
Karolinska Development

Karolinska Development (Nasdaq Stockholm: KDEV) is an investment company which offers a unique opportunity to participate in the growth in value of a number of Nordic life sciences companies with substantial commercial opportunities. All of the portfolio companies are developing potentially ground-breaking treatments for medical conditions with a substantial need for improved therapies, including heart failure, serious viral infections, sepsis, pain, systemic inflammation, bone defects and liver diseases. To date, two of the companies have launched their first products.

For further information, see www.karolinskadevelopment.com

Financial Update

- The net profit/loss for the third quarter was SEK 12.0 million (SEK -46.6 million in the third quarter of 2022). Earnings per share totaled SEK 0.04 (SEK -0.17 in the third quarter of 2022). Net profit/loss for the period January – September 2023 amounted to SEK 7.3 (-98.1) million.
- The result of the Change in fair value of shares in portfolio companies for the third quarter amounted to SEK 11.7 million (SEK -50.3 million in the third quarter of 2022). The result is largely due to the upturn in share price in the listed holdings OssDsign and Promimic. The result of the Change in fair value of shares in portfolio companies for the period January – September 2023 amounted to SEK 8.6 (-91.4) million.
- The total fair value of the portfolio was SEK 1,392.2 million at the end of September 2023, corresponding to an increase of SEK 28.1 million from SEK 1,364.1 million at the end of the previous quarter. The net portfolio fair value at the end of September 2023 was SEK 1,052.2 million, corresponding to an increase of SEK 26.0 million from SEK 1,026.2 million at the end of the previous quarter. The increase is mainly the effect of the upturn in share price of listed holdings and investments during the quarter.
- Net asset value amounted to SEK 1,253.2 million, per share SEK 4.6, at the end of September 2023 (SEK 1,237.7 million, per share SEK 4.6 at the end of September 2022).
- Net sales totaled SEK 0.4 million during the third quarter of 2023 (SEK 0.5 million during the third quarter of 2022). Net sales for the period January – September 2023 totalled SEK 1.5 (1.7) million.
- Karolinska Development invested a total of SEK 15.8 million in portfolio companies during the third quarter of 2023 (SEK 61.8 million in the third quarter of 2022). Third quarter 2023 investments in portfolio companies by Karolinska Development and other specialized life sciences investors totaled SEK 126.3 million (SEK 180.6 million in the third quarter of 2022).
- Cash and cash equivalents (including short-term investments) decreased by SEK 17.7 million during the third quarter, totaling SEK 130.0 million on 30 September 2023 (SEK 207.0 million on 30 September 2022).

Significant events during the third quarter

- The portfolio company Umeocrine Cognition presented results from a study on a preclinical model of Parkinson's disease at the 6th World Parkinson Congress in Barcelona, Spain, July 4-7. The results shows how the company's clinical drug candidate golexanolone has an effect on fatigue, anxiety, depression, and some cognitive and motor changes in the disease model (July 2023).
- The portfolio company OssDsign received clearance from FDA for the use of OssDsign Catalyst in interbody cages in spinal surgery (September 2023).
- The portfolio company OssDsign successfully completed a directed share issue to a value of approximately SEK 150 million. The net proceeds will be used to finance a strategic shift to fully focus its operations on the orthobiologic business in the U.S., in light of the extraordinary commercial performance of its high-margin nanosynthetic bone graft OssDsign Catalyst (September 2023).
- The portfolio company PharmNovo reported promising results in a preclinical study of the company's drug candidate PN6047. The results reaffirm existing safety profile data of PN6047 (September 2023).

Significant post-period events

- The portfolio company PharmNovo successfully completed its clinical phase 1 study with PN6047, a drug candidate developed as a potential treatment for neuropathic pain. The results from the study show that PN6047 is safe and well-tolerated at doses predicted to have clinically relevant effects. Furthermore, PN6047 seems to offer a significantly better safety profile compared to conventional opioids (October 2023).
- The portfolio company Modus Therapeutics decided to carry out a rights issue that can raise up to approximately SEK 40.3 million before issue costs. The capital injection will primarily be used to finance the company's continued operations and an expansion of the clinical development program for the drug candidate sevuparin to the area of anemia (November 2023).

Viktor Drvota, CEO of Karolinska Development, comments:

"It's clear that our portfolio companies have unique competence in their respective therapeutic areas. Karolinska Development will, economic turbulence notwithstanding, continue to support the development of new treatments that can extend people's lifespans and enhance their quality of life. Patients' and society's need for medical progress does not depend on the economic climate."

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Chief Executive's Report

Our portfolio company, OssDsign, implemented a strategic orientation shift in order to focus on becoming a pure play orthobiologics company at the end of the third quarter. The company also simultaneously successfully raised capital in the form of a directed share issue for institutional investors. The first phase in the launch of the company's unique nanosynthetic bone graft, OssDsign Catalyst, on the US market has been successful and we look forward to continuing to follow the company as they accelerate their growth journey. A number of other portfolio companies also announced good news during the reporting period. PharmNovo, for example, has documented the favourable safety profile of their candidate drug, PN6047, through preclinical studies and a recently completed phase 1 study, and expect to advance to a clinical phase 2 study of the drug next year. Umechrine Cognition, meanwhile, took part in the World Parkinson Congress in Spain, where the company presented promising results from a preclinical study of golexanolone in a disease model of Parkinson's disease which showed that the candidate drug has an effect on fatigue, anxiety, depression, and certain cognitive and motor changes.

OssDsign implements a strategic shift and raises SEK 150 million

In late September, our portfolio company, OssDsign, presented a major strategic shift resulting in a total focus on the commercialisation of OssDsign Catalyst in the USA. All of the company's activities in relation to the cranial implant, OssDsign Cranial, will, meanwhile, be discontinued by the end of the year. A directed share issue for ca. SEK 150 million was simultaneously completed, aimed at Karolinska Development and a number of other reputable institutional investors, including TAMT and Linc AB. The net proceeds will be used for the ongoing commercialisation and expansion of the US operations in order to drive sales of OssDsign Catalyst, which is a nanosynthetic bone graft with high scalability and a high gross margin. The capital from the issue will also enable ongoing investments in clinical programs designed to gather additional clinical evidence for the product. OssDsign will, additionally, accelerate the research portfolio based on the company's orthobiologics platform, invest in upscaling and automation. OssDsign also, in conjunction with the announcement of the strategic shift, communicated its medium-term financial targets of sales of SEK 150-200 million and achieving a cash flow positive status.

The strategy shift and capital acquisition were implemented shortly after the company obtained an important expansion in its market clearance for a completely new indication for OssDsign Catalyst from the American regulatory body, the FDA. OssDsign Catalyst can now be used by surgeons in all types of interbody cages cleared for use with synthetic bone grafts. This is an area of high demand that is estimated to comprise approximately half of all use of bone grafts in spinal surgeries.

PharmNovo reaffirms safety profile ahead of next clinical phase

PharmNovo, one of our newest portfolio companies, presented new data during the quarter, reaffirming the safety profile data for the company's candidate drug, PN6047, which is being developed as a completely new type of treatment for neuropathic pain. Neuropathic pain is a difficult-to-treat form of pain that often develops into a chronic condition. Conventional treatment with opioids is associated with severe dependence issues and opioid withdrawal symptoms. PharmNovo is working to redefine the treatment of neuropathic pain by developing an analgesic treatment with a better adverse effects profile, and a number of milestones were reached during the quarter.

A preclinical study presented in September demonstrated that PN6047 does not induce addictive effects and, at the same time, reduced withdrawal symptoms in conjunction with opioid withdrawal. Shortly thereafter, in early October, the company presented positive results from a clinical phase 1 study evaluating PN6047 in doses expected to have clinically relevant effects. The study demonstrated that PN6047 is both

safe and well-tolerated and also highlighted the benefits of the candidate drug over conventional opioids with regard both to adverse effects and its pharmacological profile. PharmNovo is now working on preparations for a clinical phase 2 study of PN6047, which is expected to start in mid-2024. We look forward to following the ongoing development work and are convinced that a new drug not associated with the same adverse effects and addiction issues as other opioids would offer enormous advantages for both patients and society as a whole.

Umecrine Cognition presents new data on Parkinson's disease

In July, Umecrine Cognition took part in the 6th World Parkinson Congress in Barcelona, Spain, where it presented the results of a study using a well-established preclinical model for Parkinson's disease. The results are based on a preclinical study conducted in collaboration with Dr Vicente Felipo at the Laboratory of Neurobiology, Centro de Investigación Príncipe Felipe in Valencia, Spain, and were summarised in a poster presentation. The study demonstrated that the company's candidate drug, golexanolone, reverses fatigue, anxiety, depression, and certain cognitive and motor changes in the disease model – all of which are hallmark symptoms observed in patients with Parkinson's disease. These strong preclinical data offer our portfolio company a new and exciting opportunity to expand the development of golexanolone to include Parkinson's disease.

A portfolio with fantastic potential

The market climate continues to be challenging and the market's appetite for risk has declined as a natural consequence of both interest rate levels and geopolitical concerns. It is particularly pleasing, in the light thereof, to see OssDsign successfully complete a major capital acquisition process and secure its financing for ongoing value creation. It is clear that our portfolio companies have unique competence in their respective therapeutic areas and that both the products they have already launched, and their development projects are based on sound scientific foundations. Karolinska Development will, economic turbulence notwithstanding, continue to support the development of new treatments that can extend people's lifespans and enhance their quality of life. Patients' and society's need for medical progress does not depend on the economic climate.

Solna, 17 November 2023

Viktor Drvota
Chief Executive Officer

Portfolio Companies

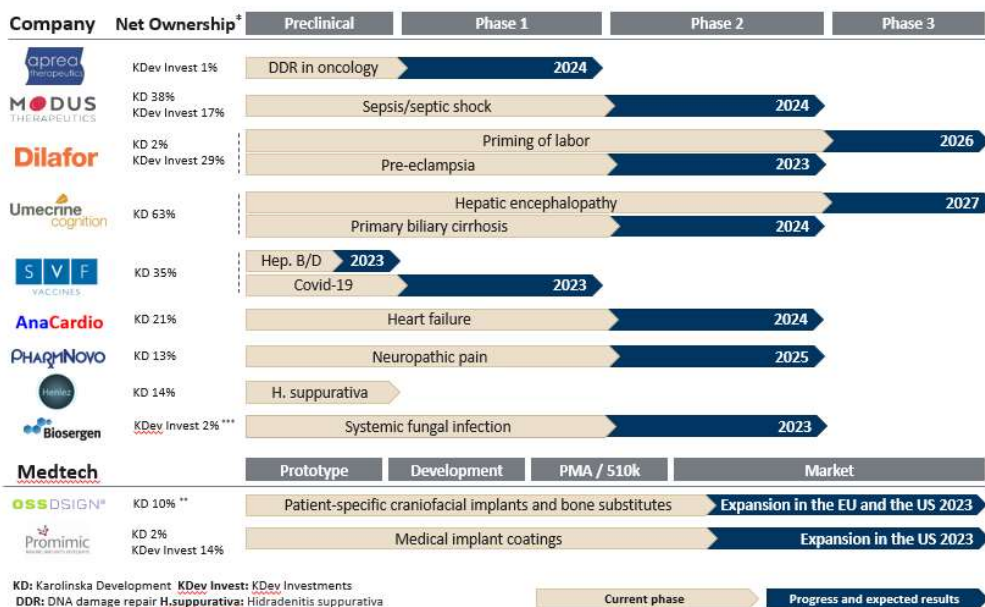
High potential for continued value inflection in portfolio

Karolinska Development's investments in therapeutic companies are conducted in syndicates with other professional life science investors, normally until proof-of-concept is demonstrated in phase 2 trials, at which point different exit options are evaluated. When engaging in MedTech companies, the business model is to finance the companies until they show a positive operating profit.

The portfolio currently consists of eleven companies focused on developing innovative treatment methods for severe or life-threatening diseases where there is currently a great need and there is a lack of effective treatment alternatives. Nine of the portfolio companies have drug candidates in ongoing or planned clinical trials and two companies have MedTech products in early commercial phases. During the period 2023–2024, three portfolio companies are expected to present data from phase 1 studies and five portfolio companies are expected to present data from phase 2 studies. These study results have the potential to significantly increase the opportunities for attractive divestments or license transactions. Comparable drug candidates have in recent years been out licensed or sold at contract values that have amounted to billions (SEK) for the individual projects.

In addition to the portfolio companies, Karolinska Development has interests in two other life science companies, Forendo Pharma and Oncopeptides, in the form of earn-out agreements.

Our current portfolio – potential for value inflection





Project (First-in class)
ATR inhibitor ATRN-119
ATR inhibitor ATRN-W1051

Primary indication
Solid tumor malignancies

Development phase
Phase 1

Holding in company*
KDev Investments 1%

Other investors
Morgan Stanley
Vanguard Group
BlackRock
Geode Capital Management

Origin
Karolinska Institutet

More information
 aprea.com

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

Deal values for similar projects

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

Aprea Therapeutics Inc



Inhibits the ability of cancerous tumors to repair DNA damage

Aprea Therapeutics (Boston, USA and Stockholm, Sweden) is focused on developing and commercializing novel drugs to combat various types of cancer by affecting the proteins involved in the ability of tumors to repair damage in their DNA.

During the second quarter of 2022, Aprea completed the acquisition of Atrin Pharmaceuticals, a biopharmaceutical company focused on developing novel cancer therapeutics targeting proteins in the DNA damage response (DDR). With the acquisition of the Atrin Pharmaceuticals drug project, Aprea shifts its primary focus to the development of ATRN-119, evaluated in a Phase 1/2 clinical trial in patients with malignant solid tumors – both as monotherapy and in combination with today's standard treatment.

ATRN-119 is an orally bioavailable, highly potent and selective small molecule inhibitor of ATR, a protein with key roles in response to DNA damage. In the third quarter 2022, Aprea initiated a clinical trial with ATRN-119 as monotherapy in cancer patients with defined gene mutations.

Aprea is also developing ATRN-W1051, an orally bioavailable, highly potent and selective small molecule inhibitor of WEE1, a key regulator of multiple phases of the cell cycle. In September 2023, preclinical data for ATRN-W1051 were presented indicating that the selective properties of ATRN-1051 may make it a more effective cancer therapy than other WEE1 inhibitors in development and that it has a promising safety profile. Complete preclinical results are planned to be presented before the end of 2023. The company expects that an application for the start of the first clinical trial can be submitted in the second half of 2023.

Aprea is listed on the NASDAQ Global Select Market in the USA since October 2019.

The market

Targeting DNA Damage Repair, several commercially available Poly ADP-ribose polymerase (PARP) inhibitors induced substantial response in patients with DNA repair defects and have received Breakthrough Therapy Designation by the US Food and Drug Administration, FDA, for several cancer indications. The notable commercial success of these PARP inhibitors has made DNA Damage and Response a clinically and commercially validated therapeutic approach. Targeting ataxia telangiectasia and Rad3-related protein (ATR) represents an emerging strategy to treat a broad spectrum of cancers, most notably those that currently lack fully effective treatments.

Recent progress

- In the third quarter 2022, Aprea's phase 1/2 clinical trial with ATRN-119 monotherapy was initiated.
- In January 2023, the first patient in the phase 1/2 clinical trial of the drug candidate ATRN-119 was dosed.
- In February 2023, a guaranteed new issue was carried out that will finance the company with USD 5.5 million before transaction costs.
- In September 2023, preclinical results for ATRN-1051 were presented with positive in vivo activity and safety profile. Full preclinical results are planned to be presented in the fourth quarter of 2023.

Project (First-in-class)

Sevuparin

Primary indication

Sepsis/Septic shock

Development phase

Phase 2

Holding in company*

Karolinska Development 38%

KDev Investments 17%

Other investors

John Öhd


Nordnet Pensionsförsäkring

Hans Wigzell

Origin

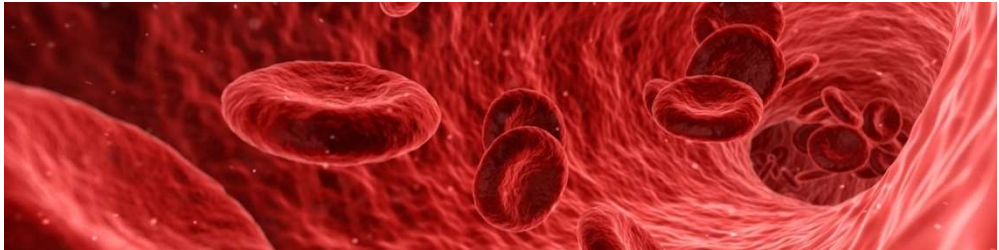
Karolinska Institutet

Uppsala University

More information modustx.com

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

Modus Therapeutics AB



Develops treatments against life-threatening sepsis/ septic shock

Modus Therapeutics (Stockholm, Sweden) is developing sevuparin as a treatment of sepsis/septic shock, a life-threatening condition that currently lacks efficient pharmaceutical therapies. Patients that are affected by sepsis are exposed to a risk of developing multi-organ failure and – in severe cases – death. Data from pre-clinical animal models as well as in vitro human cell models has revealed that sevuparin was able to protect blood vessels and counteract lung plasma leakage during systemic inflammation. Previous clinical trials in other patient groups have shown that sevuparin is well tolerated and has a favorable safety profile.

In February 2023, the company presented positive results from the clinical phase 1b study of sevuparin, where the drug candidate's safety profile and efficacy have been evaluated in a well-established disease model for systemic inflammation. The study was randomized, placebo-controlled, and the primary objective was to evaluate the safety profile of sevuparin in healthy subjects after induction with the bacterial toxin lipopolysaccharide (LPS). The results of the study will be used to select the dose and shape the design of the planned phase 2 study with sevuparin in sepsis patients which is expected to start in 2023.

The market

Septic shock is a leading cause of death in intensive care units, with mortality rates typically exceeding 30 percent. There is currently no specific pharmaceutical treatment available for the treatment of sepsis. As a result, it is one of the costliest conditions to treat in the hospital care setting. In 2019, US healthcare costs for patients with sepsis were estimated at USD 23 billion. Sepsis/septic shock is triggered by an infection and causes the same form of severe uncontrolled inflammation that can occur in conjunction with extensive surgery, trauma, burns and autoimmunity.

Recent progress

- In September 2022, the company completed its recruitment for the clinical phase 1b LPS challenge study.
- In February 2023, the company presented positive results from the clinical phase 1b study of sevuparin, where the drug candidate's safety profile and efficacy were evaluated in a well-established disease model for sepsis and septic shock.
- In May 2023, Modus announced that they have, in collaboration with a world-leading research group, generated data showing that sevuparin has the potential to be developed as a treatment for anemia in patients with certain chronic diseases.
- In November 2023, Modus decided to carry out a rights issue that can raise up to approximately SEK 40.3million.

Expected milestones

- Phase 2a trial in patients with sepsis with an estimated start during 2023.

Dilafor

Project (First-in-class)

Tafoxiparin

Primary indication

 Priming of Labor
 Preeclampsia

Development phase

Phase 2b

Holding in company*


 Karolinska Development 2%
 KDev Investments 29%

Other investors

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

Origin

Karolinska Institutet

More information

dilafor.com

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

Deal values for similar projects

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

Dilafor AB



Reducing complications in prolonged childbirth

Dilafor (Solna, Sweden) is developing tafoxiparin for obstetric indications, with particular reference to protracted labor and associated complications. Up to 30 percent of all pregnant women undergo induction in labor. In just over half of all cases, the induction fails, leading to protracted labor that entails an increased risk for both mother and child due to medical complications. Between 25 and 40 percent of women who experience protracted labor eventually require an emergency caesarean section. Surgical intervention always entails not only a risk to the patient, but substantial health care costs. With the help of tafoxiparin, the patient suffering could be reduced and save valuable health care resources.

In 2021, the results of a placebo-controlled phase 2b study were presented, which showed that tafoxiparin has a significant positive effect on cervical ripening in first-time mothers who receive treatment to initiate labor. The study included 170 first-time mothers with immature cervixes, which are treated to ripen the cervix and thereby facilitate the onset of labor. Patients were treated with either a subcutaneous injection of tafoxiparin or a placebo once daily for up to one week prior to scheduled initiation. The primary objective of the study was to document the effect of tafoxiparin on cervical ripening measured as the degree of ripening according to an internationally established scale, the Bishop score.

The study results showed that tafoxiparin affected the ripening of the cervix compared to placebo, with a difference that was statistically significant ($p < 0.009$). Based on the positive results, Dilafor extended the phase 2b study, to document the effect of tafoxiparin also in two lower doses than what has been studied thus far. The extension study included 164 women, is fully recruited, and positive results regarding dose response were presented in mid-February 2023.

The market

About a quarter of all pregnant women need labor induction. The current standard treatment includes administration of prostaglandins and oxytocin, but in over 50 percent of cases, the induction fails, leading to protracted labor, emergency caesarean sections, or other maternal and fetal complications. Market analyses show that a drug with a good effect on the ripening of the cervix has the potential to reach annual sales over USD 1 billion in the US market alone.

Recent progress

- In December 2022, recruitment was completed for the extension of the phase 2b study of the drug candidate tafoxiparin for induction of childbirth.
- In February 2023, positive results from the extension of the phase 2b study regarding dose response were presented.

Expected milestones

- Start of Phase 3 study with tafoxiparin for labor induction.



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


Primary indications
Hepatic encephalopathy
Primary biliary cholangitis

Development phase
Phase 2b

Holding in company*
Karolinska Development 63%

Other investors
Fort Knox Förvaring AB
PartnerInvest

Origin
Umeå University

More information
 umecrinecognition.com

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

Umecrine Cognition AB



Developing a new approach to alleviate cognitive impairment

Umecrine Cognition (Solna, Sweden) is developing golexanolone (GR3027), a candidate drug in a new class of pharmaceuticals that affect the GABA system, where GABA stands for gamma-aminobutyric acid, the chief inhibitory neurotransmitter in the central nervous system. The GABA system is suspected of being over-activated in liver failure, causing very serious clinical symptoms. The over-activation is also thought to lay behind certain cognitive impairments and sleep disturbances. GABAA-receptor modulating steroid antagonists, such as golexanolone, counter the increased activation of the GABA system and have been shown to restore different types of neurological impairments in experimental models. The candidate drug enters the brain and works by reversing the inhibitory effects of the neurosteroid allopregnanolone.

Umecrine Cognition is developing golexanolone for two indications: Hepatic Encephalopathy (HE) and Primary Biliary Cholangitis (PBC). The company has conducted a phase 2a clinical study of golexanolone in patients with HE, which is a serious neuropsychiatric and neurocognitive condition that occurs in acute and chronic liver damage with underlying cirrhosis. The results showed that the drug candidate was well tolerated, that the safety profile was good and that the pharmacokinetic profile was favorable. One of the effect parameters used shows that the drug candidate exerts a significant effect on brain signaling, with a correlated positive effect on extreme daytime fatigue. Based on these study results, the company has established a plan for the further development of the drug candidate within HE and in PBC, where a phase 2 study is now also underway. Golexanolone has also been tested in a preclinical model of Parkinson's disease which showed positive effects.

Deal values for similar projects

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

The market

PBC (primary biliary cholangitis) is a rare autoimmune liver disease with about 190,000 patients globally where 9 out of 10 sufferers are women. Common symptoms include fatigue, cognitive impairment, itching and, in more advanced cases, even jaundice. The global PBC treatment market is estimated at USD 584 million in 2021 and is expected to grow to USD 3 billion by 2027. HE is a serious disease with a high unmet medical need, affecting up to 1 percent of the population in the US and EU. Over a five-year period, developed HE results in a mortality rate of 22–35 percent.

Recent progress

- In January 2023, Umecrine Cognition was granted orphan drug designation by the US Food and Drug Administration for the drug candidate golexanolone within the indication PBC.
- In March 2023 Umecrine Cognition secured SEK 31.6 million in funding, where Karolinska Development part took along with a number of additional investors.
- In April 2023 the first patient was included in the phase 2 study in PBC.
- In June 2023 data is presented showing that golexanolone's mode-of-action and ability to reduce neuroinflammation.
- In July 2023, data on the positive effects of golexanolone shown in a preclinical model of Parkinson's disease from January 2023 were presented at the World Parkinson Congress.

Going forward

- Topline data from the Phase 2 study of golexanolone in patients with PBC are expected to be available in 2024.


VACCINES
Project (First-in-class)

 SVF-001
 SVF-002

Primary indication

 Hepatitis B and D
 SARS-CoV-2
 and other coronaviruses

Development phase


Phase 1

Holding in company*

Karolinska Development 35%

Origin

Karolinska Institutet

More information
 svenskavaccinfabriken.se

**Fully-diluted ownership based on current investment plans*
Deal values for similar projects

- USD 546 million Affinivax raises Series B and C financing 2020
- USD 1.4 billion MYR Gmbh (acquired) & Gilead Sciences Inc (buyer) 2020

SVF Vaccines AB



New technology for the treatment of viral diseases

SVF Vaccines (formerly Svenska Vaccinfabriken Produktion; Solna, Sweden) develops therapeutic proteins and DNA vaccines against, among other things, hepatitis B and D, as well as vaccines to prevent infections by covid-19 and potential future coronaviruses. Therapeutic vaccines, unlike preventative vaccines, have the potential to cure already infected patients.

Despite the availability of preventative vaccines and antiviral treatments, over 250 million people live with a chronic hepatitis B infection. One million chronic carriers die each year due to complications caused by the virus, such as liver cirrhosis and liver cancer. The closely related hepatitis D virus infects 15-25 million hepatitis B carriers and exacerbates the progression of the disease.

SVF Vaccines uses a proprietary immunotherapy to produce a specific form of antibodies that blocks the ability of the hepatitis virus to invade human cells. The company has generated promising efficacy data in a preclinical animal model and is now continuing its preclinical development with the goal of enabling a phase 1 study to be initiated in 2024.

Although coronavirus infections are usually mild, some virus types can lead to life-threatening conditions. To meet and prevent severe infections, SVF Vaccines has developed a platform that is expected to enable the production of vaccines against both current and future forms of coronavirus. The company also has granted patents for chimeric antigens that can create an immune response against chronic hepatitis B and D infections. In February 2023, the company initiated a phase 1 study for its vaccine candidate against covid-19, SVF-002 and filed a patent application specifically for a potential vaccine against covid-19.

The market

SVF Vaccines is currently focusing its innovative vaccine platform on the market for therapeutic vaccines for hepatitis B and D, and preventative vaccines for respiratory viral diseases, such as covid-19. The 2017 Kuick research report, "Global Hepatitis Drug Market & Clinical Trials Insight 2023" estimated the value of the annual global market for hepatitis B at USD 4-5 billion, growing to USD 5-6 billion by 2023. The annual global market for hepatitis D, by contrast, is estimated at around USD 1 billion. Investors' interest in early vaccine companies and platforms similar to SVF Vaccines' has increased markedly in recent years. This is thought to be due to an increased awareness of the potential for the commercialization of vaccines based on next generation technology, such as RNA vaccines and DNA vaccines. Interest in therapies to treat hepatitis B and D has further intensified – two areas in which the unmet medical need is still significant.

Recent progress

- In June 2022, the company presented preclinical study data indicating that the candidate therapeutic vaccine SVF-001 has the potential to elicit an immune response in a preclinical disease model of chronic hepatitis B at the EASL International Liver Congress™.
- In January 2023 the company changed its name to SVF Vaccines.
- In February 2023, the company began a phase 1 clinical study with the company's universal vaccine against covid-19, SVF-002.

Expected milestones

- Phase 1 studies of hepatitis B and D vaccines are expected to be initiated in 2024.

AnaCardio

Project (First-in-class)
AC01


Primary indication
Heart failure

Development phase
Phase 2a

Holding in company'
Karolinska Development 21%

Other investors
Flerie Invest
LLD Nybohov Invest
Industrifonden
3B Health Ventures

Origin
Karolinska Institutet
Karolinska University Hospital

More information
 anacardio.com

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

Deal values for similar projects

- USD 2.1 billion
Cardioxyl
Pharmaceuticals
(licensor) & Bristol-Myers
Squibb (licensee), 2015
- USD 620 million
Corthera (licensor) &
Novartis (licensee), 2012

AnaCardio AB



Protects heart tissue in heart failure

AnaCardio (Stockholm, Sweden) is developing a new form of drug concept that protects cardiac tissue in conjunction with heart failure. Heart failure occurs when the heart's ability to pump sufficient blood to meet the body's needs has deteriorated. The underlying condition often involves a weakening of the heart's musculature, resulting in an inability to pump the blood out of the heart's chambers. The condition arises as a sequela of high blood pressure or vasoconstriction. The chronic phase is characterized by diffuse symptoms, such as tiredness or breathlessness, which leads to the illness often being diagnosed at a late stage. Acute heart failure results in an individual's health status becoming critical, necessitating hospitalization, but a major issue with existing pharmaceuticals is that they are not designed for long-term treatment.

AnaCardio's clinical candidate drug is being developed to restore the heart's normal muscular function and blood circulation with ground-breaking and safer technique. The Company's goal is to develop an oral drug that in contrast to existing treatments can affect the underlying cause of disease. The drug candidate is based on research by Professor Lars Lund at Karolinska Institutet.

In September 2022, a series A financing round of SEK 150 million was closed in which Karolinska Development participated together with a group of reputable investors to finance a clinical phase 1b/2a study of the drug candidate AC01 in patients with heart failure.

The market

It is estimated that more than 6 million individuals in the United States and nearly 100 million globally suffer from heart failure. The risk of developing a cardiovascular disease increases with age, and 10-20 percent of the elderly population is now estimated to suffer from chronic heart failure, which is now the most common reason for hospitalization amongst the elderly. Heart failure not only causes considerable individual suffering, but it also has significant economic consequences for society in the form of both direct costs from in-patient care and indirect costs such as productivity losses. The increased medical need is reflected in the sales value of heart failure treatments, which is expected to increase from USD 6.8 billion by 2021 to USD 18.7 billion by 2028 in the world's seven largest pharmaceutical markets.

Recent progress

- In September 2022, a series A financing round of SEK 150 million was closed, in which Karolinska Development participated together with a group of reputable investors, including Flerie Invest, Industrifonden and 3B Health Ventures. The proceeds from the investment round will finance a clinical phase 1b/2a study of the drug candidate AC01 in patients with heart failure.
- In November 2022, AnaCardio received regulatory approval to initiate the Phase 1b/2a study in the EU and the UK.
- In March 2023 AnaCardio's founder published an article that supports development of heart failure drug candidate AC01
- In April 2023, the first patient was included in the company's clinical phase 1b/2a study.
- In August 2023, AnaCardio received IND approval from the FDA for AC01.

Expected milestones

- Topline data from the phase 1b/2a study of drug candidate AC01 are expected to be available in 2024.


Project (First-in-class)

PN6047

Primary indication

Allodynia/ Hyperalgesia

Development phase


Phase 1

Holding in company*

Karolinska Development 13%

Origin

Start-up

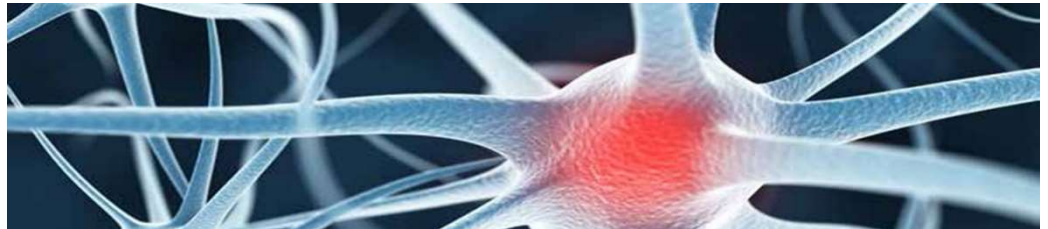
More information
 pharmnovo.com

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

Deal values for similar projects

- USD 940 million ACADIA Pharmaceuticals (acquirer) & CerSci Therapeutics (acquired), 2020
- USD 312 million Novartis (acquirer) & Spinifex Pharmaceuticals (acquired), 2015

PharmNovo AB



Innovative drug project for the treatment of nerve pain

PharmNovo (Lund, Sweden) is developing innovative drugs for the treatment of nerve pain (neuropathic pain). Neuropathic pain is one of the most prevalent types of chronic pain and affects up to 10 percent of the population. Common causes include nerve damage from type 2 diabetes, shingles and can also arise from trauma (including surgery), cancer and cancer treatments. PharmNovo's lead candidate, PN6047, focuses on allodynia and hyperalgesia, two common forms of nerve pain, affecting 15-20 percent of neuropathic pain patients. Allodynia is pain due to a stimulus that does not usually provoke pain, while hyperalgesia is increased pain from a stimulus that usually provokes pain. Current treatment options are deemed ineffective and are also associated with significant side-effects; particularly cardiovascular risks, and, with gabapentinoids or conventional opioids, a higher risk of suicide and drug abuse potential.

PharmNovo's novel drug candidate PN6047, which is based on a drug development project from AstraZeneca, targets a different receptor than conventional opiate drugs do; the delta opioid receptor, and thereby decreases the chronic pain without some of the side-effects associated with the current marketed opioids (constipation, physical dependence and, potentially, fatal respiratory depression). PN6047 has recently completed a clinical phase 1 study showing that PN6047 is safe and well-tolerated at doses predicted to have clinically relevant effects. PN6047 has also been tested in several mechanistic in vitro models and in animal models for neuropathic pain conditions, as well as for short-term tolerance and dependence. The drug candidate does not induce drug abuse behavior in non-clinical test models and indicates the capacity to reduce conventional opioid withdrawal symptoms, according to brand new results from a collaboration with researchers at the University of Washington and the University of Michigan, with financial support from the US National Institute of Drug Abuse (NIDA). PharmNovo is now preparing a phase 2 clinical study which is expected to start in mid-2024.

The market

The need for improved treatments for nerve pain is enormous. Around 10 percent of the world's population currently suffers from conditions characterized by this form of pain, leading to a severely reduced quality of life for the individual and substantial costs for society – estimated at nearly EUR 440 billion annually in Europe alone. The estimated global market value for nerve pain drugs is nearly USD 6 billion per year and the market for allodynia alone is around USD 1.25 billion per year and is expected to continue to grow, driven by an aging population and increased cancer survival.

Recent progress

- In June 2022, the company raised SEK 67 million in a new issue in which Karolinska Development participated to finance a phase 1 study of PN6047 and the company's continued development.
- In August 2022, an additional rights issue of SEK 6 million was completed.
- In September 2023, new preclinical data were presented showing that there are no signs of abuse potential and that PN6047 alleviates symptoms of withdrawal caused by conventional opioids.
- In October 2023, positive phase 1 data were presented showing that PN6047 is safe and well tolerated at doses predicted to have clinically relevant effects.

Expected milestones

- The phase 2 study with PN6047 is expected to start mid-2024.



Project (First-in-class)
HEN-001

Primary indication
Hidradenitis suppurativa

Development phase
Preclinical

Holding in company*
Karolinska Development 14%

Other investors
Eir Ventures

Origin
Start-up

More information
 henlez.com

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

Deal values for similar projects

- USD 750 million
Janssen (buyer) &
XBiotech (seller), 2019
- USD 760 million LEO
Pharma (buyer) &
PellePharm (seller), 2018

Henlez ApS



Developing a topical treatment against hidradenitis suppurativa

Henlez (Copenhagen, Denmark) is a privately owned company developing a topical enzyme-based treatment of hidradenitis suppurativa. The company was founded 2019 by former Novozymes A/S scientist and current Henlez CEO Jeppe Mouritsen.

Henlez' pre-clinical lead development program, HEN-001, is an enzyme-based, topical application directed towards hidradenitis suppurativa – a highly stigmatizing and chronic inflammatory condition characterized by severe pain, malodorous wound fluid and permanent scarring of the armpits and groin. Despite an increasing number of drug trials, the available treatment options are still insufficient. Patients and key opinion leaders unanimously identify a large unmet need for novel treatments, a problem Henlez is poised to meet.

In October 2022, the company raised EUR 1 million in seed financing from Nordic venture capital firms Eir Ventures and Karolinska Development. The proceeds will cover the formulation development of topical HEN-001 to facilitate a forthcoming clinical evaluation of the product as well as an expansion of the patent portfolio.

The market

An estimated 1 percent of the world's population is affected by hidradenitis suppurativa. The global market for therapeutic treatments of the disease is projected to reach USD 1.8 billion by 2028. Available medical treatment options for the condition mainly comprise repurposed, palliative drugs for systemic administration that are limited in both numbers, safety, and effect.

Recent progress

- In October 2022, Karolinska Development's seed financing of Henlez was made in syndication with the Nordic venture capital firm Eir Ventures, where the two parties have contributed EUR 0.5 million each.

OSSDSIGN®
Project

OssDsign® Catalyst
OssDsign® Cranial

Primary indication

Cranial implants
Bone grafts

Development phase

Marketed

Holding in company*

Karolinska Development 9%**


Other investors

TAMT
SEB Venture Capital

Origin

Karolinska University Hospital
Uppsala University

More information

 ossdesign.com

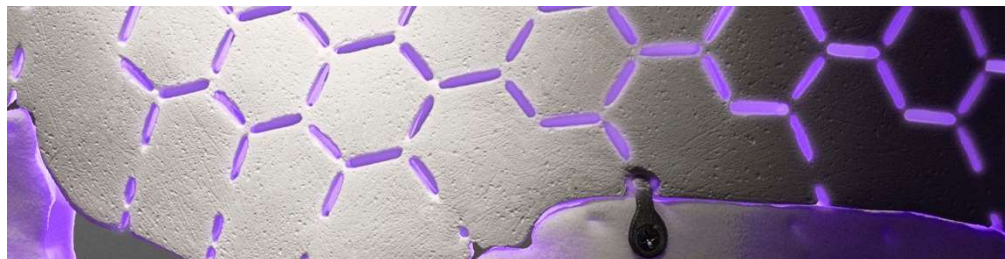
* Fully-diluted ownership based on current investment plans

** Includes indirect holdings through KCIF Co-Investment Fund

Deal values for similar projects

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

OssDsign AB



Creating the next generation bone replacement products and skull implants

OssDsign (Uppsala, Sweden) is an innovative company that designs and manufactures implants and material technology for bone regeneration. The company has historically focused on two particularly challenging areas where treatment results have so far been inadequate: cranial and spine surgeries. OssDsign announced in September 2023 that they are launching a new strategy which means that the company will focus its entire business on the orthobiologics market in the USA. The change in strategy is carried out against the background of an outstanding commercial success for the nanosynthetic bone graft OssDsign Catalyst, an "off the shelf" product with very good scalability and a high gross margin.

About 20 percent of all low back pain surgeries fail due to poor fusion between the implant and the spine. When surgeons perform the procedure, they use a combination of screws and metal braces to fix the vertebrae and bone replacement material to stimulate bone growth. OssDsign Catalyst is an innovative synthetic bone graft consisting of a proprietary nanocrystalline structure of calcium phosphate. OssDsign Catalyst mimics the body's own bone mineral structure and provides a favorable biological environment for rapid and reliable bone formation. OssDsign Catalyst can be produced with high scalability, has an attractive profit margin and great potential in the market for standardized surgical procedures. OssDsign Catalyst received FDA approval in 2020 and launched in the US in August 2021.

All activities related to the company's patient-specific cranial implant (Cranial PSI) will be phased out in a responsible manner by the end of December 2023, leading to a significant reduction in the cost base. In order to finance the strategy shift, OssDsign raised SEK 150 million in September 2023, in a targeted new issue to a number of reputable institutional investors, including TAMT and Linc AB. Karolinska Development is one of the major owners in OssDsign and participated with SEK 10 million in the issue. In connection with communicating the new strategy, OssDsign announced that the company's financial goal is to reach sales of SEK 150-200 million in the mid-term, at which point the company is also expected to be cash flow positive.

The market

The orthobiologics market is valued at USD 5 billion, by 2022. The market segment that OssDsign Catalyst specifically targets is valued at USD 1.8 billion, and is expected to have an annual growth rate of 8 percent.

Recent progress

- In November 2022, a directed share issue of SEK 65.6 million was carried out before deduction of transaction costs. The issue was subscribed for by Adrigo Small & Midcap and two of the company's largest owners, Karolinska Development and Lancelot Asset Management.
- In December 2022 positive data from long-term follow-up with OssDsign Cranial PSI were presented.
- In January 2023, a first patient report from the TOP FUSION clinical study was published, showing a complete spinal fusion six months after surgery with OssDsign Catalyst.
- In September 2023, the company announced its' new strategy to become a pure orthobiologics company with a focus on the US market.
- In September 2023, SEK 150 million was raised in a targeted new issue to a number of reputable institutional investors. Karolinska Development participated with SEK 10 million.


Project

 HA^{nano} Surface

Primary indication

Implant surface coatings

Development phase

Marketed

Holding in company*

Karolinska Development 2%

KDev Investments 14%

Other investors

K-Svets Ventures


Chalmers Ventures

Riepen LCC

Andra AP-fonden

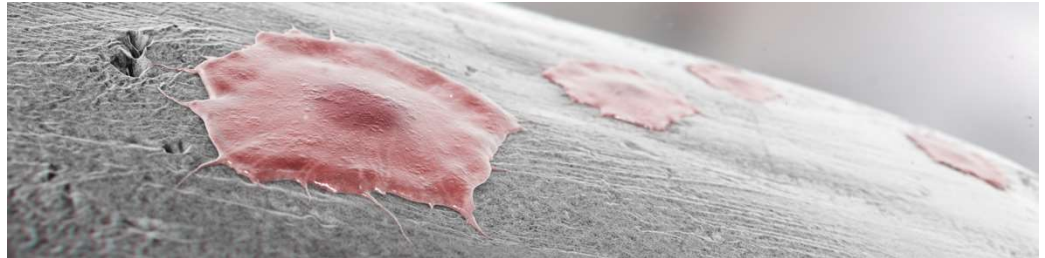
Origin

 Chalmers University of
Technology

More information
 promimic.com

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

Promimic AB



Nanocrystals of synthetic bone shorten the healing time of implants

Promimic (Gothenburg, Sweden) is the company behind HA^{nano} Surface, a surface treatment that is currently used clinically on approximately 1.5 million implants.

HA^{nano} Surface is a nanometer-thin coating of hydroxylapatite crystals that helps stimulate the growth of bone cells. This provides a stronger anchoring in bone tissue and better healing. The surface is unique in that it can be applied to all types of implant materials and geometries, including porous materials and 3D printed structures – examples of surfaces where traditional thicker HA coating can clog pores.

In the Brazilian market, Promimic collaborates with Sistema de Implante Nacional (S.I.N), a leading supplier of dental implants, which commercializes dental implants coated with HA^{nano} Surface.

In the United States, the technology is approved by the FDA, which means that new implants with HA^{nano} Surface can be quickly brought to market via a 510(k) process. This has enabled strong growth – in the last two years, the number of approved implants for clinical use has increased from 5 to 26.

Promimic has a sales office in Austin, Texas and several partnerships for development and commercialization in the US market for orthopedic implants. Currently, the market for spinal implants is the company's strongest segment. The collaboration with the company's customers includes the development and commercialization of products treated with HA^{nano} Surface technology in various application areas.

Deal values for similar projects

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

The market

Promimic focuses on two main segments, namely the markets for orthopedic and dental implants. Together, these segments represent a global market opportunity for Promimic worth up to USD 600-800 million in 2025. Within these segments, the company's target group is medium to large sized implant companies and the main market is the United States.

Recent progress

- In April 2022, Promimic successfully listed the company's share on Nasdaq First North Growth Market in a fully subscribed IPO offering.
- In June 2022, new preclinical results showed that the company's HA^{nano} Surface coating technology reduces the risk of adhesion by common pathogenic bacteria by up to 60 percent.
- In July 2022, Promimic deepened its US investment through the establishment of Nano Processing Inc. – a joint venture with Danco Medical for surface treatment for the US market.

Expected milestones

- In 2023, the company is expected to run development projects with both existing and new customers and further product launches and license agreements will be finalized and announced.

Financial Development

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

The Parent Company is reporting in accordance with the guidelines under the Swedish Annual Accounting Act and Swedish Financial Accounting Standards Council, RFR 2. The Investment Entity is required to meet the reporting requirements of listed companies and thus in accordance with IFRS adopted by the EU and the Swedish Annual Accounts Act

Amounts with brackets refer to the corresponding period previous year unless otherwise stated.

Financial development in summary for the Investment Entity

SEKm	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Jun	2022 Full-year
Condensed income statement					
Change in fair value of shares in portfolio companies	11.7	-50.3	8.6	-91.4	-76.1
Net profit/loss	12.0	-46.6	7.3	-98.1	-88.1
Balance sheet information					
Cash and cash equivalents	130.0	207.0	130.0	207.0	189.8
Net asset value (Note 1)	1,253.2	1,237.7	1,253.2	1,237.7	1,249.1
Net debt (Note 1)	-130.0	-207.0	-130.0	-207.0	-189.8
Share information					
Earnings per share, weighted average before dilution (SEK)	0.0	-0.2	0.0	-0.4	-0.3
Earnings per share, weighted average after dilution (SEK)	0.0	-0.2	0.0	-0.4	-0.3
Net asset value per share (SEK) (Note 1)	4.6	4.6	4.6	4.6	4.6
Equity per share (SEK) (Note 1)	4.6	4.6	4.6	4.6	4.6
Share price, last trading day in the reporting period (SEK)	1.6	1.8	1.6	1.8	1.7
Portfolio information					
Investments in portfolio companies	15.8	61.8	61.4	94.7	110.3
Of which investments not affecting cash flow	1.3	0.3	2.9	0.7	1.1
Portfolio companies at fair value through profit or loss	1,052.2	953.0	1,052.2	953.0	984.0

Financial Development for the Investment Entity in 2023

Investments (comparable numbers 2022)

Investments in the portfolio in the third quarter 2023 by external investors and Karolinska Development amounted to SEK 126.3 (180.6) million, whereof 88% (66%) by external investors.

Karolinska Development invested during the third quarter SEK 15.8 (61.8) million, of which SEK 14.5 (61.5) million was cash investments. Investments were made in Dilafor with SEK 6.1 million, OssDsign with SEK 5.4 million, Modus Therapeutics with SEK 2.4 million, SVF Vaccines with SEK 1.2 million, Umecrine Cognition with SEK 0.4 million and in PharmNovo with SEK 0.3 million. Non-cash investments (accrued interest on loans) amounted to SEK 1.3 (0.3) million.

Investments by external investors in the portfolio companies during the third quarter amounted to SEK 110.6 (118.7) million and were made in OssDsign with SEK 96.2 million, Dilafor with SEK 9.0 million and in Biosergen with SEK 5.4 million.

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

SEKm	Karolinska Development	External Investors	Total Invested Q1-Q3 2023
Umecrine Cognition	16.0	16.5	32.5
Dilafor	16.2	24.0	40.2
PharmNovo	10.3	8.0	18.3
Modus Therapeutics	8.0	0.0	8.0
SVF Vaccines	5.4	0.0	5.4
OssDsign ¹	5.4	96.2	101.6
Aprea	0.0	57.8	57.8
Biosergen	0.0	5.4	5.4
Total	61.3	207.9	269.2

¹ The investment in OssDsign will be fully paid in October 2023.

Portfolio Fair Value

Fair Value of the portfolio companies owned directly by Karolinska Development had a net increase by SEK 22.1 million during the third quarter 2023. The main reason for the incline in fair value was primarily the upturn in share price in the listed holdings OssDsign and Promimic together with the investments in OssDsign, Dilafor, Modus Therapeutics and SVF Vaccines.

Fair Value of the portfolio companies owned indirectly via KDev Investments increased by SEK 6.0 million during the third quarter 2023. The main reasons for the increase in Fair value of the portfolio companies was the upturn in share price in the listed holdings Promimic.

Total Fair Value from portfolio companies owned directly by Karolinska Development and indirectly via KDev Investments increased by SEK 28.1 million in the third quarter 2023.

As a consequence of the increase in Fair Value of the part of the portfolio owned via KDev Investments, the potential distribution to Rosetta Capital increased by SEK 2.1 million, resulting in Net Portfolio Fair Value increasing by SEK 26.0 million in the third quarter 2023.

SEKm	30 Sep 2023	30 Jun 2023	Q3 2023 vs Q2 2023
Karolinska Development Portfolio Fair Value (unlisted companies)	732.7	726.0	6.7
Karolinska Development Portfolio Fair Value (listed companies)	94.2	78.8	15.4
KDev Investments Portfolio Fair Value	565.3	559.3	6.0
Total Portfolio Fair Value	1,392.2	1,364.1	28.1
Potential distribution to Rosetta Capital of fair value of KDev Investments	-340.0	-337.9	-2.1
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	1,052.2	1,026.2	26.0

Profit development 2023 (comparable numbers 2022)

During the third quarter 2023, Karolinska Development's revenue amounted to SEK 0.4 (0.5) million and consists primarily of services provided to portfolio companies. For the period January - September 2023, the revenue amounted to SEK 1.5 (1.7) million.

Change in fair value of shares in portfolio companies of in total SEK 26.0 (-50.3) million includes the difference between the change in Net Portfolio Fair Value during the third quarter 2023 with SEK 11.7 million and the investment in portfolio company of SEK 15.3 million. Change in fair value of other financial assets and liabilities amounted to SEK 2.1 (8.5) million and were the consequence of changes in valuation of earn-out deals. For the period January - September 2023, the change in fair value of shares in portfolio companies amounted to SEK 8.6 (91.4) million and the change in fair value of other financial assets amounted to SEK 12.2 (19.3) million.

During the third quarter 2023 other expenses amounted to SEK 1.3 (1.3) million and personnel costs amounted to SEK 3.3 (4.4) million. For the period January – September 2023 other expenses amounted to SEK 4.6 (4.8) million and personnel cost amounted to 16.3 (20.6) million.

The operating profit/loss in the third quarter 2023 amounted to SEK 9.4 million compared to SEK -47.1 million in the third quarter 2022. The operating profit/loss for the period January - September 2023 amounted to SEK 0.8 (-96.2) million.

The financial net during the third quarter 2023 amounted to SEK 2.6 million compared to SEK 0.5 million in the third quarter of 2022. For the period January - September 2023 the financial net amounted to SEK 7.3 (-1.9) million.

The Investment Entity's Net profit/loss amounted to SEK 12.0 (-46.6) million in the third quarter 2023. Net profit/loss for the period January - September 2023 amounted to SEK 7.3 (-98.1) million.

Financial position

The Investment Entity's equity to total assets ratio amounted to 99% on 30 September 2023, which it also did on 30 September 2022.

The investment company's equity on 30 September 2023, amounted to SEK 1,248.7 million, compared to SEK 1,236.7 million on 30 June 2023. The increase is a consequence of the profit/loss for the period of SEK 12.0 million.

After the paying of operational costs and investments for the third quarter 2023, cash and cash equivalents (including short-term investments) amounted to SEK 130.0 million on 30 September 2023 compared to SEK 207.0 million on 30 September 2022. Net debt (negative net debt/ net cash) amounted to SEK -130.0 million on 30 September 2023 compared to the net debt of SEK -207.0 million on 30 September 2022.

The company is going concern. The company's ability to continue operations (going concern) is stable. The report is prepared based on the assumption of continued operation.

Financial Development – Parent Company

The Parent Company refers to Karolinska Development AB (comparable numbers 2022).

During the third quarter 2023, the Parent Company's Net profit/loss amounted to SEK 12.1 (-46.6) million.

The positive result for the third quarter of 2023 led to an increase in equity of SEK 12.1 million from SEK 1,236.7 million as of 30 June 2023 to SEK 1,248.8 million 30 September 2023.

The Share

The share and share capital

Trade in the Karolinska Development share takes place on Nasdaq Stockholm under the ticker symbol "KDEV". The last price paid for the listed B share on 30 September 2023 was SEK 1.61, and the market capitalization amounted to SEK 434 million.

The share capital of Karolinska Development on 30 September 2023 amounted to SEK 2.7 million divided into 2,555,261 A shares, each with ten votes (25,552,610 votes) and 267,522,333 B shares, each with one vote (267,522,333 votes). The total number of shares and votes in Karolinska Development on 30 September 2023 amounted to 270,077,594 shares and 293,074,943 votes.

Ownership

On 30 September 2023, Karolinska Development had 15,605 shareholders.

Shareholder	A-Shares	B-Shares	Cap %	Vote %
invoX Pharma Ltd	0	128,736,384	47.67%	43.93%
Worldwide International Investments Ltd	0	28,007,077	10.37%	9.56%
Swedbank Robur Microcap fond	0	8,750,000	3.24%	2.99%
Styviken Invest AS	0	5,236,206	1.94%	1.79%
Avanza pension	0	4,696,786	1.74%	1.60%
Stift För Främjande & Utveckling	2,555,261	1,755,818	1.60%	9.32%
Coastal Investment Management LLC	0	2,470,541	0.91%	0.84%
Handelsbanken fonder	0	1,399,513	0.52%	0.48%
Nordnet Pensionsförsäkringar	0	1,375,538	0.51%	0.47%
SEB Investment Management	0	1,348,199	0.50%	0.46%
Sum Top 10 Shareholders	2,555,261	183,776,062	68.99%	71.42%
Sum Other Shareholders	0	83,746,271	31.01%	28.58%
Sum All Shareholders	2,555,261	267,522,333	100.00%	100.00%

Information on Risks and Uncertainties

Investment Entity and Parent Company

Financial risks

Russia's invasion of Ukraine affects the economy and society as a whole, including Karolinska Development and its portfolio companies. The general downturn in the stock market since 2022 and the continued increases in interest rates have shifted the financial market's focus from growth companies to companies with positive operating cash flows, which has led to lower valuations in many previously highly valued growth companies. This affects Karolinska Development and its opportunities to not only finance its portfolio companies, but also to divest them at a suitable time for Karolinska Development.

The value of listed companies can decline, delays in clinical trial programs may occur and the opportunities for refinancing can be hampered. The Board monitors the evolution of the crises closely and Karolinska Development is working intensively to minimize the impact on the value of our investments and works continuously with different financing alternatives to secure the long-term capital requirement and thereby increase the degree of strategic and operational headroom for the future.

For a detailed description of other risks and uncertainties, see the Annual report 2022.

Signing of the report

Solna, 17 November 2023

Viktor Drvota
CEO

Review report

Karolinska Development AB, corporate identity number 556707-5048

Introduction

We have reviewed the condensed interim report for Karolinska Development AB, the Investment Entity, as of September 30, 2023 and for the nine months period that ended at that date. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

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

Conclusion

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

Solna, 17 November 2023

Ernst & Young AB

Oskar Wall

Authorized Public Accountant

Dates for Publication of Financial Information

Year-End Report January – December 2023	16 February 2024
Annual Report 2023	22 March 2024
Interim Report January – March 2024	26 April 2024
Annual meeting 2024	16 May 2024
Interim Report January – June 2024	30 August 2024
Interim Report January – September 2024	15 November 2024

Karolinska Development is required by law to publish the information in this interim report. The information was published on 17 November 2023.

This interim report, together with additional information, is available on Karolinska Development's website: www.karolinskadevelopment.com.

Note: This report is a translation of the Swedish interim report. In case of any discrepancies, the official Swedish version shall prevail.

Financial Statements

Condensed income statement for the Investment Entity

SEK 000	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Full-year
Revenue		412	527	1,481	1,738	2,300
Change in fair value of shares in portfolio companies	2,3	11,709	-50,308	8,588	-91,397	-76,083
Change in fair value of other financial assets and liabilities		2,057	8,490	12,236	19,346	20,435
Other expenses		-1,257	-1,306	-4,646	-4,849	-6,798
Personnel costs		-3,312	-4,376	-16,300	-20,559	-26,585
Depreciation of right-of-use assets		-179	-172	-536	-517	-690
Operating profit/loss		9,430	-47,145	823	-96,238	-87,421
Financial net		2,576	522	6,434	-1,906	-701
Profit/loss before tax		12,006	-46,623	7,257	-98,144	-88,122
Taxes		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		12,006	-46,623	7,257	-98,144	-88,122

Condensed statement of comprehensive income for the Investment Entity

SEK 000	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Full-year
Net profit/loss for the period		12,006	-46,623	7,257	-98,144	-88,122
Total comprehensive income/loss for the period		12,006	-46,623	7,257	-98,144	-88,122

Earnings per share for the Investment Entity

SEK	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Full-year
Earnings per share, weighted average before dilution		0.04	-0.17	0.03	-0.39	-0.34
Number of shares, weighted average before dilution		269,833,309	269,833,309	269,833,309	253,233,364	257,417,460
Earnings per share, weighted average after dilution		0.04	-0.17	0.03	-0.39	-0.34
Number of shares, weighted average after dilution		269,833,309	269,833,309	269,833,309	253,233,364	257,417,460

Condensed balance sheet for the Investment Entity

SEK 000	Note	30 Sep 2023	30 Sep 2022	31 Dec 2022
ASSETS				
Tangible assets				
Right-of-use assets		179	862	690
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2,3	1,052,188	953,043	983,995
Other financial assets	4	60,213	78,045	59,537
Total non-current assets		1,112,580	1,031,950	1,044,222
Current assets				
Receivables from portfolio companies		207	319	211
Other financial assets	4	10,925	0	15,970
Other current receivables		1,224	1,224	673
Prepaid expenses and accrued income		2,241	1,035	750
Short-term investments, at fair value through profit or loss		-	88,156	58,742
Cash and cash equivalents		129,992	118,844	131,078
Total current assets		144,589	209,578	207,424
TOTAL ASSETS		1,257,169	1,241,528	1,251,646
EQUITY AND LIABILITIES				
Total equity		1,248,695	1,231,416	1,241,438
Current liabilities				
Other financial liabilities		94	416	191
Accounts payable		851	728	439
Liability to make lease payment		258	922	753
Other current liabilities		1,840	1,437	654
Accrued expenses and prepaid income		5,431	6,609	8,171
Total current liabilities		8,474	10,112	10,208
Total liabilities		8,474	10,112	10,208
TOTAL EQUITY AND LIABILITIES		1,257,169	1,241,528	1,251,646

Condensed statement of changes in the Investment Entity's equity

SEK 000	Not	30 Sep 2023	30 Sep 2022	31 Dec 2022
Opening balance, equity		1,241,438	971,086	971,086
Share capital		2,701	2,701	2,701
Share premium		2,735,903	2,735,903	2,735,903
Retained earnings		-1,489,909	-1,507,188	-1,497,166
Closing balance, equity		1,248,695	1,231,416	1,241,438

Condensed statement of cash flows for the Investment Entity

SEK 000	Note	2023 Jan-Sep	2022 Jan-Sep	2022 Full-year
Operating activities				
Operating profit/loss		823	-96,238	-87,421
Adjustments for items not affecting cash flow				
Depreciation		536	517	690
Change in fair value		-20,824	72,051	55,648
Other items		2,474	-448	-206
Cash flow from operating activities before changes in working capital and operating investments				
		-16,991	-24,118	-31,289
Cash flow from changes in working capital				
Increase (-)/Decrease (+) in operating receivables		-1,920	-496	416
Increase (+)/Decrease (-) in operating liabilities		-1,142	-2,151	-1,661
Cash flow from operating activities				
		-20,053	-26,765	-32,534
Investment activities				
Part payment from earn-out deal		18,271	1,956	5,358
Acquisitions of shares in portfolio companies		-58,499	-93,946	-109,166
Proceeds from sale of short-term investments		59,731	-	0
Acquisitions of short-term investments		-	-40,000	-10,000
Cash flow from investment activities				
		19,503	-131,990	-113,808
Financing activities				
Cash from rights issue		-	254,911	254,911
Prospectus costs		-	-19,175	-19,175
Amortization of lease liabilities		-536	-535	-714
Cash flow from financing activities				
		-536	235,201	235,022
Cash flow for the period				
		-1,086	76,446	88,680
Cash and cash equivalents at the beginning of the year		131,078	42,398	42,398
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD				
		129,992	118,844	131,078

Condensed income statement for the Parent Company

SEK 000	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Full-year
Revenue		412	527	1,481	1,738	2,300
Change in fair value of shares in portfolio companies	2.3	11,709	-50,308	8,588	-91,397	-76,083
Change in fair value of other financial assets and liabilities		2,057	8,490	12,236	19,346	20,435
Other expenses		-1,374	-1,484	-5,182	-5,384	-7,513
Personnel costs		-3,312	-4,376	-16,300	-20,559	-26,585
Operating profit/loss		9,492	-47,151	823	-96,256	-87,446
Financial net		2,580	532	6,450	-1,870	-655
Profit/loss before tax		12,072	-46,619	7,273	-98,126	-88,101
Tax		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		12,072	-46,619	7,273	-98,126	-88,101

Condensed statement of comprehensive income for the Parent Company

SEK 000	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Full-year
Net profit/loss for the period		12,072	-46,619	7,273	-98,126	-88,101
Total comprehensive income/loss for the period		12,072	-46,619	7,273	-98,126	-88,101

Condensed balance sheet for the Parent Company

SEK 000	Note	30 Sep 2023	30 Sep 2022	31 Dec 2022
ASSETS				
Financial non-current assets				
Shares in portfolio companies at fair value through profit or loss	2,3	1,052,188	953,043	983,995
Other financial assets	4	60,213	78,045	59,537
Total non-current assets		1,112,401	1,031,088	1,043,532
Current assets				
Receivables from portfolio companies		207	319	211
Other financial assets	4	10,925	-	15,970
Other current receivables		1,224	1,224	673
Prepaid expenses and accrued income		2,241	1,035	750
Short-term investments at fair value through profit or loss		-	88,156	58,742
Cash and cash equivalents		129,992	118,844	131,078
Total current assets		144,589	209,578	207,424
TOTAL ASSETS		1,256,990	1,240,666	1,250,956
EQUITY AND LIABILITIES				
Total equity		1,248,774	1,231,476	1,241,501
Current liabilities				
Other financial liabilities		94	416	191
Accounts payable		851	728	439
Other current liabilities		1,840	1,437	654
Accrued expenses and prepaid income		5,431	6,609	8,171
Total current liabilities		8,216	9,190	9,455
Total liabilities		8,216	9,190	9,455
TOTAL EQUITY AND LIABILITIES		1,256,990	1,240,666	1,250,956

Condensed statement of changes in equity for the Parent Company

SEK 000	Not	30 Sep 2023	30 Sep 2022	31 Dec 2022
Opening balance, equity		1,241,501	971,128	971,128
Share capital		2,701	2,701	2,701
Share premium reserve		2,735,903	2,735,903	2,735,903
Retained earnings		-1,489,830	-1,507,128	-1,497,103
Closing balance, equity		1,248,774	1,231,476	1,241,501

Notes to the Financial Statements

NOTE 1 Accounting policies

This report has been prepared in accordance with the International Accounting Standard (IAS) 34 Interim Financial Reporting and the Annual Accounts Act. The accounting policies applied to the Investment Entity and the Parent Company correspond, unless otherwise stated below, to the accounting policies and valuation methods used in the preparation of the most recent annual report.

Information on the Parent Company

Karolinska Development AB (publ) ("Karolinska Development," "Investment Entity" or the "Company") is a Nordic life sciences investment company. The Company, with Corporate Identity Number 556707-5048, is a limited liability company with its registered office in Solna, Sweden. The Company focuses on identifying medical innovations and investing in the creation and growth of companies developing these assets into differentiated products that will make a difference to patients' lives and provide an attractive return on investment to its shareholders. Investments are made in companies whose sole purpose is to generate a return through capital appreciation and investment income. These temporary investments, which are not investment entities, are designated "portfolio companies" below.

New and revised accounting principles 2023

No new or revised IFRS standards or recommendations from IFRS Interpretations Committee has had significant impact on the Investment Entity.

Related party transactions

No related party transactions have taken place with owners during the reporting period.

Definitions

Interim period: The period from the beginning of the financial year through the closing date.

Reporting period: January – September 2023.

Alternative Performance Measures

The Company presents certain financial measures in the interim report that are not defined under IFRS. The Company believes that these measures provide useful supplemental information to investors and the company's management as they allow for the evaluation of the company's performance. Because not all companies calculate the financial measures in the same way, these are not always comparable to measures used by other companies. Therefore, these financial measures should not be considered as substitutes for measures as defined under IFRS.

Portfolio companies: Companies where Karolinska Development has made investments (subsidiaries, joint ventures, associated companies and other long-term securities holdings) which are active in pharmaceuticals, medtech, theranostics and formulation technology.

The Portfolio Fair Value is divided into Total Portfolio Fair Value and Net Portfolio Fair Value.

Total Portfolio Fair Value: The aggregated proceeds that would be received by Karolinska Development and KDev Investments if the shares in their portfolio companies were sold in an orderly transaction between market participants at the measurement date.

Net Portfolio Fair Value (after potential distribution to Rosetta Capital) is the net aggregated proceeds that Karolinska Development will receive after KDev Investments' distribution of proceeds to Rosetta Capital.

rNPV: "risk-adjusted net present value" is a method to value risky future cash flows. rNPV is the standard valuation method in the drug development industry, where sufficient data exists to estimate success rates for all R&D phases.

Equity per share: Equity on the closing date in relation to the number of shares outstanding on the closing date.

Net debt: Interest-bearing liabilities (SEK 0.0 million) reduced with cash and cash equivalents (including short-term investments) (SEK 130.0 million).

Equity to total assets ratio: Equity divided by total assets.

Net asset value as of 30 September 2023:

SEK 000	Number of shares	Fair value	Part of Karolinska Developments' net asset value	
			SEK per share ³	percentage
Listed assets				
Modus Therapeutics	6,144,821	31,965	0.12	2.6%
OssDesign	8,334,791	53,843	0.20	4.3%
Promimic	312,500	8,375	0.03	0.7%
Total listed assets		94,183	0.35	7.5%
Unlisted assets				
AnaCardio		45,140	0.17	3.6%
Dilafor		40,220	0.15	3.2%
Henlez		5,753	0.02	0.5%
PharmNovo		30,339	0.11	2.4%
SVF Vaccines		18,301	0.07	1.5%
Umecrine Cognition		585,097	2.17	46.7%
KCIF Co-Investment Fund KB ¹		7,897	0.03	0.6%
KDev Investments ¹		225,258	0.83	18.0%
Total unlisted assets		958,005	3.55	76.4%
Net of other liabilities and debts²		201,036	0.75	16.0%
Total net asset value		1,253,224	4.64	100.0%

¹The company has both listed and unlisted assets.

² Includes SEK 130.0 million cash and cash equivalents (including short-term investments).

³ In relation to the number of shares outstanding (269,833,309) on the closing date.

NOTE 2 Shares in portfolio companies, at fair value through profit or loss

Change in fair value of portfolio companies

SEK 000	2023 Jan-Sep	2022 Jan-Sep	2022 Full-year
Result level 1			
Listed companies, realized	-	-	-
Listed companies, unrealized	5,225	-41,058	-22,408
Total level 1	5,225	-41,058	-22,408
Result level 3			
Unlisted companies, realized	953	402	751
Unlisted companies, unrealized	2,410	-50,741	-54,426
Total level 3	3,363	-50,339	-53,675
Total	8,588	-91,397	-76,083

Shares in portfolio companies, at fair value through profit or loss

SEK 000	2023-09-30	2022-09-30	2022-12-31
Accumulated acquisition cost			
At the beginning of the year	983,995	950,170	950,170
Investments during the year	61,368	94,653	110,294
Sales during the year	-1,763	-389	-386
Changes in fair value in net profit/loss for the year	8,588	-91,397	-76,083
Closing balance	1,052,188	953,043	983,995

NOTE 3 Fair value

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

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

Fair value as of 30 September 2023

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	94,183	-	958,005	1,052,188
Other financial assets	-	-	71,138	71,138
Cash and cash equivalents and short-term investments	129,992	-	-	129,992
Total	224,175	0	1,029,143	1,253,318
Financial liabilities				
Other financial liabilities	-	-	94	94
Total	-	0	94	94

Fair value as of 30 September 2022

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	49,438	-	903,605	953,043
Other financial assets	-	-	78,045	78,045
Cash, cash equivalents and short-term investments	207,000	-	-	207,000
Total	256,438	0	981,650	1,238,088
Financial liabilities				
Other financial liabilities	-	-	416	416
Total	-	0	416	416

Fair value (level 3) as of 30 September 2023

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At beginning of the year	908,461	75,507	191
Acquisitions	47,945	-	-
Compensations	-1,764	-16,508	-
Gains and losses recognized through profit or loss	3,363	12,139	-97
Closing balance 30 September 2023	958,005	71,138	94
Realized gains and losses for the period included in profit or loss	953	16,508	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	2,410	-4,369	97

Fair value (level 3) as of 30 September 2022

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At beginning of the year	876,250	61,799	1,756
Acquisitions	78,083	-	-
Compensations	-389	-2,082	-324
Gains and losses recognized through profit or loss	-50,339	18,328	-1,016
Closing balance 30 September 2023	903,605	78,045	416
Realized gains and losses for the period included in profit or loss	402	-	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	-50,741	18,328	-1,016

The Investment Entity recognizes transfers between levels in the fair value hierarchy on the date when an event or changes occur that give rise to the transfer.

Shares in portfolio companies (Level 3) as of 30 September 2023

SEK 000	Ownership	Market value	Valuation model ¹
AnaCardio	20.7%	45,140	Last post money
Dilafor	2.2%	40,220	Last post money
Henlez	13.5%	5,753	Last post money
PharmNovo	13.1%	30,339	Last post money
SVF Vaccines	34.8%	18,301	Last post money
Umecrine Cognition	72.6%	585,097	External valuation ²
KCIF Co-Investment Fund KB	26.0%	7,897	A combination of share price listed company and fair value of financial asset ³
KDev Investments	90.1%	225,258	A combination of last post money and share price listed company ⁴
Total level 3		958,005	

¹See The Annual Report 2022 Valuation of portfolio companies at fair value, for a description of valuation models.

²Risk adjusted external valuation by an independent valuation institute in December 2022. The external valuation resulted in an rNPV value which Karolinska Development has adjusted further in order to reflect an assumed split in risk and revenues in conjunction with a license deal and also to incorporate the financial risk that Umecrine Cognition will not manage to finance fully the final parts of the research program.

³KCIF Co-Investment Fund KB holds listed shares which are valued in accordance with the closing rate on the final trading day of the period and a financial asset, at fair value through profit or loss, attributable to earn-out in the sale of Forendo Pharma.

⁴KDev Investments AB holds both listed shares which are valued in accordance with the closing rate on the final trading day of the period and unlisted shares which are valued in accordance with the most recent transaction (post-money valuation). Dilafor, which is an unlisted company, accounts for 87% of the total fair value in KDev Investments.

Impact of Portfolio Fair Value

In the table below, “Total Portfolio Fair Value” is as defined in Note 1.

Impact on Portfolio Fair Value of the agreement with Rosetta Capital

“Potential distribution to Rosetta Capital”, SEK 340.0 million, is the amount that KDev Investments according to the investment agreement between Karolinska Development and Rosetta Capital is obligated to distribute to Rosetta Capital from the proceeds received by KDev Investments (KDev Investments Fair Value). The distribution to Rosetta Capital will only happen when KDev Investments distribute dividends. KDev Investments will only distribute dividends after all eventual payables and outstanding debt has been repaid. Following dividends from KDev Investments during 2021 and 2022, all additional investments totaling SEK 44.2 million have been repaid to Rosetta Capital. In addition, SEK 1.3 million has been distributed, which reduce the first SEK 220 million in the waterfall structure. See also the annual report for 2022, note 17, for a description of the agreement with Rosetta Capital.

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

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

SEK 000	30 Sep 2023	30 Sep 2022	31 Dec 2022
Karolinska Development Portfolio Fair Value (unlisted companies)	732,747	696,143	704,443
Karolinska Development Portfolio Fair Value (listed companies)	94,183	49,438	75,534
KDev Investments Portfolio Fair Value	565,274	537,843	532,547
Total Portfolio Fair Value	1,392,204	1,283,424	1,312,524
Potential distribution to Rosetta Capital of fair value of KDev Investments	-340,016	-330,381	-328,529
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	1,052,188	953,043	983,995

NOTE 4 Other financial assets

SEK 000	30 Sep 2023	30 Sep 2022	31 Dec 2022
Other financial assets, non-current			
Earn-out agreement Forendo Pharma	60,213	78,045	59,537
Earn-out agreement Oncopeptides	0	0	0
Total	58,411	69,549	59,537
Other financial assets, current			
Earn-out agreement Forendo Pharma	10,925	-	15,970
Total	10,647	0	15,970

Earn-out agreement Forendo Pharma

Karolinska Development is entitled to earn-out payments according to the agreement with Organon regarding the sale of Forendo Pharma. Karolinska Development estimates the risk-adjusted net present value (rNPV) of future cash flows (earn-outs), after the initial payment in December 2021 and payments in 2022 and during 2023, to SEK 71.1 million, whereof SEK 10.9 million is expected to be paid during 2023. The earn-outs are expected to be paid during the period 2023–2034, and renewed rNPV valuations will be performed continuously. Forendo Pharma's previously shareholders are entitled to additional future payments totaling USD 870 million upon the achievement of certain development, registration and commercial milestones pertaining to Forendo Pharma's drug candidates.

NOTE 5 Pledge assets and contingent liabilities

SEK 000	30 Sep 2023	30 Sep 2022	31 Dec 2022
Pledge assets			
Contingent liabilities			
Investment agreement in portfolio company	7,580	7,580	7,580
Summa	13,594	7,580	7,580