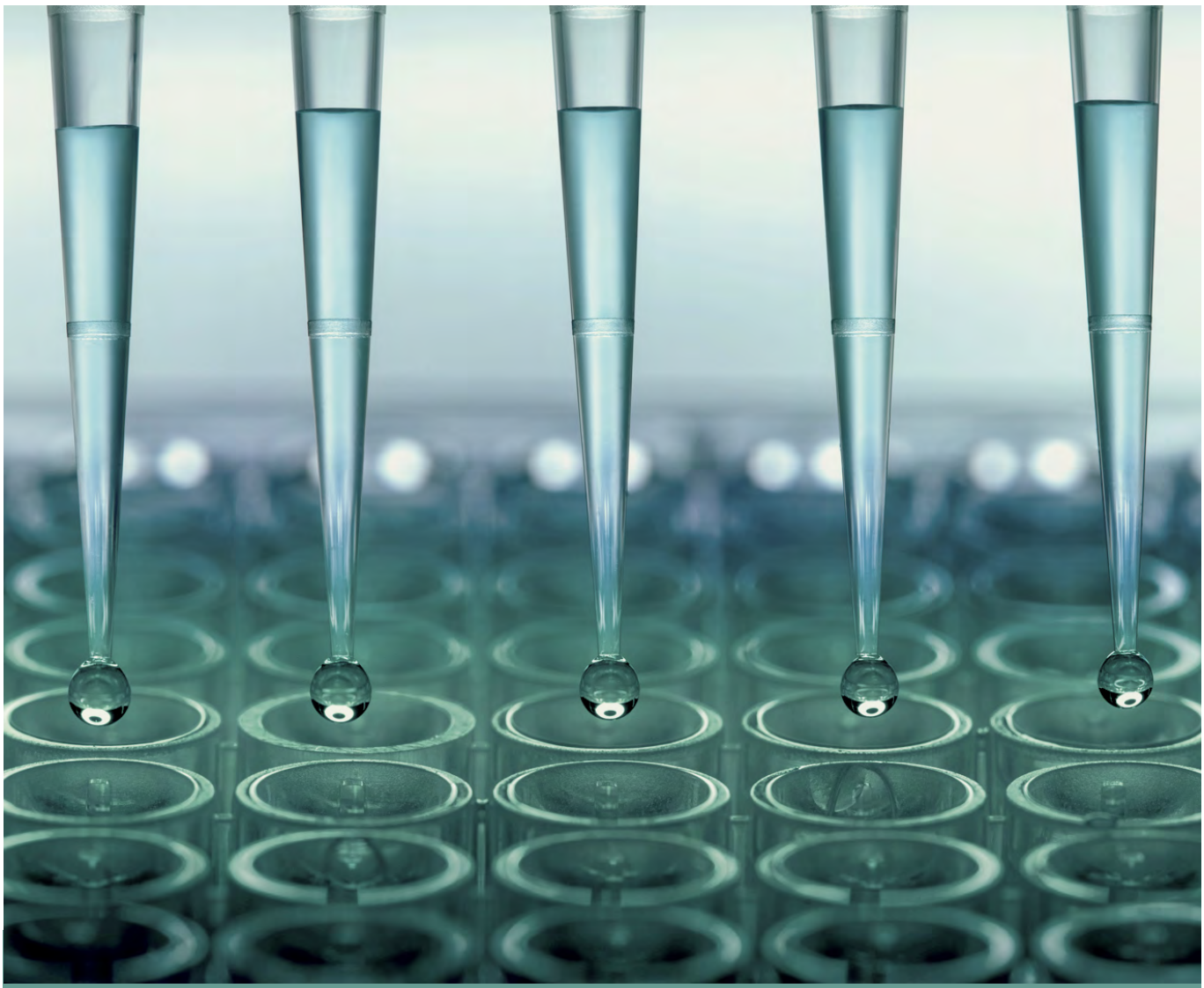
EDISON

BRILLIANT KNOWLEDGE



EDISON HEALTHCARE INSIGHT

November 2022

Published by Edison Investment Research

The Edison healthcare team

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.

Kenneth Mestemacher

Ken is a director of TMT research and has 20+ years of experience in finance and engineering. Prior to joining Edison in 2021, he spent five years in equity research in TMT and other sectors. He has an MBA with High Honors from the University of Chicago Booth School of Business and a degree in chemical engineering from Missouri University.

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.

Contents

Prices at 7 November 2022 Published 10 November 2022

Welcome to the November edition of the Edison Healthcare Insight. In this edition we have profiled 36 of our healthcare companies under coverage.

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.

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisors and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting.

We welcome any comments/suggestions our readers may have.

Neil Shah

Director of research

Company profiles

Prices at 7 November 2022

US$/£ exchange rate: 0.8817
€/£ exchange rate: 0.8691
A$/£ exchange rate: 0.5602
NZ$/£ exchange rate: 0.5062
PLN/£ exchange rate: 0.1824
SEK/£ exchange rate: 0.0793
NOK/£ exchange rate: 0.0841
CHF/£ exchange rate: 0.8832
DKK/£ exchange rate: 0.1168

Sector: Pharma & healthcare

Price: SEK0.18
Market cap: SEK189m
Market NOMX Sweden Small Cap

Share price graph (SEK)

Company description

Abliva is a Swedish biotech focused on mitochondrial medicine. Its lead assets are KL1333, an NAD+/NADH modulator (IND approved) and NV354, a succinate prodrug (preclinical). A pivotal Phase II/III trial with KL1333 in selected PMDs is due later this year. NV354 has completed pre-clinical studies and is being prepared to enter the clinic.

Price performance

%	1m	3m	12m
Actual	(1.8)	(29.5)	(64.0)
Relative*	(10.1)	(26.3)	(52.9)

* % Relative to local index

Analyst

Soo Romanoff

Abliva (ABLI)

INVESTMENT SUMMARY

Abliva is focused on primary mitochondrial diseases (PMD). The core portfolio consists of KL1333 and NV354. KL1333 is a small molecule NAD+/NADH modulator used to restore intracellular energy balance. With the investigational new drug (IND) application approved by the FDA, Abliva is preparing for the pivotal Phase II/III FALCON trial with KL1333 and is expected to start screening patients in Q422. Abliva is also progressing with its other core asset, NV354, as a systemic treatment for Leigh syndrome, with preparations ongoing for a Phase I start. In June Abliva raised c SEK200m (SEK150m private placement and SEK50m rights issue), which is expected to provide the company with a 24-month cash runway through to mid-2024.

INDUSTRY OUTLOOK

Abliva has a diversified portfolio, with all assets aimed at improving mitochondrial metabolism and function. We believe this puts Abliva among the very few experts in mitochondrial medicine.

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (fd) (öre)	P/E (x)	P/CF (x)
2020	1.9	(55.0)	(57.4)	(23.00)	N/A	N/A
2021	0.2	(117.9)	(120.4)	(34.44)	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$0.13
Market cap: A$233m
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 that occurs in chronic neurodegenerative and neuropsychiatric diseases.

Price performance

%	1m	3m	12m
Actual	35.4	100.0	(25.7)
Relative*	32.5	103.4	(19.0)

* % 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. Actinogen plans to start the Phase IIb portion on XanaMIA in patients with biomarker-confirmed early AD in H1 CY23. The XanaCIDD proof-of-concept Phase II trial in MDD is also planned to start in Q422.

INDUSTRY OUTLOOK

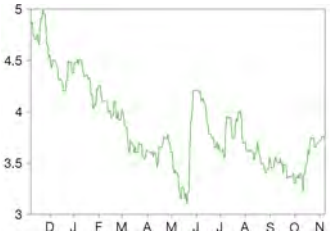
The unmet need in chronic neurocognitive disorders is tremendous due to the limited effectiveness of available treatment options. The Phase IIb portion of the XanaMIA trial will be key for validating the encouraging Xanamem data shown to date.

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$3.70
Market cap:	NZ$388m
Market	NZSX

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	8.8	2.2	(23.7)
Relative*	7.0	7.4	(9.1)

* % 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. Despite COVID-19 headwinds, operating revenue in FY22 grew strongly by 15.2% y-o-y to NZ$130.3m, mainly aided by new product launches, solid recovery in Australia and sustained growth in New Zealand. Reported group operating profit almost doubled to NZ$20.4m in FY22 versus NZ$10.7m in the same period a year ago. AFT has given FY23 guidance for operating profit in the range of NZ$27–32m. In July 2022, AFT expanded its product reach into China following registration under the country's Cross Border E-Commerce OTC platform. In September, AFT announced that along with partner Hyloris Pharmaceuticals, it will initiate additional studies to address the FDA queries (raised in July 2022) related to Maxigesic IV's packaging, with completion expected by CY23.

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	52.1	N/A
2022	130.3	21.4	18.9	19.2	19.3	31.5
2023e	155.9	30.6	27.0	20.4	18.1	21.1
2024e	194.2	47.1	43.5	30.0	12.3	11.4

Sector: Pharma & healthcare

Price:	A$0.03
Market cap:	A$17m
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	(21.2)	(3.7)	(36.6)
Relative*	(22.9)	(2.1)	(30.8)

* % 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 in future. In September 2022, Arovella signed a strategic collaboration with Imugene to investigate the combined potential of the company's lead CAR19-iNKT programme ALA-101 with Imugene's onCARlytics (CF33-CD19) platform in treating solid tumours. Following this the company has decided to cease all R&D activities related to its legacy OroMist platform.

INDUSTRY OUTLOOK

ALA 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: CHF46.05
Market cap: CHF599m
Market Swiss Stock 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	9.8	11.0	7.5
Relative*	5.3	14.8	23.2

* % Relative to local index

Analyst

Soo Romanoff

Basilea Pharmaceutica (BSLN)

INVESTMENT SUMMARY

In February Basilea announced a strategic refocusing of its core anti-infective business in 2022. The company is progressing with separating out its oncology assets with the out-licensing of three oncology assets in FY22 so far. Strong FY21 results were driven by key anti-infective assets, Cresemba and Zevtera. Global Cresemba sales were over US$300m in FY21 resulting in significantly increased royalty and milestone payments. Basilea has secured a CHF75m senior secured loan from Athyrium Capital Management (a US-based asset management company), which along with cash on books will be used to repay the outstanding convertible bonds due in December 2022 and is anticipated to bridge the company until expected operational profitability in FY23. 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 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	120.0	(10.4)	(15.3)	(129.40)	N/A	N/A
2023e	128.8	13.7	6.4	47.03	97.9	N/A

Sector: Pharma & healthcare

Price: SEK3.46
Market cap: SEK577m
Market NASDAQ OMX First North

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	(9.1)	(33.6)	(73.3)
Relative*	(16.8)	(30.6)	(65.1)

* % 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 now preparing for the Phase II/III trial in metastatic PDAC in collaboration with PanCAN. A second programme, CAN10, is being developed for treatment of myocarditis and systemic sclerosis. New supportive preclinical data were recently presented and Phase I clinical trials are planned for early 2023. Nadunolimab is being investigated across eight different cancers in different combinations. The company had an estimated cash and short-term investment position of SEK575.2m at end-August 2022.

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)	(370.3)	(369.55)	N/A	N/A
2022e	0.0	(390.4)	(393.8)	(294.78)	N/A	N/A
2023e	0.0	(364.0)	(367.5)	(220.06)	N/A	N/A

Sector: Pharma & healthcare

Price:	€13.00
Market cap:	€256m
Market	Euronext Growth

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	5.0	8.2	(52.4)
Relative*	(3.8)	10.0	(46.9)

* % Relative to local index

Analyst

Pooya Hemami

Carmat (ALCAR)

INVESTMENT SUMMARY

Carmat announced in October that it has received the regulatory approvals to resume implants of its Aeson physiologic heart replacement therapy in a commercial setting, and it expects to resume implant sales in Europe in the near future at a gradual pace. The company had implemented controls to improve Aeson quality and safety, in response to defects identified in two components that affected some of its prostheses and led to a voluntary suspension of Aeson implantations in Q421. Carmat recorded €2.3m in FY21 revenue from the sale of seven Aeson devices in Germany and Italy and three in the United States as part of an early feasibility study. After raising €40.5m in gross proceeds in April 2022, it reported a 30 June cash position of €47m, which provides a cash runway until March 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.

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$1.17
Market cap:	US$19m
Market	NASDAQ

Share price graph (US$)

Company description

Context Therapeutics is a clinical-stage women's oncology company. Lead candidate ONA-XR is a 'full' PRA being evaluated in three Phase II and one Phase Ib/II clinical trial in hormone-driven breast, endometrial and ovarian cancer. The other asset is a bi-specific monoclonal antibody, CLDN6xCD3.

Price performance

%	1m	3m	12m
Actual	0.9	(39.1)	(78.7)
Relative*	(3.6)	(33.6)	(73.8)

* % Relative to local index

Analyst

Soo Romanoff

Context Therapeutics (CNTX)

INVESTMENT SUMMARY

Context Therapeutics is developing novel therapeutics focused on women's oncology indications. Lead programme onapristone extended release (ONA-XR) is a potential first-in-class progesterone receptor antagonist being evaluated in several mid-stage clinical programs in advanced HR+/HER2- breast and hormone-driven endometrial and ovarian cancer. CLDN6xCD3, a novel bi-specific monoclonal antibody, was acquired in April 2021 is being assessed in endometrial and ovarian cancers. Context announced a collaboration with the Menarini Group to study ONA-XR in combination with elacestrant, an oral SERD for the treatment of second/third-line HR+/HER2- metastatic breast cancer (Phase Ib/II in Q422). Following this Context announced plans to cut all non-essential R&D expenses to help manage the cash runway.

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:	43.5p
Market cap:	£79m
Market	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 four 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	(18.7)	(41.5)	(71.3)
Relative*	(22.3)	(39.8)	(70.0)

* % 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 platform delivers a combination of advanced bi-polar radiofrequency (RF) and microwave energy for the purpose of dissection, resection, ablation and haemostasis of diseased tissue. The initial focus is on gastrointestinal procedures expanding into soft tissues (such as pancreas) and pulmonology. The company has had all six products within the CROMA platform CE marked, with four cleared for use by the FDA. Creo's first commercially available device, Speedboat Inject, is now used across the globe. In H122, Creo reported first licensing income from its May 2022 multi-year collaboration with robotics market leader, Intuitive and has agreed heads of terms with further potential future partners as interest grows in its Kamaptive technology. Recently, Creo signed a licence and royalty agreement with CMR Surgical, a global surgical robotics company.

INDUSTRY OUTLOOK

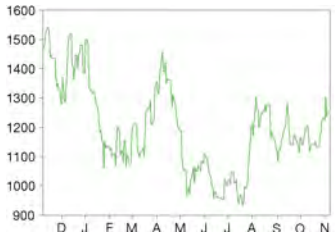
Creo Medical products are in a large and lucrative market. Conmed estimates the GI endoscopic technologies market alone is approximately $3.0–3.2bn with the RF energy based surgical device market at $2.7–2.9bn per year. Entering the robotics and laparoscopic markets further increases the scale of opportunity 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)	(12.752)	N/A	N/A
2021	25.2	(26.7)	(29.7)	(14.577)	N/A	N/A
2022e	28.7	(23.1)	(25.8)	(12.118)	N/A	N/A
2023e	33.8	(20.9)	(23.7)	(11.096)	N/A	N/A

Sector: Pharma & healthcare

Price:	1246.0p
Market cap:	£624m
Market	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	3.8	(1.3)	(15.2)
Relative*	(0.8)	1.7	(11.4)

* % Relative to local index

Analyst

Soo Romanoff

Ergomed (ERGO)

INVESTMENT SUMMARY

Ergomed's H122 results re-emphasised its robust business model and resilient growth despite the challenging macro environment. Revenues grew 24.8% y-o-y to £69.9m, underpinned by strong and sustained demand for both the clinical research services and pharmacovigilance segments. The order book, a leading indicator of forthcoming sales potential, remained robust at £284.5m, up 18.7% from end December 2021 and 24.9% from H121 (ahead of our estimates) 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 acquisition should also immediately be accretive to earnings, according to management. With a £12m cash balance at end-H122 and £80m in undrawn debt facilities, the company remains well capitalised to fund future growth.

INDUSTRY OUTLOOK

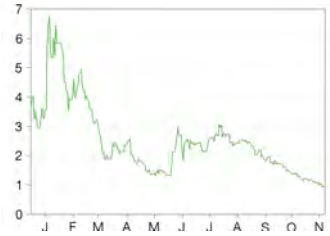
Innovation in healthcare is driving sales and growth in the number of clinical trials being initiated, as pharmaceutical and biotechnology companies continue to invest substantially. Tight operational control and execution will enable Ergomed to drive market share in high-growth orphan drug trials as 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	54.6	33.3
2021	118.6	25.4	21.6	39.6	31.5	32.3
2022e	140.1	28.2	23.9	39.0	31.9	30.1
2023e	156.5	31.7	27.7	44.7	27.9	22.7

Sector: Pharma & healthcare

Price:	US$0.89
Market cap:	US$12m
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	(31.9)	(64.8)	N/A
Relative*	(34.9)	(61.7)	N/A

* % 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 Q422. We also expect a Phase Ib study of IMX-110 in combination with tislelizumab (an anti-PD-1 antibody) to begin in Q422. To support this trial, Immix has entered a supply agreement with BeiGene/Novartis.

INDUSTRY OUTLOOK

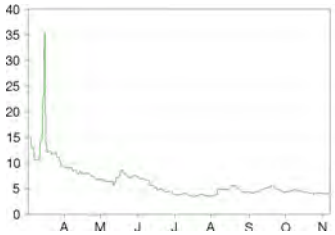
With IMX-110 Immix is targeting the STS market, a rare cancer with c 13,000–16,000 new cases reported in the United States each year and limited safe and effective treatment options. IMX-110's combination study may further expand the drug's offering into new indications.

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)	(0.51)	N/A	N/A
2021	0.0	(1.4)	(1.3)	(0.36)	N/A	N/A
2022e	0.0	(6.2)	(6.1)	(0.44)	N/A	N/A
2023e	0.0	(8.8)	(8.8)	(0.63)	N/A	N/A

Sector: Pharma & healthcare

Price:	US$3.71
Market cap:	US$226m
Market	NASDAQ

Share price graph (US$)



Company description

Listed in Australia, Incannex Healthcare is developing medicinal cannabis pharmaceutical products and psychedelic medicine therapies. These therapies are being designed to target indications with unmet need, including obstructive sleep apnoea, generalised anxiety disorder, trauma and inflammatory conditions.

Price performance

%	1m	3m	12m
Actual	(22.1)	(24.1)	N/A
Relative*	(25.5)	(17.4)	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. 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 Q422) 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 Q422. ILH-675A is in (Australian) Phase I trials for the treatment of various inflammatory disorders.

INDUSTRY OUTLOOK

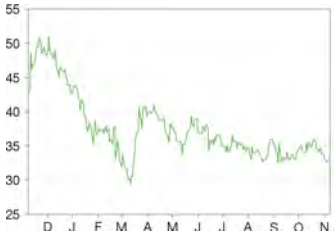
Management's strategy to pursue synergistic combination patent filings of its assets has the potential to create extensive protection within the cannabinoid treatment market. The IP position for the combinations will be further supported by method of use and formulation patents. Combination patents could 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)	(1.38)	N/A	N/A
2024e	0.1	N/A	(33.4)	(2.24)	N/A	N/A

Sector: Pharma & healthcare

Price: SEK33.75
Market cap: SEK1748m
Market NASDAQ OMX First North

Share price graph (SEK)



Company description

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

Price performance

%	1m	3m	12m
Actual	(0.7)	(0.7)	(23.6)
Relative*	(9.2)	3.8	0.0

* % 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 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 is an oral D3 antagonist has just completed recruitment in a Phase IIb trial for levodopa-induced dyskinesias (PD-LIDs) and top line data are anticipated at the year end. In 2021 Ipsen acquired a global licence (worth up to $363m plus royalties) for the future clinical development and commercialisation of mesdopetam. In addition to pirepemat IRLAB is developing a preclinical pipeline of drug candidates (IRL942 and IRL757) for the non motor symptoms of PD and a potential one a day treatment for PD without complications (P003). The company remains well funded in the medium term.

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	19.2	N/A
2022e	62.1	(108.2)	(110.3)	(213.0)	N/A	N/A
2023e	0.3	(118.9)	(121.2)	(234.0)	N/A	N/A

Sector: Pharma & healthcare

Price: US$0.70
Market cap: US$10m
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	(34.3)	(62.4)	(94.1)
Relative*	(37.1)	(59.0)	(92.7)

* % 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, however the data from this, expected in the second half of CY23, may still support registration. A Phase II trial (PNOC022), investigating the combination of ONC201 (a dopamine D2 receptor antagonist) and paxalisib in the treatment of diffuse midline glioma and diffuse intrinsic pontine glioma (DIPG), was recently expanded to two new sites.

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 (c)	P/E (x)	P/CF (x)
2021	10.5	(3.1)	(3.1)	(0.25)	N/A	N/A
2022	0.0	(14.6)	(14.6)	(1.08)	N/A	N/A
2023e	0.0	(18.6)	(18.6)	(1.23)	N/A	N/A
2024e	10.6	(16.8)	(16.8)	(1.11)	N/A	N/A

Sector: Pharma & healthcare

Price: CHF0.01
Market cap: CHF10m
Market Swiss Stock 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	(37.1)	(70.3)	(86.9)
Relative*	(39.7)	(69.2)	(84.9)

* % 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 (p38 MAPK) 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 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. 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$9.55
Market cap: A$22m
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	(19.0)	(5.4)	(65.6)
Relative*	(20.7)	(3.8)	(62.5)

* % Relative to local index

Analyst

Soo Romanoff

Medlab Clinical (MDC)

INVESTMENT SUMMARY

Medlab'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 THC and CBD (1:1) cannabinoids encapsulated in NanoCelle particles, enabling a convenient buccal spray formulation. A recent breakthrough was Medlab's announcement that it had successfully produced a synthetic version of NanaBis, allowing it to move away from a botanical extract. Now the product reformulation is completed, NanaBis will re-enter clinical development (potentially Phase III) as a fully synthetic, non-opioid pain relief drug. Medlab recently announced that laboratory work has commenced on its mRNA COVID-19 nasal vaccine using NanoCelle delivery technology. The company recorded 35% y-o-y revenue growth from continued operations in FY22 and it is currently consolidating its existing ASX shares in preparation of a potential Nasdaq listing.

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	7.7	(7.9)	(8.8)	(384.3)	N/A	N/A
2024e	7.7	(8.6)	(9.6)	(417.5)	N/A	N/A

Sector: Pharma & healthcare

Price:	SEK2.12
Market cap:	SEK423m
Market	OMX

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	10.9	(6.8)	(50.4)
Relative*	1.5	(2.6)	(35.1)

* % Relative to local index

Analyst

Soo Romanoff

Mendus (IMMU)

INVESTMENT SUMMARY

Following the transformational merger with DCprime, 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. Ilixadencel is being developed as an immune primer in combination with anti-cancer therapies, while DCP-001 is aimed at reducing the risk of cancer relapse after standard of care. DCP-001 is currently in two clinical trials: Phase II in acute myeloid leukaemia (AML, ADVANCE-II) and Phase I in ovarian cancer (ALISON). Readouts from DCP-001's use in AML and ovarian cancer are expected in Q422 and October 2022 respectively. Ilixadencel 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	1.9	(121.2)	(126.0)	(63.2)	N/A	N/A
2023e	0.0	(124.4)	(128.9)	(64.6)	N/A	N/A

Sector: Pharma & healthcare

Price:	6.5p
Market cap:	£6m
Market	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	(10.1)	(37.9)	(73.4)
Relative*	(14.1)	(36.1)	(72.2)

* % 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 disease area. Its lead asset, MTX110, is undertaking clinical studies in aggressive brain cancers such as glioblastoma (Phase Ib trial to commence in Q422) and diffuse intrinsic pontine glioma, a very rare pediatric cancer. In June 2022, the company received the US FDA fast-track designation for MTX110 in glioblastoma and an EMA orphan drug designation for the treatment of gliomas. The end-H122 cash balance of £6.42m should be sufficient to fund operations into Q123 with management actively considering options to help extend the runway.

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: 13.90PLN
Market cap: PLN195m
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	(4.1)	(14.4)	(65.6)
Relative*	(16.8)	(12.6)	(48.2)

* % 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, management anticipates OATD-02 could enter Phase I trials in solid tumour indications in Q422, subject to regulatory approval. 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	1.9	3.4
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: CHF1.31
Market cap: CHF23m
Market Swiss Stock 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	13.9	(9.7)	(36.4)
Relative*	9.2	(6.5)	(27.1)

* % 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. A potentially pivotal Phase II/III study (008A) is underway awith 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% versus H121. Newron had cash, equivalents and other of €28.4m at the end of June 2022.

INDUSTRY OUTLOOK

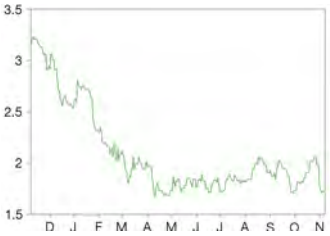
Xadago is marketed as an add-on to levodopa therapy in PD. It is sold by Zambon in Europe and by Supernus in the United States. The additional study on a dyskinesia indication should start in Q122 and could eventually boost US sales. Generic manufacturers have notified the FDA of their intention to file 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:	€1.72
Market cap:	€74m
Market	Euronext Paris

Share price graph (€)



Company description

France-based Nicox develops therapeutics for the treatment of ocular conditions. Its lead candidate NCX-470 is in Phase III studies for the treatment of glaucoma, and it is advancing NCX-4251 for DED. Nicox also receives licence revenue for its FDA-approved drugs Vyzulta and Zerviate.

Price performance

%	1m	3m	12m
Actual	(4.4)	(6.4)	(45.7)
Relative*	(12.5)	(4.9)	(39.5)

* % 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% recently 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 Phase II stage drug candidate in NCX-4251 for dry eye disease (DED), which it is seeking to out-license for further development.

INDUSTRY OUTLOOK

In addition to its IOP-lowering activity, Nicox is investigating whether NCX-470 can provide improvements to retinal perfusion, which may provide an additional protective mechanism for glaucoma treatment. Nicox had €25.6m gross cash at 30 September 2022 and has guided that it is financed into Q423, 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)	(35.98)	N/A	N/A
2023e	7.3	(15.8)	(17.5)	(39.80)	N/A	N/A

Sector: Pharma & healthcare

Price:	US$0.18
Market cap:	US$10m
Market	NASDAQ

Share price graph (US$)

Company description

OpGen is focused on revolutionising the identification and treatment of bacterial infections. Following the merger with Curetis, it has technology to detect pathogens and predict resistance. Importantly, the AMR Gene Panel and Unyvero platforms have the ability to provide results in hours instead of days.

Price performance

%	1m	3m	12m
Actual	(28.0)	(70.8)	(89.4)
Relative*	(31.1)	(68.2)	(86.9)

* % 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. Key highlights for Q322 were the signing of a second commercial contract for Acuitas AMR Gene Panel, completion of patient enrollment for UTI panel in the US, launch of ARES sequencing services in the US and collaborations with FIND and BioVersys. We will review our forecasts and valuation post the imminent publication of Q3 results.

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)	(157.43)	N/A	N/A
2021	4.3	(20.4)	(35.7)	(117.12)	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: €2.10
Market cap: €113m
Market Madrid Stock Exchange

Share price graph (€)

Company description

Oryzon Genomics is a Spanish biotech focused on epigenetics. Iadademstat is being explored for acute leukaemias and SCLC. Vafidemstat, its CNS asset, 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	(5.8)	(17.0)	(33.2)
Relative*	(12.0)	(14.9)	(23.4)

* % 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, the ALICE trial continues to show positive results 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	(5.2)	(5.2)	(5.80)	N/A	N/A
2023e	15.9	(5.7)	(6.1)	(7.08)	N/A	N/A

Sector: Pharma & healthcare

Price: €6.97
Market cap: €129m
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	21.2	7.2	(19.0)
Relative*	11.0	8.9	(9.6)

* % 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	16.0	(25.3)	(27.8)	(128.28)	N/A	N/A
2023e	0.0	(42.3)	(44.2)	(241.65)	N/A	N/A

Sector: Pharma & healthcare

Price:	316.5p
Market cap:	£305m
Market	LSE

Share price graph (p)

Company description

Oxford Biomedica's LentiVector technology supports its internal initiatives and allows it to generate significant revenue from a multitude of partners. It is implementing significant capacity upgrades to improve efficiency and support more partnering/out-licensing agreements.

Price performance

%	1m	3m	12m
Actual	(7.1)	(37.0)	(79.3)
Relative*	(11.2)	(35.1)	(78.4)

* % Relative to local index

Analyst

Soo Romanoff

Oxford Biomedica (OXB)

INVESTMENT SUMMARY

Oxford Biomedica (OXB) is a global leader in lentiviral development and manufacturing. With the formation of Oxford Biomedica Solutions in the US, OXB will offer a vector-agnostic platform to customers to continue growing its platform revenues. In the near term, revenues will continue to be driven by Novartis and AstraZeneca (AZN) as the rollout of Kymriah and the COVID-19 vaccine continues, as well as new partner programmes such as those from Bristol Myers Squibb (BMS). OXB has several established development and manufacturing partnerships including Novartis, Juno Therapeutics (BMS), Orchard Therapeutics, Boehringer Ingelheim and Beam Therapeutics. OXB also has a supply agreement with AZN for the large-scale commercial manufacture of the adenovirus vector-based COVID-19 vaccine Vaxzevria (AZD1222). Our forecasts are under review.

INDUSTRY OUTLOOK

Cell and gene therapy is the focus of much industry attention as it can dramatically alter the outcomes of many diseases. OXB's proprietary LentiVector platform has demonstrated promise in many indications. Through OXB solutions, the company is expanding into the AAV market and announced a new partnership on 14 September 2022 with a US biotech.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2020	87.7	8.3	(2.5)	(2.7)	N/A	16.0
2021	142.8	33.2	19.9	22.2	14.3	9.0
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:	€0.00
Market cap:	€6m
Market	Euronext Paris

Share price graph (€)

Company description

Pharnext is developing new therapies for both rare and common neurological disorders using its proprietary Pleotherapy platform. Lead programme PXT3003 for CMT1A has entered pivotal Phase III trials. PXT864 for Alzheimer's disease has completed Phase IIa but has been deprioritised and will be advanced through partnerships.

Price performance

%	1m	3m	12m
Actual	(25.0)	(90.9)	(99.8)
Relative*	(31.3)	(90.8)	(99.8)

* % Relative to local index

Analyst

Soo Romanoff

Pharnext (ALPHA)

INVESTMENT SUMMARY

Pharnext is an advanced clinical-stage biopharmaceutical company developing novel therapeutics for neurodegenerative diseases that currently lack curative or disease-modifying treatments. Lead programme PXT3003 is a synergistic fixed-dose combination of baclofen, naltrexone and sorbitol formulated as an oral solution, identified with the Pleotherapy R&D approach. It is in Pivotal Phase III clinical development for 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 total trial time of five years. In October, 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).

INDUSTRY OUTLOOK

PXT3003 could potentially be the first approved treatment for CMT1A. This disease is a debilitating 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:	€0.12
Market cap:	€8m
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 designed for dry-AMD. The company started implantations as part of a European pivotal study in early 2021.

Price performance

%	1m	3m	12m
Actual	(37.0)	(48.5)	(88.7)
Relative*	(42.3)	(47.7)	(87.4)

* % 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 reached its enrollment target in Q322, 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)	(21.71)	N/A	N/A
2023e	0.8	(16.2)	(18.2)	(28.62)	N/A	N/A

Sector: Pharma & healthcare

Price:	€0.19
Market cap:	€7m
Market	Euronext Paris

Share price graph (€)

Company description

Quantum Genomics is focused on the research and development of novel cardiovascular medicines. Lead asset firibastat is in two Phase III trials for the treatment of treatment-resistant hypertension (TRH) and is being investigated to treat post-myocardial infarction heart failure.

Price performance

%	1m	3m	12m
Actual	(95.2)	(92.7)	(95.3)
Relative*	(95.6)	(92.6)	(94.8)

* % 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 firibastat in 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 firibastat 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. The company will present the full results from the FRESH study at the American Heart Association congress in November. 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:	25.5p
Market cap:	£15m
Market	LSE

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 has established partners which are progressing the preclinical development of exosome-based therapeutics, utilising ReNeuron's CustomEx technology.

Price performance

%	1m	3m	12m
Actual	(7.3)	(3.8)	(76.3)
Relative*	(11.4)	(0.9)	(75.2)

* % 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)	(0.29)	N/A	N/A
2022	0.4	N/A	(11.1)	(0.17)	N/A	N/A
2023e	0.8	N/A	(11.0)	(0.17)	N/A	N/A
2024e	0.9	N/A	(12.0)	(0.18)	N/A	N/A

Sector: Pharma & healthcare

Price:	A$0.04
Market cap:	A$34m
Market	ASX, OTC QB

Share price graph (A$)

Company description

Respiri is an Australia-based company developing SaaS diagnostic solutions to support respiratory health management. 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	10.3	(12.2)	(24.6)
Relative*	7.9	(10.8)	(17.7)

* % Relative to local index

Analyst

Soo Romanoff

Respiri (RSH)

INVESTMENT SUMMARY

Respiri is an Australian medical device and software-as-a-service (SaaS) company, developing a novel remote patient monitoring approach to respiratory health management through its integrated wheezo platform. Following a strategic pivot in 2021, Respiri has redirected its focus to the US market, to leverage the country's established RPM reimbursement infrastructure. Employing a cost-effective partner-based strategy, management has onboarded its first two major hospital clients (including Michigan Children's Hospital) with first patients already enrolled. Initiation of reimbursement (expected in Q4 CY22) would make Respiri the first Australian medical device company to get paid under RPM Current Procedural Terminology (CPT) codes. Respiri recently raised A$1.6m through share placements.

INDUSTRY OUTLOOK

Notwithstanding the relatively large target patient population (asthma and COPD) in the US, the key consideration for Respiri's US push is the already established reimbursement infrastructure. In the US, the CMS has established CPT codes for RPM reimbursement coverage. With key technology patents, two telehealth partners and reimbursement arrangements in place, Respiri 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	133.3	N/A

Sector: Pharma & healthcare

Price:	SEK2.20
Market cap:	SEK90m
Market	Nasdaq First North

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	7.8	(67.8)	(87.9)
Relative*	(1.3)	(66.3)	(84.1)

* % 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 began enrolment in October 2022. While top-line readouts from the Phase II mCRC trial did not achieve the primary endpoint for efficacy, patients are continuing treatment and longer-term efficacy benefits may be realised. We estimate that the company is funded into FY24. We value Scandion Oncology at SEK279.0m or SEK6.9 per 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	0.8	(64.0)	(64.9)	(166.0)	N/A	N/A
2023e	0.8	(82.0)	(82.4)	(189.0)	N/A	N/A

Sector: Pharma & healthcare

Price:	€6.60
Market cap:	€157m
Market	Euronext Brussels

Share price graph (€)

Company description

Sequana Medical is a Belgian commercial-stage medical device company using its proprietary alfapump and DSR technologies to develop innovative treatments for diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure.

Price performance

%	1m	3m	12m
Actual	(8.6)	11.5	(16.2)
Relative*	(14.9)	16.0	1.6

* % 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

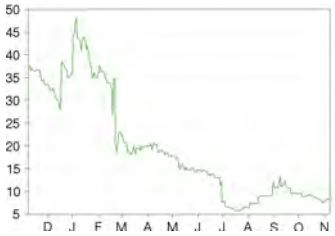
Sequana in October 2022 reported positive efficacy data from its POSEIDON North American registration study for the alfapump in recurrent and refractory ascites, and it expects to submit a US Premarket Approval application in H223, with US approval expected in 2024. Following encouraging data including 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 Ib/IIa study in H123 using its second-generation product (DSR 2.0) in a similar patient population.

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:	8.5p
Market cap:	£22m
Market	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	(4.0)	18.1	(75.7)
Relative*	(8.3)	21.6	(74.6)

* % Relative to local index

Analyst

Soo Romanoff

Shield Therapeutics (STX)

INVESTMENT SUMMARY

Shield Therapeutics is a UK-headquarted 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 and recently reported a 87% q-o-q increase in total prescriptions in Q222. 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 a net cash balance of £2.4m at end-June 2022 and raised US$10m in convertible debt from its largest shareholder in August. This should be sufficient to support its ongoing US commercial roll-out through the end of 2022.

INDUSTRY OUTLOOK

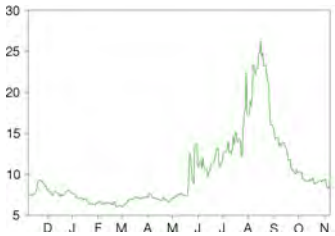
The market for iron deficiency is substantial and Feraccru/Accrufer is a unique oral formulation of iron developed to overcome the side-effect profile of salt-based oral iron therapies and provides an alternative treatment to intravenously administered iron.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2020	10.4	0.6	0.8	0.1	85.0	N/A
2021	1.5	(17.9)	(17.5)	(8.4)	N/A	N/A
2022e	5.8	(20.2)	(20.0)	(8.3)	N/A	N/A
2023e	15.9	(16.3)	(17.9)	(6.5)	N/A	N/A

Sector: Pharma & healthcare

Price:	US$9.48
Market cap:	US$692m
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, SIGA is likely to remain a beneficiary through the monkeypox epidemic.

Price performance

%	1m	3m	12m
Actual	3.3	(59.3)	28.3
Relative*	(1.3)	(55.7)	58.3

* % 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. In the United States, TPOXX was approved by the 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	11.7	10.5
2021	133.7	89.7	89.1	90.61	10.5	61.9
2022e	115.4	47.6	47.1	48.35	19.6	18.9
2023e	169.0	89.1	88.5	94.51	10.0	26.9

Sector: Pharma & healthcare

Price:	NOK90.30
Market cap:	NOK3094m
Market	Oslo

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	32.0	29.0	(28.9)
Relative*	25.1	31.9	(27.3)

* % 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 up to 90% of all cancer types. For this reason, UV1 has broad potential in a variety of cancers and in combination with other treatments. Ultimovacs' 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. In H122, the INITIUM Phase II trial in malignant melanoma completed enrolment in June, and the company recently reported positive three-year survival data from a previous Phase I trial in the same indication.

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 (öre)	P/E (x)	P/CF (x)
2020	0.0	(121.4)	(120.6)	(398.0)	N/A	N/A
2021	0.0	(161.1)	(164.7)	(509.0)	N/A	N/A
2022e	0.0	(212.3)	(213.5)	(624.0)	N/A	N/A
2023e	0.0	(216.8)	(219.1)	(640.0)	N/A	N/A

Sector: Pharma & healthcare

Price:	SEK0.64
Market cap:	SEK344m
Market	Nasdaq FN Premier

Share price graph (SEK)

Company description

Vivesto is a Swedish speciality pharma company focusing on its proprietary XR-17 and XR-18 technology platforms to develop novel formulations of well-established cytostatic oncology treatments for human and animal health. Key assets include Apealea (partnered with Elevar), docetaxel micellar and Cantrixil.

Price performance

%	1m	3m	12m
Actual	(11.4)	(14.1)	(70.3)
Relative*	(18.9)	(10.2)	(61.1)

* % Relative to local index

Analyst

Soo Romanoff

Vivesto (VIVE)

INVESTMENT SUMMARY

Vivesto is developing improved formulations of well-established cancer drugs through the application of its proprietary XR-17 and XR-18 platforms. This solubility enhancing technology has received validation though a global partnership deal for lead asset Apealea (Cremophor-free paclitaxel) with Elevar Therapeutics across a variety of cancers. Apealea is approved in Europe for second-line ovarian cancer and will be launched by Inceptua in H222. Additional studies are expected to be required before a US NDA filing. Vivesto is working on additional nanoparticle formulations, including docetaxel micellar (Phase Ib prostate cancer). In-licensed asset Cantrixil is expected to start Phase II development in ovarian cancer. In March, Vivesto completed a rights issue raising c SEK151m gross and interim results in August confirmed the company is well capitalised. In July it announced it has wound down its Russian operations and appointed Christer Nordstedt as acting CEO.

INDUSTRY OUTLOOK

Despite a slew of novel cancer drugs transforming care for many oncology indications, established chemotherapy regimens remain a cornerstone of treatment. Vivesto's XR-17 and XR-18 technology is applicable to any solubility limited drug, which includes 10–15 different cytostatic agents, and can potentially provide an improved formulation and profile.

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.5	(102.6)	(140.3)	(24.8)	N/A	N/A
2021	26.2	(99.8)	(132.7)	(24.6)	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

Company coverage

Company	Note	Date published
Abliva	Update; Update	27/05/21; 13/01/22
Actinogen Medical	Re-initiation	19/10/22
AFT Pharmaceuticals	Flash; Flash	02/09/22; 07/09/22
Arovella Therapeutics	Flash; Flash	03/11/22; 08/11/22
Basilea Pharmaceutica	Flash; Flash	25/10/22; 02/11/22
Cantargia	Flash; Flash	14/10/22; 08/11/22
Carmat	Update; Update	11/01/21; 20/09/21
Chimeric Therapeutics	Update; Update	29/07/21; 06/12/21
Context Therapeutics	Update; Update	28/09/22; 10/11/22
Creo Medical	Update; Flash	14/09/22; 25/10/22
Ergomed	Update; Update	27/07/22; 30/09/22
Immix Biopharma	Initiation	16/09/22
Incannex Healthcare	Flash; Flash	14/10/22; 31/10/22
IRLAB Therapeutics	Flash; Update	13/09/22; 09/11/22
Kazia Therapeutics	ADR Flash; ADR Flash	10/10/22; 01/11/22
Kinarus Therapeutics	Flash; Flash	05/09/22; 03/10/22
Medlab Clinical	Flash; Flash	20/09/22; 31/10/22
Mendus	Flash; Flash	18/10/22; 27/10/22
Midatech Pharma	Flash; Flash	13/06/22; 21/06/22
Molecure	Initiation	07/11/22
Newron Pharmaceuticals	Flash; Update	07/06/22; 15/09/22
Nicox	Flash; Update	31/10/22; 10/11/22
OpGen	Flash; Flash	26/10/22; 28/10/22
Oryzon Genomics	Update; Flash	03/11/22; 09/11/22
OSE Immunotherapeutics	Update; Flash	23/09/22; 03/11/22
Oxford Biomedica	Outlook; Flash	27/05/21; 05/07/22
Pharnext	Update; Flash	19/10/22; 01/11/22
Pixium Vision	Flash; Flash	14/09/22; 20/09/22
Quantum Genomics	Update; Flash	05/10/22; 28/10/22
ReNeuron Group	Flash; Re-initiation	07/10/22; 02/11/22
Respiri	Flash; Flash	06/10/22; 08/11/22
Sareum Holdings	Update; Flash	25/10/22; 09/11/22
Scandion Oncology	Update; Flash	05/10/22; 11/10/22
Sequana Medical	Flash; Update	25/10/22; 03/11/22
Shield Therapeutics	Update; Update	22/07/22; 08/09/22
SIGA Technologies	Flash; Update	14/10/22; 04/11/22
Ultimovacs	Flash; Flash	18/10/22; 25/10/22
Vivesto	Flash; Update	25/02/22; 27/06/22

Glossary

11β-HSD	11β-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	Adrenocorticotropic 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 expediates FDA review of drugs to treat serious conditions and fill an unmet medical need)
FVCPP	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
HCQ	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
HMAs	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
HRQoL	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 F2α
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
TAAs	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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Frankfurt +49 (0)69 78 8076960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas,
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205, 95 Pitt St,
Sydney NSW 2000
Australia