
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 leukemia, serious viral infections, sepsis and systemic inflammation, bone defects, and hepatic encephalopathy. 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 second quarter was SEK 23.3 million (SEK -22.3 million in the second quarter of 2022). Earnings per share totaled SEK 0.08 (SEK -0.09 in the second quarter of 2022). Net profit/loss for the period January – June 2023 amounted to SEK -4.8 (-51.5) million.
- The result of the Change in fair value of shares in portfolio companies for the second quarter amounted to SEK 21.2 million (SEK -23.9 million in the second quarter of 2022). The result is largely due to the upturn in share price in the listed holdings Modus Therapeutics, OssDsign and Promimic. The result of the Change in fair value of shares in portfolio companies for the period January – June 2023 amounted to SEK -3.1 (-41.1) million.
- The total fair value of the portfolio was SEK 1,364.1 million at the end of June 2023, corresponding to an increase of SEK 49.0 million from SEK 1,315.1 million at the end of the previous quarter. The net portfolio fair value at the end of June 2023 was SEK 1,026.2 million, corresponding to an increase of SEK 41.6 million from SEK 984.4 million at the end of the previous quarter. The increase is mainly the effect of upturn in share price of listed holdings and investments during the quarter.
- Net asset value amounted to SEK 1,242.8 million, per share SEK 4.6, at the end of June 2023 (SEK 1,284.8 million, per share SEK 4.8 at the end of June 2022).
- Net sales totaled SEK 0.5 million during the second quarter of 2023 (SEK 0.6 million during the second quarter of 2022). Net sales for the period January – June 2023 totalled SEK 1.1 (1.2) million.
- Karolinska Development invested a total of SEK 20.5 million in portfolio companies during the second quarter of 2023. Second quarter investments in portfolio companies by Karolinska Development and other specialized life sciences investors totaled SEK 38.1 million.
- Cash and cash equivalents (including short-term investments) decreased by SEK 8.9 million during the second quarter, totaling SEK 147.7 million on 30 June 2023 (SEK 273.9 million on 30 June 2022).

Significant events during the second quarter

- The portfolio company AnaCardio included the first patient in the company's clinical phase 1b/2a study of the drug candidate AC01 – a new potential treatment of heart failure (April 2023).
- The portfolio company Umecrine Cognition included the first patient in the company's clinical phase 2 study in primary biliary cholangitis (PBC) (April 2023).
- The portfolio company Modus Therapeutics, in collaboration with a world-leading research group, generated data showing that its drug candidate sevuparin has the potential to be developed as a treatment for anemia in patients with certain chronic diseases. The results were presented at the European Hematology Association's annual meeting on June 8-11 (May 2023).
- At Karolinska Development's Annual General Meeting, it was decided, among other things, to adopt the profit and loss statement and the balance sheet and the consolidated profit and loss statement and the consolidated balance sheet, to approve the allocation of the result, proposed by the Board of Directors and the CEO and to re-elect Björn Cochlovius, Philip Duong, Anna Lefevre Skjöldebrand, Ben Toogood and Theresa Tse to its Board of Directors, and to re-elect Björn Cochlovius Chairman of the Board (May 2023).
- The portfolio company Umecrine Cognition announced results from a preclinical model of cholestasis that elucidates the mechanism-of-action of the company's clinical drug candidate golexanolone in cholestatic liver disease. The results were presented as a poster at the International Liver Congress EASL in Vienna, June 21-24 (June 2023).

Significant post-period events

- The portfolio company Umecrine Cognition presented results from a study on a preclinical model of Parkinson's disease as a poster at the 6th World Parkinson Congress in Barcelona, Spain, July 4-7. The poster shows how the company's clinical drug candidate golexanolone has an effect on fatigue, anxiety, depression, and some cognitive and motor alternations in the disease model (July 2023).

Viktor Drvota, CEO of Karolinska Development, comments:

"Our portfolio companies continue to deliver significant progress and we are following the developments of the studies that have been initiated this year, as well as the processing of the clinical results that have already been generated with great interest. Research and development activities are the basis for the companies' long-term value creation and every advancement in the individual projects increases the possibility of ultimately being able to offer patient groups with major medical needs completely new types of treatments."

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Chief Executive's Report

Our portfolio companies have forged ahead, reaching a number of important milestones during the second quarter. Umecrine Cognition has, amongst other things, launched its clinical study of golexanolone which will be evaluated in patients with primary biliary cholangitis, while AnaCardio has recruited the first patient for a clinical phase 1/2a study of a potential new treatment for heart failure. Modus Therapeutics, meanwhile, is evaluating broadening the development programme for its candidate drug, sevuparin, in the light of indications that the substance shows potential as a treatment for anaemia in patients with certain chronic diseases.

Umecrine Cognition initiates phase 2 study

In April, the first patient was recruited for the clinical phase 2 study of the candidate drug, golexanolone, which is being developed by our portfolio company, Umecrine Cognition. The study is evaluating the candidate drug in the treatment of primary biliary cholangitis (PBC) – a condition that arises when the liver's bile ducts are damaged or destroyed, resulting in the incorrect suppression of brain activity and causing extreme fatigue, difficulty concentrating, and impaired motor skills. In previous preclinical and clinical studies, the candidate drug has shown strong potential for counteracting this incorrect suppression of brain activity, and the aim of the current study is to document golexanolone's pharmacodynamic and safety profile, and to analyse early efficacy signals. The study is being conducted at several centres in Europe and the topline results are expected at the end of 2024.

The quarter also saw Umecrine Cognition present data from a preclinical model of cholestasis that illustrates the mechanism of action of golexanolone in cholestatic liver disease and its ability to reduce neural inflammation. The results show that golexanolone inhibits the increase of several pro-inflammatory substances and also inhibits specific changes in the cerebellum related to the GABA system. These findings clarify the mechanism of action and indicate that the candidate drug may have beneficial effects on fatigue as well as on motor and cognitive impairment in patients with cholestatic liver disease. The results attracted considerable attention when they were presented during a poster presentation at the International Liver Congress EASL in Vienna between 21 and 24 June, which was attended by many high profile, global key opinion leaders.

AnaCardio recruits first patient for study

Our portfolio company, AnaCardio, has included the first patient in the company's clinical phase 1/2a study of the small molecule candidate drug, AC01 – a potential new treatment for heart failure. AC01 mimics the mechanism of action of the peptide hormone, ghrelin, and has been shown in previous studies to have a positive effect on the heart's contractibility and to increase the volume of blood ejected from the heart. The candidate drug's unique mechanism of action has the potential to improve the heart's capacity without increasing the risk of many of the adverse events associated with today's heart failure treatments which can, in a worst-case scenario, result in life-threatening conditions. The study will be conducted at several European centres in Sweden, the Netherlands, Italy, and the UK.

Modus broadens therapeutic indication for sevuparin

In May, Modus Therapeutics presented new data showing that its candidate drug, sevuparin, which has previously been in development for the treatment of sepsis and septic shock, also has the potential for development as a treatment for anaemia in patients with certain chronic diseases. An expansion into this new indication will enhance the portfolio company's potential to generate substantial value for large patient groups and its shareholders alike. The new findings suggest that sevuparin has the ability to strongly

suppress hepcidin at dose levels that are not considered to risk causing side effects. High levels of hepcidin have been implicated in causing and aggravating the anemias that often complicate chronic kidney disease and chronic inflammation disorders. High hepcidin is also believed to be responsible for conferring resistance to the current standard of care therapies to anemia. The results have been generated in a collaboration with a world-leading research team led by Professor Maura Poli at the University of Brescia and were presented at the European Hematology Association's annual meeting in the beginning of June.

Looking forward to continued value creation

Our portfolio companies continue to deliver significant progress and we are following with great interest the development of the studies initiated by Aprea and SVF Vaccines at the beginning of the year, as well as the processing of the clinical results generated by Dilafor, Modus and Biosergen during the first quarter. Research and development activities are the basis for the companies' long-term value creation and every advancement in the individual projects increases the possibility for ultimately offering completely new types of treatments for patient groups with substantial medical needs.

Solna, 25 August 2023

Viktor Drvota
Chief Executive Officer

Portfolio Companies

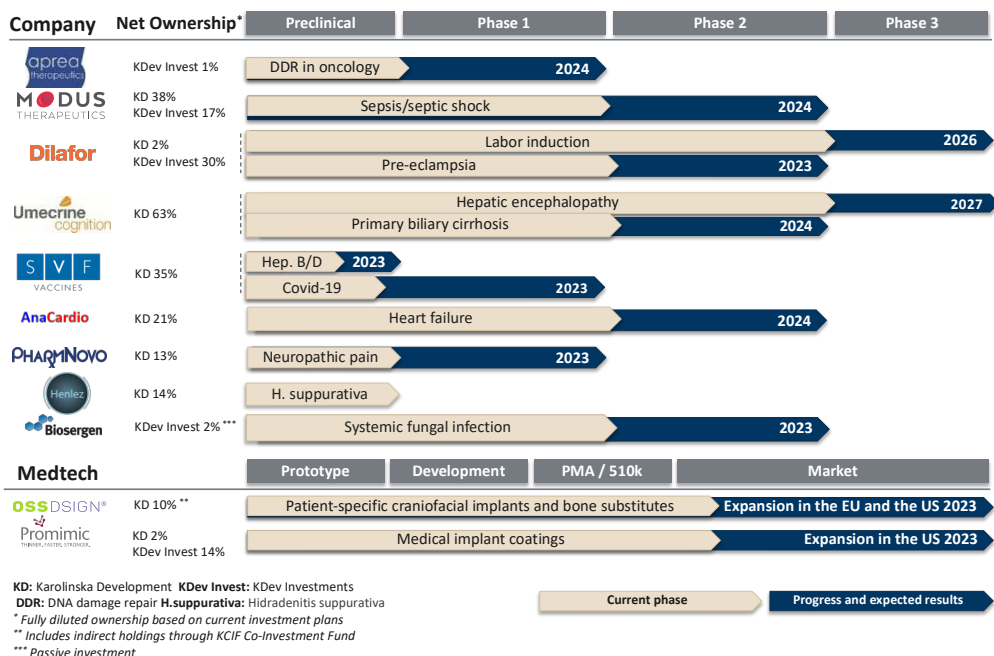
High potential for continued value inflection in portfolio

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
Renaissance Technologies
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 trials 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, 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. ATRN-W1051 is currently in preclinical development, and 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 May 2022, Aprea announced the acquisition of Atrin Pharmaceuticals.
- Following the Annual Shareholders' Meeting on July 28, 2022, Christian S. Schade transitioned to the role of Executive Chairman of the Board of Directors and Oren Gilad was appointed CEO.
- 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.

Project (First-in-class)

Sevuparin

Primary indication

Sepsis/Septic shock

Development phase

Phase 1

Holding in company*

Karolinska Development 38%

KDev Investments 17%

Other investors

John Öhd

Nordnet Pensionsförsäkring

Hans Wigzell

Origin

Karolinska Institutet

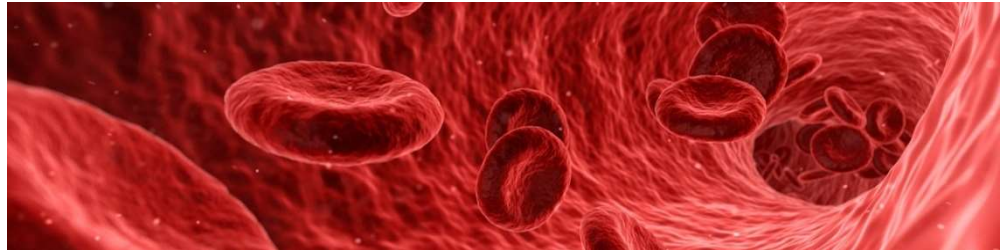
Uppsala University

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- the 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 first patient was included in the phase 1 study evaluating sevuparin in pediatric patients with severe malaria. The study is a collaboration with Imperial College, London and Wellcome foundation.
- 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, it is announced that Modus has 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.

Expected milestones

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

Dilafor

Project (First-in-class)

Tafoxiparin

Primary indication

 Labor induction
 Preeclampsia

Development phase

Phase 2b

Holding in company*


 Karolinska Development 2%
 KDev Investments 30%

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 with 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 with lower doses 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
Norrlandsfonden
Fort Knox Förvaring AB
PartnerInvest

Origin
Umeå University

More information
 umecrinecognition.com

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

Deal values for similar projects

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

Umecrine Cognition AB



Developing a new approach to alleviate cognitive impairment

Umecrine Cognition (Solna, Sweden) is developing golexanolone (GR3207), 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 has conducted a clinical phase 2a study of golexanolone in patients with hepatic encephalopathy (HE) – a serious neuropsychiatric and neurocognitive condition that occurs in conjunction with acute and chronic hepatic damage with underlying cirrhosis. The results showed that the candidate drug was well-tolerated, that the safety profile was good, and that the pharmacokinetic profile was favorable. One of the effect parameters – a well-established and sensitive form of EEG study – demonstrates that the candidate drug has 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 candidate drug in HE and primary biliary cirrhosis (PBC).

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.


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 and 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.

Expected milestones

- Topline data from the phase 1b/2a study of drug candidate AC01 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

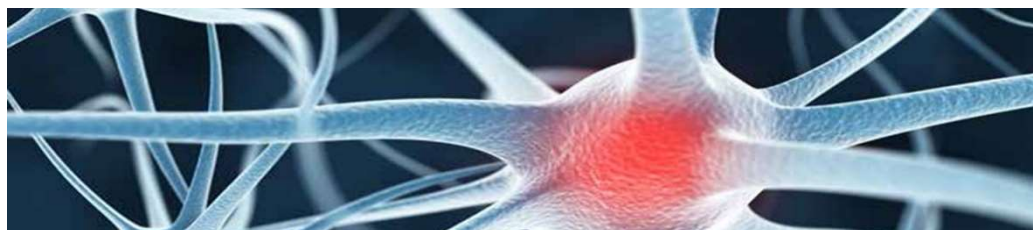
More information
 pharmnovo.com

**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. These types of pain have highly detrimental effects on the quality of life; it impairs everyday activities and social functioning and has harmful physical effects (e.g., due to lack of mobility, energy, appetite, and sleep deprivation etc.). Current treatment options are deemed ineffective and are also associated with significant side-effects; particularly cardiovascular risks, a higher risk of suicide and drug abuse potential with gabapentinoids or conventional opioids.

PharmNovo's novel drug candidate, 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 been tested in various mechanistic in vitro models and in animal models for neuropathic pain states, as well as for short term tolerance and dependence. In addition, initial safety pharmacology, pharmacokinetics, and regulatory toxicology studies have been performed.

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 and the market for allodynia alone is around USD 1.25 billion 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 share issue including investments from Karolinska Development. The new capital will be used to finance drug substance manufacture, the completion of a clinical phase 1 trial of the drug candidate PN6047 and continue the company's development.
- In August 2022, an additional rights issue of SEK 6 million was completed.
- In August 2022, the phase 1 study with PN6047 was initiated.

Expected milestones

- The phase 1 study with PN6047 is ongoing and a first read out is planned in Q3 2023.



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 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® Cranial PSI and
OSSDSIGN® Catalyst

Primary indication

Cranial implants
Bone grafts

Development phase

Marketed

Holding in company*

Karolinska Development 10%**


Other investors

SEB Venture Capital
Fouriertransform

Origin

Karolinska University Hospital
Uppsala University

More information

 ossdsign.com

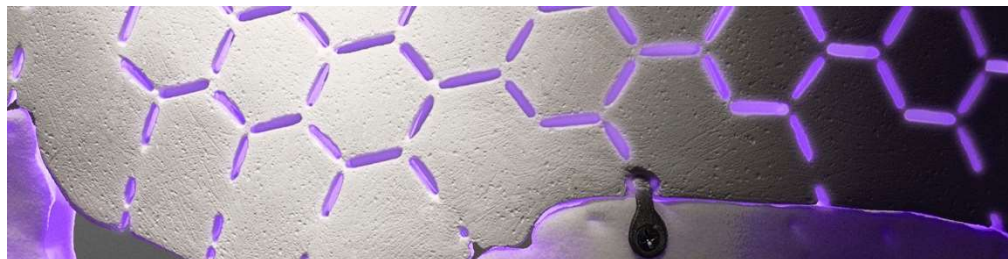
** Fully-diluted ownership based on
current investment plans*

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

**Deal values for similar
projects**

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

OssDsign AB



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 is focused on two particularly challenging areas where treatment results have so far been insufficient: cranial and spinal surgeries.

OssDsign Cranial PSI is an implant used for patients who have lost a large part of the cranium. The implant is constructed from 3D printed medical-grade titanium covered by a regenerative calcium phosphate composition. Long term follow-up data from nearly 2,000 patients with OssDsign Cranial PSI implants show an exceptional performance. Many cranial implant technologies are associated with high risks of costly complications that involve great suffering for patients and significant costs to society. Multiple studies report infection rates above 10 percent, leading to the removal of many implants. In comparison, the observed rate of explanations due to infections in patients who received OssDsign Cranial PSI was only 1.4 percent at a median follow-up time of 21 months. OssDsign Cranial PSI has regulatory approvals in Europe, USA and Japan.

Approximately 20 percent of surgeries for treating lower back pain are unsuccessful due to the lack of proper fusion between the implant and the spine. When surgeons perform the procedure, they use a combination of metal components to fixate the vertebrae and bone replacement material to stimulate bone growth. OssDsign Catalyst is an innovative synthetic bone graft composed of a proprietary nanocrystalline structure of calcium phosphate. Similar to the body's own bone mineral architecture, OssDsign Catalyst provides a favorable bone biology environment for rapid and reliable bone formation. OssDsign Catalyst is a high margin and scalable product with a large potential in the market for standard procedures, enabling extensive growth. OssDsign Catalyst received FDA clearance in 2020 and was launched in the U.S. in August 2021.

The market

The global market for cranial implants is estimated to USD 2.5 billion with an expected CAGR of 7 percent 2021–2025, whereof the addressable market for OssDsign's implant products is estimated at USD 350 million. The U.S. market for synthetic bone grafts in spinal surgeries is valued at USD 1.8 billion.

Recent progress

- In April 2022, OssDsign included the first patient in the prospective multi-center registry PROPEL for spinal fusion in the US.
- In April 2022, OssDsign's clinical study TOP FUSION was fully enrolled and patient follow-up will continue over 24 months.
- 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.


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

ALMI Invest

Chalmers Ventures

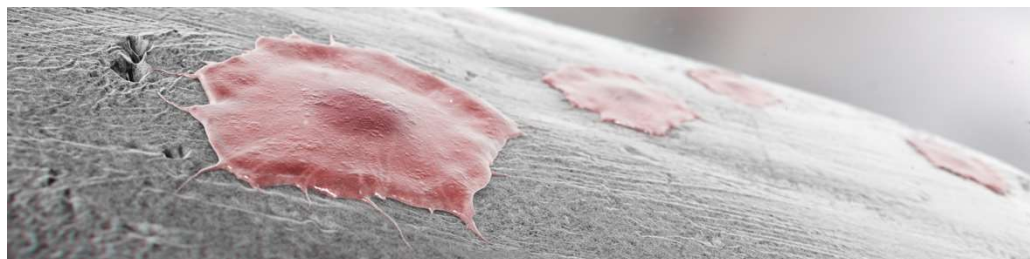
Origin

 Chalmers University of
Technology

More information
 promimic.com

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

Promimic AB



Coatings to enhance the properties of medical implants

Promimic (Gothenburg, Sweden) is a biomaterials company that develops and markets HA^{nano} Surface, an innovative coating for medical implants that strengthens its anchorage in bone tissue. HA^{nano} Surface is a nanometre-thin coating that helps to stimulate the growth of bone cells and thereby improves bone healing. The coating is unique because it can be applied to any implant geometry and material, including porous materials and 3D structures. The technology on which HA^{nano} is based is FDA-approved, which means that a new implant coated with HA^{nano} Surface can receive marketing approval through the 510(k) route and reach a new market quickly. In the past two years, Promimic has gone from five to 26 different implants that are approved for clinical use with the company's coating technology.

Promimic has an established sales operation in the USA and a series of development and commercial partnerships, including one with Sistema de Implante Nacional (S.I.N), a leading provider of dental implants in Brazil, which is commercializing dental implants coated with HA^{nano} Surface. Promimic has gradually strengthened its position in the orthopedic market by entering collaboration with Onkos Surgical and INNOVASIS Inc. The collaboration with Onkos Surgical includes the development and commercialization of products treated with HA^{nano} Surface technology for hip cancer surgery. Innovasis Inc. manufactures and sells 3D-printed spinal implants treated with HA^{nano} Surface in order to improve osseointegration and stimulate new bone formation and bone growth on the implant surface.

Danco Medical and Promimic have jointly formed NPI (Nano Processing Inc.), which offers Promimic's customers a coating service for implants with HA^{nano} Surface.

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%.
- In July 2022, Promimic and Danco Medical formed a joint venture to better serve the US market.

Expected milestones

- In 2023, the company is expected to pursue approximately 18 development projects 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 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Full-year
Condensed income statement					
Change in fair value of shares in portfolio companies	21.2	-23.9	-3.1	-41.1	-76.1
Net profit/loss	23.3	-22.3	-4.7	-51.5	-88.1
Balance sheet information					
Cash and cash equivalents	147.7	273.9	147.7	273.9	189.8
Net asset value (Note 1)	1,242.9	1,284.8	1,242.9	1,284.8	1,249.1
Net debt (Note 1)	-147.7	-273.9	-147.7	-273.9	-189.8
Share information					
Earnings per share, weighted average before dilution (SEK)	0.1	-0.1	0.0	-0.2	-0.3
Earnings per share, weighted average after dilution (SEK)	0.1	-0.1	0.0	-0.2	-0.3
Net asset value per share (SEK) (Note 1)	4.6	4.8	4.6	4.8	4.6
Equity per share (SEK) (Note 1)	4.6	4.7	4.6	4.7	4.6
Share price, last trading day in the reporting period (SEK)	1.7	2.5	1.7	2.5	1.7
Portfolio information					
Investments in portfolio companies	20.5	21.7	45.6	11.2	110.3
Of which investments not affecting cash flow	1.0	0.2	1.6	0.2	1.1
Portfolio companies at fair value through profit or loss	1,026.2	941.7	1,026.2	941.7	984.0

Financial Development for the Investment Entity in 2023

Investments (comparable numbers 2022)

Investments in the portfolio in the second quarter 2023 by external investors and Karolinska Development amounted to SEK 38.1 (116.2) million, whereof 45% (81%) by external investors.

Karolinska Development invested during the second quarter SEK 20.5 (21.7) million, of which SEK 19.5 (21.5) million was cash investments. Investments were made in PharmNovo with SEK 10.1 million, Dilafor with SEK 6.1 million, Modus Therapeutics with SEK 2.8 million, SVF Vaccines with SEK 1.1 million and in Umecline Cognition with SEK 0.4 million. Non-cash investments (accrued interest on loans) amounted to SEK 1.0 (0.2) million.

Investments by external investors in the portfolio companies during the second quarter amounted to SEK 17.0 (94.6) million and were made in PharmNovo with SEK 8.0 million and Dilafor with SEK 9.0 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-Q2 2023
Umecrine Cognition	15.6	16.5	32.1
Dilafor	10.1	15.0	25.1
PharmNovo	10.1	8.0	18.1
Modus Therapeutics	5.6	0.0	5.6
SVF Vaccines	4.3	0.0	4.3
Aprea Therapeutics	0.0	57.8	57.8
Total	45.6	97.3	142.9

Portfolio Fair Value

Fair Value of the portfolio companies owned directly by Karolinska Development had a net increase by SEK 28.5 million during the second quarter 2023. The main reason for the incline in fair value was primarily the upturn in share price in the listed holdings Modus Therapeutics, OssDsign and Promimic together with the investments in PharmNovo, Dilafor, Modus Therapeutics, SVF Vaccines and Umecrine Cognition.

Fair Value of the portfolio companies owned indirectly via KDev Investments increased by SEK 20.5 million during the second 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 and Modus Therapeutics.

Total Fair Value from portfolio companies owned directly by Karolinska Development and indirectly via KDev Investments increased by SEK 49.0 million in the second 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 7.2 million, resulting in Net Portfolio Fair Value increasing by SEK 41.6 million in the second quarter 2023.

SEKm	30 Jun 2023	31 Mar 2023	Q2 2023 vs Q1 2023
Karolinska Development Portfolio Fair Value (unlisted companies)	726.0	707.2	18.8
Karolinska Development Portfolio Fair Value (listed companies)	78.8	69.2	9.7
KDev Investments Portfolio Fair Value	559.3	538.7	20.5
Total Portfolio Fair Value	1,364.1	1,315.1	49.0
Potential distribution to Rosetta Capital of fair value of KDev Investments	-337.9	-330.7	-7.2
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	1,026.2	984.4	41.6

Profit development 2023 (comparable numbers 2022)

During the second quarter 2023, Karolinska Development's revenue amounted to SEK 0.5 (0.6) million and consists primarily of services provided to portfolio companies. For the period January - June 2023, the revenue amounted to SEK 1.1 (1.2) million.

Change in fair value of shares in portfolio companies of in total SEK 21.2 (-23.9) million includes the difference between the change in Net Portfolio Fair Value during the second quarter 2023 with SEK 41.8 million and the investment in portfolio company of SEK 20.5 million. Change in fair value of other financial assets and liabilities amounted to SEK 8.4 (11.0) million and were the consequence of changes in valuation of earn-out deals. For the period January - June 2023, the change in fair value of shares in portfolio companies amounted to SEK -3.1 (41.1) million and the change in fair value of other financial assets amounted to SEK 10.2 (10.9) million.

During the second quarter 2023 other expenses amounted to SEK 2.1 (1.8) million and personnel costs amounted to SEK 6.6 (6.5) million. For the period January – June 2023 other expenses amounted to SEK 3.4 (3.5) million and personnel cost amounted to 13.0 (16.2) million.

The operating profit/loss in the second quarter 2023 amounted to SEK 21.3 million compared to SEK -20.8 million in the second quarter 2022. The operating profit/loss for the period January - June 2023 amounted to -8.6 (-49.1) million.

The financial net during the second quarter 2023 amounted to SEK 2.0 million compared to SEK -1.5 million in the second quarter of 2022. The negative financial net in the second quarter of 2022 was due to unrealized declines in short-term investments. For the period January - June 2023 the financial net amounted to SEK 3.9 (-2.4) million.

The Investment Entity's Net profit/loss amounted to SEK 23.3 (-22.3) million in the second quarter 2023. Net profit/loss for the period January June 2023 amounted to SEK -4.7 (-51.5) million.

Financial position

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

The investment company's equity on 30 June 2023, amounted to SEK 1,236.7 million, compared to SEK 1,213.4 million on 31 March 2023. The increase is a consequence of the profit/loss for the period of SEK 23.3 million.

After the paying of operational costs and investments for the second quarter 2023, cash and cash equivalents (including short term investments) amounted to SEK 147.7 million on 30 June 2023 compared to SEK 273.9 million on 30 June 2022. Net debt (negative net debt/ net cash) amounted to SEK -147.7 million on 30 June 2023 compared to the net debt of SEK -273.9 million on 30 June 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 second quarter 2023, the Parent Company's Net profit/loss amounted to SEK 23.3 (-22.3) million.

The positive result for the second quarter of 2023 led to an increase in equity of SEK 23.3 million from SEK 1,213.4 million as of 31 March 2023 to SEK 1,236.7 million 30 June 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 June 2023 was SEK 1.70, and the market capitalization amounted to SEK 458 million.

The share capital of Karolinska Development on 30 June 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 June 2023 amounted to 270,077,594 shares and 293,074,943 votes.

Ownership

On 30 June 2023, Karolinska Development had 16,232 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%
Avanza Pension	0	4,620,228	1.71%	1.58%
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%
Nordnet Pensionsförsäkringar	0	1,390,433	0.51%	0.47%
SEB Investment Management	0	1,327,692	0.49%	0.45%
Handelsbanken Fonder	0	1,247,365	0.46%	0.43%
Adis Holding	0	1,200,000	0.44%	0.41%
Sum Top 10 Shareholders	2,555,261	179,505,538	67.41%	69.97%
Sum Other Shareholders	0	88,016,795	32.59%	30.03%
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 successive 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 likely 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 continues 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, 25 August 2023

Björn Cochlovius
Chairman

Philip Duong

Anna Lefevre Skjöldebrand

Benjamin Toogood

Theresa Tse

Viktor Drvota
CEO

This report has not been reviewed by the Company's auditors.

Dates for Publication of Financial Information

Interim Report January – September 2023	17 November 2023
Year-End Report January – December 2023	16 February 2023
Annual Report 2023	22 March 2023
Interim Report January – March 2024	26 April 2023

Karolinska Development is required by law to publish the information in this interim report. The information was published on 25 August 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 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Full-year
Revenue		521	621	1,069	1,211	2,300
Change in fair value of shares in portfolio companies	2,3	21,239	-23,911	-3,121	-41,089	-76,083
Change in fair value of other financial assets and liabilities		8,361	11,022	10,179	10,856	20,435
Other expenses		-2,104	-1,843	-3,389	-3,543	-6,798
Personnel costs		-6,550	-6,487	-12,988	-16,183	-26,585
Depreciation of right-of-use assets		-178	-172	-357	-345	-690
Operating profit/loss		21,289	-20,770	-8,607	-49,093	-87,421
Financial net		1,974	-1,523	3,858	-2,428	-701
Profit/loss before tax		23,263	-22,293	-4,749	-51,521	-88,122
Taxes		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		23,263	-22,293	-4,749	-51,521	-88,122

Condensed statement of comprehensive income for the Investment Entity

SEK 000	Note	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Full-year
Net profit/loss for the period		23,263	-22,293	-4,749	-51,521	-88,122
Total comprehensive income/loss for the period		23,263	-22,293	-4,749	-51,521	-88,122

Earnings per share for the Investment Entity

SEK	Note	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Full-year
Earnings per share, weighted average before dilution		0.09	-0.08	-0.02	-0.21	-0.34
Number of shares, weighted average before dilution		269,833,309	269,833,309	269,833,309	244,795,823	257,417,460
Earnings per share, weighted average after dilution		0.09	-0.08	-0.02	-0.21	-0.34
Number of shares, weighted average after dilution		269,833,309	269,833,309	269,833,309	244,795,823	257,417,460

Condensed balance sheet for the Investment Entity

SEK 000	Note	30 Jun 2023	30 Jun 2022	31 Dec 2022
ASSETS				
Tangible assets				
Right-of-use assets		357	1,035	690
Financial assets				
Shares in portfolio companies at fair value through profit or loss	2,3	1,026,151	941,702	983,995
Other financial assets	4	58,411	69,549	59,537
Total non-current assets		1,084,919	1,012,286	1,044,222
Current assets				
Receivables from portfolio companies		222	218	211
Other financial assets	4	10,647	0	15,970
Other current receivables		1,041	1,041	673
Prepaid expenses and accrued income		1,869	913	750
Short-term investments, at fair value through profit or loss		29,731	88,032	58,742
Cash and cash equivalents		117,985	185,895	131,078
Total current assets		161,495	276,099	207,424
TOTAL ASSETS		1,246,414	1,288,385	1,251,646
EQUITY AND LIABILITIES				
Total equity		1,236,689	1,278,039	1,241,438
Current liabilities				
Other financial liabilities		70	409	191
Accounts payable		904	778	439
Liability to make lease payment		370	1,091	753
Other current liabilities		1,393	1,446	654
Accrued expenses and prepaid income		6,988	6,622	8,171
Total current liabilities		9,725	10,346	10,208
Total liabilities		9,725	10,346	10,208
TOTAL EQUITY AND LIABILITIES		1,246,414	1,288,385	1,251,646

Condensed statement of changes in the Investment Entity's equity

SEK 000	Not	30 Jun 2023	30 Jun 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		-1,501,915	-1,460,565	-1,497,166
Closing balance, equity		1,236,689	1,278,039	1,241,438

Condensed statement of cash flows for the Investment Entity

SEK 000	Note	2023 Jan-Jun	2022 Jan-Jun	2022 Full-year
Operating activities				
Operating profit/loss		-8,607	-49,093	-87,421
Adjustments for items not affecting cash flow				
Depreciation		357	345	690
Change in fair value		-7,058	30,233	55,648
Other items		451	-492	-206
Cash flow from operating activities before changes in working capital and operating investments				
		-14,857	-19,007	-31,289
Cash flow from changes in working capital				
Increase (-)/Decrease (+) in operating receivables		-726	-307	416
Increase (+)/Decrease (-) in operating liabilities		21	-2,079	-1,661
Cash flow from operating activities				
		-15,562	-21,393	-32,534
Investment activities				
Part payment from earn-out deal		16,833	1,956	5,358
Acquisitions of shares in portfolio companies		-44,049	-32,445	-109,166
Proceeds from sale of short-term investments		30,104	-	0
Acquisitions of short-term investments		-	-40,000	-10,000
Cash flow from investment activities				
		2,888	-70,489	-113,808
Financing activities				
Cash from rights issue		-	254,911	254,911
Prospectus costs		-	-19,175	-19,175
Amortization of lease liabilities		-419	-357	-714
Cash flow from financing activities				
		-419	235,379	235,022
Cash flow for the period				
		-13,093	143,497	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				
		117,985	185,895	131,078

Condensed income statement for the Parent Company

SEK 000	Note	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Full-year
Revenue		521	621	1,069	1,211	2,300
Change in fair value of shares in portfolio companies	2.3	21,239	-23,911	-3,121	-41,089	-76,083
Change in fair value of other financial assets and liabilities		8,361	11,023	10,179	10,856	20,435
Other expenses		-2,280	-2,022	-3,808	-3,900	-7,513
Personnel costs		-6,550	-6,487	-12,988	-16,183	-26,585
Operating profit/loss		21,291	-20,776	-8,669	-49,105	-87,446
Financial net		1,978	-1,510	3,870	-2,402	-655
Profit/loss before tax		23,269	-22,286	-4,799	-51,507	-88,101
Tax		-	-	-	-	-
NET PROFIT/LOSS FOR THE PERIOD		23,269	-22,286	-4,799	-51,507	-88,101

Condensed statement of comprehensive income for the Parent Company

SEK 000	Note	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Full-year
Net profit/loss for the period		23,269	-22,286	-4,799	-51,507	-88,101
Total comprehensive income/loss for the period		23,269	-22,286	-4,799	-51,507	-88,101

Condensed balance sheet for the Parent Company

SEK 000	Note	30 Jun 2023	30 Jun 2022	31 Dec 2022
ASSETS				
Financial non-current assets				
Shares in portfolio companies at fair value through profit or loss	2,3	1,026,151	941,702	983,995
Other financial assets	4	58,411	69,549	59,537
Total non-current assets		1,084,562	1,011,251	1,043,532
Current assets				
Receivables from portfolio companies		222	218	211
Other financial assets	4	10,647	-	15,970
Other current receivables		1,041	1,041	673
Prepaid expenses and accrued income		1,869	913	750
Short-term investments at fair value through profit or loss		29,731	88,032	58,742
Cash and cash equivalents		117,985	185,895	131,078
Total current assets		161,495	276,099	207,424
TOTAL ASSETS		1,246,057	1,287,350	1,250,956
EQUITY AND LIABILITIES				
Total equity		1,236,702	1,278,095	1,241,501
Current liabilities				
Other financial liabilities		70	409	191
Accounts payable		905	778	439
Other current liabilities		1,393	1,446	654
Accrued expenses and prepaid income		6,987	6,622	8,171
Total current liabilities		9,355	9,255	9,455
Total liabilities		9,355	9,255	9,455
TOTAL EQUITY AND LIABILITIES		1,246,057	1,287,350	1,250,956

Condensed statement of changes in equity for the Parent Company

SEK 000	Not	30 Jun 2023	30 Jun 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		-1,501,902	-1,460,509	-1,497,103
Closing balance, equity		1,236,702	1,278,095	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 – June 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 147.7 million).

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

Net asset value as of 30 June 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	34,391	0.13	2.8%
OssDesign	7,381,093	37,043	0.14	3.0%
Promimic	312,500	7,406	0.03	0.6%
Total listed assets		78,840	0.29	6.3%
Unlisted assets				
AnaCardio		45,139	0.17	3.6%
Dilafor		34,123	0.13	2.7%
Henlez		5,884	0.02	0.5%
PharmNovo		30,083	0.11	2.4%
Svenska Vaccinfabriken Produktion		17,123	0.06	1.4%
Umecrine Cognition		584,723	2.17	47.0%
KCIF Co-Investment Fund KB ¹		8,878	0.03	0.7%
KDev Investments ¹		221,358	0.82	17.8%
Total unlisted assets		947,311	3.51	76.2%
Net of other liabilities and debts²		216,704	0.80	17.4%
Total net asset value		1,242,855	4.61	100.0%

¹The company has both listed and unlisted assets.

² Includes SEK 147.7 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-Jun	2022 Jan-Jun	2022 Full-year
Result level 1			
Listed companies, realized	-	-	-
Listed companies, unrealized	-2,254	-28,112	-22,408
Total level 1	-2,254	-28,112	-22,408
Result level 3			
Unlisted companies, realized	817	-438	751
Unlisted companies, unrealized	-1,684	-12,539	-54,426
Total level 3	-867	-12,977	-53,675
Total	-3,121	-41,089	-76,083

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

SEK 000	2023-06-30	2022-06-30	2022-12-31
Accumulated acquisition cost			
At the beginning of the year	983,995	950,170	950,170
Investments during the year	45,599	32,820	110,294
Sales during the year	-325	-199	-386
Changes in fair value in net profit/loss for the year	-3,121	-41,089	-76,083
Closing balance	1,026,151	941,702	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 June 2023

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	78,841	-	947,310	1,026,151
Other financial assets	-	-	69,058	69,058
Cash and cash equivalents and short-term investments	147,716	-	-	147,716
Total	226,557	-	1,016,368	1,242,925
Financial liabilities				
Other financial liabilities	-	-	70	70
Total	-	-	70	70

Fair value as of 30 June 2022

SEK 000	Level 1	Level 2	Level 3	Total
Financial assets				
Shares in portfolio companies, at fair value through profit or loss	50 804	-	890 898	941 702
Other financial assets	-	-	69 549	69 549
Cash, cash equivalents and short-term investments	273 927	-	-	273 927
Total	324 731	0	960 447	1 285 178
Financial liabilities				
Other financial liabilities	-	-	409	409
Total	-	0	409	409

Fair value (level 3) as of 30 June 2023

SEK 000	Shares in portfolio companies	Other financial assets	Other financial liabilities
At beginning of the year	908,461	75,507	191
Acquisitions	40,035	-	-
Compensations	-326	-16,508	-
Gains and losses recognized through profit or loss	-867	10,059	-121
Closing balance 30 June 2023	947,310	69,058	70
Realized gains and losses for the period included in profit or loss	842	16,508	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	-1,709	-6,449	121

Fair value (level 3) as of 30 June 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	27,822	-	-
Compensations	-197	-2,082	-324
Gains and losses recognized through profit or loss	-12,977	9,832	-1,023
Closing balance 30 June 2023	890,898	69,549	409
Realized gains and losses for the period included in profit or loss	-438	-	-
Unrealized gains and losses in profit or loss for the period included in profit or loss	-12,539	9,832	1,023

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 June 2023

SEK 000	Ownership	Market value	Valuation model ¹
AnaCardio	20.7%	45,139	Last post money
Dilafor	1.8%	34,123	Last post money
Henlez	13.5%	5,884	Last post money
PharmNovo	13.1%	30,083	Last post money
SVF Vaccines	34.8%	17,123	Last post money
Umecrine Cognition	72.6%	584,353	External valuation ²
KCIF Co-Investment Fund KB	26.0%	8,878	A combination of share price listed company and fair value of financial asset ³
KDev Investments	90.1%	221,358	A combination of last post money and share price listed company ⁴
Total level 3		947,310	

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 337,9 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 Jun 2023	30 Jun 2022	31 Dec 2022
Karolinska Development Portfolio Fair Value (unlisted companies)	725,954	679,544	704,443
Karolinska Development Portfolio Fair Value (listed companies)	78,841	50,804	75,534
KDev Investments Portfolio Fair Value	559,271	543,832	532,547
Total Portfolio Fair Value	1,364,066	1,274,180	1,312,524
Potential distribution to Rosetta Capital of fair value of KDev Investments	-337,915	-332,478	-328,529
Net Portfolio Fair Value (after potential distribution to Rosetta Capital)	1,026,151	941,702	983,995

NOTE 4 Other financial assets

SEK 000	2023-06-30	2022-06-30	2021-12-31
Other financial assets, non-current			
Earn-out agreement Forendo Pharma	58,411	69,549	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	10,647	-	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 June 2023, to SEK 69.1 million, whereof SEK 10.6 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 Jun 2023	30 Jun 2022	31 Dec 2022
Pledge assets			
Contingent liabilities			
Investment agreement in portfolio company	13,594	-	7,580
Summa	13,594	-	7,580