



EDISON

BRILLIANT KNOWLEDGE

HEALTHCARE INSIGHT

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Soo Romanoff: Head of content, healthcare

Soo has nearly 20 years of healthcare and technology capital market and advisory experience. She started her career in equity research covering internet infrastructure and telecommunications companies at UBS Warburg, where she helped companies conduct initial public offerings and secondary listings. Since then, Soo has advised on over several hundred healthcare acquisitions, mergers and partnerships for companies at every stage of the business cycle at Huron Consulting Group and Houlihan Lokey. Soo most recently focused on healthcare corporate development and strategy at Walgreens.

Pooya Hemami

Pooya joined Edison's healthcare team in November 2012 and took on additional duties as a supervisory analyst in early 2019. He is a licensed optometrist with several years of clinical practice and regulatory experience. Prior to joining Edison, he covered the Canadian healthcare sector as a research analyst at Desjardins Capital Markets. Pooya holds a Doctor of Optometry degree from the University of Montreal, and an MBA (finance concentration) from McGill University. He received his CFA charter in 2011.

Harry Shrives

Harry joined Edison's healthcare team in November 2021. Before this, he worked as a medicinal chemist at GSK, gaining experience in a range of areas including small molecule drug discovery, biopharmaceutical research and reaction automation. Harry holds a PhD in organic chemistry from the University of Manchester.

Jyoti Prakash

Jyoti joined Edison's healthcare team in December 2020. She has over 12 years' experience in equities including more than seven years as a sell-side analyst covering European healthcare stocks. Prior to joining Edison, Jyoti covered the European mid-cap healthcare sector for AlphaValue, a France-based independent equity research provider. She holds an MBA (finance concentration) and is a CFA charter holder.

Adam McCarter

Adam joined Edison's Healthcare team in June 2022. Before this, he worked as a medicinal chemist at GSK, actively contributing and gaining exposure to early to late-stage drug discovery programmes, and at Johnson Matthey, working within its downstream pharmaceutical development and manufacturing sector. Adam holds an MChem in chemistry with drug discovery and a PhD in organic chemistry from the University of Strathclyde.

Nidhi Singh

Nidhi joined Edison's healthcare team in January 2022. She has provided fully fledged support to sell-side equity research firms for over eight years, across multiple sectors. Nidhi has a postgraduate degree in management (majoring in finance) and a graduate degree in commerce.

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Prices at 6 February 2023

Published 9 February 2023

Welcome to the February edition of the Edison Healthcare Insight. In this edition we have profiled 34 of our healthcare companies under coverage. From March, we will be combining the healthcare and regular Edison Insight books, which we will publish on the last Thursday of each month.

Readers wishing more detail should visit our website, where reports are freely available for download (www.edisongroup.com). All profit and earnings figures shown are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

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We welcome any [comments/suggestions](#) our readers may have.

Neil Shah

Director of research

Company profiles

Prices at 6 February 2023

US\$/£ exchange rate: 0.8153

€/£ exchange rate: 0.8831

A\$/£ exchange rate: 0.5701

NZ\$/£ exchange rate: 0.5235

PLN/£ exchange rate: 0.1876

SEK/£ exchange rate: 0.0785

NOK/£ exchange rate: 0.0818

CHF/£ exchange rate: 0.8841

DKK/£ exchange rate: 0.1187

Sector: Pharma & healthcare

Price: A\$0.10
 Market cap: A\$177m
 Market: ASX

Share price graph (A\$)



Company description

Actinogen Medical is an ASX-listed Australian biotech developing its lead asset Xanamem, a specific and selective 11beta-HSD1 inhibitor designed to treat CI, which occurs in chronic neurodegenerative and neuropsychiatric diseases.

Price performance

%	1m	3m	12m
Actual	2.1	(24.6)	(18.3)
Relative*	(3.7)	(31.0)	(21.8)

* % Relative to local index

Analyst

Pooya Hemami

Actinogen Medical (ACW)

INVESTMENT SUMMARY

Actinogen Medical's lead asset, Xanamem®, is a once-daily oral selective 11beta-HSD1 inhibitor, designed to cross the blood brain barrier and target excess brain cortisol, which has been associated with cognitive impairment (CI). The company is targeting two CI indications: for patients with mild CI in the early stages of Alzheimer's disease (AD), and for patients with major depressive disorder (MDD). Positive clinical results in healthy adults demonstrated the drug's initial efficacy, and a recent analysis of biomarker-positive patients using newly available plasma samples from the previous XanADu study in mild AD also showed clinical activity. Having received the requisite FDA authorisations, Actinogen plans to start its Phase IIb XanaMIA trial in patients with biomarker-confirmed early AD in H1 CY23. It started the XanaCIDD proof-of-concept Phase II trial in MDD in Q422 and plans to report top line data in late 2023 or early 2024.

INDUSTRY OUTLOOK

The unmet need in chronic neurocognitive disorders is tremendous due to the limited effectiveness of available treatment options. The Phase IIb portion of the XanaMIA trial will be key for validating the encouraging Xanamem data shown to date. The XanaCIDD study may also validate the drug's potential for treating CI related to MDD.

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2021	2.0	(3.5)	(3.3)	(0.236)	N/A	N/A
2022	3.6	(9.1)	(7.9)	(0.460)	N/A	N/A
2023e	3.6	(8.2)	(8.7)	(0.482)	N/A	N/A
2024e	3.3	(37.4)	(38.7)	(2.153)	N/A	N/A

Sector: Pharma & healthcare

Price: NZ\$3.78
 Market cap: NZ\$396m
 Market: ASX, New Zealand SE

Share price graph (NZ\$)



Company description

AFT Pharmaceuticals is a specialty pharmaceutical company that operates primarily in Australasia but has product distribution agreements across the globe. The company's product portfolio includes prescription and over-the-counter (OTC) drugs to treat a range of conditions and a proprietary nebuliser.

Price performance

%	1m	3m	12m
Actual	1.6	(0.5)	(7.8)
Relative*	(3.2)	(8.0)	(4.4)

* % Relative to local index

Analyst

Soo Romanoff

AFT Pharmaceuticals (AFT)

INVESTMENT SUMMARY

AFT Pharmaceuticals is a profitable New Zealand-based specialty pharmaceutical company that sells 130 proprietary branded and generic products through its own sales force in New Zealand and Australia, with offices in SE Asia and Europe to handle its growing export business. In recently announced strategic priorities for FY23, Maxigesic remains the main commercial driver with plans to launch new variants internationally, including Maxigesic IV in the US, which was unexpectedly delayed due to FDA observations on product packaging. The R&D pipeline remains full, with multiple projects under development, including the NanoSURF nasal nebuliser, targeting FDA submission by the end of CY24. Importantly, despite its revised guidance in November 2022, AFT remains on track to pay a maiden dividend at the end of FY23.

INDUSTRY OUTLOOK

AFT is a multi-product company targeting pharmacy prescription, OTC and hospital markets. Data for Maxigesic offer it a competitive advantage in a fragmented industry.

Y/E Mar	Revenue (NZ\$m)	EBITDA (NZ\$m)	PBT (NZ\$m)	EPS (c)	P/E (x)	P/CF (x)
2021	113.1	11.8	8.2	7.1	53.2	N/A
2022	130.3	21.4	18.9	19.2	19.7	32.2
2023e	152.2	21.3	17.6	13.4	28.2	21.0
2024e	189.7	35.0	31.3	21.7	17.4	46.4

Sector: Pharma & healthcare

Price: A\$0.03
 Market cap: A\$23m
 Market: ASX

Share price graph (A\$)



Company description

Arovella Therapeutics is a biotech company focused on oncology through its iNKT cell therapy platform. In 2021 it acquired a CAR-iNKT programme for haematological malignancies and a DKK1 antibody that has potential in multiple myeloma and solid tumours. In October 2022 it announced that it would cease further development work on its legacy platform, OroMist.

Price performance

%	1m	3m	12m
Actual	40.9	19.2	(26.2)
Relative*	33.0	9.1	(29.3)

* % Relative to local index

Analyst

Soo Romanoff

Arovella Therapeutics (ALA)

INVESTMENT SUMMARY

Arovella Therapeutics is focused on the immunoncology space (in particular cell therapies) following the in-licensing in CY21 of two chimeric antigen receptor (CAR) based immunotherapies (both in preclinical stage). The first was an invariant natural killer T (iNKT) cell therapy platform in-licensed from Imperial College London in July 2021. The platform can be combined with CARs to target blood cancers, with a potential of being an allogeneic 'off-the-shelf' therapy. This was followed by the in-licensing of a novel monoclonal antibody targeting a Dickkopf-1 (DKK1) peptide from MD Anderson Cancer Center in December 2021. Arovella plans to combine the DKK1 targeting technology with the iNKT cell therapy platform. Post a strategic collaboration with Imugene for the potential combination of the CAR19-iNKT programme (ALA-101) with Imugene's onCARlytics (CF33-CD19) platform and an anticipated European patent for the iNKT platform, Arovella ceased all R&D activities related to its legacy OroMist platform.

INDUSTRY OUTLOOK

Arovella is targeting very large markets including insomnia (through ZolpiMist) and various cancers (through the CAR-iNKT programme and anagrelide).

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (c)	P/E (x)	P/CF (x)
2021	0.3	(3.1)	(3.4)	(1.15)	N/A	N/A
2022	0.3	(7.0)	(7.4)	(1.42)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A
2024e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: CHF48.65
 Market cap: CHF632m
 Market: SIX Swiss Exchange

Share price graph (CHF)



Company description

Basilea Pharmaceutica is focused on treating infectious diseases. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). The company plans to file for US approval for Zevtera.

Price performance

%	1m	3m	12m
Actual	1.2	4.4	14.9
Relative*	0.0	(0.2)	23.6

* % Relative to local index

Analyst

Soo Romanoff

Basilea Pharmaceutica (BSLN)

INVESTMENT SUMMARY

Basilea's strategic refocusing on its core anti-infective business in 2022, combined with continued strong global sales growth of its anti-infective assets (Cresemba and Zevtera), have led to an upward revision in FY22 guidance from management. We now expect the company to report an operating profit of c CHF18m (up from the previously guided CHF10–15m loss) and a net profit in FY22. Basilea secured a CHF75m senior secured loan from Athrium Capital Management (a US-based asset management company), which along with cash on books has been used to repay the outstanding convertible bonds due in December 2022. Positive results from the ERADICATE study of Zevtera in bloodstream infections complete the data package needed for NDA submission, paving the way for entry to the potentially lucrative US antibiotic market.

INDUSTRY OUTLOOK

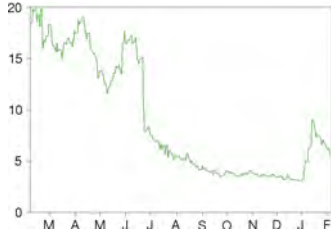
There is an ever-increasing need for therapeutic agents that are efficacious against drug-resistant strains of bacteria (eg MRSA) or fungi. Hence the opportunities for Cresemba and Zevtera could be significant.

Y/E Dec	Revenue (CHFm)	EBITDA (CHFm)	PBT (CHFm)	EPS (CHFc)	P/E (x)	P/CF (x)
2020	127.6	(7.0)	(29.6)	(288.45)	N/A	N/A
2021	148.1	1.9	(6.6)	(56.90)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: SEK5.51
 Market cap: SEK920m
 Market: Nasdaq Nordic

Share price graph (SEK)



Company description

Cantargia is a clinical-stage biotechnology company based in Sweden. It is developing two assets against IL1RAP, CAN04 and CAN10. CAN04 is being studied in several solid tumours with a main focus on NSCLC and pancreatic cancer. The most advanced trial is in Phase II.

Price performance

%	1m	3m	12m
Actual	11.1	48.9	(65.4)
Relative*	3.9	29.8	(63.3)

* % Relative to local index

Analyst

Soo Romanoff

Cantargia (CANT)

INVESTMENT SUMMARY

Cantargia is developing antibodies against IL1RAP. Data from its Phase IIa CANFOUR trial, investigating nadunolimab in first-line non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC), support the hypothesis that nadunolimab has a synergistic benefit with chemotherapy. At the ASCO Annual Meeting in June, Cantargia presented promising interim results for nadunolimab from a Phase I/IIa in PDAC and a Phase IIa trial in NSCLC. The company is preparing for the Phase II/III trial in metastatic PDAC in collaboration with PanCAN. A second programme, CAN10, is being developed for the treatment of myocarditis and systemic sclerosis. Recently reported GLP toxicity and preclinical data for CAN10 support the start of Phase I clinical trials, which the company intends to initiate in the first half of 2023. Cantargia had a cash and short-term investment position of SEK496.5m at end-Q322.

INDUSTRY OUTLOOK

Increasing understanding of inflammation in malignant processes now includes findings that cytokines are not only produced by the immune cells, but that cancer itself can produce certain cytokines and the associated receptors to escape from the immune response. Therefore, cytokines represent a potentially promising class of targets in oncology.

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.0	(170.7)	(173.1)	(193.65)	N/A	N/A
2021	0.0	(366.8)	(366.5)	(365.80)	N/A	N/A
2022e	0.0	(330.8)	(322.8)	(240.98)	N/A	N/A
2023e	0.0	(294.0)	(296.7)	(177.15)	N/A	N/A

Sector: Pharma & healthcare

Price: €10.70
 Market cap: €242m
 Market: Euronext Paris

Share price graph (€)



Company description

Carmat is developing a biocompatible, artificial heart to satisfy the lack of donor hearts available for terminal heart failure patients. Management is taking corrective actions with recent quality challenges.

Price performance

%	1m	3m	12m
Actual	0.3	(15.8)	(17.1)
Relative*	(3.8)	(24.3)	(18.7)

* % Relative to local index

Analyst

Pooya Hemami

Carmat (ALCAR)

INVESTMENT SUMMARY

Carmat announced in November 2022 that it has resumed implantations of its Aeson physiologic heart replacement therapy in a commercial setting, and it expects to continue resuming implant sales in Europe at a gradual pace as it replenishes inventory. The company had implemented controls to improve Aeson quality and safety, in response to a voluntary suspension of Aeson implantations in Q421. Carmat recorded €2.3m in FY21 revenue and is guiding for €10–13m in FY23 sales. After raising €40.5m in gross proceeds in April 2022 and €31m in December 2022, the company expects its cash runway to fund operations until July 2023.

INDUSTRY OUTLOOK

The Aeson artificial heart is being developed as a permanent replacement or destination therapy for chronic biventricular heart failure or acute myocardial infarction patients who do not have access to a human donor heart. Carmat anticipates potential break-even by FY27 and plans to expand its annual manufacturing capacity to 500 units by 2024 and 1,000 units by 2027.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	0.0	N/A	(38.7)	(285.32)	N/A	N/A
2021	2.2	N/A	(61.9)	(402.00)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: US\$0.96
 Market cap: US\$15m
 Market: Nasdaq

Share price graph (US\$)



Company description

Context Therapeutics is a clinical-stage biopharma company developing therapeutics for solid tumors, with a primary focus on female cancers. ONA-XR is being evaluated in three Phase II and one Phase Ib/II clinical trial in hormone-driven breast, endometrial and ovarian cancer. CLDN6xCD3 is a bi-specific monoclonal antibody.

Price performance

%	1m	3m	12m
Actual	23.1	(17.9)	(56.9)
Relative*	16.6	(24.7)	(52.9)

* % Relative to local index

Analyst

Soo Romanoff

Context Therapeutics (CNTX)

INVESTMENT SUMMARY

Context Therapeutics is a clinical-stage biopharmaceutical company committed to advancing medicines for female cancers. Its pipeline includes small molecule and bispecific antibody drug candidates that target cancer signaling pathways. Onapristone extended release (ONA-XR), a novel, first-in-class potent and selective progesterone receptor antagonist, is currently in three Phase II clinical trials and one Phase Ib/II clinical trial in hormone-driven breast, ovarian and endometrial cancers. In January 2023 the US FDA approved Stemline Therapeutics' elacestrant as second-line treatment for ER+/HER2-, an encouraging development for Context's Phase Ib ELONA trial for ONA-XR in combination with elacestrant. Context is also developing CTIM-76, a selective Claudin 6 (CLDN6) x CD3 bispecific antibody for CLDN6 positive tumors, currently in preclinical development.

INDUSTRY OUTLOOK

According to the American Cancer Society, there were an estimated 284,200 breast cancer cases, 66,570 endometrial cancer cases and 21,410 ovarian cancer cases in the United States in 2021 (more than 70% of these are hormone-driven). Long-term survival rates remain low (c 30% for HR+/HER2- mBC) despite recent advances, highlighting the high unmet need in the metastatic space.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	0.0	(2.6)	(3.2)	(928.15)	N/A	N/A
2021	0.0	(10.5)	(10.6)	(373.72)	N/A	N/A
2022e	0.0	(18.1)	(18.1)	(113.20)	N/A	N/A
2023e	0.0	(27.4)	(27.4)	(171.71)	N/A	N/A

Sector: Pharma & healthcare

Price: 19.6p
 Market cap: £36m
 Market: LSE AIM

Share price graph (p)



Company description

UK-based Creo Medical focuses on the development and commercialisation of minimally invasive electrosurgical devices. Its six products in the flagship CROMA platform have all been CE marked, with five cleared by the FDA. In 2020 Creo acquired Albyn Medical, which provides it with profitable products and a direct salesforce in Europe.

Price performance

%	1m	3m	12m
Actual	(19.9)	(54.9)	(88.6)
Relative*	(21.6)	(58.1)	(88.8)

* % Relative to local index

Analyst

Soo Romanoff

Creo Medical (CREO)

INVESTMENT SUMMARY

Creo Medical is developing and commercialising minimally invasive endoscopic electrosurgical devices. Its CROMA advanced energy platform delivers a combination of advanced bi-polar radio frequency (RF) and microwave energy for the purpose of dissection, resection, ablation and haemostasis of diseased tissue. Its initial focus is on gastrointestinal (GI) tract procedures expanding into soft tissue (such as pancreas and liver) and pulmonology. It has six advanced energy products CE marked with five cleared by the FDA. Its first commercially available device, Speedboat Inject, is used across the globe, with a slimmer version launched in November 2022 opening up the potential to be used in more procedures. In its FY22 trading update Creo reported 7% y-o-y revenue growth to c £27m, attributed to the 8x increase in revenue from sales of its core technology and licensing revenue. In 2022, Creo announced agreements with two surgical robotic partners.

INDUSTRY OUTLOOK

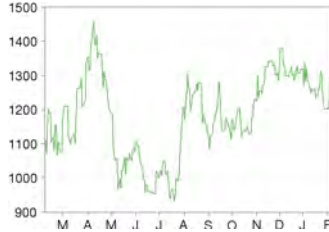
Creo's products are in a large and lucrative market. Conmed estimates the GI endoscopic technologies market alone is approximately \$3.0–3.2bn with the RF energy based surgical device market at \$2.7–2.9bn pa. Entering the robotics and laparoscopic markets further increases the scale of opportunity open to Creo.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2020	9.4	(21.4)	(23.0)	(12.75)	N/A	N/A
2021	25.2	(26.7)	(29.7)	(14.58)	N/A	N/A
2022e	27.1	(23.4)	(26.4)	(12.36)	N/A	N/A
2023e	31.0	(19.0)	(21.8)	(10.22)	N/A	N/A

Sector: Pharma & healthcare

Price: 1252.0p
 Market cap: £630m
 Market: LSE AIM

Share price graph (p)



Company description

Ergomed is a global full-service CRO business with a core focus on the US and EU. It provides Phase I-III clinical services in addition to post-marketing pharmacovigilance (Phase IV) services and is predominantly focused on oncology, orphan drugs, rare diseases and pharmacovigilance.

Price performance

%	1m	3m	12m
Actual	(2.5)	0.6	13.3
Relative*	(4.6)	(6.4)	10.8

* % Relative to local index

Analyst

Soo Romanoff

Ergomed (ERGO)

INVESTMENT SUMMARY

Ergomed's FY22 trading update re-emphasised its robust business model and resilient growth despite the challenging macro environment. Revenue grew 22.5% y-o-y to £145.3m, underpinned by sustained demand for both the clinical research organisation and pharmacovigilance segments. The order book, a leading indicator of near-term sales potential, remained robust at £295m (up 23.1% over FY21). Ergomed recently acquired ADAMAS Consulting Group. ADAMAS is a UK-based quality assurance services provider and will diversify revenue sources (its offerings do not overlap with Ergomed's). The integration of the ADAMAS business also supported both segments' growth during the year. With a £19m cash balance at end-FY22 and £80m in undrawn debt facilities, the company remains well capitalised to fund future growth.

INDUSTRY OUTLOOK

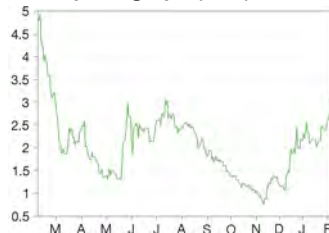
Innovation in healthcare is driving sales and growth in the number of clinical trials being initiated, as pharmaceutical and biotechnology companies continue to invest substantially. Tight operational control and execution will enable Ergomed to drive market share in high-growth orphan drug trials as well as in larger indications.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (fd) (p)	P/E (x)	P/CF (x)
2020	86.4	19.4	14.4	22.8	54.9	33.5
2021	118.6	25.4	21.6	39.6	31.6	32.5
2022e	142.1	28.1	24.4	39.4	31.8	35.3
2023e	158.3	31.4	27.5	43.8	28.6	28.1

Sector: Pharma & healthcare

Price: US\$3.12
 Market cap: US\$43m
 Market: Nasdaq

Share price graph (US\$)



Company description

Immix Biopharma is developing a new class of tissue-specific therapeutics targeting oncology and immune-dysregulated disease. In Q422, IMX-110 is due to begin a Phase IIa study for STS and a Phase Ib trial in advanced solid tumours in combination with the ICI tislelizumab. Immix also has a preclinical pipeline based on the TSTx technology.

Price performance

%	1m	3m	12m
Actual	33.3	242.9	(28.6)
Relative*	26.3	214.5	(21.8)

* % Relative to local index

Analyst

Soo Romanoff

Immix Biopharma (IMMX)

INVESTMENT SUMMARY

Immix Biopharma is a clinical-stage biopharmaceutical company focused on the development of its SMARxT tissue-specific platform producing tissue-specific therapeutics (TSTx). Its lead clinical asset, IMX-110, is being investigated for the treatment of soft tissue sarcoma (STS), where interim results from its Phase Ib trial have, so far, demonstrated positive safety and efficacy profiles. Management intends to initiate a Phase IIa of the study in first-line STS in 2023. We also expect data from a Phase Ib study of IMX-110 in combination with tislelizumab (an anti-PD-1 antibody) to begin being reported in Q123. To support this trial, Immix has entered a supply agreement with BeiGene/Novartis. In December 2022 Immix Biopharma announced the in-licensing of NXC-201, a novel CAR-T therapy, which has shown high response rates in multiple myeloma and AL amyloidosis.

INDUSTRY OUTLOOK

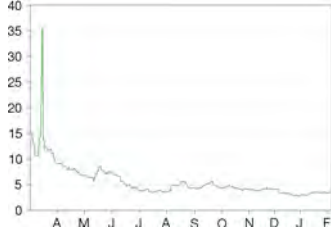
With IMX-110 Immix is targeting the STS market, a rare cancer with c 13,000–16,000 new cases reported in the United States each year and limited safe and effective treatment options. IMX-110's combination study may further expand the drug's offering into new indications.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2020	0.0	(0.5)	(0.6)	(50.88)	N/A	N/A
2021	0.0	(1.4)	(1.3)	(35.91)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: US\$3.20
 Market cap: US\$195m
 Market: Nasdaq

Share price graph (US\$)



Company description

Incannex Healthcare is an Australian dual-listed biotech company focused on developing medicinal cannabis pharmaceutical products and psychedelic medicine therapies. These therapies are being designed to target indications with unmet need, including obstructive sleep apnea, generalized anxiety disorder, trauma and inflammatory conditions.

Price performance

%	1m	3m	12m
Actual	12.7	(18.5)	N/A
Relative*	6.8	(25.2)	N/A

* % Relative to local index

Analyst

Soo Romanoff

Incannex Healthcare (IXHL)

INVESTMENT SUMMARY

Incannex Healthcare specializes in the development of treatments for chronic conditions through a unique approach. Specifically, the company is investigating the use of cannabinoids and psychedelics, leveraging its synergistic combination intellectual property (IP). Most recently, it has achieved proof-of-concept in Australia for IHL-42X, its lead asset for the treatment of obstructive sleep apnea. Incannex intends to file an investigational new drug application with the FDA (in CY Q123) following positive Phase II results from its Australian clinical trial data. It is also progressing development of its (Australian) Phase II clinical asset, psilocybin in combination with psychotherapy in generalized anxiety disorder with mid-trial readouts expected in Q123. ILH-675A is in (Australian) Phase I trials for the treatment of various inflammatory disorders.

INDUSTRY OUTLOOK

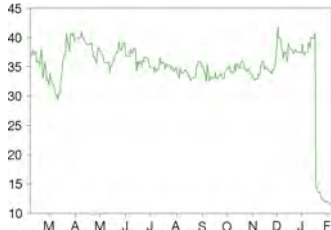
Management's strategy to pursue synergistic combination patent filings of its assets has the potential to create extensive protection within the cannabinoid treatment market. The IP position for the combinations will be further supported by method of use and formulation patents. Combination patents could therefore be a significant source of value for the company should approval be granted.

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2021	2.0	N/A	(8.2)	(0.83)	N/A	N/A
2022	0.8	N/A	(14.9)	(1.25)	N/A	N/A
2023e	0.1	N/A	(20.6)	(1.35)	N/A	N/A
2024e	0.1	N/A	(33.4)	(2.12)	N/A	N/A

Sector: Pharma & healthcare

Price: SEK11.14
 Market cap: SEK577m
 Market: Nasdaq Nordic

Share price graph (SEK)



Company description

Based in Sweden, IRLAB Therapeutics is focused on developing novel drugs for the treatment of neurodegenerative diseases utilising its ISP technology platform. Its two lead assets are in late-stage clinical trials for the symptomatic treatment of PD: mesdopetam (D3 antagonist) and pirepemat (PFC enhancer).

Price performance

%	1m	3m	12m
Actual	(70.2)	(65.9)	(70.2)
Relative*	(72.2)	(70.3)	(68.4)

* % Relative to local index

Analyst

Soo Romanoff

IRLAB Therapeutics (IRLABA)

INVESTMENT SUMMARY

IRLAB Therapeutics is focused on developing novel, potential first-in-class treatments for the symptoms of Parkinson's disease (PD) and other central nervous system (CNS) disorders. Its proprietary ISP discovery platform has been validated by the progress of its two lead assets, pirepemat and mesdopetam, which have novel mechanisms of action. Pirepemat is an oral prefrontal cortex enhancer in a Phase IIb trial for the treatment of impaired balance and falls in PD. Mesdopetam, an oral D3 antagonist, failed to hit primary endpoints in a Phase IIb trial for levodopa-induced dyskinesias (PD-LIDs) in January 2023. IRLAB has licensed the global rights for mesdopetam to Ipsen and we await further communication on how this data will define Ipsen's future development strategy for the drug. IRLAB is also developing a three preclinical assets, IRL942, IRL757 and IRL117 for various CNS indications. The company remains well funded in the medium term. Our valuation and estimates are under review.

INDUSTRY OUTLOOK

PD is characterised by a triad of cardinal motor symptoms, although non-motor symptoms are as debilitating and remain undertreated. Despite substantial efforts to develop disease-modifying approaches in PD, symptomatic treatment remains the mainstay.

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.4	(89.2)	(91.4)	(192.0)	N/A	N/A
2021	207.9	56.1	91.1	176.0	6.3	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: US\$1.01
 Market cap: US\$15m
 Market: Nasdaq

Share price graph (US\$)



Company description

Kazia Therapeutics is a late-stage clinical pharmaceutical company with lead asset paxalisib (a PI3K inhibitor that can cross the BBB, licensed from Genentech) in a pivotal study for GBM and in early-stage studies in childhood brain cancers, DIPG and AT/RT. The other asset is the Phase I drug EVT801, an inhibitor of VEGFR3.

Price performance

%	1m	3m	12m
Actual	28.4	46.4	(84.7)
Relative*	21.7	34.2	(83.2)

* % Relative to local index

Analyst

Soo Romanoff

Kazia Therapeutics (KZIA)

INVESTMENT SUMMARY

Kazia is developing the anti-cancer compound paxalisib (GDC-0084) for glioblastoma (GBM). Paxalisib is a PI3K inhibitor, a well understood class with activity across a wide range of tumour types and multiple previously approved drugs. Paxalisib, unlike other drugs of this class, can cross the blood brain barrier (BBB), opening the potential to treat cancers of the brain. Paxalisib has not progressed to stage 2 of the Phase III GBM AGILE study, although the first stage (~150 patients) remains ongoing, with final data expected in H2 CY23. A Phase II DIPG study (paxalisib in combination with ONC201) is ongoing at 22 sites globally, with initial data anticipated in CY23. With a recent A\$4.5m fund-raise through a two-stage private placement, the period-end net cash balance stood at A\$4.4m, which should provide headroom into H2 CY23, based on current burn rates.

INDUSTRY OUTLOOK

GBM is the most common primary cancer of the brain with c 12,500–13,000 new cases reported in the United States per year. There are very limited treatment options for GBM and there is a very low survival rate. Paxalisib is currently being developed for use in the adjuvant setting after initial resection and radiation treatment. EVT801 will target the multibillion-dollar angiogenesis cancer market.

Y/E Jun	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2021	10.7	(3.1)	(3.1)	(25.09)	N/A	N/A
2022	0.0	(14.9)	(14.9)	(110.57)	N/A	N/A
2023e	0.0	(19.0)	(19.0)	(111.41)	N/A	N/A
2024e	10.8	(17.2)	(17.2)	(82.84)	N/A	N/A

Sector: Pharma & healthcare

Price: CHF0.02
 Market cap: CHF18m
 Market: SIX Swiss Exchange

Share price graph (CHF)



Company description

Based in Switzerland, Kinarus Therapeutics is a clinical-stage pharmaceutical company focused on advancing lead candidate KIN001 in inflammatory, fibrotic and/or viral infection-related conditions.

Price performance

%	1m	3m	12m
Actual	(18.0)	90.7	(78.8)
Relative*	(19.0)	82.3	(77.2)

* % Relative to local index

Analyst

Pooya Hemami

Kinarus Therapeutics (KNRS)

INVESTMENT SUMMARY

Kinarus Therapeutics is advancing KIN001, a patented orally dosed combination of p38 mitogen-activated protein kinase inhibitor pamapimod and pioglitazone. Preclinical data suggest this combination may have anti-inflammatory and anti-fibrotic activity, as well as antiviral properties against COVID-19. KIN001 is under development for the treatment of wet age-related macular degeneration (wet AMD), its lead indication, as well as idiopathic pulmonary fibrosis (IPF) and COVID-19. Wet AMD is a leading cause of vision loss in older adults and there are no oral drugs approved to treat the condition, signalling a potentially significant unmet need.

INDUSTRY OUTLOOK

Upon availability of new funding, Kinarus plans to start a Phase II study in wet AMD, backed by preclinical data suggesting potential benefit in reducing choroidal neovascularisation lesions, and in IPF. Having shown in vitro antiviral activity against many COVID-19 variants, KIN001 is currently being assessed in the KINFAST Phase II study in ambulatory COVID-19 patients.

Y/E Dec	Revenue (CHFm)	EBITDA (CHFm)	PBT (CHFm)	EPS (fd) (CHFc)	P/E (x)	P/CF (x)
2020	0.0	(1.5)	(1.5)	(31.17)	N/A	N/A
2021	0.0	(5.1)	(4.9)	(0.41)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: A\$7.00
 Market cap: A\$16m
 Market: ASX

Share price graph (A\$)

Company description

Based in Australia, Medlab Clinical is developing therapeutics using its proprietary delivery platform NanoCelle. Its most advanced programme is in cancer pain management with lead drug candidate NanaBis, a medicinal cannabis product for cancer-related bone pain.

Price performance

%	1m	3m	12m
Actual	3.7	(30.7)	(62.7)
Relative*	(2.1)	(36.6)	(64.2)

* % Relative to local index

Analyst

Soo Romanoff

Medlab Clinical (MDC)

INVESTMENT SUMMARY

Medlab Clinical's proprietary platform, NanoCelle, is a patented nanomicellar formulation that can improve the delivery of drugs. Medlab's lead product is NanaBis, a combination of synthetic THC and CBD (1:1) cannabinoids encapsulated in NanoCelle particles, enabling a convenient buccal spray formulation. Supported by recently reported real-world data NanaBis will re-enter clinical development (potentially Phase III) as a fully synthetic, non-opioid pain relief drug. The company recently received approval from the UK Medicines and Healthcare Products Regulatory Agency for NanaBis to be used under its Named Patient Program and other compassionate areas. Medlab recorded 35% y-o-y revenue growth from continued operations in FY22. The company's plans for a potential Nasdaq listing are currently on hold.

INDUSTRY OUTLOOK

There is a growing consensus in the medical community that medicinal cannabis has a place in chronic pain management. With the opioid crisis unravelling, we believe support for non-opioid pain killers from various stakeholders will only grow.

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (c)	P/E (x)	P/CF (x)
2021	8.1	(11.4)	(12.4)	(627.0)	N/A	N/A
2022	6.0	(7.4)	(8.4)	(314.0)	N/A	N/A
2023e	6.5	(13.0)	(13.9)	(604.1)	N/A	N/A
2024e	4.3	(20.8)	(21.7)	(943.9)	N/A	N/A

Sector: Pharma & healthcare

Price: SEK2.27
 Market cap: SEK453m
 Market: Nasdaq Nordic

Share price graph (SEK)

Company description

Mendus is a clinical-stage immunoncology (IO) company based in Sweden and the Netherlands. The company specialises in allogeneic dendritic cell (DC) biology and currently has two lead, cell-based, off-the-shelf therapies for haematological and solid tumours.

Price performance

%	1m	3m	12m
Actual	(10.3)	11.3	(28.3)
Relative*	(16.1)	(3.0)	(23.8)

* % Relative to local index

Analyst

Soo Romanoff

Mendus (IMMU)

INVESTMENT SUMMARY

Mendus aims to become a global leader in off-the-shelf, allogeneic cell therapies, using its expertise in DC biology. It has two advanced clinical-stage pipeline products, addressing both solid tumours and haematological malignancies. DCP-001 is aimed at reducing the risk of cancer relapse after standard of care and is currently in two clinical trials: Phase II (currently in follow-up) in acute myeloid leukaemia (AML, ADVANCE-II) and Phase I in ovarian cancer (ALISON). Key survival data from DCP-001's use in AML was reported on 12 December 2022, demonstrating a competitive profile, in our view. The company's second asset, Ilixadencel, is being developed as an immune primer and is currently in preparations to start a Phase II trial in gastrointestinal stromal tumours, which we expect to begin later this year. In FY22 the company secured financing commitments of SEK250m, which if fully executed we expect could fund the company to H224.

INDUSTRY OUTLOOK

IO is a frenetic pharmaceutical development area with many clinical combination studies being conducted by pharmaceutical and biotech companies. Investors should expect relatively rich newsflow from this subsector over the next few years.

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (fd) (öre)	P/E (x)	P/CF (x)
2020	0.0	(85.1)	(89.2)	(117.1)	N/A	N/A
2021	0.0	(130.1)	(133.4)	(73.0)	N/A	N/A
2022e	3.2	(125.9)	(130.9)	(65.7)	N/A	N/A
2023e	0.0	(129.4)	(138.5)	(69.5)	N/A	N/A

Sector: Pharma & healthcare

Price: 2.2p
 Market cap: £2m
 Market: LSE AIM

Share price graph (p)



Company description

Midatech is a drug-delivery specialist focused on re-engineering therapeutics through its technology platforms (MidaSolve, local drug-delivery; Q-Sphera, sustained-release; MidaCore, targeted delivery) to improve biodistribution and delivery.

Price performance

%	1m	3m	12m
Actual	(15.4)	(67.4)	(85.6)
Relative*	(17.2)	(69.7)	(85.9)

* % Relative to local index

Analyst

Soo Romanoff

Midatech Pharma (MTPH)

INVESTMENT SUMMARY

Midatech is a drug delivery technology company with three key platforms focusing on commercialising and developing products in central nervous system, anti organ rejection and brain cancer. The core asset, Q-Sphera, is a sustained release technology; proprietary microspheres that can be tailored to deliver a precise release profile for numerous drugs. The second asset, MidaSolve, is a nanosaccharide technology used to liquefy inherently insoluble drugs to aid local delivery to a disease area. Its lead asset, MTX110, is undertaking clinical studies in aggressive brain cancers such as glioblastoma (Phase Ib trial commenced in Q422 with first patient recruitment) and diffuse intrinsic pontine glioma, a very rare pediatric cancer. In December 2022, Midatech announced an all stock-acquisition of Bioasis Technologies, however, the company's shareholders did not approve the deal. Following the shareholders' decision, Midatech only has cash to last until mid-March 2023 and will urgently need to secure alternative sources of financing.

INDUSTRY OUTLOOK

The proprietary platforms develop products that address debilitating conditions with significant clinical needs. Applications are expected to be out-licensed for development following proof of concept.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2020	0.3	(9.5)	(11.1)	(22.92)	N/A	N/A
2021	0.6	(6.6)	(6.1)	(6.78)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: 17.20PLN
 Market cap: PLN241m
 Market: Warsaw Stock Exchange

Share price graph (PLN)



Company description

Molecure is a clinical-stage biotechnology company. It uses its medicinal chemistry and biology capabilities to discover and develop first-in-class small molecule drug candidates that directly modulate the function of RNA and underexplored protein targets designed to treat multiple incurable diseases.

Price performance

%	1m	3m	12m
Actual	11.4	19.0	(53.6)
Relative*	10.9	2.1	(45.9)

* % Relative to local index

Analyst

Soo Romanoff

Molecure (MOC)

INVESTMENT SUMMARY

Molecure aims to discover and develop drugs that have novel mechanisms of action to address inflammation, fibrosis and oncology. The company's two lead assets, OATD-01 (a chitotriosidase inhibitor) and OATD-02 (an ARG1/2 inhibitor), are approaching important clinical development milestones. After a purely strategic decision by partner Galapagos (June 2022), the rights to OATD-01 were returned to the company. Molecure now plans to leverage newly collected data to commence a Phase II trial with OATD-01 in sarcoidosis in mid-2023. Top-line results are expected in Q125. In addition, following the recent approval from the Polish health authorities, OATD-02 is expected to begin Phase I trials in solid tumour indications in Q123. With a cash position of PLN80.7m at end-September 2022, the company guides that its current runway is into Q224.

INDUSTRY OUTLOOK

There remain serious unmet medical needs in the treatment of inflammatory and fibrotic diseases such as sarcoidosis, idiopathic pulmonary fibrosis and non-alcoholic steatohepatitis. Additionally, there is a constant need for new, targeted cancer treatments. The development of drugs which act through novel mechanisms of action could address these problems.

Y/E Dec	Revenue (PLNm)	EBITDA (PLNm)	PBT (PLNm)	EPS (fd) (gr)	P/E (x)	P/CF (x)
2020	124.9	73.9	112.0	745.0	2.3	4.2
2021	1.2	(13.5)	(11.0)	(79.0)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: CHF3.50
 Market cap: CHF62m
 Market: SIX Swiss Exchange

Share price graph (CHF)

Company description

Newron Pharmaceuticals is focused on the central nervous system. Xadago for Parkinson's disease (PD) is sold in Europe, Japan and the United States. Evenamide, a novel schizophrenia add-on therapy, is involved in a Phase II/III trial programme targeting schizophrenia.

Price performance

%	1m	3m	12m
Actual	28.2	169.2	148.2
Relative*	26.6	157.4	167.1

* % Relative to local index

Analyst

Soo Romanoff

Newron Pharmaceuticals (NWRN)

INVESTMENT SUMMARY

Newron is developing evenamide (30mg twice per day) as an add-on to treat poorly managed and resistant schizophrenia, for which the company recently reported encouraging interim safety and efficacy data. A potentially pivotal Phase II/III study (008A) is underway with readouts expected in H123. Further US studies will be needed. Newron hopes to partner evenamide for larger indications and to sell the product directly for clozapine-resistance. H122 results showed Xadago royalties of €2.8m (up 6% vs H121). Newron had cash, equivalents and other of €28.4m at the end of June 2022.

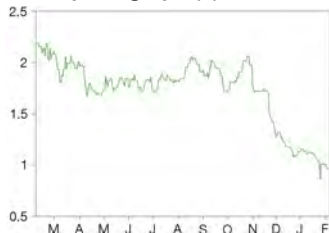
INDUSTRY OUTLOOK

Xadago is marketed as an add-on to levodopa therapy in PD. It is sold by Zambon in Europe and by Supernus in the United States. The additional study on a dyskinesia indication should start in Q122 and could eventually boost US sales. Generic manufacturers have notified the FDA of their intention to file generic Xadago products. Newron is contesting these filings. After 2022, Xadago is protected by a set of patents, which expire no earlier than 2027 if upheld.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2020	5.3	(16.4)	(18.2)	(109.48)	N/A	N/A
2021	5.8	(11.4)	(14.1)	(79.23)	N/A	N/A
2022e	6.6	(11.6)	(15.5)	(86.93)	N/A	N/A
2023e	7.9	(16.2)	(16.4)	(92.00)	N/A	N/A

Sector: Pharma & healthcare

Price: €0.94
 Market cap: €47m
 Market: Euronext Paris

Share price graph (€)

Company description

France-based Nicox develops therapeutics for the treatment of ocular conditions. Lead candidate NCX-470 is in Phase III studies for the treatment of glaucoma and it is advancing NCX-4251 for dry eye disease. Nicox receives licence revenue for its FDA-approved drugs Vyzulta and Zerviate.

Price performance

%	1m	3m	12m
Actual	(16.7)	(45.2)	(57.3)
Relative*	(20.0)	(50.7)	(58.1)

* % Relative to local index

Analyst

Pooya Hemami

Nicox (COX)

INVESTMENT SUMMARY

Nicox develops drugs for eye diseases, with lead candidate NCX-470 targeting the topical ocular treatment of glaucoma. NCX-470 combines an NO-donating molecule with an analogue of established prostaglandin F2a drug, bimatoprost. NCX-470 0.1% showed non-inferiority compared to latanoprost 0.005% in the lowering of intraocular pressure (IOP) in the Mont-Blanc Phase III study and the company is pursuing a second Phase III study (Denali). Nicox also has a Phase II stage drug candidate in NCX-4251 for dry eye disease, which it is seeking to out-license for further development.

INDUSTRY OUTLOOK

In addition to its established IOP-lowering activity, Nicox is starting a Phase IIIb study in H123 to investigate whether NCX-470 can provide improvements to retinal perfusion, which may provide an additional protective mechanism for glaucoma treatment. Nicox had €27.7m gross cash at 31 December 2022 and has guided that it is financed into Q224, based on the development of NCX-470 alone.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	14.4	(5.3)	(10.2)	(30.33)	N/A	N/A
2021	8.6	(16.5)	(15.5)	(34.83)	N/A	N/A
2022e	5.2	(19.0)	(17.3)	(33.49)	N/A	N/A
2023e	7.3	(15.8)	(17.4)	(34.43)	N/A	N/A

Sector: Pharma & healthcare

Price: US\$1.83
 Market cap: US\$5m
 Market: Nasdaq

Share price graph (US\$)

Company description

OpGen is primarily a lab diagnostic manufacturer focused on identifying and treating bacterial infections. It has the technology to detect pathogens and predict resistance and through the dual platform offering of the AMR Gene Panel and Unyvero, it can provide diagnostic results in hours instead of days.

Price performance

%	1m	3m	12m
Actual	(30.9)	(49.6)	(89.8)
Relative*	(34.6)	(53.8)	(88.8)

* % Relative to local index

Analyst

Soo Romanoff

OpGen (OPGN)

INVESTMENT SUMMARY

OpGen is a diagnostics company focused on the identification and treatment of bacterial infections. Its portfolio of molecular diagnostic tests includes the Unyvero platform with five CE-IVD-marked tests and two FDA-cleared cartridges; Ares Genetics' next-generation antimicrobial resistance (AMR) testing services; the 510(k) cleared Acuitas AMR Gene Panel in bacterial isolates; and ARES Genetics (NGS and bioinformatics platform). OpGen's products are differentiated by short turnaround time, large range of pathogen detection and AMR profiling. In recent announcements, OpGen reported FY22 revenue of \$2.7m (within the guidance range of \$2.5–3.0m), along with a 1:20 share consolidation and a \$7.5m equity issue in January 2023.

INDUSTRY OUTLOOK

It currently takes days to test a patient sample to find out if they have an infection, what they are infected with and to which drugs that infection might be susceptible. This can lead to a delay in treatment or the wrong treatment being prescribed. According to the Centers for Disease Control and Prevention, there are over two million cases of drug-resistant bacterial infections every year.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2020	4.2	(19.6)	(24.7)	(3148.5)	N/A	N/A
2021	4.3	(20.4)	(35.7)	(2342.4)	N/A	N/A
2022e	3.2	(19.9)	(25.4)	(1021.6)	N/A	N/A
2023e	5.3	(16.7)	(21.8)	(751.5)	N/A	N/A

Sector: Pharma & healthcare

Price: €2.48
 Market cap: €140m
 Market: Madrid SE

Share price graph (€)

Company description

Oryzon Genomics is a Spanish biotech focused on epigenetics. Iadademstat is being explored for acute leukaemias, SCLC and neuroendocrine carcinomas. CNS asset Vafidemstat has completed several Phase IIa trials and a Phase IIb trial in BPD is now the lead study, but Oryzon is rapidly expanding its CNS R&D pipeline.

Price performance

%	1m	3m	12m
Actual	(11.9)	18.9	(15.2)
Relative*	(16.3)	3.1	(20.5)

* % Relative to local index

Analyst

Soo Romanoff

Oryzon Genomics (ORY)

INVESTMENT SUMMARY

Oryzon develops small molecule inhibitors for epigenetic targets. The two lead drugs are iadademstat for oncology and vafidemstat for central nervous system (CNS) indications (both are LSD1 inhibitors, an epigenetic target). In oncology, positive top-line data has been reported from the ALICE trial in acute myeloid leukaemia (AML) while new trials FRIDA in AML and STELLAR in small cell lung cancer (SCLC) could potentially be pivotal, with the FDA having now granted orphan drug designation for iadademstat in AML and SCLC. In CNS, vafidemstat is being evaluated in two Phase IIb trials, PORTICO in borderline personality disorder (BPD) and EVOLUTION in schizophrenia, with interim results from PORTICO expected in Q123. Oryzon is also hoping to register vafidemstat in its Phase I/II HOPE study targeting Kabuki syndrome, a rare disorder that affects multiple CNS systems, with an objective to target further orphan drug designation in this indication.

INDUSTRY OUTLOOK

Oryzon is among the leading clinical stage drug developers with a second generation of epigenetic therapeutics, which have greater selectivity and potentially a favourable safety/efficacy profile than the first generation HDAC inhibitors.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	9.5	(4.1)	(4.8)	(6.90)	N/A	N/A
2021	10.6	(6.9)	(7.2)	(8.83)	N/A	N/A
2022e	14.4	(5.0)	(5.0)	(5.38)	N/A	N/A
2023e	15.9	(5.5)	(5.8)	(6.37)	N/A	N/A

Sector: Pharma & healthcare

Price: €6.41
 Market cap: €119m
 Market: Euronext Paris

Share price graph (€)



Company description

OSE Immunotherapeutics is based in Nantes and Paris in France and is listed on the Euronext Paris exchange. It is developing immunotherapies for the treatment of solid tumours and autoimmune diseases and has established several partnerships with large pharma companies.

Price performance

%	1m	3m	12m
Actual	(0.3)	(8.7)	(22.2)
Relative*	(4.3)	(17.9)	(23.7)

* % Relative to local index

Analyst

Soo Romanoff

OSE Immunotherapeutics (OSE)

INVESTMENT SUMMARY

OSE Immunotherapeutics (OSE) and its three pharma partners have made progress with all key clinical and preclinical assets. The final analysis of the data from the most advanced trial in OSE's R&D pipeline, the Phase III ATALANTE-1 study investigating lung cancer vaccine Tedopi, revealed a potential path to market and OSE aims to begin a new Phase III trial in FY23. The three partnered assets – BI 765063, S95011/OSE-127 and VEL-101/FR104 – are in different stages of clinical development and generate relatively steady licensing fee income. Upcoming newsflow from many other projects in the pipeline should provide continued catalysts and hence support the share price.

INDUSTRY OUTLOOK

OSE has products in development for both immunological diseases and various cancer indications. As a result, the R&D pipeline is diversified and the outlook does not depend on developments in any specific subsector.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2020	10.4	(18.1)	(18.5)	(101.83)	N/A	N/A
2021	26.3	(13.6)	(16.5)	(89.03)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: A\$1.46
 Market cap: A\$407m
 Market: ASX

Share price graph (A\$)



Company description

Paradigm Biopharmaceuticals is an Australian biotechnology company focused on the development of injectable pentosan polysulfate (iPPS). Its most advanced clinical programme is investigating the drug's use as a potentially disease modifying treatment for knee-osteoarthritis. iPPS is in pivotal Phase III trials.

Price performance

%	1m	3m	12m
Actual	3.9	4.7	10.6
Relative*	(1.9)	(4.2)	5.9

* % Relative to local index

Analyst

Soo Romanoff

Paradigm Biopharma (PAR)

INVESTMENT SUMMARY

Paradigm Biopharmaceuticals is a late-stage Australian drug developer focused on developing injectable pentosan polysulfate sodium (PPS). The company's most advanced clinical programme is investigating injectable PPS (iPPS) as a potentially disease modifying treatment for knee osteoarthritis (kOA), a globally prevalent condition with unmet medical needs. Paradigm's comprehensive Phase III programme is designed to maximise the potential of iPPS in kOA. At end-December 2022, the company had A\$83.9m in cash, supported by an August 2022 capital raise of A\$66.0m, which management expects will provide a runway into FY24. Additional cash will be needed to fund the final part of the Phase III programme.

INDUSTRY OUTLOOK

Knee osteoarthritis is a highly prevalent and quality-of-life impacting disease. Currently no disease modifying drugs are available for the condition, resulting in serious unmet medical needs and a potentially significant opportunity for drug developers.

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2021	8.9	(51.5)	(34.3)	(16.74)	N/A	N/A
2022	0.1	(55.7)	(39.2)	(16.87)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A
2024e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: €0.002
 Market cap: €0.3m
 Market: Euronext Paris

Share price graph (€)



Company description

Pharnext is an advanced clinical-stage biopharmaceutical company developing novel therapies for neurodegenerative diseases lacking curative and/or disease-modifying treatments. PXT3003 for CMT1A is currently in advanced Phase III clinical trials with top-line data expected in Q423.

Price performance

%	1m	3m	12m
Actual	(90.6)	(99.8)	(100.0)
Relative*	(90.9)	(99.8)	(100.0)

* % Relative to local index

Analyst

Soo Romanoff

Pharnext (ALPHA)

INVESTMENT SUMMARY

Pharnext's lead programme is PXT3003, a synergistic fixed-dose combination of baclofen, naltrexone and sorbitol formulated as an oral solution and identified with the Pleotherapy R&D approach. It is in pivotal Phase III clinical development for Charcot-Marie-Tooth disease type 1A (CMT1A). Top line data are expected in Q423. Data from the open label PLEO-CMT-FU extension study of the first Phase III programme suggests continuous treatment benefit after a total trial time of five years. In October 2022, Pharnext finalised a strategic financing agreement worth €20.7m with Neovacs by issuing bonds and associated warrants, possibly giving Neovacs access to one-third of Pharnext's capital if fully converted (vests in January 2024). In January 2023 the agreement was extended for up to an additional €24m in funding through December 2023.

INDUSTRY OUTLOOK

PXT3003 could potentially be the first approved treatment for CMT1A. This disease is a debilitating and rare (prevalence of 1/5,000) peripheral neuropathy with high unmet medical need where patients suffer from pain, progressive muscle atrophy and cramps in the limbs. The CMT1A development pipeline is early stage, with PXT3003 the most clinically advanced asset (Phase III) for this indication.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	2.8	(18.2)	(21.4)	(117.33)	N/A	0.0
2021	3.6	(22.2)	(30.6)	(100.67)	N/A	0.0
2022e	2.4	(25.3)	(31.7)	(1.09)	N/A	0.0
2023e	2.5	(28.4)	(30.9)	(0.54)	N/A	0.0

Sector: Pharma & healthcare

Price: €0.07
 Market cap: €5m
 Market: Euronext Paris

Share price graph (€)



Company description

Pixium Vision develops bionic vision systems for patients with severe vision loss. Its lead product, Prima, is a wireless sub-retinal implant system for dry age-related macular degeneration. The company started implantations for the European PRIMAVera pivotal study in Q422.

Price performance

%	1m	3m	12m
Actual	(23.3)	(32.4)	(90.1)
Relative*	(26.4)	(39.2)	(90.3)

* % Relative to local index

Analyst

Pooya Hemami

Pixium Vision (PIX)

INVESTMENT SUMMARY

Pixium Vision is developing the Prima System, a wireless photovoltaic sub-retinal implant combined with proprietary smart glasses. Prima is designed to apply proprietary algorithms and artificial intelligence to generate a form of bionic vision for patients who have lost their sight due to severe retinal diseases. Positive 36-month data from its EU feasibility study in patients with geographic atrophy associated with dry age-related macular degeneration (GA-AMD) showed sustained improvements on the Landolt C visual acuity scale versus baseline, the ability to restore reading capabilities and continued implant safety and stability.

INDUSTRY OUTLOOK

Pixium started the PRIMAVera European pivotal study in Q420 and completed its target of 38 implantations in Q422, which we believe could lead to top-line data being reported in late 2023 or early 2024. GA-AMD is a leading cause of blindness in older adults, affecting over 2.5 million persons in the United States and Europe, and there is no approved treatment. Pixium reported €8.5m gross cash on 30 September 2022 and expects its current cash position to maintain operations to the middle of Q223.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	2.1	(7.6)	(8.7)	(25.58)	N/A	N/A
2021	2.7	(9.7)	(10.9)	(22.56)	N/A	N/A
2022e	1.8	(12.1)	(12.3)	(21.43)	N/A	N/A
2023e	0.8	(16.2)	(18.1)	(26.07)	N/A	N/A

Sector: Pharma & healthcare

Price: €0.17
 Market cap: €6m
 Market: Euronext Paris

Share price graph (€)



Company description

Quantum Genomics is a Paris-based biotechnology company focused on addressing unmet medical needs.

Price performance

%	1m	3m	12m
Actual	38.0	(24.3)	(95.5)
Relative*	32.4	(32.0)	(95.6)

* % Relative to local index

Analyst

Soo Romanoff

Quantum Genomics (ALQGC)

INVESTMENT SUMMARY

Following the announcement that results from the Phase III FRESH study, investigating the use of fribastat in treatment-resistant hypertension (TRH) were non-significant versus placebo, Quantum Genomics has terminated a second, longer-term Phase III trial (REFRESH) in TRH and will stop the development of fribastat in cardiology. The company estimates it will have c €11m after the full discontinuation of cardiology development with which to pursue new opportunities to develop new assets. Our estimates and valuation for Quantum Genomics are under review.

INDUSTRY OUTLOOK

The global market for cardiovascular drugs is considerable; in 2021 the market for hypertension drugs alone was estimated to be worth c US\$13bn. Quantum Genomics has already secured seven licensing deals worldwide (worth up to c US\$123m) but has not yet signed an agreement in the key US or EU5 regions. We view the signing of a licensing agreement in these regions as key to maximising the commercial impact of the asset.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2020	4.0	(13.1)	(14.7)	(72.0)	N/A	N/A
2021	6.2	(14.9)	(15.4)	(58.0)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price: 11.1p
 Market cap: £6m
 Market: LSE AIM

Share price graph (p)



Company description

ReNeuron Group is a UK biotech focused on the development of its stem cell-derived exosome drug delivery platform (CustomEx). It operates as a CRDO and its established partners are progressing the preclinical development of exosome-based therapeutics utilising its CustomEx technology.

Price performance

%	1m	3m	12m
Actual	25.7	(58.0)	(64.7)
Relative*	23.0	(61.0)	(65.5)

* % Relative to local index

Analyst

Soo Romanoff

ReNeuron Group (RENE)

INVESTMENT SUMMARY

ReNeuron Group is a UK biotech focused on the development of its stem cell-derived exosome drug delivery platform (CustomEx). The company operates as a contract research and development organisation (CRDO) and has established seven discovery stage collaborations with pharma, biotech and academic institutions, through which its proprietary CustomEx exosome platform is being investigated for application in targeted drug delivery. ReNeuron's exosomes have shown encouraging preclinical proof-of-concept data to deliver complex therapeutic payloads with high tissue specificity.

INDUSTRY OUTLOOK

Drug delivery remains a major challenge in both central nervous system (CNS) and cell and gene drug development, and we view these as key markets for ReNeuron to target with its exosome drug delivery platform. Additionally, ReNeuron's diversification in exosome producing stem cell lines and ability to produce exosomes with enhanced natural tissue targeting affinity, particularly neural stem cell lines to target CNS indications, may offer market differentiation against single cell line competitors.

Y/E Mar	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (fd) (p)	P/E (x)	P/CF (x)
2021	0.3	N/A	(13.4)	(29.00)	N/A	N/A
2022	0.4	N/A	(11.1)	(17.01)	N/A	N/A
2023e	0.8	N/A	(8.9)	(13.27)	N/A	N/A
2024e	0.9	N/A	(9.6)	(14.37)	N/A	N/A

Sector: Pharma & healthcare

Price: A\$0.05
 Market cap: A\$40m
 Market: ASX

Share price graph (A\$)



Company description

Respi is an Australia-based medical device and SaaS company focused on respiratory health management through its integrated wheezo platform. Its technology records data such as wheeze rates, breath recordings and other environmental factors and medication usage. Wheezo was launched in the US in December 2021.

Price performance

%	1m	3m	12m
Actual	0.0	35.1	(3.8)
Relative*	(5.6)	23.7	(7.9)

* % Relative to local index

Analyst

Soo Romanoff

Respi (RSH)

INVESTMENT SUMMARY

Respi is an Australian medical device and SaaS company, developing a novel remote patient monitoring approach to respiratory health management through its integrated wheezo platform. Following a strategic pivot in 2021, Respi has redirected its focus to the US market. In H2 CY22, it signed six commercial agreements (including Minnesota Lung Center and Arkansas Heart Hospital) for the wheezo RPM programme. With patient onboarding commenced across multiple sites, the initiation of reimbursement (expected in CY23) would make Respi the first Australian medical device company to get paid under current procedural terminology (CPT) RPM codes. Respi recently raised A\$1.5m through a security purchase plan, extending its cash runway to Q423.

INDUSTRY OUTLOOK

Notwithstanding the relatively large target patient population (asthma and chronic obstructive pulmonary disease) in the US, the key consideration for Respi's US push is the already established reimbursement infrastructure. The Centers for Medicare and Medicaid Services has established CPT codes for RPM reimbursement coverage. With key technology patents, two telehealth partners and reimbursement arrangements in place, Respi is well positioned and has a first-mover advantage.

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2021	1.4	(8.4)	(8.5)	(1.22)	N/A	N/A
2022	0.8	(6.2)	(6.3)	(0.87)	N/A	N/A
2023e	5.0	(2.3)	(2.3)	(0.29)	N/A	N/A
2024e	8.1	0.4	0.4	0.03	166.7	N/A

Sector: Pharma & healthcare

Price: SEK2.94
 Market cap: SEK120m
 Market: Nasdaq Nordic

Share price graph (SEK)



Company description

Scandion Oncology is focused on the development of add-on therapies to reverse chemotherapy resistance in oncology. Lead asset SCO-101 is in a Phase II trial for mCRC and a Phase Ib trial for pancreatic cancer.

Price performance

%	1m	3m	12m
Actual	5.6	34.2	(82.3)
Relative*	(1.3)	16.9	(81.2)

* % Relative to local index

Analyst

Soo Romanoff

Scandion Oncology (scOL)

INVESTMENT SUMMARY

Scandion Oncology is a biotechnology company focused on the development of add-on therapies to reverse chemotherapy resistance in oncology. The company's lead asset SCO-101 is currently in a Phase II trial for metastatic colorectal cancer (mCRC) and a Phase Ib trial for pancreatic cancer. In H222 management undertook a rights issue, raising c SEK75m gross, mainly to fund the expansion of the SCO-101 clinical development programme to include patients harbouring RAS mutations. As such, part 3 of the CORIST trial in mCRC is currently recruiting. While top-line readouts from the CORIST part 2 mCRC trial did not achieve the primary endpoint for efficacy, patients are continuing treatment and longer-term efficacy benefits may be realised. In December 2022, Francois Martelet was appointed CEO of Scandion. We estimate that the company is funded into FY24. We value Scandion Oncology at SEK241.1m or SEK5.9/share.

INDUSTRY OUTLOOK

Tumours often develop resistance to chemotherapeutic regimens. Widely available drugs, such as irinotecan and paclitaxel, are commonly associated with tumour resistance. The existence of add-on therapies to reverse resistance of this type will be an attractive prospect to many clinicians, in our view.

Y/E Dec	Revenue (DKKm)	EBITDA (DKKm)	PBT (DKKm)	EPS (ore)	P/E (x)	P/CF (x)
2020	1.0	(23.5)	(21.5)	(53.0)	N/A	N/A
2021	0.8	(54.8)	(57.2)	(161.0)	N/A	N/A
2022e	0.6	(85.1)	(87.7)	(225.0)	N/A	N/A
2023e	0.6	(76.0)	(75.8)	(173.0)	N/A	N/A

Sector: Pharma & healthcare

Price: €5.40
 Market cap: €128m
 Market: Euronext Brussels

Share price graph (€)



Company description

Based in Belgium, Sequana Medical develops products to treat diuretic-resistant fluid overload, a frequent complication of liver disease and heart failure. Its proprietary alfapump and DSR approaches aim to provide significant clinical and quality-of-life benefits.

Price performance

%	1m	3m	12m
Actual	(9.7)	(18.2)	(14.6)
Relative*	(10.7)	(24.2)	(11.9)

* % Relative to local index

Analyst

Pooya Hemami

Sequana Medical (SEQUA)

INVESTMENT SUMMARY

Sequana's alfapump and Direct Sodium Removal (DSR) platforms are being advanced as long-term treatments for diuretic-resistant fluid overload related to liver disease, malignant ascites and heart failure (HF). The alfapump removes localised excess fluid build-up in the peritoneal cavity, and it is being advanced for treating fluid overload (ascites) resulting from liver disease including non-alcoholic steatohepatitis. Sequana's larger opportunity lies within its DSR programme for chronic HF patients with persistent congestion.

INDUSTRY OUTLOOK

In October 2022 Sequana reported positive efficacy data from its POSEIDON North American registration study for the alfapump in recurrent and refractory ascites and it expects to submit a US Premarket Approval application in H223, with US approval expected in 2024. Following encouraging data including sustained improvements in diuretic response from its Phase IIa SAHARA DSR study in HF patients with persistent congestion, the company plans to start the MOJAVE US Phase I/IIa study in H123 using its second-generation product (DSR 2.0) in a similar patient population. In Q422 Sequana dosed the first patient with DSR 2.0 in a Canadian Phase I study (YUKON).

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	1.0	(17.5)	(19.0)	(125.07)	N/A	N/A
2021	0.4	(23.4)	(24.4)	(136.37)	N/A	N/A
2022e	0.8	(24.3)	(26.3)	(111.64)	N/A	N/A
2023e	0.8	(23.0)	(25.4)	(106.54)	N/A	N/A

Sector: Pharma & healthcare

Price: 6.4p
 Market cap: £37m
 Market: LSE AIM

Share price graph (p)



Company description

Shield Therapeutics is a commercial-stage pharmaceutical company. Its proprietary product, Feraccru/Accrufer, is approved by the EMA and FDA for iron deficiency. Outside the United States, Feraccru is marketed internationally through Shield and its commercial partners.

Price performance

%	1m	3m	12m
Actual	(1.5)	(20.1)	(81.8)
Relative*	(3.7)	(25.8)	(82.2)

* % Relative to local index

Analyst

Soo Romanoff

Shield Therapeutics (STX)

INVESTMENT SUMMARY

Shield Therapeutics is a UK-headquartered commercial-stage speciality pharmaceutical company focused on the commercialisation of Feraccru/Accrufer (oral ferric maltol), approved by the EMA and FDA for the treatment of iron deficiency in adults, with or without anaemia. Shield launched the product in the US in July 2021 as part of its self-commercialisation strategy, however, it signed a co-commercialisation deal for Accrufer in the US with Viartis in December 2022. The commercialisation of Feraccru in Europe, Australia and New Zealand is managed by distribution partner Norgine, and the product has been licensed to ASK Pharm in China, Korea Pharma in South Korea and KYE Pharma in Canada. Shield had an estimated net cash balance of £13.8m at end-December 2022 and raised US\$18.5m through an equity issue and additional US\$10m funding from its largest shareholder, AOP Health. This should be sufficient to take the company to break-even, provided revenue targets are achieved.

INDUSTRY OUTLOOK

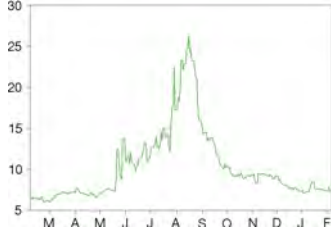
The market for iron deficiency is substantial and Feraccru/Accrufer is a unique oral formulation of iron developed to overcome the side-effect profile of salt-based oral iron therapies and provides an alternative treatment to intravenously administered iron.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (fd) (p)	P/E (x)	P/CF (x)
2020	10.4	0.6	0.8	0.1	64.0	N/A
2021	1.5	(17.9)	(17.5)	(8.4)	N/A	N/A
2022e	8.8	(15.9)	(15.7)	(6.5)	N/A	N/A
2023e	24.4	(19.9)	(21.2)	(4.2)	N/A	N/A

Sector: Pharma & healthcare

Price: US\$7.12
 Market cap: US\$520m
 Market: Nasdaq

Share price graph (US\$)



Company description

SIGA Technologies is focused on the treatment of smallpox and other orthopoxviruses. It has contracts with the US and Canadian governments for TPOXX, its treatment for smallpox and is looking to expand internationally. As the leading smallpox therapeutic manufacturer, it is likely to remain a beneficiary through the monkeypox epidemic.

Price performance

%	1m	3m	12m
Actual	(1.7)	(22.7)	12.5
Relative*	(6.8)	(29.1)	23.1

* % Relative to local index

Analyst

Soo Romanoff

SIGA Technologies (SIGA)

INVESTMENT SUMMARY

SIGA Technologies is a commercial-stage company focused on the treatment of smallpox and other orthopoxvirus. Lead drug TPOXX was approved by the US FDA in 2018 for the treatment of smallpox and in the EU and UK under the broad label including all orthopox pathogens in 2022. In addition, three randomized, placebo-controlled trials were launched in October 2022 to assess the safety and efficacy of TPOXX in treating patients with monkeypox. The near-term outlook seems positive with upcoming BARDA contract-related deliveries for oral and IV TPOXX and upside optionality from additional/recurring government contracts.

INDUSTRY OUTLOOK

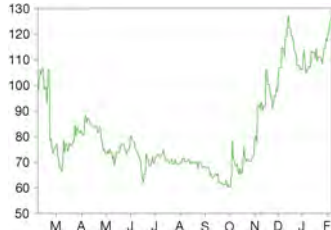
With about 64k global cases and 23k cases in the United States, monkeypox remains a growing concern for governments and health agencies. SIGA's antiviral product TPOXX is the leading therapeutic, originally designed to treat smallpox. TPOXX was approved by the US FDA for smallpox and is now available to treat monkeypox through the Centers for Disease Control and Prevention's expanded access investigational new drug protocol. Currently, it is the only allowed therapy for all orthopoxvirus pathogens, including monkeypox, approved in both the UK (July 2022) and the EU (January 2022).

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	125.0	88.6	81.5	80.97	8.8	7.9
2021	133.7	89.7	89.1	90.61	7.9	46.5
2022e	115.4	47.6	47.1	48.35	14.7	14.2
2023e	169.0	89.1	88.5	94.51	7.5	20.2

Sector: Pharma & healthcare

Price: NOK128.00
 Market cap: NOK4403m
 Market: Oslo SE

Share price graph (NOK)



Company description

Ultimovacs is developing novel immunotherapies against cancer. Lead product candidate, UV1, is a peptide-based vaccine against the universal cancer antigen telomerase, which is expressed by c 85% of all cancer types. UV1 therefore has a broad potential in a variety of different settings and combinations.

Price performance

%	1m	3m	12m
Actual	20.8	45.3	28.9
Relative*	20.7	48.9	31.8

* % Relative to local index

Analyst

Soo Romanoff

Ultimovacs (ULTI)

INVESTMENT SUMMARY

Ultimovacs is a biotechnology company focused on developing a next generation cancer vaccine with virtually universal potential. Lead asset, UV1, activates the immune system to recognise cancer cells that express human telomerase reverse transcriptase (hTERT, or telomerase), which is present in c 85% of all cancer types. For this reason, UV1 has broad potential in a variety of cancers and in combination with other treatments. The company's R&D strategy is to combine UV1 with checkpoint inhibitors due to an expected treatment synergy. The broad R&D programme includes five Phase II trials in different solid tumours, which will enrol more than 600 patients in total. Readouts are expected over 2023–24, all within cash reach. The most near-term catalysts for the share price are top-line readouts from the Phase II INITIUM trial in malignant melanoma and the Phase II NIPU study in pleural mesothelioma expected in H123.

INDUSTRY OUTLOOK

Novel drug projects in oncology comprise the lion's share of total R&D investments in the industry. Around 85% of all cancer types express high levels of hTERT, which means that UV1 has a broad potential in a variety of different settings, including combinations with other cancer treatments.

Y/E Dec	Revenue (NOKm)	EBITDA (NOKm)	PBT (NOKm)	EPS (fd) (öre)	P/E (x)	P/CF (x)
2020	0.0	(121.4)	(120.6)	(398.39)	N/A	N/A
2021	0.0	(161.1)	(164.7)	(508.83)	N/A	N/A
2022e	0.0	(168.0)	(159.2)	(465.10)	N/A	N/A
2023e	0.0	(201.6)	(196.0)	(572.58)	N/A	N/A

Company coverage

Company	Note	Date published
Actinogen Medical	Flash; Flash	23/12/22; 06/02/22
AFT Pharmaceuticals	Flash; Flash	25/01/23; 02/02/23
Arovela Therapeutics	Flash; Flash	03/11/22; 08/11/22
Basilea Pharmaceutica	Flash; Flash	12/01/23; 25/01/23
Cantargia	Flash; Update	08/11/22; 11/11/22
Carmat	Update; Update	11/01/21; 20/09/21
Chimeric Therapeutics	Update; Update	29/07/21; 06/12/21
Context Therapeutics	Flash; Flash	31/01/23; 06/02/23
Creo Medical	Flash; Outlook	18/01/23; 19/01/23
Ergomed	Flash; Update	18/11/22; 21/12/22
Immix Biopharma	Update; Flash	14/11/22; 19/12/22
Incanx HealthCare	Flash; Flash	01/02/23; 09/02/23
IRLAB Therapeutics	Flash; Flash	12/01/23; 18/01/23
Kazia Therapeutics	ADR Flash; ADR Flash	19/12/22; 01/02/22
Kinarus Therapeutics	Flash; Flash	24/11/22; 07/12/22
Medlab Clinical	Flash; Outlook	17/01/23; 23/01/23
Mendus	Flash; Update	13/12/22; 14/12/22
Midatech Pharma	Flash; Flash	13/01/23; 24/01/23
Molecure	Initiation; Update	04/11/22; 08/12/22
Newron Pharmaceuticals	Update; Flash	15/09/22; 03/01/23
Nicox	Update; Flash	23/11/22; 19/01/23
OpGen	Flash; Flash	18/01/23; 19/01/23
Oryzon Genomics	Flash; Flash	16/12/22; 18/01/23
OSE Immunotherapeutics	Update; Flash	20/12/22; 22/12/22
Paradigm Biopharma	Initiation; Update	14/12/22; 02/02/23
Pharnext	Update; Flash	19/10/22; 01/11/22
Pixium Vision	Update; Flash	15/12/22; 17/01/23
Quantum Genomics	Update; Flash	05/10/22; 28/10/22
ReNeuron Group	Re-initiation; Flash	06/12/22; 09/12/22
Respiri	Flash; Flash	26/01/23; 07/02/23
Sareum Holdings	Update; Flash	25/10/22; 09/11/22
Scandion Oncology	Flash; Flash	18/11/22; 01/12/22
Sequana Medical	Flash; Flash	03/11/22; 18/11/22
Shield Therapeutics	Update; Update	08/09/22; 16/12/22
SIGA Technologies	Flash; Update	14/10/22; 04/11/22
Ultimovacs	Flash; Flash	21/12/22; 23/01/22

Glossary

11 β -HSD	11 β -Hydroxysteroid dehydrogenase
AACR	American Association for Cancer Research
AAV	Adeno-associated virus
ABSSSI	Acute bacterial skin and skin structure infections
AC	Anterior chamber
Accelerated approval	Faster FDA approval based on a surrogate endpoint for drugs that fill an unmet medical need for serious conditions. Phase IV confirmatory trial required post-approval to demonstrate clinical benefit
ACEs	Angiotensin converting enzymes
AChEI	Acetylcholinesterase
ACTH	Adrenocorticotrophic hormone
AD	Alzheimer's disease
ADC	Antibody-drug conjugate
AdCom	FDA Advisory Committee meeting
ADHD	Attention deficit hyperactivity disorder
ADME	Absorption, distribution, metabolism and excretion
AdV	Adenovirus
AEs	Adverse events
AfDC	Affimer drug conjugates
AGvHD	Acute graft vs host disease
AH	Aqueous humour
AHI	Apnea hypopnea index
AI	Adrenal insufficiency
AKI	Acute kidney injury
ALL	Acute lymphoblastic leukaemia
AM	Alpha-mannosidosis
AMD	Age-related macular degeneration
AMF	Alternating magnetic field
AMI	Acute myocardial infarction
AML	Acute myeloid leukaemia
ANDA	Abbreviated new drug application
AOBP	Automated office blood pressure
APD	Atypical antipsychotic drugs
API	Active pharmaceutical ingredient
APPA	American Pet Products Association
AR	Augmented reality
ARBs	Angiotensin receptor blockers
ARDS	Acute respiratory distress syndrome
ARG1/2	Arginase-1/2 (inhibitor)
ASCO	American Society of Clinical Oncology
ASCT	Autologous stem cell transplantation
ASD	Autism spectrum disorder
AUC	Area under the curve (total drug exposure over time)
BALF	Broncho-alveolar lavage fluid
B-ALL	B-cell acute lymphoblastic leukaemia
BARDA	Biomedical Advanced Research and Development Authority (US agency that supports research into drugs, vaccines and other products that are considered priorities for national health security)
BBB	Blood-brain barrier
BC	Breast cancer
BCAL	Breast cancer-associated secondary lymphedema
BDNF	Brain-derived neurotrophic factor
BE	Bronchiectasis
BET	bromodomain and extraterminal domain proteins
bid	Twice daily (prescription)
BLA	Biologics License Application (FDA filing approval for biologic drugs)
BLC	Blue light cystoscopes
BM	Bone marrow
BMBC	Brain metastases from breast cancer
BMI	Body mass index
BMs	Brain metastases
BMT	Bone marrow transplantation
B-NHL	B-cell non-Hodgkin lymphoma
BOI	Burden of illness study
BPD	Borderline personality disorder
BTC	Biliary tract carcinoma
BTD	Breakthrough therapy designation (Expediates development and FDA review of drugs intended to treat a serious condition and may demonstrate substantial improvement on available therapies)
BTR	Bridge-to-recovery

BTT	Bridge-to-transplant
BVCA	Best Corrected Visual Acuity
BVS	Bionic vision system
CABP	Community-acquired bacterial pneumonia
CAF	Cancer-associated fibroblast
CAH	Congenital adrenal hyperplasia
Cancer stages	
I	The cancer or tumour is small and is still in the place that it started and hasn't spread to nearby tissue
II-III	The cancer or tumour is larger and may have spread to the surrounding tissue and/or lymph nodes
IV	The cancer has spread to one or more other organs of the body and is considered metastatic
CAR-T	Chimeric antigen receptor T cell
CBD	Hemp-derived cannabidiol
CBN	Cannabinol
ccRCC	Clear cell renal cell carcinoma
CDC	Centers for Disease Control and Prevention (US agency that aims to protect public health through the control and prevention of disease, injury and disability)
CDK	cyclin-dependent kinase
CDMO	Contract development and manufacturing organisation
CDR	Clinical Dementia Rating Scale
CDx	Companion diagnostic
CE mark	Notified body issued authorisation for medical devices that pass the conformity assessment (health, safety and environmental protection) and are sold in the European economic area
CEC	Circulating endothelial cells
CF	Cystic fibrosis
CGT	Cell and gene therapies
cGvHD	Chronic graft vs host disease
CHF	Congestive heart failure
CHIT1	Chitotriosidase (inhibitor)
CHMP	Committee for Medicinal Products for Human Use (a committee of the EMA)
CI	Cognitive impairment
CINV	Chemotherapy-induced nausea and vomiting
CKD	Chronic kidney disease
CLL	Chronic lymphocytic leukaemia
Cmax	Maximum concentration of drug exposure
CMO	Contract manufacturing organisation
CMS	Centers for Medicare & Medicaid Services (US federal agency that operates the Medicare program and works in partnership with state governments to operate the Medicaid program)
CMT	Charcot-Marie-Tooth disease
CNS	Central nervous system
CNV	Choroidal neovascularisation
COPD	Chronic obstructive pulmonary disease
CPAP machine	Continuous positive airway pressure machine
CPI	Checkpoint inhibitor
CPT	Current Procedural Terminology codes (for RPS reimbursement, US CMS)
CR	Complete response
CR	Complete remission
CRC	Colorectal cancer
CRE	Carbapenem-resistant Enterobacteriaceae
CRL	Complete response letter (reflects FDA's complete review of a new or generic drug application that has not been approved for marketing)
CRO	Contract research organisation
CsA	Cyclosporin A
CSF	Cerebrospinal fluid
CTA	Clinical trial application (EU version of an IND)
CTB	Cogstate Cognitive Test Battery
CTN	Clinical Trials Notification Scheme (Australian version of an IND)
CTX	Cortex
CV	Cardiovascular
CXCR4	C-X-C chemokine receptor type 4
DC	Dendritic cell
DCR	Disease control rate
DDI	Drug-drug interaction
DEA	Drug Enforcement Administration (US agency focused on controlled substances)
DFS	Disease-free survival
DGF	Delayed graft function
DIPG	Diffuse intrinsic pontine glioma
DLBCL	Diffuse large B-cell lymphoma
DLT	Dose-limiting toxicity
DME	Diabetic macular edema
DMF	Drug master file (submission to FDA to provide confidential, detailed information about facilities or processes used in the manufacturing, processing, packaging, and storing of human drug products)

DMPK	Drug metabolism and pharmacokinetics
DMT	Disease modifying therapy
DoR	Duration of response
DR	Diabetic retinopathy
DRG	Diagnosis-related group code
Dry-AMD	Dry age-related macular degeneration
DSMB	Data safety monitoring board
DSST	Digit Symbol Substitution Test
DT	Destination therapy
DTC	Direct to consumer
EB	Epidermolysis bullosa
EBT	External-beam radiation therapy
ECM	Extracellular matrix
EDL	Essential drug list (list of medicines that must be in stock at public hospitals and clinics in China)
EGFR	Epidermal growth factor receptor
EMA	European Medicines Agency (European regulator)
epNET	Non-pancreatic neuroendocrine tumour
ER	Estrogen receptor
ES	Effect size
ESAT-6	Early secreted antigenic target 6Da
ESMO	European Society for Medical Oncology
EUA	Emergency Use Authorization
FDA	Food and Drug Agency (US regulator)
FeNO	Fractional exhaled nitric oxide
FEV1	Forced expiratory volume
FGFR	Fibroblast growth factor receptors
FISH	Fluorescence in situ hybridization
FL	Follicular lymphoma
FTD	Fast Track Designation (facilitates development and expedites FDA review of drugs to treat serious conditions and fill an unmet medical need)
FVCP	Percent-predicted forced vital capacity
GA	General anaesthesia
GA	Geographic atrophy
GA-AMD	Geographic atrophy associated with dry age-related macular degeneration
GAD	Generalised anxiety disorder
GBM	Glioblastoma
GC	Gastric cancer
G-CSF	Granulocyte colony-stimulating factor
GDI	Glaucoma drainage implant
GDUFA	Generic Drug User Fee Act date (when FDA is expected to approve/not approve ANDA)
GI	Gastrointestinal
GINA	Global Initiative for Asthma
GIST	Gastrointestinal stromal tumours
GMP	Good manufacturing practice
GPR	G-protein-coupled receptor
GvHD	Graft vs host disease
H2H	Head-to-head
HAIs	Hospital-acquired infections
HbV	Haemoglobin
HBV	Hepatitis B virus
HCC	Hepatocellular cancer
HCO	Hydroxychloroquine sulphate
HDAC	Histone deacetylase
HDL	How-density lipoprotein (cholesterol)
HER	Human epidermal growth factor receptor
HF	Heart failure
HHT	Human heart transplantation
HHV	Human herpesvirus
HLA	Human leukocyte antigen
HMA	Hypomethylating agents
HNSCC	Head and neck squamous cell carcinoma
HPA	Hypothalamic pituitary adrenal
hpSCs	Human parthenogenetic stem cells
HPV	Human papilloma virus
HR	Hazard ratio
HR-MDS	Higher-risk myelodysplastic syndrome
hRPC	Human retinal progenitor cell
HRQL	Health-related quality-of-life
HRRP	Hospital Readmissions Reduction Program (US)
HSCT	Hematopoietic stem cell transplant

HSIL	High-grade squamous intraepithelial lesion
IBD	Inflammatory bowel disease
IBS-D	Irritable bowel syndrome with diarrhoea
iCCA	Intrahepatic cholangiocarcinoma
ICER	Institute for Clinical and Economical Review
ICI	Immune checkpoint inhibitor
ICU	Intensive care unit
ID	Iron deficiency
IDA	Iron deficiency anaemia
IDMC	Independent Data Monitoring Committee
IDN	Integrated delivery network
IHC	Immunohistochemistry
IIT	Investigator-initiated trials
ILD	Interstitial lung disease
IMP	Investigational medicinal product (Australia TGA terminology)
IND	Investigational New Drug Application (submission to FDA required to start clinical trials)
IO	Immuno-oncology
IOP	Intraocular pressure
IPF	Idiopathic pulmonary fibrosis
IR	Insulin receptor
ITP	Immune thrombocytopenia
ITT	Intention-to-treat (analysis includes all patients randomised in the clinical study)
iv, im, sc	Intravenous, intramuscular, subcutaneous
IVT	Intravitreal
KOL	Key opinion leader
LAI	Long-acting injectable
LCD	Local coverage determination (MAC decision whether to cover a particular treatment in its jurisdiction)
LDAC	Low-dose cytarabine
LDL	Low-density lipoprotein (cholesterol)
LDTs	laboratory-developed tests
LHON	Leber's hereditary optic neuropathy
LMWH	Low molecular weight heparin
LNP	Lipid nanoparticle
LPAD	Limited population pathway for antibacterial and antifungal drugs (FDA pathway to approval for antibacterial and antifungal drugs that treat serious infections in a small population of patients with unmet needs)
LPAD	Left pulmonary artery diameter
LSC	Leukaemia stem cells
LSIL	Low-grade squamous intraepithelial lesions
LT	Laser trabeculoplasty
LVEF	Left ventricular ejection fraction
LVESV	Left ventricle end systolic volume
LVV	Lentiviral vector
MAA	Marketing Authorisation Application (EMA regulatory filing for approval)
MAC	Medicare Administrative Contractor (private insurer that has been awarded geographic jurisdiction to process claims)
MAC	Mycobacterium avium complex
MACE	Major adverse cardiac event
MAD	Multiple ascending dose
MAPK	Mitogen-activated protein kinase
mBC	Metastatic breast cancer
MC	Mast cell
mCDRPC	Metastatic castration and docetaxel resistant prostate cancer
MCI	Minimal/mild cognitive impairment
MCL	Mantle cell lymphoma
mCRC	Metastatic colorectal cancer
mCRPC	Metastatic castration-resistant prostate cancer
MCS	Mechanical circulatory support
MDD	Major depressive disorder
MDS	Myelodysplastic syndrome
MDSC	Myeloid-derived suppressor cell
MES	Molecular epidemiology study
MET	Mesenchymal epithelial transition factor
MFS	Metastasis-free survival
MHRA	Medicines and Healthcare Products Regulatory Agency (UK regulator)
MI	Myocardial infarctions
MIGS	Minimally invasive glaucoma surgeries
MM	Multiple myeloma
MMP-2	Matrix metalloproteinase-2
MoA	Mode of action
mOS	Median overall survival

MPC	Mesenchymal precursor cell
mPFS	Median progression-free survival
MRI	Magnetic resonance imaging
MRP	Mutual recognition procedure (one route of filing in the EU)
MRSA	Methicillin-resistant Staphylococcus aureus
MS	Multiple sclerosis
MSA	Medical savings account (allows owner to withdraw earmarked funds to pay for treatments)
MSC	Mesenchymal stem cell
MT	Monotherapy
MTD	Maximum tolerated dose
MTK	Multiple tyrosine kinase
MTR	Molecularly targeted radiation
MWCNT	Multi-walled carbon nanotubes
NAFLD	Non-alcoholic fatty liver disease
nAMD	Neovascular age-related macular degeneration
NASH	NASH activity score
NASH	Non-alcoholic steatohepatitis
NCI	National Cancer Institute (US agency for cancer research)
NDA	New Drug Application (FDA filing application for approval for chemical/small molecule drugs)
NET	Neuroendocrine tumour
NGF	Nerve growth factor
NGS	Next generation sequencing
NHL	Non-Hodgkin's lymphoma
NHP	Non-human primate
NHSA	National Healthcare Security Administration (agency in China that manages medical insurance schemes)
NIAID	National Institute of Allergy and Infectious Diseases (US agency for the research of infectious, immunologic and allergic diseases)
NICE	National Institute for Health and Clinical Excellence (develops clinical guidelines for NHS)
NIH	National Institutes of Health (US)
NK	Natural killer cell
NME	New molecule entity (FDA regulatory pathway)
NMIBC	Non-muscle invasive bladder cancer
NMPA	Chinese National Medical Products Administration (China regulator)
NO	Nitric oxide
NRDL	National reimbursement drug list (includes drugs reimbursable by public insurance schemes in China)
NSC	Neural stem cells
NSCLC	Non-small cell lung cancer
NTAP	New technology add-on payments (CMS provides additional payment to hospitals for new, high-cost medical services and technologies)
NTM	Pulmonary non-tuberculous mycobacteria
OAG	Open-angle glaucoma
OC	Ovarian cancer
ODAC	Oncologic Drugs Advisory Committee (makes recommendations to FDA about the safety and effectiveness of marketed and investigational oncology drugs)
ODD	Orphan drug designation (provides tax incentives and a period of market exclusivity to treatments targeting rare diseases or conditions)
ODI	Oxygen desaturation index
OFP	Oral ferrous product
OIC	Opioid-induced constipation
OR	Odds ratio
ORR	Objective response rate
OS	Overall survival
OTC	Over-the-counter
PA	Passive avoidance
pALL	Paediatric acute lymphoblastic leukaemia
PARP	Poly-ADP-ribose polymerase
PCLS	Precision cut liver slices
PCR	Polymerase chain reaction
PD	Parkinson's disease
PD-(L)1	Programmed death-ligand 1
PD-1	Programmed cell death protein 1
PDAC	Pancreatic ductal adenocarcinoma
PDUFA date	Prescription Drug User Fee Act date (when FDA is expected to approve/not approve NDA or BLA)
PDX	Patient-derived xenograft
PEP	Post-exposure prophylaxis
PET	Positron emission tomography
PFAS	Perfluoroalkyl substances
PFS	Progression-free survival
PGA	Prostaglandin F2 α
PGDGF	Platelet-derived growth factor

PGP	P-glycoprotein - multidrug resistance protein
Phase I	Testing of a new treatment in healthy volunteers (can also be in patients with the disease or condition) to assess safety and determine the RP2D dose. Less than 100 participants.
Phase Ia	Single ascending dose. Patients receive a single dose of the treatment, and if no adverse side effects are observed, the dose is increased for the next cohort of patients to determine the MTD.
Phase Ib	Multiple ascending dose. Patients receive multiple doses of the treatment at the same dose level, and if no adverse side effects are observed, the dose is increased for the next cohort of patients to determine the MTD. Provides preliminary efficacy data.
Phase II	Testing of a new treatment in patients with the disease or condition to assess efficacy and side effects. Up to several hundred participants.
Phase III	Testing of a new treatment in patients with the disease or condition to assess efficacy and clinical benefit, as well as monitoring adverse reactions (and long-term side effects). Up to several thousand participants.
Phase IV	Post-marketing surveillance to assess the safety (rare and long-term side effects) and efficacy of an approved treatment in patients that are prescribed it.
PICU	Paediatric intensive care unit
PK	Pharmacokinetics
PMA	Pre-market approval (FDA approval required for Class III medical devices that support or sustain human life before marketing)
PMC	Pseudomembranous colitis
PMDA	Pharmaceutical and Medical Device Agency (Japan regulator)
PMDs	Primary mitochondrial diseases
pNET	Pancreatic neuroendocrine tumour
PoC	Point-of-care
PONV	Post-operative nausea and vomiting
PoS	Probability of success
PP	Per protocol (analysis only includes patients that complied with the clinical study protocol)
PPE	Personal protective equipment
PR	Partial response
PR	Progesterone receptor
PRCC	Papillary renal cell carcinoma
Preclinical	Testing of drug in non-human subjects, to gather efficacy, toxicity and pharmacokinetic information
Priority review	FDA aims to take action on an application within 6 months (compared to 10 months under standard review)
PRRT	Peptide receptor radionuclide therapy
PRV	Priority review voucher
PS	Procedural sedation
PSA	Prostate-specific antigen
PSC	Pulmonary sarcomatoid carcinoma
Pt	Patient
pTau	Phosphorylated Tau
PTCL	Peripheral T-cell lymphoma
PV	Pharmacovigilance
qd	Once daily
QIDP	Qualified infectious disease product designation
QoL	Quality-of-life
RA	Rheumatoid arthritis
RBC	Red blood cell
RCC	Renal cell carcinoma
RCT	Randomised clinical trial
RECIST	Response evaluation criteria in solid tumours
RFS	Relapse free survival
RGC	Retinal ganglion cell
RI	Rapid infusion
RMAT	Regenerative medicine advanced therapy (FDA designation for regenerative medicine therapies that enables eligibility for expediated programs)
RP	Retinitis pigmentosa
RP2D	Recommended Phase II dose
RPDD	Rare paediatric disease designation
RTD	Ready to dilute formulation
RTF	Refusal to file (allows FDA to inform sponsors of deficiencies in their NDA or BLA as soon as possible, instead of waiting to issue a CRL)
RTK	Receptor tyrosine kinase
RT-PCR	Reverse transcriptase polymerase chain reaction
RVO	Retinal vein occlusions
Rx	Prescription
SAA	Severe aplastic anaemia
SAB	Staphylococcus aureus bacteraemia
SAD	Single ascending dose
SAE	Serious adverse event
SAP	Statistical analysis plan

SARS	Severe acute respiratory syndrome
SCCHN	Squamous cell carcinoma of the head and neck
SCLC	Small cell lung cancer
SD	Stable disease
SDAM	Serotonin-dopamine activity modulator
SMA	Spinal muscular atrophy
SMC	Safety monitoring committee
SNRI	Serotonin/norepinephrine reuptake inhibitor
SNS	Strategic National Stockpile
SoC	Standard of care
SPA	Special protocol assessment (FDA process to reach agreement with sponsors on the design and size of certain clinical trials)
SPECT	Single photon emission computed tomography
SPION	Super paramagnetic iron oxide nanoparticle
SRE	Skeletal-related event
SSRI	Selective serotonin reuptake inhibitor
STS	soft tissue sarcoma
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TAAAs	Tumour-associated antigens
TAH	Total artificial heart
TAM	Tumour-associated macrophage
TBI	Traumatic brain injury
TCM	Traditional Chinese medicine
TCR	T-cell receptor
TD	Travellers' diarrhoea
TEAE	Treatment-emergent adverse event
TfR	Transferrin receptor
TGA	Therapeutic Goods Administration (Australia regulator)
TGF	Transforming growth factor
TGI	Tumour growth inhibition
Th cell	T helper cell
THC	Tetrahydrocannabinol
TKI	Tyrosine kinase inhibitor
TLR	Toll-like receptor
TM	Trabecular meshwork
TMAC	Tissue microenvironment-activated conjugates
TME	Tumour microenvironment
TNBC	Triple-negative breast cancer
TNK	Tumour necrosis factor
TPS	Tumour proportion score
TSAs	Tumour-specific antigens
TSTx	Tissue-Specific Therapeutics
TTFields	Tumour-treating fields
TTP	Time-to-progression
TURBT	Transurethral resection of the bladder tumour
Tx	Treatment
UBC	Umbilical cord blood
UC	Urothelial cancer
URD	Unrelated matched donor
USP7	Ubiquitin specific protease-7
VADs	Visual acuity
VADs	Ventricular assistance devices (L = left, R = right and Bi=biventricular)
VEGFR	Vascular endothelial growth factor receptors
vHC	Viral haemorrhagic cystitis
VMIC	Vaccines Manufacturing and Innovation Centre
VOC	Variants of concern
WHO	World Health Organisation
WT	Wild type

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