyst

Employed since August 2010. Born 1982. MSc in Molecular Biotechnology Engineering, MSc in Business and Economics. Daniel Bolanowski has worked for Karolinska Development for more than three years since joining as a university graduate. Other appointments Part of the business development teams in Axelar AB and Akinion Pharmaceuticals AB. Holdings in Karolinska Development 100 shares.



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 1,667 shares.



MICHAEL OWENS
Controller

Controller since 2007 and employed since 2010. Born 1956. BsBA in accounting. Michael Owens was an auditor at Arthur Andersen & Co. and Authorized Public Accountant at Ernst & Young AB and held the position as CFO for 12 years at Vitamex AB. Several years of experience as Management consultant. Other appointments Advisor to portfolio companies. Holdings in Karolinska Development 7,888 shares.



MARIA FERM
Executive Assistant

Employed since December 2011. Born 1969. Maria Ferm has previously had Executive Assistant and Office Manager roles including at Vectura Consulting, Manpower and Spray. Holdings in Karolinska Development 2,000 shares.

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# Directors' report

The Board of Directors and the CEO of Karolinska Development AB (publ), corporate identity number 556707-5048, hereby present their annual report for the Investment Entity and parent company for the financial year 2014.

#### SIGNIFICANT EVENTS DURING THE FINANCIAL YEAR

Karolinska Development AB

#### Financing

Directed share issue amounting to SEK 63 million

Karolinska Development completed a private placement totaling SEK 63m before issue costs to the leading Asian life science investor Sino Biopharmaceutical Limited, a member of the Thai Charoen Pokphand Group (CP Group). The subscription price was SEK 13 per share, which was 4.4 percent lower than the share price at the closing of NASDAQ OMX Stockholm on 4 November 2014, the previous trading day, and 10.7 percent higher than the volume weighted average price during the period from 8 October to 4 November 2014. The subscription price was agreed upon after negotiations between Karolinska Development and the subscriber, based on the quoted market value of the share.

#### Issue of convertible loans

The Extraordinary General Meeting in Karolinska Development resolved to approve the Board of Directors' decision (pending the general meeting's approval) to raise convertible loans through a rights issue of convertible bonds and a directed issue of convertible bonds to CP Group with nominal amounts not exceeding approximately SEK 228m and SEK 173m, respectively.

Efter the end of 2014 the issue of convertible loans were completed after Karolinska Development received applications to subscribe for convertibles without subscription rightsafter the end of the subscription period to an aggregate amount of SEK 39m from Paradigm Capital Value Fund SICAV and EMF Europäische Marketing und Finanzmanagement AG, which had not previously been shareholders in the company. To be able to allot the convertibles, the Board of Directors of Karolinska Development decided to extend the subscription period until 28 February 2015. As a result, the rights issue of convertibles was subscribed to approximately 94% and provided Karolinska Development with nominal proceeds of approximately SEK 214.0m before transaction costs. Together with the directed issue of convertibles with a nominal amount of approximately SEK 172.9m to CP Group, Karolinska Development generated proceeds of approximately SEK 386.9m before transaction costs.

# Karolinska Development presented its new strategy at the Company's Capital Markets Day

During the fourth quarter, Karolinska Development presented a new and more focused strategy to optimize and unlock value in the existing portfolio. Karolinska Development's Board and management are convinced this new strategy will put Karolinska Development in a stronger position to take advantage of the business opportunities that the portfolio companies offer:

- Karolinska Development invests in a focused portfolio of scientifically attractive programs, where well-defined unmet medical needs exist, focused on specialty care products and orphan drugs.
- The Company spurs strong leadership in its portfolio companies with a focus on clinical development towards significant value inflection points.
- Karolinska Development maximizes value creation through a differentiated investment strategy, where companies in the portfolio are financed based on significant value inflection points in order to reach an exit which is optimal with regard to the unique situation of each portfolio company.
- Karolinska Development proactively seeks syndication with professional investors within the life science sector in order to further expand the Company's expertise and network.

New Board Directors elected at the Company's Annual General Meeting Karolinska Development's Annual General Meeting on 14 May elected Robert Holland, Henrijette Richter and Carl Johan Sundberg as new members of the Board of Directors. Bo Jesper Hansen (Chairman), Vlad Artamonov, Charlotte Edenius, Hans Wigzell and Klaus Wilgenbus were re-elected. Rune Fransson and Per-Olof Edin declined re-election.

#### Changes in management

Bruno Lucidi, who earlier in the year was appointed CEO of KDev Oncology and the portfolio companies Aprea and Akinion Pharmaceuticals, was named CEO of Karolinska Development. Previously, a month earlier, Torbjörn Bjerke stepped down as CEO.

Christian Tange succeeded Robin Wright as CFO. Christian Tange (b. 1966) has over 15 years' experience in international growth companies and in recent years has acted as a consultant to private equity funds and corporate finance advisors in M&A deals within life science. During the period 2003-2012, he worked as global CFO of CMC Biologics, an international biotech contract manufacturing company. Christian holds a master's degree in economics and law from Copenhagen Business School.

### Portfolio companies

#### Business development

Forendo Pharma announced the US licensing of fispemifene to Apricus Biosciences

Forendo Pharma Oy announced that it has entered into a definitive agreement to out-license the US development and commercialization rights for fispemifene to Apricus Biosciences Inc. Under the terms of the agreement, Apricus will make a USD 5m upfront cash payment to Forendo and will transfer approximately 3.6 million Apricus common shares, representing USD 7.5m in value based on the 360-day average market price of the Apricus stock. The agreement includes additional potential clinical and regulatory milestones payments to Forendo for up to USD 45m, including FDA approval, as well as commercial milestone payments totaling up to USD 260m based on achieving specified annual net sales of fispemifene levels up to USD 1 billion in the US. Apricus will also pay tiered double-digit royalties based on net sales once the product is commercialized. Apricus will be responsible for the clinical development and costs of the program, as well as all future commercialization in the US. Apricus anticipates commencing a Phase IIb clinical trial during the first half of 2015 to confirm the optimal fispemifene doses to treat men with secondary hypogonadism, and provide proof-of-concept data to evaluate the anti-estrogenic and anti-inflammatory effects on the lower urinary tract and prostate in aging men.

# Forendo Pharma closed a EUR 12 million financing round to develop a novel therapy for endometriosis

Forendo Pharma announced the successful closing of a EUR 12m financing round. Novartis Venture Fund and MS Ventures will participate in the financing round, alongside the current major shareholders Karolinska Development, Novo Seeds and Finnvera.

# Dilafor entered into a license and partnership agreement with Lee's Pharmaceutical

Pursuant to the terms of the agreement, Dilafor and Lee's Pharmaceutical will jointly develop tafoxiparin for obstetrical and gynecological indications. The joint clinical development program of tafoxiparin will initially focus on reducing labor times for patients who do not start labor spontaneously and are induced into labor. Dilafor received an upfront cash payment and is entitled to future milestone payments under product development and commercialization. In addition, Dilafor is entitled to royalties on sales of the product which will be manufactured and sold by Lee's Pharmaceutical in China, Hong Kong, Macao and Taiwan. Lee's Pharmaceutical will conduct and finance Phase II and Phase III trials in China, so that the results can be used as the basis for additional development outside the countries covered by the agreement.

Boehringer Ingelheim decided not to exercise its option rights with Athera Biotechnologies on the development of PC-mAb

Athera Biotechnologies announced that Boehringer Ingelheim International GmbH will not exercise the option agreement to license Athera's cardiovascular antibody due to re-evaluation of Boehringer Ingelheim's R&D strategy. The ongoing clinical development program at Athera of the fully human antibody PC-mAb is not affected by the termination of the agreement. PC-mAb is intended for the treatment of patients with cardiovascular disease, who are at an increased risk of secondary events and death. Boehringer Ingelheim's decision to terminate the option agreement has been made as a consequence of a re-focus in its corporate R&D strategy. Athera's ongoing Phase I study with PC-mAb will proceed as planned and the co-financing of future development costs through the EU FP7 program CARDIMMUN is not affected by Boehringer Ingelheim's decision.

NovaSAID initiated a partnership with Cadila Pharmaceuticals to develop innovative treatments in inflammation and pain management NovaSAID and Cadila Pharmaceuticals announced that they will collaborate on preclinical and clinical development of a number of drug candidates that have been developed by NovaSAID. Development will be conducted at Cadila Pharmaceuticals' facility in Ahmedabad, India. According to the agreement, all revenue generated from the sale and marketing in India, the Middle East and Africa of products covered by the agreement will be retained by Cadila and net sales in all other countries will be shared by the two companies. Cadila will bear all costs associated with the program through Phase II.

#### Clinical development

XSpray announced positive Phase I data for HyNap™ Nilotinib XSpray Microparticles AB announced that its proprietary HyNap™ formulation of nilotinib demonstrated significantly improved uptake and reduced food interaction in a Phase I clinical trial compared with previously reported data for the commercially available formulation of nilotinib. In the completed cross-over Phase I clinical trial, XSpray measured the exposure of its proprietary HyNap™ formulation of nilotinib in healthy individuals. When administered in the fasted state, a HyNap™ nilotinib dose of 150 mg produced the same AUC values (area under the curve) as those reported for a dose of 400 mg of the marketed product. After a high-fat meal, the study showed an increase in drug exposure of 25 percent for HyNap™ nilotinib, measured both as peak concentration (Cmax) and AUC. The corresponding increases for the marketed product after a high-fat meal are reported to be 112 percent and 82 percent, respectively. In addition to the clinical results obtained for HyNap™ nilotinib, XSpray has in a number of comparative in vivo preclinical studies showed improved results for both exposure and

#### Dilaforette presents results from exploratory Phase I/II clinical trial in uncomplicated malaria

Dilaforette AB announced the results from an exploratory Phase I/ II clinical trial in malaria with its candidate drug sevuparin. Sevuparin was studied in adult patients with uncomplicated falciparum malaria as adjunct treatment and was found to be safe and well tolerated. The study results indicate important early anti-adhesive effects with a potential to improve the outcome for patients with severe malaria, even though the primary efficacy endpoint was not met.

reduced pH dependency for a number of other marketed PKIs.

The aim of the present trial was to study sevuparin in adult patients with uncomplicated falciparum malaria prior to studies in patients with severe malaria. Due to slow recruitment and in order to progress the program into severe malaria, it was decided to prematurely terminate the study when a total of 53 of the planned 89 patients had been treated. Among the 53 patients that were treated, 23 patients received SoC and 30 patients received SoC plus sevuparin. The study results showed that sevuparin is safe and well-tolerated in adult patients with uncomplicated falciparum malaria. The study did not reach statistical significance on its primary efficacy endpoint, i.e., an increase in appearance of mature parasitized red blood cells into the blood circulation over the first 11

hours after start of sevuparin treatment. However, due to the premature termination of the trial, the results do not suffice as the basis for conclusive determination of the effect of sevuparin. Exploratory analyses indicated a higher number of mature parasites in the circulating blood just one hour after the first dose of sevuparin. This observation is consistent with the intended effect of sevuparin, which is to reverse blockage of blood vessels by mature parasitized red blood cells, which normally stick to the vessel wall and obstruct the blood flow. In addition, the number of young parasitized cells consistently decreased over the early time period after the initial sevuparin injection, which is in line with the assumed capacity of sevuparin to block parasite invasion into red blood cells. As patients with uncomplicated malaria have a much lower parasite load than patients with severe disease, the exploratory analysis supports further clinical studies in severe malaria with the aim to show that sevuparin can reverse the binding, which should improve blood flow and clinical outcome.

Umecrine Mood reported results from exploratory Phase II study with UC1010 in premenstrual dysphoric disorder (PMDD)

In an exploratory double blind, randomized multicenter study, 120 patients with PMDD received placebo or one of two doses of UC1010 during one menstrual cycle. The primary efficacy end point was assessed using a validated daily rating scale (DRSP) to measure premenstrual symptoms before and after treatment with UC1010 vs. placebo. As reported in June 2014, the primary end point was not met.

A post hoc analysis indicated two key variables impacted the outcome. Despite patient randomization, the baseline follicular phase symptoms prior to treatment showed a skewed distribution. Recalculation of the results to correct for individual follicular symptoms revealed a statistically significant improvement in symptoms with UC1010 compared with placebo in the study population (p<0.05 for the total premenstrual symptom score). Secondly, due to inconsistencies in the assessment of ovulation, 32% of patients did not receive treatment as intended according to the protocol. Including only patients treated as intended, there were highly significant beneficial effects from UC1010 (both doses) compared with placebo, both for the cardinal PMDD symptoms (p=0.003) and total premenstrual symptom scores (p=0.006), as well as for the impairment score (p=0.01), which specifically measures the impact of symptoms on daily life. The study also showed that there were no safety concerns with UC1010 and that it was well tolerated. The company is now focused on finding a partner and investors for further development of UC1010.

Dosing initiated Phase I/II clinical trial of APR-246 in ovarian cancer Aprea AB announced that dosing has begun in the Phase I/II proof-of-concept clinical trial of APR-246 in combination with chemotherapy in patients with relapsed platinum sensitive high grade serous ovarian cancer. Aprea has successfully developed substances that can restore normal function to the p53 protein and thereby induce efficient cancer cell death and overcome resistance to antitumoral therapy. To the company's knowledge, APR-246 is the only compound with this mechanism of action in clinical development.

Athera initiated Phase I trial with fully human antibody PC-mAb Athera Biotechnologies AB announced that first dosing of healthy volunteers has been done in a Phase I study of its fully human antibody PC-mAb. Athera's fully human monoclonal antibody PC-mAb is intended for the treatment of patients with cardiovascular disease, who are at an increased risk of secondary events and death. It is known from previous published studies that low plasma levels of endogenous antibodies against phosphorylcholine (anti-PC) are linked to poor prognosis in acute heart attack patients, as well as in patients with peripheral arterial disease undergoing vein graft surgery. The current Phase I study will include up to 48 healthy volunteers in a single ascending dose protocol with safety outcome measures.

# Pharmanest presented study data suggesting SHACT could benefit women undergoing hysteroscopies

The primary objective of the study was to obtain information about the feasibility of administering SHACT to patients in conjunction with hysteroscopy. The non-comparative open label study was conducted at Södersjukhuset in Stockholm, Sweden. Secondary objectives included safety, tolerability and handling properties of SHACT and its instillation

device. Ten patients were included in the trial and parameters such as visibility for the examiner, ease of application and time required for use of SHACT were documented. The results indicate that SHACT is not interfering negatively with the examination and that the product can be used in the outpatient setting to ease women's pain and discomfort. No safety or tolerability issues were recorded in the study. The potential pain relief offered by SHACT was not evaluated in this particular study and has therefore to be confirmed in a forthcoming clinical trial.

#### Regulatory news

OssDsign's Cranioplug received marketing approval in the US OssDsign AB announced that its bioceramic burr hole plug. Cranioplug. had received 510(k) clearance by the US Food and Drug Administration (FDA). In the 500,000 open brain surgeries carried out annually worldwide, burr holes and circular cuts between the burr holes are made to allow the surgeon to access the brain for the intended intervention. The bone flap is then re-anchored to the surrounding skull bone after the procedure is completed. These solutions typically leave the burr hole open, to the cosmetic and psychological detriment of patients. In contrast to metal-based competitors, Cranioplug, which is based on bone-like ceramic materials, has the potential of integrating with surrounding bone.

Clanotech received orphan drug designation in the EU for its product candidate in glaucoma surgery

Clanotech AB received orphan drug designation for its candidate drug CLT-28643 by the European Medicines Agency (EMA) for prevention of scarring post glaucoma filtration surgery. Clanotech's lead substance, an  $\alpha 5\beta 1$ -integrin antagonist, has anti-angiogenic, anti-fibrotic and antiinflammatory properties that are expected to benefit the wound healing processes following glaucoma surgery. The orphan drug designation will significantly shorten a future market approval process and reinforce market exclusivity for a launched product.

#### SIGNIFICANT EVENTS AFTER THE BALANCE SHEET DATE

### Karolinska Development

Following an extension of the subscription period, Karolinska Development finalized its financing through the issue of convertibles After the end of the subscription period, Karolinska Development received applications to subscribe for convertibles without subscription rights to an aggregate amount of SEK 39m from Paradigm Capital Value Fund SICAV and EMF Europäische Marketing und Finanzmanagement AG, which had not previously been shareholders in the company. To be able to allot the convertibles, the Board of Directors of Karolinska Development decided to extend the subscription period until 15 January 2015. As a result, the rights issue of convertibles was subscribed to approximately 94% and provided Karolinska Development with nominal proceeds of approximately SEK 214.0m before transaction costs. Together with the directed issue of convertibles with a nominal amount of approximately SEK 172.9m to CP Group, Karolinska Development generated proceeds of approximately SEK 386.9m before transaction costs.

#### Jim Van heusden appointed as CEO

Jim Van heusden was appointed CEO of Karolinska Development after Bruno Lucidi left the company. Prior to joining Karolinska Development, Jim founded his own company bioskills in 2013, providing an entrepreneurial approach towards fundraising and strategic advice for biotech companies and life science funds. From 2001 to 2013, he held various positions at Gimv focusing on investments in life sciences, and since 2007 as a partner, Jim has an excellent and proven track record in building successful companies. Prior to joining Gimv, he was working as a senior scientist at the department of Oncology at Janssen Pharmaceutical, a Johnson & Johnson company. Jim is a Belgian citizen and has a PhD in molecular and cellular biology from the University of Maastricht.

#### The shares in Axelar were divested

Karolinska Development sold its shares in Axelar to Östersjöstiftelsen as a part of implementing the new strategy with an increased focus on the strategic portfolio. The fair value of Karolinska Development's holding in Axelar was written off in 2014.

Decrease in portfolio fair value due to write-offs

On April 28, 2015 Karolinska Development AB announced a decrease in reported portfolio fair value for the January-March Interim Report 2015, amounting to SEK 225.2 million, resulting in a portfolio valuation of SEK 1,277.0 million. Following decisions to discontinue further investment in Pergamum AB, Umecrine Mood AB and NeoDynamics AB (opportunistic portfolio companies) and after exploring several options, Karolinska Development decided to fully write off these companies. Pergamum value was written off with the amount of SEK 120.2 million, Umecrine Mood with the amount of SEK 58.9 million and NeoDynamics AB with the amount of SEK 9.7 million – all compared to the year-end 2014 valuations. Additional adjustments of fair value of the portfolio amounted to SEK -36.4 million.

### Portfolio companies

Dilaforette signed co-development agreement with Ergomed for sickle-cell disease treatment

Under the terms of the agreement, Ergomed has been appointed as the clinical development organization to conduct Dilaforette's multicentre. multinational, randomized Phase II study in SCD patients suffering from VOC. The study is scheduled to start in Q2 2015. Ergomed will furthermore co-invest a proportion of its revenues from the clinical and regulatory activities of the trial in return for an equity stake in Dilaforette.

### FINANCIAL DEVELOPMENT FOR THE INVESTMENT ENTITY IN 2014 (SEKM)

Result from change in fair values in portfolio companies

The effect of the change in fair value of portfolio investments for year 2014 amounted to SEK -310.4m (SEK -140.0m).

#### Value development

During the year, the Investment Entity's operating loss amounted to SEK -372.2m (SEK -198.7m), a change of SEK -173.5m compared with the same period in 2013.

During the year, several projects in the portfolio met development milestones, which had a positive effect on the fair values of these portfolio companies. At the same time, a number of projects in the portfolio developed at a slower rate than previously projected, which resulted in negative changes in fair values. The operating loss during the year was affected by a change in fair value of KDev Investments' holdings in Axelar AB of SEK -220.7m after the partnering process failed to meet expectations. The fair value change in Biosergen AS affected the operating loss by SEK -28.3m, due to a lack of financing for future development. During the year, the fair value was affected positively by adjustments of the discount rates (WACC) (see "Information on fair value measurement in level 3" in Note 18).

Other expenses have decreased by SEK 8.8m year-over-year. Expenses for legal services, consultants and travel have decreased year-over-year, and the comparative period's operating result was charged with oneoff expenses of SEK 3.5m related to the Rosetta transaction. During the period, personnel costs were charged with severance provisions for the former CEO, Torbjörn Bjerke, of SEK 7.2m, including pension and social security expenses and bonus reserves for management of SEK 8.5m including social security expenses.

#### Results

The Investment Entity's loss before tax during the year amounted to SEK -375.8m (SEK -157.3m).

#### Financial position

The Investment Entity's equity to total assets ratio was 96% (99%) on 31 December 2014 and equity amounted to SEK 1,645.5m (SEK 1,957.6m). Cash, cash equivalents and short-term investments in the Investment Entity amounted to SEK 141.3m (SEK 200.7m), of which SEK 124.2m is provisionally allocated for anticipated follow-on investments in the KDev Investments portfolio. Total assets amounted to SEK 1,710.4m (SEK 1,979.6m).

#### Cash flow

Cash flow for the Investment Entity amounted to SEK -22.4m (SEK -73.4m) in 2014. Cash flow from operating activities amounted to SEK -108.4m (SEK -70.9m). Financing activities provided the Investment Entity with SEK 85.9m (SEK 0.0m) through an issue of new shares and pending issue of convertibles, while shares were repurchased for SEK 0.0m (SEK -2.5m).

#### Investments in portfolio companies

Investments in portfolio companies during the year amounted to SEK 84.0m (SEK 266.2m).

Investments made during the year in KDev Investments' portfolio amounted to SEK 47.2m (Dilaforette Holding AB, SEK 18.0m; Aprea AB SEK 6.4m; Dilafor AB, SEK 6.0m; Umecrine Mood AB, SEK 5.8m; NeoDynamics AB SEK 3.6m; Clanotech AB, SEK 2.9m; Pergamum AB, SEK 1.8m; Promimic AB, SEK 1.8m; and Inhalation Sciences Sweden AB, SEK 0.9m) as well as in Umecrine Cognition AB, SEK 15.0m; XSpray Microparticles AB, SEK 6.7m; Pharmanest AB, SEK 7.7m; KCIF Co-Investment Fund KB, SEK 3.8m; and Forendo Pharma Oy SEK 3.6m.

# FINANCIAL DEVELOPMENT FOR THE PARENT COMPANY IN 2014 (SEKM)

During year 2014, the Parent Company's operating loss amounted to SEK -76.8m (SEK 47.3m), a change of SEK -124.1m compared with the same period in 2013. Operating profit for the comparative period includes a capital gain of SEK 123.7m on the sale of shares in KDev Investments AB to Rosetta.

The operating result for the year was charged with impairment losses on the holdings in Athera Biotechnologies AB SEK -12.0m, share of losses in KCIF Co-Investment Fund KB SEK -1.9m, Umecrine AB -0.9m and KDev Oncology AB SEK -0.1m. Other expenses have decreased by SEK 8.9m year-over-year. Expenses for legal services, consultants and travel have decreased year-over-year, and the comparative period's operating result was charged with one-off expenses of SEK 3.5m related to the Rosetta transaction. During the year, personnel costs were charged with severance provisions for the former CEO, Torbjörn Bjerke, of SEK 7.2m, including pension and social security expenses and bonus reserves for management of SEK 8.5m including social security expenses.

The Parent Company's net loss during the year amounted to SEK -78.1m (SEK 47.3m).

# Remuneration guidelines for the CEO and other senior executives as well as other conditions

Remuneration guidelines for senior executives are prepared and approved by the Board of Directors. The guidelines are adopted by the Annual General Meeting (Note 5).

#### Holding of treasury shares

At year-end, the company held 244,285 treasury shares, corresponding to SEK 122,143 of the share capital, and the consideration paid totaled SEK 4.7m. The purpose of the share repurchases is to cover social security costs related to incentive programs PSP 2012, PSP 2013 and PSP 2014.

#### Future development

Historically, Karolinska Development has financed its operations through equity, which is also the intent going forward. Long-term capital requirements are increasingly expected to be covered by cash flow generated from exits from certain portfolio companies and licensing agreements.

Karolinska Development does not provide any forecasts with regard to the divestment of its portfolio companies.

#### 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 the applicable

health and safety regulations and offers its employees a safe and sound working environment.

#### Information on risks and uncertainties

#### Valuation risks

Companies active in pharmaceutical development and medical technology at an early phase are, by their very nature, difficult to value, as lead times are very long and development risks are high. Due to the uncertainty in these assessments and the subjectivity in the inputs, the estimated value of the portfolio may deviate substantially from future generated value. This is largely due to sensitivities in the valuation calculations to movement of expected milestone or exit dates, costs of trials and similar assumptions, which are not necessarily accounted for in arriving at an actual deal value in negotiations with partners. Financing strategy decisions can have an effect on valuations.

#### Project development risks

Risks and uncertainties are primarily associated with investments in portfolio companies and the development of projects in these companies. The operations of the portfolio companies consist of the development of early stage pharmaceutical projects. By their very nature such operations are distinguished by very high risk and uncertainty in terms of results.

#### Financial risks

Financial risks consist of investments in the form of equity and debt instruments in portfolio companies as well as risks in the management of liquid assets.

#### Future financing needs

Karolinska Development invests in companies where good returns can be generated. Development of the portfolio companies' research projects will require capital from their investors in order to realize the values in the companies. There is no guarantee, however, that the portfolio companies can obtain enough capital to finance the projects on favorable terms or that such capital can be obtained at all.

Long-term financing of the portfolio companies' capital requirements is satisfied by Karolinska Development investing alone or together with other investors. Although Karolinska Development maintains a strategy to continuously invest in portfolio companies in syndication with other investors, it may deviate from investing its pro rata share in the portfolio companies, which could affect Karolinska Development's valuation of the portfolio companies. In the event the portfolio companies are unsuccessful in attracting other investors, Karolinska Development may decide to invest alone, which could also affect the valuation of the portfolio companies.

Priorities must be set to optimize the return. The portfolio companies may fail to achieve milestones or develop according to plan. In such cases the portfolio companies may have to limit their operations. Karolinska Development's ownership interest may be diluted by other investors, and co-investors may abstain from co-investing on the same terms. If any of these risks were to occur, it could have a negative effect on the portfolio companies operations and on Karolinska Development's valuation of the portfolio companies. There may also be a risk that Karolinska Development will refrain from participating in investments in the opportunistic portfolio. If a project lacks co-investors that validate the portfolio companies' valuations, it could negatively affect those valuations.

Investments in portfolio companies in 2015 are expected to increase year-over-year since more portfolio companies in the strategic portfolio are engaged in critical operations in valuation terms, or intend to launch such activities during the year. Several companies are expected to enter into licensing agreements with partners, and non-dilutive contributions such as EU funding and third-party financing are expected to increase. In both the strategic and opportunistic portfolio, the strategy to seek out more co-investors may lead to a greater potential for success.

#### Uncertainty in forecasts

Judgments and assumptions about the future outcome of development projects involving pharmaceuticals and medical technology are always associated with great uncertainty. There are no guarantees of the accuracy of forecasted developments.

For a detailed description of risks and uncertainties, see pages 55–56.

### Five-year summary

		Investment Entity <sup>1</sup>			
		2013	2012	2011	
SEKm	2014	(restated)	(restated)	(restated)	2010 (restated)
Income statement	_	_			
Revenue	5	5	4	2	11
Operating expenses	-69	-64	-60	-64	-57
Result from change in fair value	-310	-140	121	-176	-233
Result from sale of portfolio companies	2	-	-	-	
Operating profit/loss	-372	-199	65	-238	-279
Financial net	-4	41	-22	-6	6
Profit/loss after financial items	-376	-157	43	-244	-273
Balance sheet					
Tangible non-current assets	1	1	-	-	-
Shares in portfolio companies	1,502	1,729	1,827	1,547	1,455
Loans receivable from portfolio companies	12	6	13	4	-
Other financial assets	38	38	9	-	-
Total non-current assets	1,553	1,774	1,849	1,551	1,455
Other current assets	17	5	6	7	101
Short-term investments	128	165	174	457	137
Cash and cash equivalents	13	35	109	68	73
Total current assets	158	206	288	532	311
Total assets	1,711	1,980	2,137	2,083	1,765
Equity	1,646	1,958	2,116	2,075	1,755
Long-term liabilities	35	9	11	-	-
Current liabilities	30	12	11	8	9
Total liabilities and equity	1,711	1,979	2,137	2,083	1,765
Cash flow					
Cash flow from operating activities	-109	-71	43	-568	-304
Cash flow from financing activities	86	-2	-2	563	-7
Cash flow for the year	-22	-73	41	-5	-311
Key ratios					
Capital employed	1,680	1,967	2,126	2,075	1,755
Return on equity	-23%	-8%	2%	-12%	-16%
Return on capital employed	-22%	-8%	2%	-12%	-16%
Equity to total assets ratio	96%	99%	99%	100%	99%
Average number of employees	13	14	16	16	15
Data per share	7.70	2.25	0.00	F F 6	0.22
Profit/loss after tax, SEK	-7.73	-3.25	0.89	-5.56	-8.22
Equity, SEK	30.9	40.5	43.6	42.7	52.7
Net asset value, SEK	30.8	40.7	43.8	42.8	49.9
Share price at year-end, SEK	13.3	30.9	15.30	25.80	-
Dividend, SEK	0.0	0.0	0.0	0.0	0.0
Share price/Equity per share	43%	76%	35%	60%	-
Share price/Net asset value per share	42%	76%	35%	60%	-
Number of shares at year-end	53,384,558	48,531,417	48,531,417	48,531,417	33 331 417
Weighted average number of shares before and after dilution	48,606,243	48,350,016	48,529,767	43,908,951	33,263,938

<sup>&</sup>lt;sup>1</sup> Karolinska Development has adopted Investment Entity standards for the fiscal year beginning January 1, 2014. Historical periods have therefore been restated, see note 45.

### Proposed appropriation of profit (SEK)

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

Retained loss	-502,587,412
Share premium reserve	1,838,917,865
Net profit/loss for the year	-78,130,046
Total	1,258,200,407

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

Total	1,258,200,407
To be carried forward	1,258,200,407

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).

# Financial statements

# Income statement for the Investment Entity

SEK 000	Note	2014	2013 (restated)
Revenue	2	5,030	4,948
Other external expenses	3,4	-16,447	-25,292
•			
Personnel costs	5	-51,933	-38,290
Depreciation of tangible non-current assets		-212	-114
Change in fair value of shares in portfolio companies	18	-310,399	-139,996
Result from sale of shares in portfolio companies		1,745	-
Operating profit/loss		-372,216	-198,744
Interest income		637	5,887
Interest expenses		-4	-49
Other financial gains and losses	6	-4,232	35,591
Financial net		-3,599	41,429
Profit/loss before tax		-375,815	-157,315
Taxes	7	-	-
NET PROFIT/LOSS FOR THE YEAR		-375,815	-157,315

# Earnings per share

			2013
SEK	Note	2014	(restated)
Earnings per share, weighted average, before and after dilution		-7.73	-3.25
Number of shares, weighted average	14	48,606,243	48,350,016

# Statement of comprehensive income for the Investment Entity

			2013
SEK 000	Note	2014	(restated)
Net profit/loss for the year		-375,815	-157,315
Total comprehensive income for the year		-375.815	-157.315

# Balance sheet for the Investment Entity

SEK 000	Note	31 Dec 2014	31 Dec 2013 (restated)	31 Dec 2012 (restated)
ASSETS				
Non-current assets				
Tangible non-current assets	8	317	529	9
Shares in portfolion companies, at fair value through profit or loss	9	1,502,186	1,729,465	1,827,190
Loans receivable from portfolio companies	10	12,062	5,894	12,856
Other financial assets	18	38,113	38,113	8,907
Total non-current assets		1,552,678	1,774,001	1,848,962
Current assets				
Accounts receivable	11	-	3	106
Receivables from portfolio companies		895	254	563
Other current receivables	12	3,103	3,225	2,476
Prepaid expenses and accrued income	13	12,364	1,477	2,463
Short-term investments, at fair value through profit or loss	18	128,443	165,334	174,160
Cash and cash equivalents	18	12,885	35,323	108,680
Total current assets		157,690	205,616	288,448
TOTAL ASSETS		1,710,368	1,979,617	2,137,410
EQUITY AND LIABILITIES				
Equity				
Share capital	14	26,692	24,266	24,266
Share premium		1,828,844	1,768,179	1,768,179
Retained earnings including net profit/loss for the year		-209,992	165,159	323,060
Total equity		1,645,544	1,957,604	2,115,505
Long-term liabilities				
Convertible loan	15	22,858	-	-
Other financial liabilities	18	11,686	9,438	10,889
Total long-term liabilities		34,544	9,438	10,889
Current liabilities				
Accounts payable		4,668	2,426	2,510
Liabilities to portfolio companies		442	442	473
Other current liabilities	16	1,023	1,593	1,512
Accrued expenses and prepaid income	17	24,147	8,114	6,521
Total current liabilities		30,280	12,575	11,016
Total liabilities		64,824	22,013	21,905
TOTAL EQUITY AND LIABILITIES		1,710,368	1,979,617	2,137,410

# Statement of changes in the Investment Entity's equity

		Equity att	ributable to Paren				
SEK 000	Note	Share capital	Share premium	Retained earnings	Total	Non-controlling interests	Total equity
Opening equity at 1 Jan 2014	14	24,266	1,768,179	165,159	1,957,604		1,957,604
Net profit/loss for the year				-375,815	-375,815		-375,815
Total comprehensive income for the year				-375,815	-375,815		-375,815
Share issue		2,426	60,665		63,091		63,091
Effect of incentive programs				664	664		664
Closing equity at 31 Dec 2014		26,692	1,828,844	-209,992	1,645,544		1,645,544
Opening equity at 1 Jan 2013 (restated)	14	24,266	1,768,179	323,060	2,115,505		2,115,505
Net profit/loss for the year				-157,315	-157,315		-157,315
Total comprehensive income for the year				-157,315	-157,315		-157,315
Effect of incentive programs				1,897	1,897		1,897
Share repurchase				-2,483	-2,483		-2,483
Closing equity at 31 Dec 2013 (restated)		24,266	1,768,179	165,159	1,957,604		1,957,604
Opening equity at 1 Jan 2012	14	24,266	1,768,179	-122,547	1,669,898	354,294	2,024,192
Effect of change in accounting policy to Investment Entity	45			404,640	404,640	-354,294	50,346
Adjusted opening equity at 1 Jan 2012		24,266	1,768,179	282,093	2,074,538	-	2,074,538
Net profit/loss for the year				43,210	43,210		43,210
Total comprehensive income for the year				43,210	43,210		43,210
Share repurchase				-2,243	-2,243		-2,243
Closing equity at 31 Dec 2012 (restated)		24.266	1.768.179	323.060	2.115.505	-	2.115.505

# Statement of cash flows for the Investment Entity

SEK 000	Note	2014	2013 (restated)
Operating activities			
Operating profit/loss		-372,216	-198,744
Adjustments for items not affecting cash flow			
Depreciation	8	212	114
Change in fair value	18	310,399	139,996
Result from sale of portfolio companies		-1,745	-
Other items		17,253 <sup>1</sup>	2,171
Proceeds from short-term investments		1,478	1,062
Interest received/paid		356	5,312
Cash flow from operating activities before changes in working capital and operating investments		-44,263	-50,089
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables		-12,175	1,116
Increase (+)/Decrease (-) in operating liabilities		1,117	2,575
Operating investments			
Sale of shares in portfolio companies		1,923	194,924
Investments in shares in portfolio companies	34, 35, 36	-77,326	-198,120
Loans provided to portfolio companies	10	-15,712	-27,750
Sale of short-term investments <sup>3</sup>		38,049	7,105
Acquisitions of tangible non-current assets		-	-635
Cash flow from operating activities		-108,387	-70,874
Financing activities			
Share repurchase		-	-2,483
Share issue		63,091	-
Convertible debenture issue <sup>2</sup>		22,858	-
Cash flow from financing activities		85,949	-2,483
Cash flow for the year		-22,438	-73,357
Cash and cash equivalents at the beginning of the year	18	35,323	108,680
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR	18	12,885	35,323

<sup>&</sup>lt;sup>1</sup> Adjustment for not cash flow affecting items related to severance pay, bonus to management and cost for incentive programs

# Supplemental disclosure<sup>3</sup>

CEV COO	204	2013
SEK 000	lote <b>201</b> 4	(restated)
Cash and cash equivalents at the end of the year	12,885	35,323
Short-term investments, market value at closing date	128,443	165,334
CASH AND CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS AT THE END OF THE YEAR	141,328	200,657

<sup>3</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 consequently are not reported as cash and cash equivalents and therefore are included in cash flow from operating activities. The supplemental disclosure is presented to provide a comprehensive overview of the Investment Entity's available  $\dot{\text{funds}}$  , including cash, cash equivalents and short-term investments.

<sup>&</sup>lt;sup>2</sup> Pending issue of convertible debentures has been finalized in February 2015 which in addition generated SEK 364m.

# Income statement for the Parent Company

SEK 000	Note	2014	2013
Net sales	24	5,030	4,948
Revenue		5,030	4,948
Other expenses	25,26	-16,447	-25,293
Personnel costs	27	-51,933	-38,290
Depreciation of tangible non-current assets		-212	-114
Impairment losses on shares in subsidiaries, joint ventures, associated companies and other long-term securities holdings	28	-14,911	-24,701
Result from sale of shares in portfolio companies	29	1,693	90,909
Operating profit/loss		-76,780	7,459
Interest income and similar income items	30	2,497	39,999
Interest expenses and similar expense items	31	-3,847	-144
Financial net		-1,350	39,855
Taxes	32	-	-
NET PROFIT/LOSS FOR THE YEAR		-78,130	47,314

# Statement of comprehensive income for the Parent Company

SEK 000	Note	2014	2013
Net profit/loss for the year		-78,130	47,314
Total comprehensive income for the year		-78,130	47,314

# Balance sheet for the Parent Company

SEK 000	Not	31 Dec 2014	31 Dec 2013
ASSETS			
Non-current assets			
Machinery and equipment	33	317	529
Financial non-current assets			
Shares in subsidiaries	34	40,212	32,875
Shares in joint ventures	35	1,058,415	997,972
Shares in associated companies	35	33,012	31,036
Other long-term securities holdings	36	7,115	8,714
Loans receivable from joint ventures and associated companies	38	12,062	5,894
Other financial assets		33,493	32,522
Total non-current assets		1,184,626	1,109,542
Current assets			
Accounts receivable	39	_	202
Receivables from portfolio companies	33	895	55
Other receivables	40	3,103	3,225
Prepaid expenses and accrued income	41	12,364	1,477
Short-term investments		128,443	165,334
Cash and cash equivalents		12,885	35,323
Total current assets		157,690	205,616
TOTAL ASSETS		1,342,316	1,315,158
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	14	26,692	24,266
Unrestricted equity		,,,,	,
Share premium reserve		1,838,918	1,778,253
Retained earnings		-502,588	-550,566
Net profit/loss for the year		-78,130	47,314
Total equity		1,284,892	1,299,267
Long-term liabilities			
Convertible loan	15	22,858	
Pension obligations	13	4,286	3,315
Total long-term liabilities		27,144	3,315
Current liabilities			
Accounts payable		4,668	2,426
Liabilities to portfolio companies		442	442
Other current liabilities	42	1,023	1,594
Accrued expenses and prepaid income	43	24,147	8,114
Total current liabilities		30,280	12,576
Total liabilities		57,424	15,891
TOTAL EQUITY AND LIABILITIES		1,342,316	1,315,158

# Pledged assets and contingent liabilities

SEK 000	Note	31 Dec 2014	31 Dec 2013
Pledged assets	19	4,286	3,315
Total		4.286	3.315

# Statement of changes in equity for the Parent Company

		Restricted equity	Un	restricted equity		
SEK 000	Note	Share capital	Share premium reserve	Accumulated losses	Net profit/loss for the year	Total equity
Opening equity at 1 Jan 2014	14	24,266	1,778,253	-550,566	47,314	1,299,267
Appropriation of profit				47,314	-47,314	0
Net profit/loss for the year					-78,130	-78,130
Total		24,266	1,778,253	-503,252	-78,130	1,221,137
Share issue		2,426	60,665			63,091
Effect of incentive programs				664		664
Closing equity at 31 Dec 2014		26,692	1,838,918	-502,588	-78,130	1,284,892
Opening equity at 1 Jan 2013	14	24,266	1,778,253	-397,269	-152,711	1,252,539
Appropriation of loss				-152,711	152,711	0
Net profit/loss for the year					47,314	47,314
Total		24,266	1,778,253	-549,980	47,314	1,299,853
Share repurchase				-2,483		-2,483
Effect of incentive programs				1,897		1,897
Closing equity at 31 Dec 2013		24.266	1.778.253	-550.566	47.314	1.299.267

# Statement of cash flows for the Parent Company

SEK 000	Note	2014	2013
Operating activities			
Operating profit/loss		-76,780	7,459
Adjustments for items not affecting cash flow			
Depreciation and impairment losses	28,33	15,123	24,815
Result from sale of portfolio companies		-1,693	-90,909
Other items		17,253 <sup>1</sup>	1,897
Proceeds from short-term investments		1,478	1,062
Interest received/paid		356	5,312
Cash flow from operating activities before changes in working capital and Operating investments		-44,263	-50,364
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables		-12,174	2,406
Increase (+)/Decrease (-) in operating liabilities		1,116	1,559
Investing activities			
Acquisitions of tangible non-current assets		-	-634
Acquisitions of subsidiaries	34	-7,677	-21,782
Investments in shares in joint ventures and associated companies	35	-69,649	-176,330
Investments in other long-term securities		-	-8
Sale of short-term investments <sup>3</sup>		38,049	7,105
Sale of shares in subsidiaries		-	4,031
Sale of shares in joint ventures and associated companies		1,923	190,893
Loans provided to associated companies	38	-15,712	-27,750
Cash flow from operating activities		-108,387	-70,874
Financing activities			
Repurchased shares		-	-2,483
Share issue		63,091	-
Convertible debenture issue <sup>2</sup>		22,858	
Cash flow from financing activities		85,949	-2,483
Cash flow for the year		-22,438	-73 357
Cash and cash equivalents at the beginning of the year		35,323	108,680
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR		12,885	35,323

<sup>&</sup>lt;sup>1</sup> Adjustments for not cash flow affecting items related to severance pay, bonus to management and cost for incentive programs

# Supplemental disclosure<sup>3</sup>

SEK 000	Note	2014	2013
Cash and cash equivalents at the end of the year		12,885	35,323
Short-term investments, market value at closing date		128,443	165,334
CASH AND CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS AT THE END OF THE YEAR		141,328	200,657

<sup>&</sup>lt;sup>3</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 consequently are not reported as cash and cash equivalents and therefore are included in cash flow from operating activities. The supplemental disclosure is presented to provide a comprehensive overview of the Parent Company's available funds, including cash, cash equivalents and short-term investments.

 $<sup>^2</sup>$  Pending issue of convertible debentures has been finalized in February 2015 which in addition generated SEK 364m

# Notes to the financial statements

## Note 1 Accounting policies

#### OPERATIONS IN GENERAL

Karolinska Development AB (publ) ("Karolinska Development," "Investment Entity" or the "Company") obtains funds from several independent investors/ shareholders by issuing and selling shares and interest-bearing instruments. The Company invests the proceeds in portfolio companies that develop medical innovations, as described below, and whose sole purpose is to generate a return through capital appreciation and investment income. These temporary investments, which are not investment entities, are designated "portfolio companies" below. The Company, with Corporate Identity Number 556707-5048, is a limited liability company with its registered office in Solna, Sweden. Karolinska Development AB aims to create value for investors, patients and researchers by investing in portfolio companies that develop products that can be sold or out-licensed with high returns. The business model is to select the most commercially attractive medical innovations, develop innovations to the stage where the greatest return on investment can be achieved and commercialize innovations through the sale of portfolio companies or out-licensing of products. A deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements, delivers a continuous flow of innovations.

#### 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 3-9 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 (except subsidiaries that provide services related to the Investment Entity's investment activities), 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.

#### AMENDMENTS TO THE ACCOUNTING POLICIES AND DISCLOSURES

#### New and amended standards applied by the Investment Entity

The Company is an investment entity according to IFRS 10 Consolidated Financial Statements, which took effect for financial years beginning on January 2014, with early adoption permitted. Pursuant to the rules for investment entities, Karolinska Development does not consolidate its subsidiaries, provided that they are not investment entities themselves. These financial statements comprise information on the Investment Entity, where subsidiaries which are not investment entities themselves, joint ventures, associated companies and other financial investments are measured at fair value in the balance sheet with changes in value in profit or loss in accordance with IAS 39 Financial Instruments: Recognition and Measurement. According to the Swedish Financial Reporting Board, these separate financial statements meet the requirements for consolidated financial statements according to the Annual Accounts Act. Karolinska Development has also applied the other new and amended standards in the "package of five" standards on consolidation as of 1 January 2014: IFRS 10 Consolidated Financial Statements, IFRS 11 Joint Arrangements, IFRS 12 Disclosures of Interests in Other Entities, IAS 27 Consolidated and Separate Financial Statements, and IAS 28 Investments in Associates and Joint Ventures, Karolinska Development has implemented the amended accounting policies retroactively in accordance with the transition rules in IFRS 10 Consolidated Financial Statements and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors. Note 45 shows the effects of the amended accounting policies for 2012-2013.

Other new or amended IFRS standards and interpretations from the IFRS Interpretations Committee have not had an impact on the Investment Entity.

# New and amended IFRS and interpretations that have not yet entered into force The Investment Entity has chosen not to apply the following new and amended

The Investment Entity has chosen not to apply the following new and amended IFRS and interpretations that have issued but not yet been adopted:

IFRS 9 Financial Instruments covers the classification, measurement and recognition of financial liabilities and assets. IFRS 9 requires financial assets to be classified in two categories: at fair value or accrued cost. The classification is determined upon initial measurement based on the Company's business model and the characteristics of contractual cash flows. For financial liabilities, there are no major changes compared with IAS 39. The largest change relates to liabilities at fair value, where part of the change in fair value attributable to the liability's credit risk will be recognized in other comprehensive income rather than profit or loss, provided this does not cause inconsistency in the accounts. The Investment Entity intends to apply the new standard no later than the financial year beginning 1 January 2018 and has not yet evaluated the effects. 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 essentially 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 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 IAS 39 Financial Instruments: Recognition and Measurement.

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.

Investment Entity considers all the facts and circumstances in assessing whether controls an investee. The Investment Entity 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 percent 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 IAS 39 Financial Instruments: Recognition and Measurement. 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.

The Investment Entity 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.

# 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 of 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;
- 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 criteria of evaluating 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 terms 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.

#### Influence over the portfolio companies

Karolinska Development's ownership interests in its portfolio companies range from a few percent up to 100%. A relatively large proportion of Karolinska Development's share of the portfolio companies lies within the range of 40-60% 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 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.

#### 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 of portfolio companies

As a complement to the application of IFRS 13, fair value is measured according to the fundamental valuation methodology based on International Private Equity and Venture Capital Valuation Guidelines (IPEV Guidelines).

#### Valuation method

Each portfolio company is regularly evaluated based on interviews with its CEO, market and competitor analyses based on information from databases, public material, interviews with scientists and physicians, etc. The portfolio valuation is a so-called "sum-of-the-parts" (SOTP) of risk-adjusted net present value (rNPV) from discounted cash flow (DCF) valuations, valuations based on third party transactions and other recorded company values in the portfolio. Cash flows are discounted with two different discount rates. One reflects the risk in a small company ("Biotech WACC") and a lower discount rate from the time of licensing of a project to a global pharmaceutical company ("Pharma WACC"). The following are important factors when determining fair value:

#### Discounted cash flow

- DCF valuation is used for the majority of the companies.
- Estimated income generally consists of one-time payments and royalty payments on sales.
- Costs are estimated for each phase of development based on the companies' information or according to industry standards.
- Costs and revenue are probability adjusted based on the phase of development.
- A WACC of 11.02% (11.90%) was used regarding biotechnological companies and 7.32% (8.20%) regarding pharma companies. Both of these discount rates are calculated based on the risk-free interest rate, market risk premiums and in biotech's case the risk premium for small companies.

#### Price of related investments

- In applying the price of recent investment method, the Investment Entity uses the initial cost of the investment or, if add-on investments have been made, the price at which the significant share of the new investments in the company have been made, to estimate the company's value, but only if it is considered to represent fair value and only during a limited period after the date when the transaction was executed. During a limited period after the date when the transaction was executed, the Investment Entity assesses for each reporting date whether changes or events have occurred after the transaction in question that could mean a change in the investment's fair value.
- Significant events occurring after the date of valuation according to the previous paragraph have been taken into account in the valuation to the extent that such events would have affected the value on the closing date.

#### General valuation policies

#### Market analysis

 Estimates are made regarding total population, target population, prevalence and treatable patients in the U.S., Europe and the Japanese market. These markets represented approximately 70% of global pharmaceutical sales in 2012 (according to IMS Health). As a precautionary principle, other markets are excluded in the valuation.

#### License agreement/exit

- Estimates are made regarding product launch year and time of exit based on development plans.
- Licensing is usually assumed to be carried out after Phase II.
- For medical technology companies, an exit is usually assumed after launch of the product.

#### Peak sales and royalty rates

- Estimates are made regarding market penetration, market share and total annual treatment cost for each market.
- A sales curve is generated based on an estimation of peak sales, time to peak and decline in sales after patent expiry.
- The estimated royalty rates depend on the time of licensing, product type and market potential.
- All sales are adjusted downwards by the estimated probability of not reaching the market

#### Value of contracts and value distribution

- The estimated contract value (including royalties) is based on an estimate of sales potential and the buyer's development, manufacturing and marketing costs for the particular project.
- Contract value is based on a value allocation principle in which the seller's portion of the total value increases with the maturation of the project.
- In the model, the portfolio company receives approximately 40% of total rNPV after Phase II.
- Payments are probability adjusted based on the development phase the project is in at the time of the contract.

#### Costs

- Estimates are made of the cost of each phase of development based either on the companies' forecasts or according to industry standards.
- For pharmaceutical projects, the costs are probability adjusted depending on the phase of development.
- For medical technology companies, no probability adjustment of development costs is made.

#### Probability adjustment

- The probability of reaching each phase of development is estimated.
- Recognized statistics are used as a reference.

A change in any of these assumptions would affect the valuation and may have a significant impact on the Investment Entity's results of operations. Additional disclosures on the sensitivity in these valuations to reasonable possible changes in inputs as described above are included in the notes to these financial statements.

#### **FOREIGN CURRENCIES**

#### Transactions in foreign currencies

Transactions in foreign currencies are translated into the functional currency at the exchange rate prevailing on the transaction date. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rate prevailing on the closing date. Exchange differences arising on translation are recognized through profit or loss. Non-monetary assets and liabilities measured at historical cost are translated into the exchange rate on the transaction date. Non-monetary assets and liabilities carried at fair value are translated into the functional currency at the rate prevailing on the date when the fair value was determined. The change in exchange rates is then recognized in the same manner as other changes in the value of the asset or liability.

The Invesment Entity's functional currency, as well as its reporting currency, is Swedish kronor.

#### Revenue

Revenue is measured at the fair value of the remuneration received or receivable, net of value added tax.

#### Sales of services

Revenue primarily consists of invoiced services rendered to portfolio companies. These services consist of 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.

#### 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 the 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.

Issue costs and similar 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/loss for the year attributable to the Investment Entity'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 shares of the Investment Entity and this reduces earnings per share after dilution.

#### 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 acquisition 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 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.

IAS 39 classifies financial instruments in categories. 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 valued after initial accounting.

The Investment Entity has financial instruments in the following categories:

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

This category has two subgroups: held for trading and financial assets designated at FVTPL. Financial assets in this category are measured continuously at fair value with changes in value recognized through profit or loss. This category includes shares in portfolio companies, other financial assets and short-term investments.

#### 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;
- 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 profittaking; or
- is a derivative that is not designated as an effective hedging instrument.

Fixed income funds and corporate bonds have been assessed to belong to this category.

#### Loans receivable and accounts receivable

Loans receivable and accounts receivable 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. Accounts receivable are recognized at the amount that is expected to be received after an allowance for impaired receivables. As the expected maturity time is short, the nominal value is recognized without discounting. Cash and cash equivalents, including short-term investments with a maximum three-month term, as well as other current receivables, have been assessed to belong 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 and receivables," which are measured at the amortized cost. Because the bank balances are payable upon demand, amortized cost corresponds to the nominal amount.

#### Financial liabilities at fair value through profit or loss

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.

#### Other financial liabilities

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

#### IMPAIRMENT TESTING OF FINANCIAL ASSETS

Financial assets, with the exception of those measured at fair value through profit or loss, are tested for impairment when there is an indication of impairment at the end of each reporting period. Financial assets are considered impaired when there is objective proof, as a result of one or more events that have occurred after the initial date of recognition of the financial asset, that the estimated future cash flows for the investment have been impacted.

For financial assets at amortized cost, the impairment represents the difference between the asset's carrying amount and the present value of estimated future cash flows discounted to the original effective interest rate.

#### SHARE CAPITAL

#### Dividends

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

#### **EMPLOYEE BENEFITS**

#### Defined contribution pension plans

Obligations regarding 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 visà-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 Performance and Matching Share Rights allotted to senior executives are measured at fair value on the allotment date. The fair value of Performance and Matching Share Rights 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 Performance and Matching Share Rights it expects to be vested. On each closing date, the Investment Entity reevaluates its estimate of the number of Performance and 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 payment 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.

#### INFORMATION ON RISKS AND UNCERTAINTIES

#### **Investment Entity and Parent Company**

Risks and uncertainties primarily consist of risks associated with the Investment Entity's investment activities and indirectly of operational risks in the portfolio companies' development operations, and financial risks.

#### Future financing 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.

#### Risks concerning availability of new investment opportunities

Sweden's so-called teacher's exemption means that researchers own their inventions, not the university or graduate school where they work. A number of universities and graduate schools have also established organizations or companies that focus on evaluating, developing and financing innovations from their own researchers to support them in their work. Karolinska Institutet, for example, has established Karolinska Institutet Holding AB (KIHAB) as a holding company for such investments and Karolinska Institutet Innovations AB (KIAB) to evaluate business opportunities originating from the researchers' innovations. A change in or elimination of the teacher's exemption could affect Karolinska Development's access to investment opportunities.

The availability of new investment opportunities for Karolinska Development is highly dependent upon the flow of business expected to be provided by KIAB according to the so-called deal flow agreement, which is described on page 65.

Karolinska Development is indirectly dependent on KIAB's ability to attract researchers with new projects and the competency of staff to evaluate the investment opportunities effectively. To be exposed to new ideas, KIAB must maintain a strong position in academic circles and the business community, act professionally and demonstrate a merit list of successful commercialization. Even if KIAB is successful in these respects, there are no guarantees that the cooperation between KIAB and Karolinska Development will be successful. If the cooperation fails as planned, it can be assumed that this will have a significant negative impact on Karolinska Development's access to business opportunities, and therefore on the Company's business prospects.

#### Uncertainties in future assessments

Judgments and assumptions about the future outcome of development projects involving pharmaceuticals and medical technology are always associated with great uncertainty. There are no guarantees of the accuracy of forecasted developments.

#### Development of portfolio companies

The majority of portfolio companies are at an early stage of development. In spite of the fact that the portfolio companies, in the opinion of Karolinska Development, have great commercial potential and in many cases have completed significant development work, additional research and development remains necessary before the companies' innovations and technologies can be commercialized. The results of future research and development will be crucial to the portfolio companies' product candidates. The portfolio companies' product development may fail, just like all development of pharmaceuticals or other biotechnological

products, e.g., if one or all of the portfolio companies' product candidates lack the targeted effect, give rise to side effects or otherwise fail to meet regulatory requirements, or fail to obtain regulatory approvals or licenses.

Expected positive cash flow from the sale of portfolio companies is dependent upon the scientific results of development projects. Such results may be a successfully demonstrated target profile, failure or a partially demonstrated target profile. Each result has a direct impact on the potential value of a portfolio company. Other factors affecting the future cash flow are the success of competitors and demand from potential buyers at any given point in time.

#### Long time to product launch

The time it takes for a product candidate to pass through the whole research and development process, establish strong intellectual property rights, meet all regulatory requirements and find strong marketing and distribution partners is often underestimated. Introducing previously unknown or accepted products and technologies with unknown compensation models takes time and involves significant marketing and sales costs.

#### Competitors

The market for the portfolio companies' product candidates and new technologies is subject to fierce competition and is rapidly changing. Competitors of the portfolio companies are often large multinationals. These companies are already established in the portfolio companies' markets and may have competitive advantages. They can swiftly allocate major resources to new research and development and to new market conditions. They may also, in contrast with the portfolio companies, have superior financial resources and expertise in research and development, clinical trials, obtaining regulatory approvals and marketing. However, it is worth noting that these companies can also function as strategic partners or customers of the portfolio companies.

Competitors may develop more effective, cheaper or more suitable products, obtain patent protection more rapidly, or manage to commercialize their products faster than Karolinska Development's portfolio companies. These competing products may make the portfolio companies' product candidates obsolete or limit the portfolio companies' opportunities to generate profits from their product candidates.

#### Risks concerning the portfolio companies intellectual property rights

The success of the portfolio companies rests in large part on their ability to protect the methods and technologies they develop with patents and other intellectual property rights. Even if the portfolio companies obtain patents, they eventually may not provide comprehensive protection or be effective in claims against third parties.

#### Risks regarding valuations

Companies active in pharmaceutical development and medical technology at an early stage are, by their very nature, difficult to value, since the lead times are very long and development risks are significant. Due to the uncertainty inherent in forecasts, the estimated portfolio value may deviate greatly from the actual future outcome. This is mainly due to the sensitivity of valuation estimates to changes in anticipated milestones and planned sales, study costs and similar assumptions which do not necessarily have an effect on the actual value of a transaction in negotiations with partners.

#### Interest rate risk

Interest rate risk is the risk that changes in market interest rates could affect cash flow or the fair value of financial assets or liabilities. Karolinska Development has no significant loans or other long-term debt, so the Investment Entity's interest rate risk is primarily attributable to surplus liquidity. Surplus liquidity in the Investment Entity is invested in money market funds or interest-bearing instruments: see also Note 18.

#### Risk diversification

Karolinska Development invests in early stage projects, which are generally associated with higher risk than investments in mature companies. Karolinska Development's ambition is to diversify this risk by investing in a broad portfolio of biotechnology, diagnostics and medical technology companies at different stages of maturity.

### Note 2 | Revenue distribution

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

#### Revenue per significant revenue source

		2013
SEK 000	2014	(restated)
Services rendered	5,013	4,908
Other revenue	17	40
Total revenue	5,030	4,948

## Note 3 Other external expenses

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

SEK 000	2014	2013 (restated)
Deloitte		
Audit services	719	665
Audit related services	1,431	311
Tax consulting	877	771
Other services	231	_
Total	3,258	1,747

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 operating leases. Expensed leasing payments and future contractual leasing payments are indicated below.

SEK 000	2014	2013 (restated)
Expensed leasing payments during the period	1,992	1,708
Future leasing payments		
Within one year	1,462	1,455
Between one year and five years	996	2,182
Total future leasing payments	2,458	3,637

# Note 5 Employees and personnel costs

#### Average number of employees

Full-time equivalent	2014	Of whom men	2013 (restated)	Of whom men
Investment Entity	13	73%	14	79%
Total	13	73%	14	79%

# Remuneration expenses for employees

Salaries, other remuneration and social security expenses

		2014	2013	(restated)
	Salaries	Social	Salaries	Social
	and remune-	security	and remune-	security
SEK 000	ration	expenses	ration	expenses
Investment Entity	43,399	7,363	26,908	8,085
(of which pension expenses)	5,524	1,340	5,792	1,405

#### 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 regulations of each plan. During the year the cost for defined contribution pension plans amounted to SEK 5.6m (SEK 5.8m).

#### Remuneration to senior executives

The remuneration guidelines for senior executives are prepared by the Board and resolved by the Annual General Meeting. According to the 2014 remuneration guidelines for senior executives, the main features are as follows. Karolinska Development will maintain the 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 senior executives 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 long-term value creation; (ii) is governed by 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 CEO has a six-month term  $\,$ of notice and other senior executives have a maximum nine-month term of notice. Severance applies only to the CEO.

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

2014	Base salary¹/	Variable remu-	Other benefits and	Pension	Total remune-
SEK 000	Board fee	neration	remuneration	costs	ration
Bruno Lucidi, CEO	783		45	73	901
Torbjörn Bjerke, former CEO	3,569		4,729	1,693	9,991
Klaus Wilgenbus, former CEO	450				450
Terje Kalland, Deputy CEO	2,223		5	663	2,891
Bo Jesper Hansen, Chairman	400				400
Hans Wigzell, Board member	200				200
Per-Olof Edin, (for- mer Board member)	200				200
Rune Fransson, (former Board member)	40				40
Klaus Wilgenbus, (former Board member)	200				200
Charlotte Edenius, Board member	200				200
Vlad Artamonov, Board member	200				200
Henrijette Richter, Board member	200				200
Robert Holland, Board member	200				200
Carl Johan Sundberg, Board member	200				200
Other senior executives (7 persons)	9,880	6,473²	19	2,644	19,016
Total	18,945	6,473	4,798	5,072	35,288

<sup>1</sup> Base salary excluding vacation compensation

<sup>&</sup>lt;sup>2</sup> Reserve for Bonus program 2014:1

2013 SEK 000	Base salary¹/ Board fee	Variable remu- neration	Other benefits and remuneration	Pension costs	Total remune- ration
Torbjörn Bjerke, CEO	3,472		255	731	4,458
Terje Kalland, Deputy CEO	2,162		5	713	2,880
Bo Jesper Hansen, Chairman	175				175
Hans Wigzell, Board member (former Chairman)	350		5		355
Per-Olof Edin, Board member	200				200
Rune Fransson, Board member	48				48
Raymond Hill, for- mer Board member	83				83
Klaus Wilgenbus, Board member	200				200
Charlotte Edenius, Board member	200				200
Vlad Artamonov, Board member	200				200
Other senior executives (9 persons)	11,743		113	3,289	15,145
Total	18,833	0	378	4,733	23,944

<sup>&</sup>lt;sup>1</sup> Base salary excluding vacation compensation

#### GENDER DISTRIBUTION OF BOARD AND MANAGEMENT

The data refers to the ratio at closing.

	2014	2013
Board		
Men	5	6
Women	2	1
	7	7
CEO and other senior executives		
Men	4	9
Women	2	2
	6	11

#### Compensation to former CEOs

#### Torbjörn Bjerke

Torbjörn Bjerke, who stepped down as CEO on 30 September 2014, is entitled to a six-month term of notice and twelve months of severance. During this period, Torbjörn Bjerke has a contractual pension amounting to 21 percent of his gross salary, which is comprised of a premium-based provision.

#### Bruno Lucidi

Bruno Lucidi, who assumed the position of CEO on 15 October 2014 and stepped down as CEO on 28 January 2015, has a contractual term of notice of six months. During his term of notice, Bruno Lucidi has a contractual pension amounting to 21 percent of his gross salary, which is comprised of a premium-based provision. Risk for additional severance pay can not be ruled out.

#### Other senior executives

Severance terms

No severance agreements are in place for other senior executives of Karolinska Development.

#### Variable remuneration

Karolinska Development has three programs with variable salaries. One is a combined warrant and profit-sharing program for senior executives, consisting of three program stages, which was adopted by the AGM's in 2008, 2009 and 2010 (all programs have experid without any subscription by the participants). In 2012, 2013 and 2014, the AGM's resolved to introduce new Performance Share Programs, PSP 2012 for senior executives and PSP 2013 and PSP 2014 for all personnel.

### 2008-2010 programs

Warrant programs

Through the subsidiary KD Incentive AB, Karolinska Development has issued share warrants in three separate programs. These warrants have been sold at market value, calculated according to the Black & Scholes option pricing model, and are not associated with any vesting conditions. All programs have expired without any subscriptions by participants.

		2014		2013
	Number	Weighted	Number	Weighted
SEK 000	OŤ.	redemption	10	redemption
	warrants	price	warrants	price
At beginning of the year	88,901	107.68	185,772	104.00
Expired warrant program 2010	-88,901	-107.68	-96,871	-100.63
Closing balance	-	-	88,901	107.68

#### **Profit-sharing programs**

The profit-sharing plan is based on annual sub-plans, similar to the warrant portion of the incentive program. The first sub-plan relates to Karolinska Development's investment portfolio as of 31 December 2007. The subsequent sub-plans relate to the investments in Karolinska Development as of December 31 which the Company completed during the calendar year immediately preceding the issuance of the respective sub-plan.

Each profit sharing plan lasts 15 years and provides entitlement to a certain portion of return proceeds from divested investments to which the plan refers. The first settlement will take place after the fifth year of the term; this payment takes into account the returns during years 1-5 of the term. Thereafter, payments are made annually, retroactively until all the investments that the sub-plan refers to have finally been disposed of or until the 15-year limit is reached and the sub-plan matures. Payments must be made as soon as possible after the AGM has been held.

Each sub-plan provides entitlement to a cash payment equivalent to a total of 5 percentage points of the portion of returns realized from the investments that the sub-plan relate to, in excess of a threshold rate of 6 percent for the years 2008-2012 and 8 percent for the year 2013 onwards.

Disbursement pursuant to each sub-plan should be limited as follows: To the extent that returns exceed an annual return of 35 percent, the portion that exceeds the returns accruing to participants in the profit-sharing plan will be halved (i.e., if the rate was previously 5 percent, as indicated above, it will in this part instead be 2.5 percent). To the extent that returns exceed 50 percent, the amount in excess of 50 percent will be further halved (i.e., if the rate was previously 2.5 percent, as indicated above, it will in this part instead be 1.25 percent). Excess returns above 60 percent are not eligible for profit-sharing.

All investment managers (including the CEO and CFO) who were employed during all, or part of, the preceding calendar year, and who are still employed and have not been terminated on the issue date of the sub-plan, participate in the sub-plan. Participation in each sub-plan is proportionate to participation in the portion of the warrant program issued in conjunction therewith, in accordance with the above, whereby 50 percent participation in a portion of the warrant program leads to full participation in the profit-sharing plan. Conny Bogentoft and Ola Flink will participate in the profit-sharing plan as described above even after termination of employment under the same conditions as in the warrant program, with the corresponding increase in the total profit-sharing space that this can lead to after a successor has been hired

Termination of employment during the term: Unearned profit-sharing expires automatically. Each sub-plan is vested at a rate of 20 percent per year from issuance. For Conny Bogentoft and Ola Flink, vesting occurs even after the termination of employment provided that they are still active in the Company on a consulting basis.

The cooperation with the European Investment Fund entitles Karolinska Development to a share in the profits of the co-investment structure beyond Karolinska Development's capital input in the structure, provided that 37.5 percent of this profit is further distributed through Karolinska Development's profit-sharing plan. This redistribution has been implemented in the profit-sharing plan so that this right to profit-sharing is divided between the sub-plans for 2010, 2011 and 2012 in relation to the size of the plans. The right to profit-sharing through the cooperation with the European Investment Fund therefore applies beyond the profit-sharing based on excess returns as described above. Because of the limited returns to date, this approach has not had any accounting effects.

### Performance Share Program 2012 (PSP 2012)

On 23 May 2012, the Annual General Meeting decided on a Performance Share Program for management based on the participants acquiring shares ("Saving Shares") on the open market. For each Savings Share, participants will be allotted, free of charge, one Matching Share Right and a maximum of five Performance Share Rights. The maximum number of Performance and Matching Share Rights is 480,000. The program comprises a maximum of ten participants.

Each Performance and Matching Share Right is entitled to the allocation of one subscription option. Each subscription option entitles its holder to acquire one series B share at a subscription price corresponding to the share's par value and assuming that the option is exercised as soon as possible after receiving the subscription option. Subscription options will be allocated after publication of the company's interim report for the first quarter 2015, though no earlier than three years after the agreement on PSP 2012 was signed (vesting period).

There are no performance conditions for the Matching Share Rights, but each participant must remain an employee during the vesting period and may not have sold their Savings Shares. The Performance Share Rights have the same terms as the Matching Share Rights. In addition, there is 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 is measured as the average over ten trading days. The Board of Directors determines the measurement period. However, the measurement must be made not later than 23 November 2012. The established measurement period was 27 August 2012 through 7 September 2012. The Start Price was set at SEK 15.70. The End Price is measured as the average over 10 trading days beginning on 2 May 2015. For any allotment to be made,

the share price must rise by six percent annually. For a maximum allotment (five Performance Shares per Saving Share), the share price must rise by 30 percent. Within this span, allotments will be made proportionately. Allotments are capped at ten times the Start Price, after which the number of allotted Performance Share Rights is reduced. The participants will be compensated in cash for dividends paid during the period.

In December 2012, the participants acquired 80,000 Savings Shares. The fair value of a Matching Share Right on the allotment date in December 2012 has been set that SEK 14 based on the Black-Scholes option pricing model. The inputs in the model were a share price of SEK 14.65, an exercise price of SEK 0.5, an anticipated maturity 3.1 years, an anticipated volatility of 42.5%, an anticipated dividend of zero percent and a risk-free rate of interest of 0.87%. The fair value of a Performance Share Right on the allotment date in December 2012 was set at SEK 7.20 based on a Monte Carlo simulation. The inputs in the model were a share price of SEK 14.65, an exercise price of SEK 0.5, an anticipated maturity 3.1 years, an anticipated dividend of zero percent and a risk-free rate of interest of 0.87%. The condition related to share price performance has been taken into account in the valuation of the Performance Share Rights. Anticipated volatility is based on historical volatility and comparisons with similar companies.

The company has covered social security contributions related to the program by acquiring 150,600 of its own shares.

An expense of SEK 0.0m (1.9) was recognized for the share-based incentive program in 2014.

#### Performance Share Program 2013 (PSP 2013)

On 14 May 2013, the Annual General Meeting decided on a new Performance Share Program for employees where participants acquire shares ("Saving Shares") on the open market. For each Savings Share participants receive, free of charge, a maximum of one Matching Share Right and five Performance Shares. The maximum number of Performance Shares and Matching Share Rights is 480,000. The program comprises a maximum of seventeen participants.

Each Performance and Matching Share Right is entitled to the allotment of one subscription option. Each subscription option entitles its holder to acquire one series B share at a subscription price corresponding to the share's par value and assuming that the option is exercised as soon as possible after receiving the subscription option. Subscription options will be allotted after publication of the company's interim report for the first quarter 2016, though no earlier than three years after the agreement on PSP 2013 was signed (the vesting period).

There are no performance conditions for the Matching Share Rights, but each participant must remain an employee during the vesting period and may not have sold their Saving Shares. The Performance Shares have the same terms as the Matching Share Rights. In addition, there is 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 is measured as an average over ten trading days. The Board of Directors determines the measurement period. However, the measurement must be made not later than 14 November 2013. The established measurement period was 27 June 2013 through 10 July 2013. The Start Price was set at SEK 26.44. The End Price is measured as the average over 10 trading days beginning on 2 May 2016. For an allotment to be made, the share price must rise by six percent annually. For a maximum allotment (five Performance Shares per Savings Share), the share price must rise by 30 percent. Within this span, allotments are made proportionately. Allotments are capped at twenty 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

In September 2013, participants acquired 49,700 Saving Shares. The fair value of a Matching Share Right on the allotment date in September 2013 was set at SEK 26.12 based on the Black-Scholes option-pricing model. The inputs in the model were a share price of SEK 26.60, an exercise price of SEK 0.5, an anticipated maturity of 3.1 years, an anticipated volatility of 42.5%, an anticipated dividend of zero percent and a risk-free rate of interest of 1.47%. The fair value of a Performance Share on the allotment date in September 2013 was set at SEK 14.98 based on a Monte Carlo simulation. The inputs in the model were a share price of SEK 26.60, an exercise price of SEK 0.5, an anticipated maturity of 3.1 years, an anticipated dividend of zero percent and a risk-free rate of interest of 1.47%. The condition related to share price performance has been taken into account in the valuation of the Performance Share Rights. Anticipated volatility is based on historical volatility and comparisons with similar companies.

The company has covered social security contributions related to the program by acquiring 93,685 of its own shares.

An expense of SEK 0.9m (0.7) was recognized for the share-based incentive program in 2014.

#### Performance based share incentive program 2014 (PSP 2014)

On 14 May 2014, the Annual General Meeting adopted a new 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 is 761,350. The program comprises a maximum of fourteen participants.

Although there are no performance conditions for the Matching Share Rights, each participant must remain an employee 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 18 May 2014 through 28 May 2014, is SEK 24.45. The End Price is measured as the average over ten trading days beginning on 2 May 2017. For an allotment, the share price must rise by a total of 30% above the Start Price. For a maximum allotment (five Performance Shares per Savings Share), the share price must rise by 75% 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 contributions related to the program by acquiring and transferring a maximum of 182,000 of its own shares. As of 31 December 2014, 41,200 Savings Shares had been acquired. Repurchase of the company's own shares will not take place. The reason is that personnel participating in previous PSP programs have left their employments and that the company's holding related thereto is sufficient to cover also PSP 2014. The performance based share incentive program has not had any effect on the results or financial position of the Parent Company or the Investment Entity as of 31 December 2014.

#### Performance based share incentive program 2014 II (PSP 2014 II)

Performance based share incentive program PSP 2014 II, adopted by the Extraordinary General Meeting on 4 December 2014, has not been implemented.

#### Short Term Incentive Program 2014 (STI 2014)

In March 2014, the Board of Directors decided on a Short Term Incentive Program for senior executives based on a number of specific corporate goals set by the Board for 2014. The goals are designed to promote Karolinska Development's long-term value appreciation. Each goal is weighed based on priority, which impacts the calculation of the remuneration. The remuneration is dependent on whether one or more goals are met and has a fixed cap corresponding to two months' base salary for each participant. Goals were partly met which will render an accrual in 2015 amounting to 269 KSEK including social costs.

#### Bonus Program 2014:1

In October 2014, the Board of Directors decided on a bonus program for senior executives that entitles participants to a bonus if the Investment Entity, before 31 March 2015, implements a directed issue of shares or other securities in return for cash payment to external investors that are not already shareholders in the Investment Entity. The total bonus amount in the program (which will also covers social security expenses) amounts to a total of two percent of the issue proceeds excluding transaction costs. The maximum bonus per participant is SEK 5m (including social security expenses). Proceeds from the directed issue and proceeds from any part of the rights issue not subscribed by current shareholders serve as the basis for the calculation. Participants will use at least half (net after tax) of the amount paid to participants to acquire shares in Karolinska Development after the payment. As of 31 December 2014, a bonus reserve of SEK 8.5m was charged against personnel costs, including social security expenses.

# Board of Directors' proposal for remuneration guidelines for senior executives to the Annual General Meeting 2015

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 senior executives must be competitive, reasonable and appropriate. Fixed base salary is determined based on the individual's area of responsibility and experience. Vari-

able salary (i) is formulated with the aim of encouraging Karolinska Development's long-term value creation; (ii) be 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 CEO has a six-month term of notice and other senior executives have a maximum nine-month term of notice. Severance applies only to the CEO.

# Note 6 Other financial gains and losses

SEK 000	2014	2013 (restated)
Change in value of short-term investments	1,188	1,078
Foreign currency exchange rate gains and losses	-56	702
Revaluation of financial liability	-2,249	1,451
Reversal of impairment of receivables from portfolio companies	-	31,976
Impairment of receivables from portfolio companies	-3,786	384
Other financial income	671	-
Total	-4,232	35,591

### Note 7 Taxes

#### Reconciliation of effective tax rate

SEK 000	%	2014	9/	2013 (restated)
Profit/loss before tax	/0	-375,815	/0	-157,315
Trongloss serore tax		373,013		137,313
Income tax expense calculated at applicable rate in the Parent Company	22.0%	82,679	22.0%	34,609
Tax effect of				
Non-deductible expenses		-2,018		-1,098
Tax-exempt revenue		546		7,122
Issue costs		2,233		-
Changes in fair value, non-taxable		-68,288		-30,799
Increase in tax losses carried forward without corresponding capitalization of				
deferred taxes		-15,152		-9,834
Recognized current tax	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. Deferred tax assets have 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 against 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 89,323 thousand (SEK 74,171 thousand) at year-end 2014, of which SEK 64,337 thousand (SEK 64,337 thousand) relates to deficits that are restricted by Group contributions and mergers.

## Note 8 Tangible non-current assets

SEK 000	31 Dec 2014	31 Dec 2013 (restated)
Accumulated acquisition cost		
At the beginning of the year	659	25
Investments during the year	-	634
Closing balance	659	659
Accumulated amortization and impairments		
At the beginning of the year	-130	-16
Depreciation for the year	-212	-114
Closing balance	-342	-130
Carrying amount	317	529

#### Finance leases

The Investment Entity did not enter into any finance leases in 2014, 2013 or any prior period.

# Note 9 Shares in portfolio companies

		31 Dec 2013
SEK 000	31 Dec 2014	(restated)
Accumulated fair value		
At the beginning of the year	1,729,465	1,827,190
Investments during the year	83,984	266,173
Sale of portfolio companies	-864	-223,902
Changes in fair value in profit/loss for the year	-310,399	-139,996
Closing balance	1,502,186	1,729,465

Karolinska Development is an Investment Entity according to IFRS 10 and does not consolidate its subsidiaries. The holdings are recognized at fair value with changes in value through profit or loss in accordance with IAS 39 Financial Instruments. For a list of subsidiaries that are not consolidated, see Note 34.

# Note 10 | Loans receivable from portfolio companies

		31 Dec 2013
SEK 000	31 Dec 2014	(restated)
Loans receivable from portfolio companies		
At the beginning of the year	5,894	12,856
Loans provided	15,712	34,712
Reversal of impairments	-	30,000
Conversions	-5,894	-66,897
Repayments	-	-4,777
Impairment losses	-3,650	-
Total	12,062	5,894

The Investment Entity normally invests in portfolio companies, but in certain cases other financing solutions can be arranged. The loans are interest bearing and mature or are converted to shares within 12 months.

### Note 11 Accounts receivable

#### Maturity structure

SEK 000	31 Dec 2014	31 Dec 2013 (restated)
Receivables not past due	-	3
Overdue receivables without provision		
1-30 days	-	-
31-90 days	-	-
91-180 days	-	-
>180 days	-	-
Total	-	3

No provisions for bad debt were considered necessary for any of the years above.

## Note 12 Other current receivables

SEK 000	31 Dec 2014	(restated)
Tax receivable	958	2,093
VAT receivable	2,068	374
Other	77	758
Total	3,103	3,225

### Note 13 Prepaid expenses and accrued income

SEK 000	31 Dec 2014	31 Dec 2013 (restated)
Prepaid rental expenses	510	-
Accrued interest income	367	828
Insurance premiums	459	413
Accrued income	364	-
Prepaid issue costs	10,148	-
Other	516	236
Total	12,364	1,477

# Note 14 | Equity

#### Changes in share capital

Year	Transaction	No. of shares	Share capital	No. of A shares	No. 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 2013		53,384,558	26,692,279	1,503,098	51,881,460		0.5

Net asset value per share Investment Entity 31 Dec 2013 **SEK 000** 31 Dec 2014 (restated) Net assets Cash and cash equivalents 12,885 35,323 Short-term investments 128,443 165,334 Loans receivable from portfolio companies 12.062 5.894 Financial assets/liabilities 3,569 28,675 Convertible loan -22 858 Total net assets 134,101 235,226 Estimated fair value of portfolio companies 1,502,186 1,729,465 Total net asset value 1,636,287 1,964,691 Number of share (excluding own holdings) 53,140,273 48,287,132 Net asset value per share 30,79 40.69

#### Investment Entity

The number of shares amounts to 53,384,558, of which 1,503,098 are series A shares and 51,881,460 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 regarding profit distributions. All series B shares have been listed for trading on the main list of NASDAQ Stockholm since 15 April 2011.

During the fourth quarter 2012, the Parent Company and the Investment Entity repurchased 150,600 shares with a par value of SEK 0.5 for consideration amounting to SEK 2,243,879. The shares were repurchased to cover the social security expenses in the incentive program PSP 2012 resolved by the Annual General Meeting in 2012.

During the third quarter 2013, the Parent Company and the Investment Entity repurchased 93,685 shares with a par value of SEK 0.5 for consideration amounting to SEK 2,483,025. The shares were repurchased to cover the social security expenses in the incentive program PSP 2013 resolved by the Annual General Meeting in 2013.

The Investment Entity and the Parent Company are holding 244,285 treasury shares. This represents a total of SEK 122,143 of the share capital, and the consideration paid amounts to SEK 4,726,904.

#### Other contributed capital

Relates to capital contributed by the owners.

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

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

#### Number of shares basic and diluted

Through its subsidiary, KD Incentive AB, Karolinska Development has issued warrants in three separate program stages at market value according to Black & Scholes (see detailed description in Note 5). All the warrant programs have expired without any subscriptions by participants.

Issued options are not included in diluted earnings per share, since they did not give rise to dilution in 2014 or 2013.

Share rights related to the incentive programs PSP 2012-2014 have not affected the calculation of earnings per share after dilution in 2014 or 2013, as they did not give rise to dilution, based on the terms of the programs in relation to the share price.

Karolinska Development may under certain circumstances subject to shareholders approval issue additional shares under the agreement with Rosetta to compensate for its obligation under the put option. The number of shares are maximazed to 10% of the shares outstanding equivalent to 5,338,455 shares based on total number of shares on 31 December 2014. Since the number of shares is antidilutive, it would not have an impact on the diluted earnings per share, as the Investment Entity reported a net loss.

#### Earnings per share basic and diluted

		2011	2013
SE	K 000	2014	(restated)
Ne	et profit/loss for the year	-375,815	-157,315
W	eighted average number of shares	48,606,243	48,350,016
Ea	arnings per share, SEK	-7.73	-3.25

## Note 15 Convertible loan

Issued convertibles have a nominal interest rate of 8 percent during the period 1 January 2015 - 31 December 2019. The convertibles grant a right to convert into shares at a price of SEK 22 per share. In the event that the convertibles are not converted into shares, the convertible loan is payable in its entirety on 31 December 2019. Interest is only payable on the due date.

Proceeds received as of 31 December 2014 regarding the pending issue of convertible debentures amount to SEK 22.9m. As conversion rights begin in 2015, the proceeds received are disclosed as debt, and when the conversion rights apply in 2015, a portion of the debt will be reclassified as equity.

## Note 16 Other current liabilities

		31 Dec 2013
SEK 000	31 Dec 2014	(restated)
Other taxes and fees	1,021	1,546
Other	2	47
Total	1,023	1,593

# Note 17 Accrued expenses and prepaid income

SEK 000	31 Dec 2014	31 Dec 2013 (restated)
Salaries and remuneration to employees	13,042	1,744
Accrued remuneration to Board of Directors	216	911
Accrued auditor and consultant fees	2,306	701
Payroll tax and accrued pension costs	3,571	3,109
Accrued employer's contributions	4,903	594
Other	109	1,055
Total	24,147	8,114

## Note 18 Financial assets and liabilities

#### Financial assets and liabilities by category

# Financial assets at fair value through profit or loss

	Financial assets	Held for	Loan and	Other financial	Total carrying	
SEK 000	designated at FVTPL	trading	receivables	liabilities	amount	Fair value
2014						
Shares in portfolio companies at fair value through profit or loss	1,502,186				1,502,186	1,502,186
Loans receivable from portfolio companies			12,062		12,062	12,062
Other financial assets	38,113				38,113	38,113
Receivables from portfolio companies			895		895	895
Short-term investments at fair value through profit or loss		128,443			128,443	128,443
Cash and cash equivalents			12,885		12,885	12,885
Total	1,540,299	128,443	25,842	0	1,694,584	1,694,584
Convertible loan				22,858	22,858	22,858
Other financial liabilities				11,686	11,686	11,686
Accounts payable				4,668	4,668	4,668
Liabilities to portfolio companies				442	442	442
Total	·			39,654	39,654	39,654

# Financial assets at fair value through profit or loss

SEK 000	Financial assets designated at FVTPL	Held for trading	Loan and receivables	Other financial liabilities	Total carrying amount	Fair value
2013 (restated)						
Shares in portfolio companies at fair value through profit or loss	1,729,465				1,729,465	1,729,465
Loans receivable from portfolio companies			5,894		5,894	5,894
Other financial assets	38,113				38,113	38,113
Accounts receivable			3		3	3
Receivables from portfolio companies			254		254	254
Short-term investments at fair value through profit or loss		165,334			165,334	165,334
Cash and cash equivalents			35,323		35,323	35,323
Total	1,767,578	165,334	41,474	0	1,974,386	1,974,386
Other financial liabilities				9,438	9,438	9,438
Accounts payable				2,426	2,426	2,426
Liabilities to portfolio companies				442	442	442
Total				12,306	12,306	12,306

#### 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 2014

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares and participations at fair value through profit or loss			1,502,186	1,502,186
Loans receivable from portfolio companies		12,062		12,062
Other financial receivables			38,113	38,113
Receivables from portfolio companies		895		895
Short-term investments at fair value through profit or loss	128,443			128,443
Cash and cash equivalents	12,885			12,885
Total	141,328	12,957	1,540,299	1,694,584
Financial liabilities				
Convertible loan		22,858		22,858
Other financial liabilities			11,686	11,686
Accounts payable		4,668		4,668
Liabilities to portfolio companies		442		442
Total		27,968	11,686	39,654

#### Investment Entity's assets and liabilities at fair value as of 31 December 2013

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares and participations at fair value through profit or loss			1,729,465	1,729,465
Loans receivable from portfolio companies		5,894		5,894
Other financial receivables			38,113	38,113
Accounts receivable		3		3
Receivables from portfolio companies		254		254
Short-term investments at fair value through profit or loss	165,334			165,334
Cash and cash equivalents	35,323			35,323
Total	200,657	6,151	1,767,578	1,974,386
Financial liabilities				
Other financial liabilities			9,438	9,438
Accounts payable		2,426		2,426
Liabilities to portfolio companies		442		442
Total	•	2,426	9,438	12,306

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."

#### Loans receivable, short-term portfolio companies

Fair value is based on market prices and generally accepted methods, which means that future cash flows have been discounted at the current rate for the remaining term.

#### Financial assets and liabilities at amortized cost

A fair value estimate based on discounted future cash flows, where the most significant input is a discount rate that reflects the counterparty's credit risk, does not produce a significant difference compared with the carrying amounts of recognized financial assets and liabilities in Level 2. The carrying amounts of all financial assets and liabilities are therefore considered a good approximation of fair value.

#### Changes in financial assets and liabilities on Level 3 in 2014

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At the beginning of the year	1,729,465	38,113	9,438
Transfers to and from Level 3	-	-	-
Acquisitions	83,984	-	-
Disposals	-864	-	-
Gains and losses realized in profit or loss	-310 399	-	2,210
Carrying amount at year-end	1,502,186	38,113	11,648
Total unrealized gains and losses for the period included in profit or loss	-310,399	-	-2,210
Gains and losses in profit/loss for the year for assets included in the closing balance	-310,399	-	-2,210

#### Changes in financial assets and liabilities on Level 3 in 2013

	Shares in	Other	Other
	portfolio	financial	financial
SEK 000	companies	assets	liabilities
At the beginning of the year	1,827,190	8,907	10,889
Transfers to and from Level 3	-	-	-
Acquisitions	266,173	29,206	0
Disposals	-223,902	-	-1,451
Gains and losses realized in profit			
or loss	-139,996	-	_
Carrying amount at year-end	1,729,465	38,113	9,438
Total unrealized gains and losses for			
the period included in profit or loss	-139,996	-	1,451
Gains and losses in profit/loss for			
the year for assets included in the			
closing balance	-139,996	-	1,451

#### 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. 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. Present value calculations are made with discounted cash flows which comprise:

- Estimated revenue, which generally consist of one-time milestone payments and royalty payments on sales. The estimated contract value (including royalties) is based on an estimate of sales potential and the buyer's development, manufacturing and marketing costs for the particular project. Contract value is based on a value allocation principle in which the seller's portion of the total value increases with the maturation of the project. In the model, the portfolio company receives approximately 40% of the total rNPV after Phase II.
- Sales forecasts are made by estimating the total patient population, target
  patient population, prevalence and treatable patients, market penetration and
  treatment costs in the US, Europe and the Japanese market. These markets
  represent approximately 70% of global pharmaceutical sales in 2012 (IMS).
- Estimates are made regarding product launch year and time of exit based on development plans. Drug licensing is usually assumed to be carried out after Phase II. For medical technology companies, an exit is usually assumed after launch of the product. Sales are then based on these estimated times together with the product's expected patent expiry, after which sales are assumed to decrease sharply.
- Estimates are made of the cost of each phase of development based on either the companies' forecasts or according to industry standards.
- Revenue and expenses are probability adjusted for each phase of development according to accepted statistics.

- Two different discount rates (weighted average cost of capital, or "WACC") are calculated to discount net cash flow from each project: a "Biotechnology WACC" for the in-house development period and a lower discount rate from the time the project is expected to be licensed to global pharmaceutical companies, a "Pharma WACC." The components of the discount rates are (i) the risk-free interest, represented by the Swedish Riksbank's 10-year government bond, (ii) the market risk premium, defined as the difference between the expected annuity quote and risk-free interest on the NASDAQ Stockholm stock exchange, and (iii) the premium supplement for private/small cap companies, which is a supplement to the market risk premium which represents the risk supplement for project companies with a market capitalization under SEK 100m on the NASDAQ Stockholm stock exchange. The premium supplement for private/small cap companies constitutes the difference between the Biotechnology WACC and Pharma WACC.
- On 31 December 2014, the Biotechnology WACC was 11.02% (11.90%) and the Pharma WACC was 7.32% (8.20%). The adjustments of the WACC made for the second quarter portfolio valuation were due to changes in the risk-free interest of -0.48% and the market risk premium of -0.4% compared with the previous WACC adjustment on 30 June 2013.

To estimate the effect of changes in the discount rate on the portfolio valuation, WACC has been adjusted by -1 percent and +1 percent.

		31 December 2014 Biotech WACC: C adjust- 11.02% WACC adjunt –1% Pharma WACC: 7.32% ment +1%			
MSEK	Fair value	Change	Fair value	Fair value	Change
Fair value difference for shares in portfolio companies	1,672.1	169,9	1,502.2	1,356.7	-145,5

 Current tax rates are used and exchange rates calculated according to historical averages.

A change in any of these assumptions affects the valuation and may if significant have a material effect on the Investment Entity's results.

The Investment Entity has a team responsible for the fair value measurements of the portfolio company holdings required for the financial reporting according to IPEV, including Level 3 fair values. All valuations in Level 3 are based on assumptions and judgments that management considers reasonable under current circumstances. This team reports directly to the Chief Financial Officer. Significant events that have occurred since the above-mentioned time of measurement have been taken into account in the measurement to the extent they would have affected the value on the closing date. Companies that have not been valued after transactions that have included third parties or present value calculations have been valued either at (i) net asset value or (ii) for early-stage development projects; the amount invested by Karolinska Development.

#### 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 2014	31 Dec 2013 (restated)
Loans receivable from portfolio companies	12,062	5,894
Other financial assets	38,113	38,113
Accounts receivable	-	3
Receivables from portfolio companies	895	254
Other current receivables	3,103	3,225
Short-term investments	128,443	165,334
Cash and cash equivalents	12,885	35,323
Maximum exposure to credit risk	195,901	248,146

#### 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 (see Sensitivity Analysis on the previous page).

#### 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 (see Sensitivity Analysis on the previous page).

#### 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 six-month period. The Investment Entity's liquid funds on the closing date provide the Investment Entity with the scope to maintain an active strategy with regard to investments in the portfolio companies for 12 months. This makes it possible to retain current ownership interests in the portfolio companies.

	Within 3	3-12	1–5	Over	
SEK 000	months	months	years	5 years	Total
2014					
Convertible loan	-	-	22,858	-	22,858
Accounts payable	4,668	-	-	-	4,668
Liabilities to portfolio companies	442	-	-	-	442
Other current liabilities	1,023	-	-	-	1,023
Total	6,133	-	22,858	-	28,991
2013					
Accounts payable	2,426	-	-	-	2,426
Liabilities to portfolio companies	442	-	-	-	442
Other current liabilities	1,593	-	-	-	1,593
Total	4,461	-	-	-	4,461

#### 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 for other stakeholders. The Investment Entity's policy is to minimize the risks in capital management.

## Note 19 | Pledged assets and contingent liabilities

SEK 000	31 Dec 2014	31 Dec 2013
Pledged assets		
Endowment insurance	4,286	3,315
Total pledged assets	4,286	3,315

#### **Endowment insurance**

Individual pension undertakings have been guaranteed in the form of Companyowned 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 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-avis 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 special payroll contributions, related to these endowment insurance policies. The Parent Company recognizes an asset and corresponding liability.

#### Other contingent liabilities

#### KIΔR

In January 2008, Karolinska Development and Karolinska Institutet Innovations AB (KIAB) entered a deal flow agreement to ensure Karolinska Development's access to research projects through KIAB's flow of innovations from cutting-edge research at Karolinska Institutet and other seats of learning in the Nordic countries. According to the agreement, Karolinska Development has a right of first refusal to invest in projects evaluated by KIAB. The agreement runs through January 2019 and will be extended until further notice with a notice period of three years unless notice of termination has been given at least three years prior. For each in-depth evaluation, KIAB is entitled to compensation with a mark-up of 100 percent on KIAB's internal costs and a mark-up of 10 percent on external costs. In addition, KIAB is entitled to a success fee corresponding to 6 percent of Karolinska Development's estimated accumulated result before financial items and tax as of 1 January 2008, which includes a so-called threshold amount of SEK 652m. No success fee is paid before the accumulated result amounts to at least SEK 652m, after which only surplus amounts are used as the basis of calculation. To be used as a basis of calculation, the accumulated result must be cash positive. At year-end 2013, the accumulated deficit was SEK -1.313m.

The basis of calculation for the success fee was established after the 2014 AGM. Since the calculation for 2014 leads to a negative accumulated result, no success fee will be charged for 2014.

### Note 20 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.

The Investment Entity has entered into a deal flow agreement with KIAB (see description above under contingent liabilities), a wholly owned subsidiary of KIHAB, one of Karolinska Development's largest shareholders. Within the framework of the agreement, the Investment Entity has compensated KIAB for evaluation expenses during the reporting period. Furthermore, the Investment Entity has rendered services to both KIAB and the portfolio companies on technical studies and administration. During the reporting period, KIHAB rendered administrative and accounting services for the Investment Entity. The prices of these services rendered are market based.

Karolinska Development and the European investment fund ("EIF") have 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"). In November 2009, KCIF entered into an agreement with Karolinska Development according to which KCIF will invest 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 12.9m, and Karolinska Development, which has committed EUR 4.5m. 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 2014 amounted to SEK 1,053 thousand (75).

FMAB is 37.5 percent owned by Karolinska Development, 25 percent by KIAB and 37.5 percent by investment managers employed by Karolinska Development. The investment managers hold high-vote shares and together control a majority of the votes in FMAB. Karolinska Development, KIAB and the investment managers have entered into to a shareholder agreement regarding FMAB. The shareholder agreement includes a number of rules to protect the minority shareholders, Karolinska Development and KIAB.

#### Compensation and profit distribution

FMAB is entitled to an annual management fee corresponding to 2.5 percent of the capital committed to KCIF during the investment period and 1 percent 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 percent on this amount. Secondly, 80 percent of the remaining funds will be distributed to EIF and Karolinska Development in proportion to their capital investment. The remaining 20 percent will be distributed to Karolinska Development on the condition that 25 percent of the amount is redistributed to KIAB according to the deal flow agreement (see above) and at least 37.5 percent is redistributed to the investment managers through Karolinska Development's profit-sharing program.

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.

For information of remuneration to CEO and other senior executives see note 5.

#### Agreements regarding KDev Investments AB Background

On 21 December 2012, Karolinska Development entered into an agreement with Rosetta Capital IV LP ("Rosetta") regarding the sale of a minority share of Karolinska Development's holdings in 13 of the Company's portfolio companies (the "Rosetta Transaction"). The Rosetta Transaction was completed during the first quarter of 2013. Karolinska Development has transferred the holdings in the 13 concerned portfolio companies to a new investment company; KDev Investments AB. Karolinska Development is the majority owner and Rosetta is the minority owner of KDev Investments AB. The shareholders have entered into a shareholder's agreement regarding the management of KDev Investments AB, and exercises joint control over the Company. KDev Investments AB group is considered a joint venture for accounting purposes.

#### Portfolio companies in the transaction

The KDev Investments AB group consists of 13 companies (in addition to the parent company KDev Investments AB) representing development projects in various phases and various areas. Seven of the companies develop pharmaceuticals and have projects in clinical trials: Akinion Pharmaceuticals AB, Aprea AB and Axelar AB, which are active in oncology; Dilafor AB and Umecrine Mood AB, which develop treatments in the area of women's health; Dilaforette Holding AB, which owns all the shares in Dilaforette AB, and develops sevuparin for use against malaria and sickle cell anemia; and Pergamum AB, which develops Karolinska Development's wound healing and dermatology portfolio. Three companies have development projects in or before preclinical development: Biosergen AS (systemic fungal infections), Clanotech AB (eye diseases) and Novasaid AB (inflammatory diseases). Three companies are involved in the development of technology products: Inhalation Sciences Sweden AB, NeoDynamics AB and Promimic AB.

#### Management of KDev Investments AB

Karolinska Development owns 87.09 percent of the shares in KDev Investments AB. The management of the company is governed by a shareholders' agreement. The parties have joint control of KDev Investments AB.

#### Terms for the preference shares

Rosetta's preference shares in KDev Investments AB will have preference to profit distributions as explained below (after SEK 58.4 million have been divided equally

between Rosetta and Karolinska Development, half of which represents the remaining purchase price in the Rosetta Transaction), after which allocations will be made to holders of common shares.

- (i) 100 percent of total future returns up to SEK 220 million;
- (ii) 30 percent of total future returns between SEK 220 million and SEK 880 million;
- (iii) 18.33 percent of total future returns between SEK 880 million and SEK 1,320 million: and
- (iv) 0 percent of total future returns over SEK 1,320 million.

#### Put option

According to the transfer agreement between Karolinska Development and Rosetta, Karolinska Development is obligated, under certain conditions, to acquire Rosetta's shares in KDev Investments AB on or after 7 March 2018. Rosetta has the right to request such acquisition (i.e. has a put option) if Rosetta has not received a return equivalent to 2.5 times the capital Rosetta invested in the Rosetta Transaction. The obligation is limited to a value corresponding to ten percent of the outstanding shares in Karolinska Development and can be fulfilled through the issuance of shares in Karolinska Development to Rosetta, by payment in cash or a combination thereof. Karolinska Development has the right to choose the form of payment.

#### Cash provisionally allocated for expected follow-on investments

According to a guarantee agreement, entered into in connection with the Rosetta Transaction, Karolinska Development has, as of the balance sheet date, allocated approximately SEK 124.2 million for expected additional investments in KDev Investments AB's portfolio companies until December 2017.

			2014			2013
			Purchase			Purchase
	Sale of	Interest	of	Sale of	Interest	of
SEK 000	services	income	services	services	income	services
Associate relationship						
Owner: Karolinska Institutet Holding						
Group	1	-	2,227	97	-	1,912
(of which rental cost)			(1,949)			(1,708)
Portfolio companies	3,206	269	20	4,040	3,788	20
Total	3,207	269	2,247	4,137	3,788	1,932

	3	31 Dec 2014	3	31 Dec 2013
SEK 000	Liability to associates	Receiva- ble from associates	Liability to associates	Receiva- ble from associates
Associate relationship				
Karolinska Institutet Holding Group	187	-	8	3
Portfolio companies	462	13,228	-	7,162
Total	648	13,228	8	7,165

#### **Note 21** Significant events after the closing date

See Directors' report, page 39.

# Note 22 The 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 3-9 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 with regard to 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 acquisition cost in the Parent Company's financial statements. Acquisition-related costs for subsidiaries, which are expensed in the consolidated financial statements, comprise a portion of the acquisition cost of shares in subsidiaries.

#### Associated companies and joint ventures

Shares in associated companies and joint ventures are recognized at cost in the Parent Company's financial statements. Dividends are recognized as revenue when these are adopted by the Annual General Meeting.

#### Other long-term securities holdings

Shares in other long-term securities holdings are recognized at cost in the Parent Company's financial statements.

#### **Impairments**

The Company reports holdings in subsidiaries, joint ventures, associated companies and other long-term securities holdings according to the cost method. If holdings in subsidiaries, joint ventures, associated companies or other long-term securities holdings are valued at below cost on the closing date, the holding is written down to the lower value.

#### Shareholder contributions

Shareholder contributions are recognized directly against shareholders' equity and in the shares and participations of the contributor to the extent that impairment is not required.

#### Pensions

In the Parent Company, the endowment insurance owned by the Company is recognized at acquisition cost in the balance sheet as a financial asset. The pension obligation is recognized as a provision for an equal amount.

#### Changes in accounting policies

The changes in RFR 2 have not had a significant effect on the Parent Company's financial statements.

# Note 23 | Information on the Parent Company

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

### Note 24 Revenue distribution

SEK 000	2014	2013
Service revenue from portfolio companies	5,013	4,908
Invoiced costs	17	40
Total revenue	5,030	4,948

## Note 25 Other external expenses

#### Auditor and consultant fees

SEK 000	2014	2013
Deloitte		
Audit services	719	665
Audit related services	1,431	311
Tax consulting	877	771
Other services	231	-
Total	3,258	1,747

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 President, 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 26 Operating leases

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

		2013
SEK 000	2014	(restated)
Expensed leasing payments during the period	1,992	1,708
Future leasing payments		
Within one year	1,462	1,455
Between one year and five years	996	2,182
Total future leasing payments	2,458	3,637

### Note 27 | Employees and personnel costs

#### Average number of employees

Full-time equivalent	2014	Of whom men	2013	Of whom men
Parent Company	13	73%	14	79%
Total	13	73%	14	79%

#### **Employee benefits**

SEK 000	2014	2013
Salaries and remuneration	37,875	21,116
Social security costs	7,363	8,085
Pension costs	5,524	5,792
Total	50,762	34,993

# Salaries and other remuneration distributed between Board members and other employees

		2014		2013
SEK 000	Board and CEO	Other employees	Board and CEO	Other employees
Salaries and remuneration	13,844	24,031	7,355	13,761
Pension costs	2,428	3,096	1,444	4,348
Total	16,272	27,127	8,799	18,109

Severance pay to former CEO, Torbjörn Bjerke, is included in salaries and remuneration to Board and CEO amounting to SEK 4.6m and in pension costs to Board and CEO amounting to SEK 0.9m.

## Note 28 | Impairment

SEK 000	2014	2013
Impairment of shares in subsidiaries	-142	-20,954
Impairment of shares in joint ventures and associated companies	-13,888	-447
Impairment of other long-term securities holdings	-881	-3,300
Total	-14,911	-24,701

# Note 29 Result on sale of shares in portfolio companies

SEK 000	2014	2013
Capital gain/loss		
BioChromix AB	-	-3,734
BioChromix Pharma AB	355	-29,790
KDev Exploratory AB	1,413	755
KDev Investments AB	-	123,678
Limone AB	-35	-
HBV Theranostica AB	-29	-
BioChromix Newco AB	-8	-
NephroGenex Inc	-3	-
Gain/loss on sale of portfolio companies	1,693	90,909

# Note 30 Interest income and similar income

SEK 000	2014	2013
Interest income	637	5,888
Change in value of short-term investments	1,188	1,078
Foreign currency exchange rate gains	-	673
Reversal of impaired receivables from joint ventures and associated companies	-	31,976
Other financial income	672	384
Total	2,497	39,999

# Note 31 Interest expenses and similar expenses

SEK 000	2014	2013
Interest expenses	-4	-5
Exchange rate losses	-58	-139
Impairment of receivables from joint ventures		
and associated companies	-3,785	_
Total	-3,847	-144

# Note 32 Taxes

SEK 000	%	2014	%	2013
Profit/loss before tax		-78,130		47,314
Income tax expense calculated at applica-		.=		
ble rate in the Parent Company	22.0%	17,189	22.0%	-10,409
Tax effect of				
Non-deductible expenses		-4,814		-14,254
Tax-exempt income		546		34,497
Issue costs		2,233		-
Increase in tax losses carried forward without corresponding capitalization of				
deferred tax		-15,152		-9,834
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. 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 2014 amounted to SEK 89,323 thousand (SEK 74,171 thousand), of which SEK 64,337 thousand (SEK 64,337 thousand) refers to deficits that are restricted by Group contributions and mergers.

# Note 33 Tangible non-current assets

SEK 000	31 Dec 2014	31 Dec 2013
Accumulated acquisition cost		
At the beginning of the year	659	25
Investments during the year	-	634
Closing balance	659	659
Accumulated amortization and impairments		
At the beginning of the year	-130	-16
Depreciation for the year	-212	-114
Closing balance	-342	-130
Carrying amount	317	529

# Note 34 Shares in subsidiaries

SEK 000	2014	2013
Accumulated book values		
At the beginning of the year	32,875	440,479
Investments during the year	7,677	21,786
Reclassifications to/from joint ventures and associated companies	-	-405,036
Disposals	-198	-3,400
Impairment	-142	-20,954
Closing balance, book value	40,212	32,875

#### Specification of holdings in subsidiaries

Name	Book value in					
	Total h	olding¹	Parent (	Parent Company		
SEK 000	31 Dec 2014	31 Dec 2013	31 Dec 2014	31 Dec 2013		
Avaris AB	94.87%	94.87%	308	362		
HBV Theranostica AB (liquidated)	-	100.00%	-	27		
KCIF Fund Manage- ment AB	37.50%	37.50%	196	190		
KD Incentive AB	100.00%	100.00%	172	175		
KDev Oncology AB	100.00%	100.00%	253	319		
Gligene AB (liquidated)	-	100,00%	-	-		
Limone AB (liquidated)	-	100.00%	-	197		
Pharmanest AB	62.66%	60.24%	39,283	31,605		
Total book value			40,212	32,875		

<sup>&</sup>lt;sup>1</sup> Including indirect ownership interest through portfolio companies. 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 controlling interest.

#### Investments in subsidiaries

SEK 000	2014	2013
HBV Theranostica AB	-	4
KCIF Fund Management AB	-	200
KD Incentive AB	-	150
KDev Exploratory AB	-	11,000
KDev Oncology AB	-	1,600
Limone AB	-	400
Pharmanest AB	7,677	8,432
Total investments in subsidiaries	7.677	21.786

#### Non-cash investments in subsidiaries

SEK 000	2014	2013
Other non-cash investments		
HBV Theranostica AB	-	4
Total non-cash investments	-	4

# Note 35

# Shares in joint ventures and associated companies

SEK 000	2014	2013
Accumulated book value		
At the beginning of the year	1,029,008	505,923
Investments during the year	76,307	244,379
Reclassifications to/from subsidiaries	-	405,036
Disposals	-	-125,883
Impairment	-13,888	-447
Closing balance at book value	1,091,427	1,029,008

#### Specification of holdings in joint ventures

	Book value in Pa			in Parent
	Total	holding <sup>1</sup>	Comp	any
	31 Dec	31 Dec	31 Dec	31 Dec
SEK 000	2014	2013	2014	2013
Athera Biotechnologies AB	65.44%	65.44%	89,048	101,087
Bioneris AB (liquidated)	-	26.31%	-	0
Forendo Pharma Oy	18,42%	20.70%	13,074	9,530
KDev Investments AB	87.09%	86.98%	840,564	793,341
Akinion Pharmaceuticals AB	80.73%	80.62%	-	-
Aprea AB	61.74%	61.66%	-	-
Aprea Personal AB	61.74%	61.66%	-	-
Axelar AB	43.31%	43.26%	-	-
Biosergen AS	59.76%	56.69%	-	-
Clanotech AB	79.68%	79.29%	-	-
Dilafor AB	47.03%	49.35%	-	-
Dilaforette Holding AB	63.58%	59.92%	-	-
Dilaforette AB	63.58%	59.92%	-	-
Inhalation Sciences Sweden AB	68.17%	67.70%	-	-
NeoDynamics AB	18.04%	18.02%	-	-
NovaSAID AB	77.44%	77.34%	-	-
Pergamum AB	56.38%	56.31%	-	-
DermaGen AB	56.38%	56.31%	-	-
Herantis Pharma Oy	0.95%	3.13%	-	-
Lipopeptide AB	58.38%	56.31%	-	-
XImmune AB	4.49%	4.69%	-	-
Promimic AB	30.75%	28.57%	-	-
Umecrine Mood AB	38.37%	38.65%	-	-
Lipidor AB	49.89%	52.55%	18,239	18,239
Umecrine Cognition AB	68.52%	54.87%	36,700	21,700
XSpray Microparticles AB	63.42%	62.92%	60,790	54,075
Total book value			1,058,415	997,972

<sup>&</sup>lt;sup>1</sup> 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 controlling interest.

## Specification of holdings in associated companies

	Total holding <sup>1</sup>		Book value in Parent Company	
SEK 000	31 Dec 2014	31 Dec 2013	31 Dec 2014	31 Dec 2013
KCIF Co-Investment Fund KB	26,00%	26,00%	23 157	21 181
OssDsign AB	25,81%	25,81%	9 855	9 855
Total book value			33 012	31 036

<sup>&</sup>lt;sup>1</sup> 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 controlling interest.

#### Investments in joint ventures and associated companies

SEK 000	2014	2013
Athera Biotechnologies AB	-	3,650
BioChromix Pharma AB	-	2,000
Forendo Pharma Oy	3,544	9,530
KCIF Co-Investment Fund KB	3,823	7,756
KDev Investments AB	47,224	185,549
Lipidor AB	-	5,242
OssDsign AB	-	6,205
Umecrine Cognition AB	15,000	7,000
XSpray Microparticles AB	6,716	17,447
Total investments in joint ventures and associated		
companies	76,307	244,379
Non-cash investments in joint ventures and associated c	ompanies	
SEK 000	2014	2013
Conversions of previously provided loans		
KDev Investments AB	6,658	64,264

# Note 36 Other long-term securities holdings

XSpray Microparticles AB

Total non-cash investments

SEK 000	2014	2013
Accumulated book value		
At the beginning of the year	8,714	15,841
Investments during the year	-	8
Disposals	-718	-3,835
Impairment	-881	-3,300
Closing balance at book value	7,115	8,714

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

Name	Total holding <sup>1</sup>			ralue in Company
SEK 000	31 Dec 2014	31 Dec 2013	31 Dec 2014	31 Dec 2013
BioArctic NeuroScience AB	3.17%	3.17%	600	600
BioChromix Newco AB (divested)	-	12.72%	-	8
BioResonator AB (liquidated)	-	7.62%	-	-
CytoGuide Aps (liquidated)	-	9.06%	-	-
NephroGenex Inc. (divested)	-	0.58%	-	708
Umecrine AB	10.41%	10.41%	6,515	7,398
Total book value			7,115	8,714

<sup>&</sup>lt;sup>1</sup> Including indirect ownership interest through portfolio companies. 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 controlling interest.

#### Investments in other long-term securities

SEK 000	2014	2013
BioChromix Newco AB	-	8
Total investments in other long-term securities	_	8

3,785

68,049

6,658

# Note 37 Parent Company's holdings in subsidiaries, joint ventures and associated companies

Company	Registered office	Corporate Identity Number	Number of shares	Equity, SEK 000 <sup>1</sup>	Profit/loss, SEK 000
Akinion Pharmaceuticals AB	Solna	556777-0978	39,450	6,419 <sup>2</sup>	-20,658
Aprea AB	Stockholm	556631-2285	537,488	-10,566 <sup>2</sup>	-26,136
Aprea Personal AB	Stockholm	556771-4034	1,000	100	0
Athera Biotechnologies AB	Solna	556620-6859	866,300	10,689	2,540
Avaris AB	Huddinge	556614-2112	443,580	308	0
Axelar AB	Stockholm	556623-6708	147,158	21,723	-15,388
Biosergen AS	Trondheim	NO 687622075	4,506,669	741	-2,603
ClanoTech AB	Solna	556706-6658	64,628	4,212 <sup>2</sup>	-9,012
Dilafor AB	Stockholm	556642-1045	245,425	6,402	-15,938
Dilaforette Holding AB	Stockholm	556851-9523	716,888	65,060 <sup>2</sup>	-1,445
Forendo Pharma Oy	Åbo	FI 2520329-3	1,028	68,013	33,801
Inhalation Sciences Sweden AB	Solna	556665-6038	371,005	1,094	-176
KCIF Fund Management AB	Solna	556777-9219	37,500	220	-25
KCIF Co-Investment Fund KB	Solna	969744-8810	26	89,048	-7,102
KD Incentive AB	Solna	556745-7675	100,000	162	-10
KDev Investments AB	Solna	556880-1608	1,097,877	775,263	-178,299
KDev Oncology AB	Solna	556683-9345	313,345	253	-94
Lipidor AB	Stockholm	556779-7500	897	960	-3,951
NeoDynamics AB	Stockholm	556656-3341	8,495	14,391	-13,320
NovaSAID AB	Solna	556669-2181	530,505	453	-322
OssDsign AB	Uppsala	556841-7546	26,084	1,736 <sup>2</sup>	-11,547
Pergamum AB	Solna	556759-9203	13,046,138	74,516	-2,640
Pharmanest AB	Solna	556785-1158	318,029	-1,721	-14,781
Promimic AB	Göteborg	556657-7754	139,221	4,015	-1,691
Umecrine Cognition AB	Umeå	556698-3655	2,531,283	2,269 <sup>2</sup>	-6,248
Umecrine Mood AB	Umeå	556698-0750	1,972,840	5,825	-6,941
XSpray Microparticles AB	Solna	556649-3671	818,731	2,005	-14,876

# Note 38 Loans receivable from portfolio companies

SEK 000	31 Dec 2014	31 Dec 2013
Loans receivable from portfolio companies		
At the beginning of the year	5,894	12,856
Loans provided	15,712	34,712
Reversal of impairments	-	30,000
Conversions	-5,894	-66,897
Repayments	-	-4,777
Impairment losses	-3,650	-
Total	12,062	5,894

# Note 39 Accounts receivable

SEK 000	31 Dec 2014	31 Dec 2013
Trade receivables not past due	-	202
Overdue receivables not considered bad debts		
1-30 days	-	-
31-90 days	-	-
91-180 days	-	-
>180 days	-	-
Total	-	202

No provisions for bad debt were considered necessary for any of the years above.

# Note 40 Other current receivables

SEK 000	31 Dec 2014	31 Dec 2013
Tax receivables	958	2,093
VAT receivables	2,068	374
Other	77	758
Total	3,103	3,225

# Note 41 Prepaid expenses and accrued income

SEK 000	31 Dec 2014	31 Dec 2013
Prepaid rental expenses	510	-
Accrued interest income	367	828
Insurance premiums	459	413
Accrued income	364	-
Prepaid issue costs	10,148	-
Other	516	236
Total	12,364	1,477

# Note 42 Other current liabilities

SEK 000	31 Dec 2014	31 Dec 2013
Other taxes and fees	1,021	1,546
Other	2	48
Total	1,023	1,594

## Note 43 Accrued expenses and prepaid income

SEK 000	31 Dec 2014	31 Dec 2013
Salaries and remuneration to personnel	13,042	1,744
Remuneration to Board of Directors	216	911
Auditor and consulting fees	2,306	701
Payroll tax and accrued pension costs	3,571	3,109
Social security contributions	4,903	594
Other	109	1,055
Total	24,147	8,114

## Note 44 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.

The Company has entered into a deal flow agreement with KIAB, a wholly owned subsidiary of KIHAB, one of Karolinska Development's largest shareholders. The agreement ensures the inflow of research projects which have been evaluated by KIAB. Within the framework of the agreement, Karolinska Development has compensated KIAB for evaluation expenses during the reporting period. Furthermore, Karolinska Development has rendered services to both KIAB and the portfolio companies on technical studies and administration. During the reporting period, KIHAB rendered administrative and accounting services for Karolinska Development. The prices of these services rendered are market based.

	Sale of	Interest	2014 Purchase of	Sale of	Interest	2013 Purchase of
SEK 000	services	income	services	services	income	services
Associate relationship						
Owner: Karolinska Institutet Holding Group	1	-	2,227	97	-	1,912
(of which rental cost)			(1,949)			(1,708)
Subsidiaries	1,317	148	-	1,382	2	20
Joint ventures and associated companies	3,206	121	20	2,658	3,786	-
Total	4,524	269	2,247	4,137	3,788	1,932

	3	1 Dec 2014	3	31 Dec 2013		
SEK 000	Liability to associate	Receiva- ble from associate	Liability to associate	Receiva- ble from associate		
Associate relationship						
Owner: Karolinska Institutet Holding Group	187	-	8	3		
Subsidiaries	442	2,620	-	497		
Joint ventures and associated companies	20	10,608	-	6,665		
Total	648	13,228	8	7,165		

## Note 45 | Transition to investment entity

Karolinska Development applies IFRS 10 Consolidated Financial Statements, IFRS 11 Joint Arrangements, IFRS 12 Disclosure of Interests in Other Entities, IAS 27 (revised 2011) Separate Financial Statements and IAS 28 Investments in Associates and Joint Ventures, and has applied the transition guidance amendments to IFRS 10, 11 and 12, all effective 1 January 2013. Karolinska Development has early adopted the investment entity amendments to IFRS 10, IFRS 12 and IAS 27, which are effective 1 January 2014, with early adoption permitted.

Karolinska Development published a prospectus in accordance with the standards for Investment Entities on 5 December 2014, in which historical financial statements for years 2011, 2012 and 2013 are restated.

IFRS 10 Consolidated Financial Statements, including the amendments, establish policies for the presentation and preparation of consolidated financial statements. It sets out how to apply the principle of control to identify whether an investor controls an investee and therefore must consolidate the investee. It also sets out the accounting requirements for the preparation of consolidated financial statements. The amendments to IFRS 10 define an investment entity and introduce an exemption from the consolidation requirements for investment entities.

On adoption, Karolinska Development has determined that it meets the definition of an investment entity. As a result, Karolinska Development has amended its accounting policies with respect to its investments in subsidiaries. The subsidiaries, which were previously consolidated, are now measured at fair value through profit or loss. This change in accounting policy has been applied retroactively in accordance with the transition provisions of IFRS 10 and the amendments to IFRS 10. The transition provisions require retroactive application in accordance with IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors.

IFRS 12, Disclosure of Interests in Other Entities and the amendments to it require entities to disclose significant judgments and assumptions made in determining whether the entity controls, jointly controls, significantly influences or has some other interests in other entities. Entities will also be required to provide more disclosures around certain "structured entities." The amendments also introduce new disclosure requirements related to investment entities. Adoption of the standard has impacted the Karolinska Development's level of disclosures in certain of the above noted areas.

IAS 27 (revised 2011), Consolidated and Separate Financial Statements, including the amendments, prescribe the accounting and disclosure requirements when an entity prepares separate financial statements. The amendments require an investment entity as defined in IFRS 10 to present separate financial statements as its only financial statements in cases where it measures all of its subsidiaries at fair value through profit or loss and to disclose that fact.

IFRS 11, Joint Arrangements and IAS 28 (revised 2011), Associates and Joint Ventures and related amendments have also been adopted early, although these standards have had no impact on Karolinska Developments' financial statements.

#### Amended accounting policy for shares in portfolio companies

Shares in portfolio companies are categorized as financial assets/liabilities at fair value in the condensed balance sheet for the Investment Entity. These assets and liabilities are recognized at estimated fair value on each closing date, while changes in fair value are recognized in the condensed income statement. Transaction costs are recognized through profit or loss in the income statement.

# Summary of effects of change in accounting policy to investment entity The largest effects of the change in accounting policy are that:

- Investment entities do not consolidate subsidiaries that they control. This
  means that the individual income statement, balance sheet and cash flow line
  items of previously consolidated subsidiaries are not included in the Investment
  Entity's financial statements.
- Deferred tax liabilities related to surplus values from subsidiary acquisitions are no longer recognized.
- Non-controlling interests are no longer recognized.

The effects of the change in accounting policies on the Group's financial position, comprehensive income and cash flow for 2013 are reported in the following tables.

### Effects of change in accounting policy on income statement for comparative figures 2013

SEK 000	<b>2013</b> Full-year (previously published)	Change in accounting policy	<b>2013</b> Full-year (restated)
Revenue	9,940	-4,992	4,948
Other external expenses	-53,772	28,480	-25,292
Personnel costs	-58,745	20,455	-38,290
Depreciation and amortization of tangible and intangible non-current assets	-2,627	2,513	-114
Change in fair value of shares in portfolio companies	-	-139,996	-139,996
Change in fair value of shares in joint ventures and associated companies	-153,711	153,711	-
Change in fair value of other long-term securities holdings	-2,289	2,289	-
Result from sale of subsidiaries	834	-834	-
Result from transaction with Rosetta Capital IV LP	404,646	-404,646	-
Operating profit/loss	144,276	-343,020	-198,744
Financial net	40,890	539	41,429
Profit/loss before tax	185,166	-342,481	-157,315
Deferred taxes	2,926	-2,926	-
Current taxes	-	-	-
NET PROFIT/LOSS FOR THE PERIOD	188,092	-345,407	-157,315
Attributable to:			
Parent Company's shareholders	197,163	-354,478	-157,315
Non-controlling interests	-9,071	9,071	-
TOTAL	188,092	-345,407	-157,315

## Effects of change in accounting policy on statement of comprehensive income for comparative figures 2013

SEK 000	<b>2013</b> Full-year (previously published)	Change in accounting policy	2013 Full-year (restated)
Net profit/loss for the period	188,092	-345,407	-157,315
Total comprehensive income for the period	188,092	-345,407	-157,315
Attributable to:			
Parent Company's shareholders	197,163	-354,478	-157,315
Non-controlling interests	-9,071	9,071	-
TOTAL	188,092	-345,407	-157,315

#### Effects of change in accounting policy on consolidated balance sheet for comparative figures 2013 and 2012

SEK 000	31 Dec 2013 (previously published)	Change in accounting policy	31 Dec 2013 (restated)	31 Dec 2012 (previously published)	Change in accounting policy	31 Dec 2012 (restated)
ASSETS						
Non-current assets						
Intangible non-current assets	8,340	-8,340	-	9,864	-9,864	-
Tangible non-current assets	529	-	529	4,985	-4,976	9
Shares in joint ventures and associated companies	1,605,469	-1,605,469	-	219,173	-219,173	-
Other long-term securities holdings	24,568	-24,568	-	26,949	-26,949	-
Shares in portfolio companies	-	1,729,465	1,729,465	-	1,827,190	1,827,190
Loans receivable from portfolio companies	5,894	-	5,894	12,856	-	12,856
Other financial assets	38,113	_	38,113	8,907	-	8,907
Total non-current assets	1,682,913	91,088	1,774,001	282,734	1,566,228	1,848,962
	,,.	,	, , , , , , ,	- , -	,,	,,
Current assets						
Accounts receivable	258	-255	3	513	-407	106
Receivables from portfolio companies	-	254	254	-	563	563
Other current receivables	3,803	-578	3,225	3,955	-1,479	2,476
Prepaid expenses and accrued income	1,767	-290	1,477	4,578	-2,115	2,463
Short-term investments	165,334	_	165,334	174,160	-	174,160
Cash and cash equivalents	41,639	-6,316	35,323	117,033	-8,353	108,680
Total current assets	212,801	-7,185	205,616	300,239	-11,791	288,448
Assets which have been transferred to KDev Investments Group	-	-	-	1,632,025	-1,632,025	-
Total current assets	212,801	-7,185	205,616	1,932,264	-1,643,816	288,448
TOTAL ASSETS	1,895,714	83,903	1,979,617	2,214,998	-77,588	2,137,410
EQUITY AND LIABILITIES Equity						
Share capital	24,266	-	24,266	24,266	-	24,266
Share premium	1,768,179	-	1,768,179	1,768,179	-	1,768,179
Retained earnings including net profit/loss for the year	74,380	90,779	165,159	-122,547	445,607	323,060
Equity attributable to Parent Company's shareholders	1,866,825	90,779	1,957,604	1,669,898	445,607	2,115,505
Non-controlling interests	3,514	-3,514	0	354,294	-354,294	-
Total equity	1,870,339	87,265	1,957,604	2,024,192	91,313	2,115,505
Long-term liabilities						
Other financial liabilities	9,438	-	9,438	10,889	-	10,889
Total long-term liabilities	9,438	-	9,438	10,889	-	10,889
Current liabilities						
Accounts payable	3,779	-1,353	2,426	4,215	-1,705	2,510
Liabilities to portfolio companies	-	442	442	-	473	473
Other current liabilities	2,636	-1,043	1,593	2,775	-1,263	1,512
Accrued expenses and prepaid income	9,522	-1,408	8,114	8,166	-1,645	6,521
Total current liabilities	15,937	-3,362	12,575	15,156	-4,140	11,016
Liabilities attributable to assets which have been transferred to KDev Investments Group	-	-	-	164,761	-164,761	-
Total current liabilities	1,870,339	87,265	1,957,604	179,917	-168,901	11,016
Total liabilities	25,375	-3,362	22,013	190,806	-168,901	21,905
TOTAL EQUITY AND LIABILITIES	1,895,714	83,903	1,979,617	2,214,998	-77,588	2,137,410

#### Effects of change in accounting policy on statement of cash flows for comparative figures 2013

g g,	2013		
	Full-year	Change in	2013
SEK 000	(previously published)	accounting policy	Full-year (restated)
Operating activities	ривнянеи)	policy	(restateu)
Operating activities  Operating profit/loss	144,276	-343,020	-198,744
Adjustments for items not affecting cash flow	144,270	343,020	150,744
Adjustment for depreciation of amortization	2,627	-2,513	114
Adjustment for changes in fair value	156,000	-16,004	139,996
Result from transaction with Rosetta Capital IV LP	-404,646	404,646	-
Other non-cash items	2,171		2,171
Realized changes in value of short-term investments	1,062	_	1,062
Interest paid	-70	65	-5
Interest received	5,353	-36	5,317
Cash flow from operating activities before changes in working capital and operating investments	-93,227	43,138	-50,089
cash now from operating activities before changes in working capital and operating investments	-33,227	43,130	-30,083
Cash flow from changes in working capital			
Increase (-)/Decrease (+) in operating receivables	8,421	-7,305	1,116
Increase (+)/Decrease (-) in operating liabilities	2,779	-204	2,575
Operating investments			
Acquisitions of intangible non-current assets	-879	879	-
Acquisitions of tangible non-current assets	-1,018	383	-635
Sale of tangible non-current assets	4,000	-4,000	-
Sale of subsidiaries	4,031	-4,031	-
Acquired/divested cash and cash equivalents in subsidiaries	-2,548	2,548	-
Investments in shares in portfolio companies	-	-198,120	-198,120
Investments in shares in joint ventures and associated companies	-176,330	176,330	-
Investments in other long-term securities	-8	8	-
Cash and cash equivalents which have been transferred to KDev Investments Group	-51,723	51,723	-
Change in short-term investments	7,105	-	7,105
Sale of shares in portfolio companies	190,893	4,031	194,924
Loans provided to associated companies	-27,750	-	-27,750
Cash flow from operating activities	-136,254	65,380	-70,874
Financing activities			
Share of subsidiary issue for non-controlling interest	3,757	-3,757	_
Share repurchase	-2,483	-	-2,483
Cash flow from financing activities	1,274	-3,757	-2,483
Cash flow for the year	-134,980	61,623	-73,357
Cash and cash equivalents at the beginning of the year	176,619	-67,939	108,680
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR	41,639	-6,316	35,323

### Signing of the annual financial statements

The Board of Directors and CEO herery certify that the annual report for the Investment Entity have been prepared according to International Financial Reporting Standards (IFRS), as adopted by the EU, and it provides a true view and fair of the Investment Entity's position and result.

The annual report for the parent company has been prepared according RFR 2 and it provides a true and fair view of the parent company's position and result.

The administration report for the Investment Entity and parent company provides a true and fair overview of the development of the Investment

Entity's and parent company's operations, position and results, and that it describes significant risks and factors of uncertainty facing the Investment Entity and parent company.

The annual report for the Investment Entity and parent company have been approved for presentation by the Board on 7 April 2015. The Investment Entity's and parent company's income statement and balance sheet will be presented for adoption by the Annual General Meeting of shareholders on May 20 2015.

Solna, 28 April 2015 Bo Jesper Hansen Charlotte Edenius Vlad Artamonov Chairman Board member Board member Hans Wigzell Carl Johan Sundberg Henrijette Richter Board member Board member Board member Robert Holland Jim Van heusden CEO Board member

Our Auditor's Report was presented on 28 April 2015

Deloitte AB

Thomas Strömberg
Authorized Public Accountant

### Auditor's report

# TO THE ANNUAL MEETING OF THE SHAREHOLDERS OF KAROLINSKA DEVELOPMENT AB (PUBL) CORPORATE IDENTITY NUMBER 556707-5048

### Report on the annual accounts and the investment entity's financial report

We have audited the annual accounts and the investment entity's financial report of Karolinska Development AB (Publ) for the financial year 2014-01-01 – 2014-12-31. The annual accounts and the investment entity's financial report of the company are included in the printed version of this document on pages 37–75.

Responsibilities of the Board of Directors and the Managing Director for the annual accounts and the investment entity's financial report

The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of these annual accounts in accordance with the Annual Accounts Act and of the the investment entity's financial report in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the Managing Director determine is necessary to enable the preparation of annual accounts and the investment entity's financial report that are free from material misstatement, whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to express an opinion on these annual accounts and the investment entity's financial report based on our audit. We conducted our audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and the investment entity's financial report are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and the investment entity's financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the annual accounts and the investment entity's financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and the investment entity's financial report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the annual accounts and the investment entity's financial report.

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

#### **Opinions**

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 2014 and of its financial performance and its cash flows for the year then ended in accordance with the Annual Accounts Act. The investment entity's financial report 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 2014 and

of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards, 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 investment entity's financial report.

We therefore recommend that the annual meeting of shareholders adopt the income statement and balance sheet for the parent company and the investment entity.

#### Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and the investment entity's financial report, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the Managing Director of Karolinska Development AB (Publ) for the financial year 2014-01-01 – 2014-12-31.

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, and the Board of Directors and the Managing Director are responsible for administration under the Companies Act.

#### Auditor's responsibility

Our responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on our audit. We conducted the audit in accordance with generally accepted auditing standards in Sweden.

As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss, we examined whether the proposal is in accordance with the Companies Act.

As a basis for our opinion concerning discharge from liability, in addition to our audit of the annual accounts and the investment entity's financial report, we examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the Managing Director is liable to the company. We also examined whether any member of the Board of Directors or the Managing Director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

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

#### **Opinions**

We recommend to the annual meeting of shareholders that the loss 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.

Stockholm, 28 April 2015

Deloitte AB

Signature on Swedish original

Thomas Strömberg
Authorized Public Accountant

### Corporate Governance Report for 2014

#### INTRODUCTION

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 (http://www.karolinskadevelopment.com/en/ir/corporate-governance/).

#### General meetings

The principles for the general meetings, decisions by the general meetings, the rights of the shareholders and how these rights are exercised, comply with applicable legal requirements.

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

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 2014, eight directors and no deputies were elected. Since October 1, 2014 the number of director is seven.

### 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 May 14, 2014 authorized the Board, for the period up until the next annual general meeting to adopt decisions, whether on one or several occasions without pre-emption rights for the shareholders to issue new shares of series B up to a maximum of ten percent of the share capital. Under the authorization the board decided on November 5, 2014 on a new share issue directed to Cino Biopharmaceutical Limited.

The Annual General Meeting also authorized the Board to decide on acquisition of up to 182,000 own shares to cover social security charges related to the PSP 2014 incentive program and later up to 136,560 own shares for PSP 2014:II. No repurchase has been executed under these mandates. The reason is that personnel participating in previous PSP programs have left their employments and that the company's holding related thereto is sufficient to cover also PSP 2014. The company's total holding is 244,285 shares.

#### 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 25.64 percent of the votes (6.80 percent of the shares).

#### Nomination Committee

The five largest owners (as set forth in the share register kept by Euroclear Sweden AB as of 31 August 2014) have each appointed one member of the Nomination Committee for the Annual General Meeting 2015. The members of the Nomination Committee have elected a chairman among themselves. The Nomination Committee did initially consisted of Gillis Cullin, Chairman, appointed by Östersjöstiftelsen (The Foundation of Baltic and East European Studies); Magnus Persson, appointed by Karolinska Institutet Holding AB; Peter Lundqvist, appointed by Tredje AP-fonden (Third Swedish National Pension Fund); Claes Kinell, appointed by Jarla Investeringar AB; and Todd Plutsky, appointed by Coastal Investment Management LLC. Following the new issue of shares in November 2014 Claes Kinell was replaced by Tse Ping appointed by Sino Biopharmaceutical.

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 seven directors, Bo Jesper Hansen (Chairman), Hans Wigzell, Henrijette Richter, Robert Holland, Carl Johan Sundberg Charlotte Edenius and Vlad Artamonov. Klaus Wilgenbus who was elected by the AGM resigned from the board October 1 when he was appointed acting CEO. 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 "Employees and costs for employees".

#### **Elected directors**

Bo Jesper Hansen Chairman and director since 2013. Born 1958. MD. PhD. Other appointments Chairman of Swedish Orphan Biovitrum AB and Topotarget A/S. Board member of Hyperion Therapeutics Inc., GenSpera Inc., Newron SA, Ablynx NV, Orphazyme A/S and CMC Kontrast AB. Previous appointments include various positions in Swedish Orphan International AB since 1993, including CEO 1998–2010. Medical advisor for Synthélabo, Pfizer, Pharmacia and Yamanouchi. Founder of Scandinavian Medical Research. Holdings in Karolinska Development SEK 400,000 convertible loan.

Hans Wigzell Director since 2006. Born 1938. Professor Emeritus of Immunology and MD. Other appointments Chairman of Rhenman & Partner Asset Management AB. Board member of Swedish Orphan Biovitrum AB, Valneva SA, 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 8,491 shares.

**Henrijette Richter** Director since 2014. Born 1971. PhD MSc. Other appointments Partner at Sofinnova Partners, Paris. Previous positions include Investment Director at Novo Seeds, Novo A/S, (2007-2014) where she served on the boards of Cytoguide ApS, Avilex Pharma ApS, Affinicon ApS, Orphazyme A/S and EpiTherapeutics A/S. In addition she

is on the Board of Directors for the Green Development and Demonstration Programme (GUDP) of the Danish Food, Agriculture and Fisheries Ministry. No holdings in Karolinska Development.

Robert Holland Director since 2014. Born 1955. MD, PhD. Other appointments Board director of Newron Pharmaceuticals SpA and Early Clinical Development Consulting Ltd. Medical Director and part of senior management at Oxford Gene Technology IP Ltd. Previous assignments include, leading position in AstraZeneca, including Head of Personalized Healthcare & Biomarkers and Head of Neuroscience, positions in clinical research at Wellcome, Solvay and Upjohn, Fellow of the Faculty of Pharmaceutical Medicine. No holdings in Karolinska Development.

Carl Johan Sundberg Director since 2014. Born 1958. Professor of Physiology. Other appointments Board Director of Cobra Biologics AB, Coordinator Science and Society, the Vice-Chancellor's Office at KI, member of Karolinska Institutet Innovation Council, director of the Unit of Bioentrepreneurship, Fellow of the Royal Swedish Academy of Engineering Sciences, member of the Medical Commission of the International Olympic Committee, Inspector General of the Medical Association and Chairman of Research Sweden. Previous assignments include Investment Director at Karolinska Investment Fund, Board Director of Global Genomics AB, AngioGenetics AB, NsGene AS, Cellectricon AB, Alfta Rehab Center Holding AB, Karolinska Education AB and Feelgood Swedish AB, Vice President of Euroscience and Chairman of the Swedish Professional Associations for Physical Activity and Sports Medicine. No holdings in Karolinska Development.

Charlotte Edenius Director since 2012. Born 1958. PhD. Medical Degree. Other appointments Executive VP Development at Medivir AB. Previous appointments include Senior VP Preclinical & Clinical R&D at Orexo AB, CSO at Biolipox AB, several positions within Clinical R&D at AstraZeneca, academic research at Karolinska Institutet and Board Member of Karolinska Institutet Innovations AB and Qlucore AB. No holdings in Karolinska Development.

Vlad Artamonov Director 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).

#### Independence requirements

The table below indicates 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, according to the definitions stipulated in the Code.

Independent of:

Name	Function	Elected	company/ mgmt.	major holders
Bo Jesper Hansen	Chairman	2013	yes	yes
Hans Wigzell	director	2006	yes	yes
Henrijette Richter	director	2014	yes	yes
Robert Holland	director	2014	yes	yes
Carl Johan Sundberg	director	2014	yes	no
Klaus Wilgenbus	director	2012	yes	yes
Charlotte Edenius	director	2012	yes	yes
Vlad Artamonov	director	2012	yes	yes

Klaus Wilgenbus resigned as director October 1, 2014.

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 the year, the Board held 21 meetings. The extraordinary meetings were summoned mainly to deal with matters arisen between scheduled meetings, to a large extend related to the financing of the company. Board members have been present as follows: Bo Jesper Hansen 21 meetings, Hans Wigzell 20 meetings, Charlotte Edenius 21 meetings and Vlad Artamonov 19 meetings. And as for the director elected by the 2014 AGM, Henrijette Richter 13 meetings, Robert Holland 15 meetings and Carl Johan Sundberg 14 meetings. Klaus Wilgenbus, who resigned October 1, 2015 attended 10 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 Policy, IT Security Policy, Gender Equality Policy, Environmental Policy, HR Policy, Ethics Policy, Investment Policy and Dividend Policy.

The Board has not decided on any specific allocation of work within the Board, save for the work of the Audit Committee and the Remuneration Committee

#### **Audit Committee**

Karolinska Development's Audit Committee consists of three members: Bo Jesper Hansen (Chairman), Hans Wigzell and Henrijette Richter, each being independent in relation to the Company and its management as well as in relation to the Company's major shareholders.

The main tasks of the Audit Committee are to

- monitor the company's financial reporting,
- monitor the efficiency of the Company's internal control, internal audit and risk management, with respect to financial reporting;
- remain informed about the audit of Investment Entity reporting and financial statements.
- review and monitor the impartiality and independence of the auditor, and in that respect particularly pay attention to non-audit services provided by the auditor, and
- assist in the preparation of proposals to the Annual General Meeting regarding election of auditors.

The Audit Committee has met four times during the year. The members have been present at all meetings. Henrijette Richter became a member of the committee after its last meeting 2014 and has accordingly not attended any meetings during 2014.

#### Remuneration Committee

Karolinska Development's Remuneration Committee consists of four members: Bo Jesper Hansen (Chairman), Hans Wigzell, and Vlad Artamonov, each being independent in relation to the Company and its management as well as in relation to the Company's major shareholders, and Carl Johan Sundberg representing Karolinska Institutet Holding AB.

The main tasks of the Remuneration Committee are to

- prepare the board's decisions on issues concerning principles for remuneration, remunerations and other terms of employment for the executive management,
- monitor and evaluate programs for variable remuneration, both ongoing and those that have ended during the year, for the executive management, and
- monitor and evaluate the application of the guidelines for remuneration that the Annual General Meeting is legally obliged to establish, as well as the current remuneration structures and levels in the company.

The Remuneration Committee has met four times during the year. The members have been present at all meetings.

#### CEO

Jim Van heusden (Born 1971) PhD. Jim Van heusden has over 20 years of experience within venture capital, research and development within the pharmaceutical industry, including as Founder and Managing Director at Bioskills (2013-2015) and as Partner at the European investment company Gimv (2001-2013). During his appointment at Gimv he also served as a Board member in several biotech companies including Multiplicom NV (as Chairman), Ablynx NV, ActoGeniX NV, Pronota NV and Prosensa. During 1993-2001, Jim Van heusden worked as Senior Scientist at Janssen Pharmaceuticals (Johnson & Johnson). No holdings in Karolinska Development.

#### **DEPUTY CEO**

Terje Kalland (Born 1951). MD, PhD. More than 20 years experience from senior positions in the pharmaceutical industry, including as Senior Vice President, Biopharmaceuticals Research at Novo Nordisk (2005-2011), CSO of Biovitrum (2002-2005) and Global Head of Oncology Research at Pharmacia Corporation (1988-2002). Terje Kalland is a member of the Royal Swedish Academy of Engineering Sciences. Other appointments Chairman of KDev Oncology AB and Akinion Pharmaceuticals AB. Board member of ARTs Biologics A/S and Axelar AB. Holdings in Karolinska Development 45,000 shares and SEK 164,850 convertible loan.

# 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, authorization 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 an 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 April 2015

Board of Directors of Karolinska Development AB

### Auditor's report on the Corporate governance statement

#### TO THE ANNUAL GENERAL MEETING OF THE SHARE-HOLDERS OF KAROLINSKA DEVELOPMENT AB (PUBL), CORPORATE IDENTITY NUMBER 556707-5048

It is the Board of Directors who is responsible for the corporate governance statement for the year 2014 included in the printed version of this document on pages 77–79, and that it has been prepared in accordance with the Annual Accounts Act.

We have read the corporate governance statement and based on that reading and our knowledge of the company and the investment entity we believe that we have a sufficient basis for our opinions. This means

that our statutory 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.

In our opinion, the corporate governance statement has been prepared and its statutory content is consistent with the annual accounts and the consolidated accounts.

Stockholm, April 28, 2015

Deloitte AB

Thomas Strömberg
Authorized/Approved Public Accountant

#### **Definitions**

#### **DEFINITION OF KEY TERMS**

#### Capital employed

Total equity and interest-bearing liabilities

#### Return on equity

Profit/loss after financial items divided by equity

#### Return on capital employed

Profit/loss after financial items divided by capital employed

#### Equity to total assets ratio

Equity divided by total assets

#### 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 asset value per share

Estimated fair value of total portfolio holdings, cash and cash equivalents, financial assets less interest-bearing liabilities in relation to the number of shares outstanding at year-end

#### **DEFINITIONS:**

#### Deal flow agreement

Agreement between Karolinska Development and KIAB giving Karolinska Development access to research projects that are evaluated by KIAB

#### 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

#### **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) and Karolinska Institutet Science Park AB

#### KIAB

Karolinska Institutet Innovations AB, Corporate Identity Number 556528-3909

KIAB, which is owned (indirectly) 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.

#### Karolinska Development

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

#### Portfolio companies

Companies that are wholly or partially owned by Karolinska Development (subsidiaries, associated companies and other long-term securities holdings) and are active in pharmaceuticals, medical technology, theranostics and formulation technology

#### Fair value

From the regulatory framework for issuers it is clear that companies listed on a public marketplace that constitute groups must apply the International Financial Reporting Standards, IFRS. These standards apply only to the consolidated financial statements. Application of these standards allows groups of an investment nature to apply fair value in the calculation of the assets' values. These calculations are made on the basis of established principles and are not included in the legal entities included in the Group's reporting and do not affect cash flow. This is exemplified by the fact that that the Parent Company's assets are not recognized at acquisition cost rather than fair value.

Fair value is calculated according to the International Private Equity and Venture Capital Valuation Guidelines. Accordingly, fair value is calculated differently depending on what is considered to provide the best estimate of market value in the particular case. For Karolinska Development, this means that the fair value of many portfolio companies may be obtained by using a model for calculating the value of discounted and risk-adjusted cash flows. In other cases, Karolinska Development's total investment is used as the best estimate of fair value. In any further cases, the valuation in the most recent transaction is used.

## Glossary

Adhesion	Abnormal joining of otherwise separate tissues.	EU5	Denotes the five largest pharmaceutical markets in the EU: United Kingdom, France, Germany, Spain and Italy.	
Adjuvant treatment	An add-on treatment in order to prevent disease relapse by increasing the overall efficacy of a treatment.	Ex vivo	From Latin, literally 'outside of the living'. Refers to studies done in laboratory settings, conducted on tissue	
Amino acids	Amino acids are the chemical building blocks that can be combined in chains, or sequences, to form proteins	FDA.	separated from the organism.	
AML	and peptides.  Acute myeloid leukemia. A form of blood cancer that	FDA	Food and Drug Administration. US authority that, among other things, is responsible for regulating pharmaceutical and medicinal technology products.	
	originates from the bone marrow. The disease results in high growth of defective white blood cells that stunt growth of normal white blood cells and thereby harming the immune response.	FLT-3	Fms-like Tyrosine Kinase-3. A receptor involved in cell survival and cell division among certain white blood cells. Mutations in FLT-3 can lead to development of leukemia.	
Antibodies	Proteins that are a part of the immune response system. Antibodies bind foreign agents (e.g. pathogens) thereby marking those agents for attack from the immune system.	GABA system	Receptors and target molecules in the brain that regulate mood and irritability.	
Antifungal	Antibiotic-like substances used to treat fungal infection.	Heparin	A natural anticoagulant substance that prevents the formation of blood clots as well as the extension of existing blood clots.	
Antimicrobial	A substance that has the ability to kill microorganisms (bacteria, fungus or parasites).	In vivo	From Latin, literally 'inside of the living'. Refers to stu- dies conducted on living organisms.	
Antithrombotic	Prevents blood clots (thrombosis).	Intracellular	Inside cells.	
Apoptosis	Programmed cell death.	Intraocular	Inside the eye.	
Autoimmune reaction	When the immune system start attacking the body's own cells.	Intravenous injection	An injection directly into a vein using a needle.	
Bioavailability	A measurement of what portion of an administered pharmaceutical that reaches circulation and the intended target tissue.	Invasive (surgery or procedure)	Involving a surgical opening into the body.	
Biomarker	Substance that indicates specific biological processes, for example diseases, and can therefore be used as a tool for diagnosis.	Kinase	A group of enzymes responsible for cell signaling, for example from receptors at the cell membrane to proteins inside the cell.	
Biopsy	Removal of tissue for sampling by genetic analysis and microscopy in order to determine a diagnosis.	Macrophages	A type of white blood cell that is a part of the non-specific immune response.	
Cell line	A cell culture derived from tissue that is able to proliferate seemingly indefinitely given the right conditions.	Monoclonal antibodies	Type of antibodies that are derived from identical parental cells and therefore have the same specificity.	
	These cultures can be used to model living organs in the laboratory.	Multicenter study	A clinical study that includes several hospitals. This setup makes it easier to recruit the desired amount of patients.	
Chemotherapy	See cytotoxics.	Multifactorial	Diseases that arise as a consequence of several underly-	
Cytotoxics	Pharmaceuticals that target fast growing cells, for example cancer cells. These compounds usually work		ing causes are said to be multifactorial.	
	by halting the cell division process. The treatment of a cancer patient with cytotoxics is referred to as chemotherapy.	Mutated gene	Changes in a cell's DNA that may change the function of a gene.	
Double blind (study)	A setup of a clinical study where neither the individuals participating in the study or the study staff know which treatment group the individuals are in.	Neurodegenerative diseases	Collective name for diseases where neuron cells are degraded in the brain, for example Parkinson disease and Alzheimer's disease.	
Dysphoria	Sadness, malaise, irritability.	Obstetrics	$\label{thm:medical branch that includes pregnancy and childbirth.} \\$	
Endogenous	Derived from Greek 'proceeding from within'. Substances that originates from within the own body.	Over-expressed gene or protein	An abnormal activation of a gene causing mass production of the protein product.	
Endocrine system	The collection of glands of an organism that secrete hormones directly into the circulatory	Palliative treatment	Treatments that aim to reduce disease symptoms. The goal is to reduce pain and increase quality of life.	
	system to be carried toward a distant target organ.	Pathogen	Infectious agent that causes disease.	
Endometrium	The inner mucous membrane of the mammalian uterus.	Peptides	Short amino acid chains. Peptides have the same build- up as proteins but are smaller.	
Epidural anesthesia	Pain relief that is injected into the spinal canal.		ap as process suctine simulet.	

Pharmacokinetics	The study that includes absorption, distribution and metabolism of a pharmaceutical.	SCID mice	Severe combined immunodeficiency. A genetic disease which implies the lack of a functioning immune response. Mice with SCID are often used as animal
Phosporylcholine (PC)	A molecule that is present on the surface of red blood cells.		models as it is easy to transplant cells or organs into them without rejection.
Placebo-controlled study	A clinical study that includes a control group that receives an inactive (placebo) treatment but is otherwise treated exactly like the group that receives the real treatment.	Small molecule	Molecule with a low molecular weight. As opposed to large molecules like therapeutic proteins or antibodies, small molecules can be administered orally.
PMDD	Premenstrual Dysphoric Disorder. A more serious form of premenstrual syndrome (PMS) that affects 3–8% of	Steroids	Type of organic molecules that among other things include natural hormones.
	all fertile women. PMDD arises in cycles in connection with menstruation and causes depression, anxiety, cyclic mood swings and fatigue.	Synergistic effect	When addition of two or more treatments gives an effect greater than the theoretical additative effect.
Programmed cell death	A suicide mechanism a cell may go through if it is somehow damaged.	Systemic	Affecting multiple organs, systems, tissues, or the entire body.
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 cata-	Targeted therapy	Pharmaceuticals that are designed towards binding specifically to one or a group of target molecules in order to be more disease specific.
	lyze chemical reactions in the form of enzymes and they are involved in the signaling in and between cells.	Thrombosis	Formation of a blood clot in blood vessels.
Randomized (study)	A study in which the trial participants are randomly allocated into two or more treatment groups that are	Topical	Administration through body surfaces, usually through the skin.
	given different treatments or placebo.	Toxicology	Study of the poisonous effect of substances. In the pharmaceutical context, toxicology is mainly concerned with
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		whether the substance is tolerable in its therapeutic dose.
Rheumatoid arthritis	effect on the cell to which it binds to.  An autoimmune disease affecting the body's joints. The	Venous leg ulcers	Wounds that occur when blood valves are defective and cannot stop reflow of blood in the veins. This way pressure builds up and ulcers are formed.
rineumatoru ar tifflus	disease is characterized by inflammatory reactions in cartilage, bone and joints which lead to disfigurements.	Wild-type gene	A natural, normal (ie. non mutated or modified) gene.

## Dates for publication of financial information

Interim report January-March 2015 6 May 2015
Interim report January - June 2015 26 August 2015
Interim report January - September 2015 25 November 2015
Year-end report January - December 2015 February 2016
Annual report 2015 April 2016

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