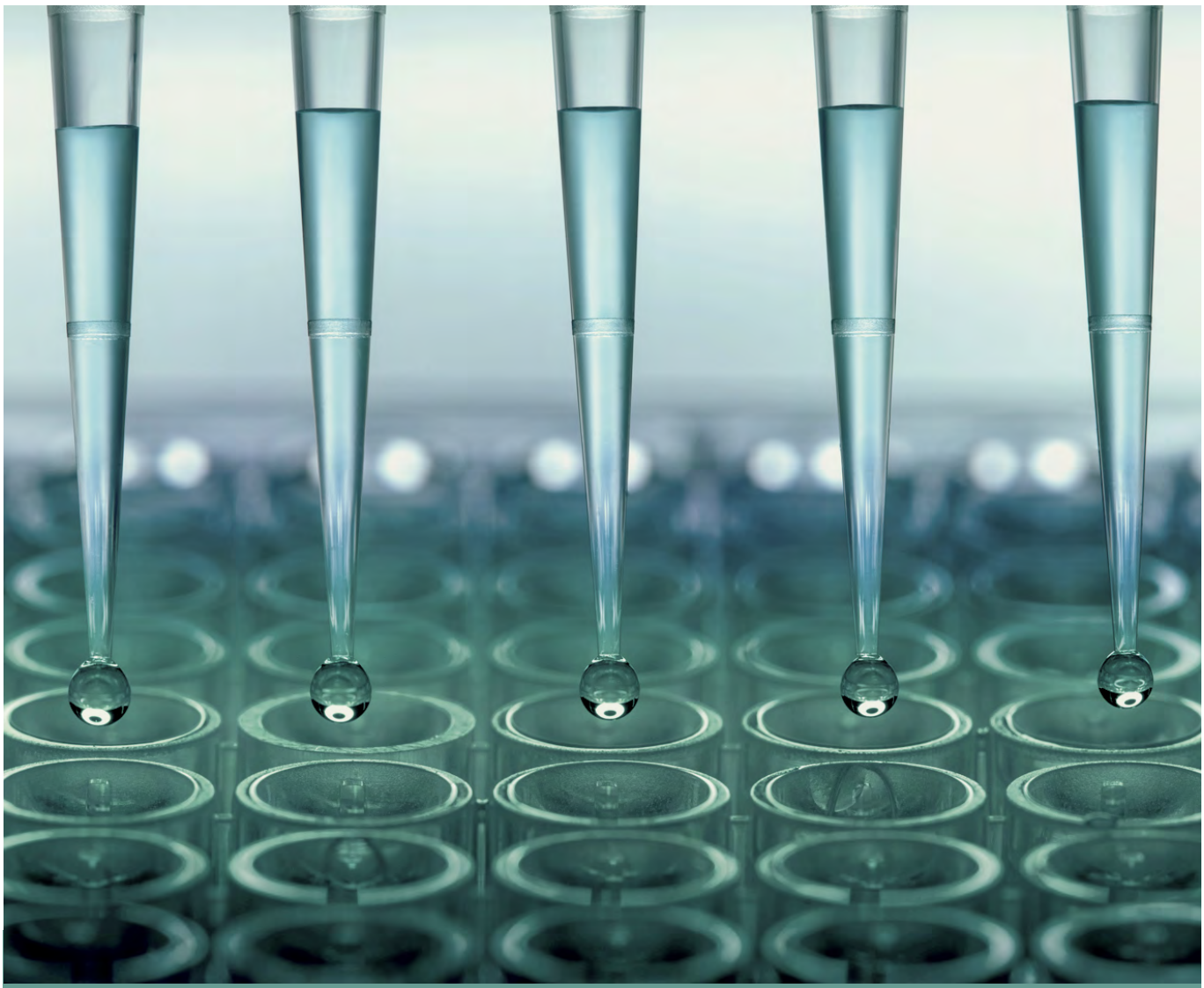
EDISON

BRILLIANT KNOWLEDGE



EDISON HEALTHCARE INSIGHT

May 2022

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The Edison healthcare team

www.edisongroup.com

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.

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.

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.

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.

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.

Karl Egeland

Karl Egeland has a research and analysis background in various sectors including biotechnology and semiconductor technology. He has contributed to several financial outlets on topics including immuno-oncology, infectious diseases/vaccines, inflammatory-fibrotic diseases, cell therapy, critical care, hyperinflammation and Alzheimer's disease. Karl has a BSc in mechanical engineering from Grove City College and an executive MBA from the Jack Welch Management Institute in Washington, DC.

Contents

Prices at 9 May 2022

Published 12 May 2022

Welcome to the May 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 9 May 2022

US$/£ exchange rate: 0.7842
€/£ exchange rate: 0.8387
A$/£ exchange rate: 0.5677
NZ$/£ exchange rate: 0.5184
SEK/£ exchange rate: 0.0809
DKK/£ exchange rate: 0.1127
NOK/£ exchange rate: 0.0861
JPY/£ exchange rate: 0.0061
CHF/£ exchange rate: 0.8167

Sector: Pharma & healthcare

Price:	SEK0.39
Market cap:	SEK156m
Market	Nasdaq FN Premier

Share price graph (SEK)

Company description

Abliva is a Swedish biotech with deep expertise in mitochondrial medicine. Its lead assets are KL1333, an NAD+ modulator (IND approved) and NV354, a succinate prodrug (preclinical). Abliva plans to start a pivotal Phase II/III trial with KL1333 in selected PMDs later this year.

Price performance

%	1m	3m	12m
Actual	(19.3)	(25.2)	(45.8)
Relative*	(6.1)	(7.7)	(35.7)

* % Relative to local index

Analyst

Kenneth Mestemacher

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+ modulator used to restore intracellular energy balance. With the investigational new drug (IND) application approved by the FDA, Abliva is getting ready for the pivotal Phase II/III FALCON trial with KL1333. The FALCON study will enrol up to 180 PMD patients, who will be randomised to receive treatment with KL1333 or placebo twice daily for 12 months. Positive Phase Ia/b data with KL1333 with first findings from treating patients were published in 2021. Abliva is also progressing with its other core asset NV354 as a systemic treatment for Leigh syndrome and plans to initiate a Phase I trial in 2022.

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	0.2	(126.1)	(128.6)	(31.92)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	A$0.06
Market cap:	A$110m
Market	ASX

Share price graph (A$)

Company description

Actinogen Medical is an ASX-listed Australian biotech developing lead asset Xanamem, a brain-penetrant 11beta-HSD1 inhibitor designed to treat cognitive impairment and other symptoms that occur in chronic neurological diseases.

Price performance

%	1m	3m	12m
Actual	(34.0)	(46.1)	8.8
Relative*	(30.3)	(44.5)	8.3

* % Relative to local index

Analyst

Soo Romanoff

Actinogen Medical (ACW)

INVESTMENT SUMMARY

Listed on the ASX and headquartered in Sydney, Australia, Actinogen is a biotechnology company developing its lead product Xanamem, 11beta-HSD1 inhibitor, a novel once-a-day oral cognitive enhancer. The company's focus at present is cognition impairment in a variety of diseases, with a focus on early-stage Alzheimer's disease (AD) and Major Depressive Disorder (MDD). The XanaMIA Part A trial (n=107) investigated the ability of Xanamem to enhance cognition in healthy older volunteers, with positive safety and efficacy results recently reported. The Part B Phase II trial will investigate the use of Xanamem in patients with the early stages of AD and should commence later in 2022. The second indication is MDD, which is based on the rationale that elevated cortisol levels have been associated with depression, with a Phase II trial to start later in the year.

INDUSTRY OUTLOOK

The unmet need in chronic neurological and neuropsychiatric disorders is high due to limited effectiveness of available treatment options. As there are not many options available, there is a notable market opportunity for an effective cognitive enhancing drug in AD and MDD (used alone or in combination with other therapies).

Y/E Jun	Revenue (A$m)	EBITDA (A$m)	PBT (A$m)	EPS (c)	P/E (x)	P/CF (x)
2020	3.6	(5.3)	(5.3)	(0.474)	N/A	N/A
2021	2.0	(3.9)	(3.9)	(0.277)	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:	NZ$3.37
Market cap:	NZ$353m
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	(6.4)	(17.8)	(29.8)
Relative*	(0.7)	(9.4)	(19.4)

* % Relative to local index

Analyst

Jyoti Prakash

AFT Pharmaceuticals (AFT)

INVESTMENT SUMMARY

AFT Pharmaceuticals is a profitable New Zealand-based specialty pharmaceutical company that sells 125 proprietary branded and generic products through its own sales force in New Zealand and Australia, with offices in SE Asia and Europe to handle its growing export business. In H122, operating revenue grew strongly by 14% y-o-y to NZ$55.5m, despite the impact of COVID-19 across the business (extended lockdowns in Australia and delayed launches in international markets were the biggest COVID-19 related headwinds). Reported group operating profit was NZ$5.5m versus NZ$2.4m in the same period a year ago. Importantly, AFT is continuing to guide for operating profit of NZ$18–23m in FY22.

INDUSTRY OUTLOOK

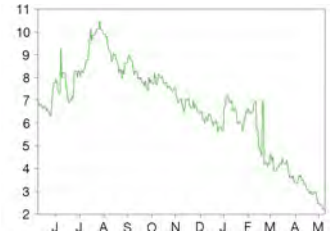
AFT is a multi-product company targeting pharmacy prescription, OTC and hospital markets. Data for Maxigesic offer it a competitive advantage in a fragmented industry.

Y/E Mar	Revenue (NZ$m)	EBITDA (NZ$m)	PBT (NZ$m)	EPS (c)	P/E (x)	P/CF (x)
2020	105.6	12.5	3.4	3.3	102.1	14.9
2021	113.1	11.8	8.2	7.1	47.5	81.1
2022e	130.2	20.5	16.6	15.4	21.9	16.8
2023e	150.3	33.0	29.4	22.3	15.1	10.4

Sector: Pharma & healthcare

Price:	SEK2.29
Market cap:	SEK116m
Market	Nasdaq FN Premier

Share price graph (SEK)



Company description

AlzeCure Pharma is a clinical-stage biotech company based in Sweden focused on developing innovative, small molecule drugs for the treatment of Alzheimer's disease (AD, symptomatic as well as disease modifying) and pain (neuropathic and osteoarthritic).

Price performance

%	1m	3m	12m
Actual	(34.4)	(65.9)	(65.8)
Relative*	(23.7)	(57.9)	(59.4)

* % Relative to local index

Analyst

Soo Romanoff

AlzeCure Pharma (ALZCUR)

INVESTMENT SUMMARY

AlzeCure is a pure play biotech focused on neurological disorders. The pipeline consists of three small-molecule platforms targeting AD and pain. The NeuroRestore platform, with lead asset ACD856, is focused on novel symptomatic treatment of AD. Both the SAD and MAD part of Phase I trials with ACD856 are currently ongoing. The Alzstatin platform (preclinical) is specifically aimed at modifying the course of AD. We find the strategy to target both settings in AD as a rational approach given the complex history of drug development in this vast indication. The third Painless platform consists of two non-opioid pain assets: ACD440, a topical treatment for neuropathic pain (Phase Ib data presented, planning to file for Phase II); and preclinical project TrkA-NAM for osteoarthritic and other severe pain (a drug candidate should be announced soon).

INDUSTRY OUTLOOK

Treatments for progressive neurodegenerative disorders, such as AD, remain a significant focus for the industry despite few treatment options being successfully developed available. Mild cognitive impairment due to AD is a large, unmet medical need. Likewise, non-opioid based analgesics for the treatment of pain are of growing interest.

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.0	(71.1)	(71.4)	(189.0)	N/A	N/A
2021	0.0	(77.4)	(77.8)	(206.0)	N/A	N/A
2022e	0.0	(79.2)	(79.8)	(211.0)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	A$0.04
Market cap:	A$24m
Market	ASX

Share price graph (A$)

Company description

Arovella Therapeutics has the ex-North America rights to ZolpiMist, the spray version of Ambien for insomnia. It recently acquired a CAR-iNKT programme for haematological malignancies and a DKK1 antibody that has potential in multiple myeloma and solid tumours.

Price performance

%	1m	3m	12m
Actual	(12.2)	(16.3)	(5.3)
Relative*	(7.3)	(13.8)	(5.7)

* % Relative to local index

Analyst

Jyoti Prakash

Arovella Therapeutics (ALA)

INVESTMENT SUMMARY

Historically a drug delivery company focused on reformulating established drugs into oro-mucosal spray (via its OroMist platform) formulations for better bioavailability, Arovella Therapeutics pivoted its focus towards 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. With recent fund-raising activity, we believe the company has sufficient funds to run its clinical studies until CY23.

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)
2020	0.5	(3.4)	(3.6)	(2.78)	N/A	N/A
2021	0.3	(3.1)	(3.4)	(1.15)	N/A	N/A
2022e	0.4	(7.0)	(7.5)	(1.37)	N/A	N/A
2023e	2.4	(5.3)	(5.8)	(0.94)	N/A	N/A

Sector: Pharma & healthcare

Price:	CHF30.25
Market cap:	CHF391m
Market	Swiss Stock Exchange

Share price graph (CHF)

Company description

Basilea is focused on infectious diseases and oncology. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic).

Price performance

%	1m	3m	12m
Actual	(19.2)	(26.9)	(31.6)
Relative*	(11.7)	(21.0)	(33.2)

* % 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, which it is separating out from its oncology assets for which it is exploring strategic options. Strong FY21 results were driven by key anti-infective assets, Cresemba and Zevtera, which contributed 65% of the year's non-deferred revenue growth. Global Cresemba sales were over US$300m in FY21 resulting in significantly increased royalty and milestone payments. Management envisages sustainable profitability and positive operating cashflow from 2023. Basilea is awaiting results from the key ERADICATE study of Zevtera in bloodstream infections (top-line data in mid 2022). If positive, this will complete the data package needed for NDA submission, paving the way for entry to the US antibiotic market. In oncology, potential value uplift could come from positive readouts from lead asset derazantinib in trials for intrahepatic cholangiocarcinoma (FIDES-01) and gastric cancer (FIDES-03). Readouts are expected from both in H122.

INDUSTRY OUTLOOK

There is an ever-increasing need for therapeutic agents that are efficacious against drug-resistant strains of bacteria (eg MRSA), fungus or cancer. Hence, the opportunities for Cresemba, Zevtera and Basilea's oncology pipeline 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	109.5	(21.5)	(30.1)	(254.06)	N/A	N/A
2023e	128.1	22.6	14.0	161.06	18.8	N/A

Sector: Pharma & healthcare

Price:	NOK15.30
Market cap:	NOK1357m
Market	Oslo

Share price graph (NOK)

Company description

BerGenBio is a clinical stage biopharmaceutical company developing innovative drugs for aggressive diseases, including immune-evasive cancers and COVID-19. It focuses on AXL inhibitors bemcentinib (small molecule) and tilvestamab (mAb).

Price performance

%	1m	3m	12m
Actual	(24.1)	(19.9)	(43.3)
Relative*	(16.9)	(17.9)	(47.1)

* % Relative to local index

Analyst

Pooya Hemami

BerGenBio (BGBIO)

INVESTMENT SUMMARY

BerGenBio (BGBIO) is a pioneer in AXL biology and following a recent business strategy update, it will focus lead asset bemcentinib in first-line (1L) non-squamous non-small cell lung cancer (NSCLC) patients with STK11 mutations (STK11m), and also in hospitalised COVID-19 patients. AXL is a negative prognostic marker in most cancers, but also implicated in fibrosis and viral infections. AXL inhibition may counter drug resistance, stop immune suppression and potentially augment the efficacy of other drug classes, particularly immunotherapies. The company's Phase II BGB008 study in 2L NSCLC has already shown some efficacy in STK11m patients when combined with pembrolizumab.

INDUSTRY OUTLOOK

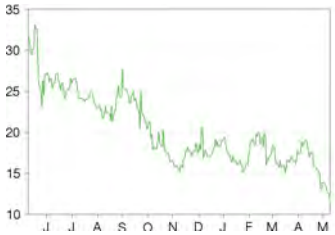
BGBIO plans to initiate a Phase Ib/IIa study in 1L NSCLC with STK11m in H222. For COVID-19, BGBIO will use the EU-SolidAct platform trial to confirm initial efficacy signals observed across its Phase II ACCORD2 study. The trial is set to begin recruitment shortly in a sub-protocol arm designed to enrol 500 COVID-19 patients across European sites.

Y/E Dec	Revenue (NOKm)	EBITDA (NOKm)	PBT (NOKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.6	(260.4)	(257.0)	(343.07)	N/A	N/A
2021	0.8	(313.1)	(309.4)	(351.72)	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:	SEK11.58
Market cap:	SEK1160m
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	(39.1)	(41.5)	(63.6)
Relative*	(29.1)	(27.8)	(56.8)

* % 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. Cantargia reported positive efficacy data update from the PDAC arm of CANFOUR (December 2021), while the latest data from the NSCLC arm was presented at the ESMO Congress (September 2021). Cantargia is preparing for the Phase II/III trial in metastatic PDAC in collaboration with PanCAN. Nadunolimab is now being investigated in eight different cancers across different combinations. At the upcoming ASCO Annual Meeting (June), Cantargia will present three posters with a clinical data update from the lead Phase IIa CANFOUR trial and the first efficacy data from the Phase Ib CIRIFOUR trial.

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	(365.1)	(368.5)	(367.84)	N/A	N/A
2023e	0.0	(365.7)	(369.1)	(368.39)	N/A	N/A

Sector: Pharma & healthcare

Price:	€11.25
Market cap:	€221m
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	(10.7)	(12.8)	(55.4)
Relative*	(4.3)	1.5	(52.7)

* % Relative to local index

Analyst

Soo Romanoff

Carmat (ALCAR)

INVESTMENT SUMMARY

Carmat continues to implement controls to improve the safety in the development of its physiologic heart replacement therapy (PHRT) to address its recent challenges. The company announced that it had implanted nine of its PHRTs since July 2021, six of which were commercial implants while three were part of the early feasibility study (EFS) in the United States. These nine implants are associated with approximately €2m in product revenue, to be booked in H221. However, Carmat suffered a serious set-back in late 2021 due to device malfunction leading to the death of two patients. The implants are currently being revised in close dialogue with the regulatory bodies and guidance is for sales and clinical trials to resume in Q422. Moreover, Carmat is currently looking to prepare the next financing round, stating a cash runway until July 2022.

INDUSTRY OUTLOOK

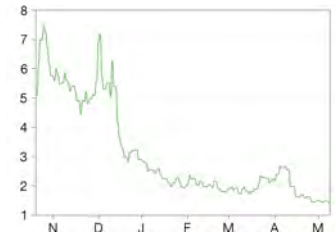
The Carmat artificial heart is being developed as a permanent replacement or destination therapy for chronic biventricular heart failure or acute myocardial infarction patients who do not have access to a human donor heart.

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$1.36
Market cap:	US$22m
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' PR antagonist currently being evaluated in three Phase II clinical trials in hormone-driven breast, endometrial and ovarian cancer. Preliminary data from at least one trial are expected in mid-2022.

Price performance

%	1m	3m	12m
Actual	(46.5)	(37.0)	N/A
Relative*	(39.8)	(27.6)	N/A

* % Relative to local index

Analyst

Jyoti Prakash

Context Therapeutics (CNTX)

INVESTMENT SUMMARY

Context Therapeutics is a Nasdaq-listed biopharma company developing novel therapeutics focused on women's oncology indications. Lead programme onapristone extended release (ONA-XR) is a potential first-in-class progesterone receptor (PR) antagonist being evaluated in several mid-stage clinical programmes in advanced HR+/HER2- breast as well as hormone-driven endometrial and ovarian cancer, all areas with significant unmet need and all expected to release preliminary data in 2022. The other asset CLDN6xCD3, is a novel bi-specific monoclonal antibody, acquired in April 2021 and being assessed in endometrial and ovarian cancers. The company held an investor webinar on 13 April to review data from the presentations it made on ONA-XR (as a combination therapy with different therapeutic classes) and CLDN6xCD3 at the American Association for Cancer Research conference.

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 US in 2021 (more than 70% of these are hormone-driven). Long-term survival rates remain low in the metastatic setting (c 30% for HR+/HER2- breast cancer) despite recent advances, highlighting the high unmet need in the 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	(17.1)	(16.1)	(100.62)	N/A	N/A
2023e	0.0	(23.0)	(22.3)	(139.76)	N/A	N/A

Sector: Pharma & healthcare

Price:	103.5p
Market cap:	£188m
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 and four have been cleared by the FDA. It recently acquired Albyn Medical, which provides it with profitable products and a direct sales force in Europe.

Price performance

%	1m	3m	12m
Actual	(2.4)	(33.7)	(48.2)
Relative*	4.3	(28.8)	(47.2)

* % Relative to local index

Analyst

Jyoti Prakash

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 (GI) procedures expanding into soft tissues (such as the pancreas) and pulmonology. The company has had all six products within the CROMA platform CE marked with four cleared for use by the FDA and the other two expected to be cleared in the coming months. Creo's first commercially available device, Speedboat Inject, is now used across the globe.

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.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2019	0.0	(18.2)	(18.6)	(13.1)	N/A	N/A
2020	9.4	(21.4)	(23.0)	(12.7)	N/A	N/A
2021e	25.9	(21.2)	(22.7)	(12.3)	N/A	N/A
2022e	28.4	(22.9)	(24.4)	(13.3)	N/A	N/A

Sector: Pharma & healthcare

Price:	13.2p
Market cap:	£22m
Market	AIM

Share price graph (p)

Company description

Diurnal Group is a specialty pharma company developing new formulations of hormone-based products for the treatment of endocrine disorders. Its product Alkindi is marketed for paediatric AI in the US and EU. Efmody is approved for the treatment of CAH in the EU and UK.

Price performance

%	1m	3m	12m
Actual	(15.9)	(76.6)	(80.4)
Relative*	(10.2)	(74.8)	(80.0)

* % Relative to local index

Analyst

Jyoti Prakash

Diurnal Group (DNL)

INVESTMENT SUMMARY

Diurnal's strategy is to develop hormone therapeutics for lifelong treatment for rare and chronic endocrine conditions including congenital adrenal hyperplasia (CAH), adrenal insufficiency (AI), hypogonadism and hypothyroidism. The company first launched Alkindi, a formulation of hydrocortisone intended to treat AI in paediatric patients. Efmody, an oral modified-release formulation of hydrocortisone, has been approved in the EU and UK, and subsequently launched in Germany, UK and Austria, to treat CAH in individuals aged 12 years and older. While the sudden departure of the CEO, the Scottish Medicines Consortium issues with Efmody and lowered guidance have provoked short-term investor anxiety, the company expects Efmody to become a profitable franchise in 2024.

INDUSTRY OUTLOOK

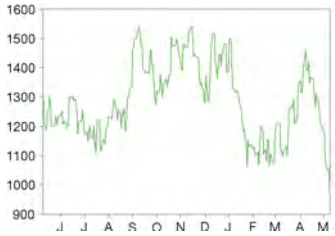
The company's lead products, Alkindi and Efmody, are treatments for deficiencies in the hormone cortisol (aka hydrocortisone). AI affects 250–400 per million individuals in the United States and Europe. A smaller fraction (1/10,000 to 1/18,000 live births) are born with CAH, for which Efmody is approved in Europe.

Y/E Jun	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (fd) (p)	P/E (x)	P/CF (x)
2020	6.3	(5.2)	(5.1)	(4.1)	N/A	N/A
2021	4.4	(11.1)	(11.1)	(7.0)	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:	967.0p
Market cap:	£479m
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	(30.4)	(16.3)	(26.5)
Relative*	(25.7)	(10.1)	(25.0)

* % Relative to local index

Analyst

Kenneth Mestemacher

Ergomed (ERGO)

INVESTMENT SUMMARY

Ergomed's FY21 results showed that adjusted EBITDA of £25.4m was ahead of our estimate of £24.0m and consensus of £23.4m. A strong order book (£239.7m, up 24.2% y-o-y), continued overall business growth and a rapidly improving balance sheet position the company for another solid year of growth. 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.

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	42.4	25.9
2021	118.6	25.4	21.6	39.6	24.4	25.1
2022e	140.3	28.1	26.3	42.6	22.7	22.4
2023e	156.3	31.6	29.8	48.1	20.1	20.2

Sector: Pharma & healthcare

Price:	SEK2.05
Market cap:	SEK409m
Market	OMX

Share price graph (SEK)

Company description

Immunicum 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	(2.6)	(35.9)	(62.7)
Relative*	13.3	(21.0)	(55.7)

* % Relative to local index

Analyst

Soo Romanoff

Immunicum (IMMU)

INVESTMENT SUMMARY

Following the transformational merger with DCprime, Immunicum 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 AML (ADVANCE-II) with first efficacy data released in December 2021; and Phase I in ovarian cancer (ALISON) with the first patient recruited in June 2021.

INDUSTRY OUTLOOK

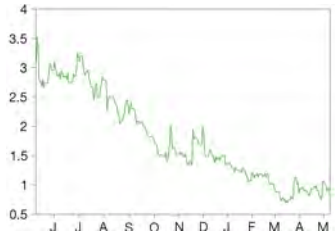
IO is a frenetic pharmaceutical development area with many clinical combination studies being conducted by pharmaceutical and biotech companies. Investors should expect relatively rich newsflow from this subsector over the next few years.

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.0	(85.1)	(89.2)	(117.0)	N/A	N/A
2021	0.0	(130.1)	(133.4)	(73.0)	N/A	N/A
2022e	0.0	(133.1)	(136.3)	(68.0)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	US$0.80
Market cap:	US$11m
Market	NASDAQ, TSX

Share price graph (US$)



Company description

North America based InMed Pharmaceuticals is a leader in the research, development, manufacturing and commercialization of rare cannabinoids. With its subsidiary BayMedica, InMed has multiple and flexible cannabinoid manufacturing capabilities to serve a spectrum of consumer markets, including pharmaceutical and health and wellness.

Price performance

%	1m	3m	12m
Actual	(8.9)	(32.4)	(76.9)
Relative*	2.5	(22.3)	(75.5)

* % Relative to local index

Analyst

Kenneth Mestemacher

InMed Pharmaceuticals (INM)

INVESTMENT SUMMARY

InMed Pharmaceuticals (INM) continues its transition from a pure-play pharma R&D firm to one also benefiting from commercial sales into the health and wellness market. Product launches of high-value, rare cannabinoids into this market should provide the majority of its revenue in the near future. INM also made notable advances in its pharmaceutical drug development programs, including its ongoing 755-201-EB Phase II trial and preparing for an FDA pre-investigational new drug meeting on glaucoma drug candidate INM-088. We expect to see a different InMed going forward, one that offers near-term revenue generation combined with the longer-term value of its pharma drug development programs.

INDUSTRY OUTLOOK

The cannabis and cannabinoid markets are growing rapidly, reaching global sales of US$21.3bn in 2020, soaring c 50% over 2019, and are forecasted to reach US$55.9bn by 2026 according to BDSA. Furthermore, US cannabis sales are expected to be US$41bn by 2026.

Y/E Jun	Revenue (US$m)	EBITDA (US$m)	PBT (US$m)	EPS (c)	P/E (x)	P/CF (x)
2020	0.0	(9.0)	(9.0)	(172.80)	N/A	N/A
2021	0.0	(9.8)	(10.3)	(153.02)	N/A	N/A
2022e	1.8	(14.6)	(14.8)	(109.25)	N/A	N/A
2023e	10.2	(13.1)	(13.8)	(96.39)	N/A	N/A

Sector: Pharma & healthcare

Price:	SEK35.65
Market cap:	SEK1842m
Market	NASDAQ OMX First North

Share price graph (SEK)

Company description

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

Price performance

%	1m	3m	12m
Actual	(10.9)	(5.7)	(10.4)
Relative*	3.7	16.4	6.4

* % Relative to local index

Analyst

Soo Romanoff

IRLAB Therapeutics (IRLABA)

INVESTMENT SUMMARY

IRLAB Therapeutics is focused on developing novel, potential first-in-class treatments for the symptoms of Parkinson's disease (PD) and other central nervous system disorders. IRLAB's proprietary ISP research platform is at the heart of its discovery engine and has been validated by the progress of its two lead assets, mesdopetam and pirepemat, which have novel mechanisms of action. Pirepemat is an oral prefrontal cortex enhancer currently in development for the treatment of impaired balance and falls in PD; a global Phase IIb study is expected to start shortly. Mesdopetam, an oral D3 antagonist, is currently in a global Phase IIb/III study for levodopa-induced dyskinesias and top-line data are expected in H222. A global licensing deal (worth up to $363m) for mesdopetam puts all future clinical development and commercialisation in the hands of partner Ipsen, enabling IRLAB to focus on its preclinical pipeline which consists of IRL942, IRL 757 and compounds from its P003 programme. IRLAB is 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)
2019	0.4	(92.9)	(95.1)	(234.0)	N/A	N/A
2020	0.4	(89.2)	(91.4)	(192.0)	N/A	N/A
2021e	207.9	56.1	91.1	176.0	20.3	35.1
2022e	42.9	(91.4)	(95.7)	(185.0)	N/A	N/A

Sector: Pharma & healthcare

Price:	US$5.58
Market cap:	US$77m
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. It also recently in-licensed the Phase I drug EVT801, an inhibitor of lymphangiogenesis in tumors.

Price performance

%	1m	3m	12m
Actual	(33.4)	(25.7)	(44.5)
Relative*	(25.1)	(14.6)	(41.1)

* % Relative to local index

Analyst

Jyoti Prakash

Kazia Therapeutics (KZIA)

INVESTMENT SUMMARY

Kazia is developing the anti-cancer compound paxalisib (GDC-0084) for glioblastoma (GBM) multiforme. 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. The pivotal GBM AGILE study is currently enrolling patients. The second product candidate is EVT801, a novel small molecule inhibitor VEGFR3. A Phase I trial of EVT801 in solid tumours enrolled its first patient in November 2021 with interim data expected in H2 CY22.

INDUSTRY OUTLOOK

GBM is the most common primary cancer of the brain with 11,500 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 multi billion dollar angiogenesis cancer market.

Y/E Jun	Revenue (US$m)	EBITDA (US$m)	PBT (US$m)	EPS (c)	P/E (x)	P/CF (x)
2020	0.8	(7.8)	(7.8)	(1.04)	N/A	N/A
2021	11.0	(3.2)	(3.2)	(0.26)	N/A	N/A
2022e	0.0	(17.2)	(17.2)	(1.27)	N/A	N/A
2023e	0.0	(19.9)	(19.9)	(1.47)	N/A	N/A

Sector: Pharma & healthcare

Price:	€2.06
Market cap:	€62m
Market	Scale

Share price graph (€)

Company description

MagForce has the first European-approved, nanotechnology-based therapy to treat brain tumours. NanoTherm therapy consists of nanoparticle instillation into the tumour, activated by an alternating magnetic field, producing heat and thermally destroying or sensitising tumours.

Price performance

%	1m	3m	12m
Actual	2.0	(11.6)	(49.4)
Relative*	8.9	2.3	(41.7)

* % Relative to local index

Analyst

Kenneth Mestemacher

MagForce (MF6)

INVESTMENT SUMMARY

MagForce is progressing its strategy to drive uptake of its nanoparticle-based NanoTherm therapy for the treatment of prostate cancer in the United States and glioblastoma (GBM) in Europe. Four treatment centers in Europe are commercially treating GBM patients (Germany and Poland) and MagForce recently signed a cooperation agreement with a hospital in Spain, treatments are expected to start in H122. Negotiations with clinics in Italy and Austria are ongoing. The pivotal US trial for the treatment of intermediate risk prostate cancer is progressing, having successfully completed the first two stages. MagForce has now received FDA approval for the final protocol and initiated Stage 2b. The study should complete by mid-2022, potentially enabling approval and launch by H123. Loan facilities are in place to bridge the gap until profitability, with €11m zero interest bearing convertible notes and a €22m EIB loan facility remaining. Our forecasts are under review.

INDUSTRY OUTLOOK

MagForce's NanoTherm therapy system is designed to directly target cancerous tissue while not damaging surrounding healthy tissue. Superparamagnetic nanoparticles are directly instilled into the tumour or resection cavity and then activated by the NanoActivator device. This can either thermally ablate tumours or sensitise them to other treatments.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2019	0.8	(5.6)	(7.6)	(0.28)	N/A	N/A
2020	0.6	19.3	(9.7)	(0.35)	N/A	N/A
2021e	N/A	N/A	N/A	N/A	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	A$0.10
Market cap:	A$33m
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. It is also developing a synthetic THC/CBD analogy of NanaBis.

Price performance

%	1m	3m	12m
Actual	10.3	(27.5)	(48.1)
Relative*	16.6	(25.4)	(48.3)

* % Relative to local index

Analyst

Kenneth Mestemacher

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, which enable a convenient buccal spray formulation. A recent breakthrough was Medlab's announcement that it had successfully produced a synthetic version of NanaBis, which will allow it to move away from a botanical extract. Once the product reformulation is completed, NanaBis will re-enter clinical development (potentially Phase III) as a fully synthetic, non-opioid pain relief drug aimed at a vast market. Using NanoCelle delivery technology, Medlab is also expanding beyond cannabinoids and is pursuing several small and large molecule programmes (including a non-invasive mRNA COVID-19 vaccine).

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)
2020	5.8	(12.3)	(13.5)	(5.9)	N/A	N/A
2021	8.1	(11.4)	(12.4)	(4.2)	N/A	N/A
2022e	8.0	(11.7)	(12.7)	(3.7)	N/A	N/A
2023e	10.4	(9.9)	(11.0)	(3.2)	N/A	N/A

Sector: Pharma & healthcare

Price:	A$1.00
Market cap:	A$650m
Market	ASX

Share price graph (A$)

Company description

Mesoblast is developing adult stem-cell therapies based on its proprietary MPC and MSC platforms. Its lead programmes are in pediatric aGvHD, heart failure, ARDS and lower back pain, all of which are in Phase III or later.

Price performance

%	1m	3m	12m
Actual	(11.9)	(16.0)	(42.5)
Relative*	(6.9)	(13.5)	(42.8)

* % Relative to local index

Analyst

Jyoti Prakash

Mesoblast (MSB)

INVESTMENT SUMMARY

Mesoblast is an Australia-headquartered biotechnology company focused on its pipeline which is based on proprietary mesenchymal precursor cells (MPC) and culture-expanded mesenchymal stem cells (MSC) technologies. Novartis signed a partnership with the company to develop remestemcel-L for acute respiratory distress syndrome (ARDS), whether or not the ARDS was caused by COVID-19. Mesoblast recently met with the FDA on the path forward in COVID-19 related ARDS and another trial is necessary for authorisation. The company also announced data from its MPC-06-ID back pain trial. Rexlemestrocel-L in combination with hyaluronic acid significantly reduced pain and reduced the need for opioids. In the heart failure trial, Revascor had a significant impact on major adverse cardiovascular events such as cardiovascular death and ischemic events.

INDUSTRY OUTLOOK

Mesoblast is a leading MSC company based in Australia. It is targeting large indications such as ARDS, congestive heart failure and back pain.

Y/E Jun	Revenue (US$m)	EBITDA (US$m)	PBT (US$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	31.6	(64.8)	(79.6)	(13.28)	N/A	N/A
2021	7.4	(89.3)	(104.3)	(17.09)	N/A	N/A
2022e	8.6	(83.2)	(92.6)	(14.29)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	10.5p
Market cap:	£10m
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; QSphera, sustained-release; MidaCore, targeted delivery) to improve their bioavailability and delivery.

Price performance

%	1m	3m	12m
Actual	(22.2)	(31.2)	(63.2)
Relative*	(17.0)	(26.1)	(62.4)

* % Relative to local index

Analyst

Jyoti Prakash

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 multiforme and diffuse intrinsic pontine glioma, a very rare pediatric cancer.

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)
2019	0.7	N/A	(10.9)	(49.85)	N/A	N/A
2020	0.3	N/A	(11.1)	(22.92)	N/A	N/A
2021e	N/A	N/A	N/A	N/A	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	CHF1.45
Market cap:	CHF26m
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 therapy, has started one Phase III and may start a further US trial in H122.

Price performance

%	1m	3m	12m
Actual	5.1	1.4	(34.1)
Relative*	14.8	9.6	(35.6)

* % 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 and could report by Q422. Further US studies will be needed. Newron hopes to partner evenamide for larger indications and to sell the product directly for clozapine-resistance. FY21 results showed Xadago royalties of €5.8m, up 9.4% versus FY20. Newron had cash, equivalents and other of €34.6m at the end of December 2021.

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)
2019	7.0	(18.6)	(18.0)	(101.0)	N/A	N/A
2020	5.3	(16.4)	(18.2)	(109.0)	N/A	N/A
2021e	5.5	(13.7)	(16.7)	(94.0)	N/A	N/A
2022e	6.0	(26.3)	(29.9)	(167.0)	N/A	N/A

Sector: Pharma & healthcare

Price:	€1.84
Market cap:	€80m
Market	Euronext Paris

Share price graph (€)

Company description

Based in France, Nicox develops therapeutics for the treatment of ocular conditions. Lead development candidate NCX-470 is in Phase III studies for the treatment of glaucoma. Nicox also receives licence revenue from its partners for its FDA-approved drugs Vyzulta and Zerviate.

Price performance

%	1m	3m	12m
Actual	9.9	(15.8)	(56.6)
Relative*	17.9	(2.0)	(54.0)

* % Relative to local index

Analyst

Pooya Hemami

Nicox (COX)

INVESTMENT SUMMARY

Nicox develops drugs for eye diseases, with lead candidate NCX-470 in Phase III trials 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 0.065% has shown up to 1.4mmHg additional lowering of intraocular pressure (IOP) compared to latanoprost in the Phase II study, and the Phase III programme is testing a higher 0.1% drug concentration. Nicox is also advancing NCX-4251 for dry eye disease following a positive post-hoc analysis of its Phase IIb trial data.

INDUSTRY OUTLOOK

NCX-470, if approved, could become the most efficacious single-agent glaucoma drug on the market in terms of IOP-lowering activity. Mont Blanc, the first of two Phase III NCX-470 studies, recently exceeded 98% enrolment and results are expected in Q123. The company also expects to start a DED study for NCX-4251 in 2023. Nicox had €35.1m gross cash at 31 March 2022, which we model should last into 2024.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2019	8.3	(17.2)	(16.0)	(40.10)	N/A	N/A
2020	14.4	(5.3)	(10.2)	(30.33)	N/A	N/A
2021e	5.8	(19.8)	(20.6)	(51.23)	N/A	N/A
2022e	9.0	(14.9)	(16.2)	(37.28)	N/A	N/A

Sector: Pharma & healthcare

Price:	€0.36
Market cap:	€40m
Market	Euronext Paris

Share price graph (€)

Company description

Onxeo's proprietary platON platform is based on a unique decoy technology in the field of DNA damage repair inhibition. The compounds have been shown in preclinical studies to be synergistic with DNA breaking therapies and have an ability to reverse tumour resistance to PARP inhibitors and TKIs.

Price performance

%	1m	3m	12m
Actual	(11.5)	(9.2)	(46.9)
Relative*	(5.1)	5.6	(43.7)

* % Relative to local index

Analyst

Soo Romanoff

Onxeo (ONXEO)

INVESTMENT SUMMARY

Onxeo recently announced in a major update that it has appointed a new CEO, Dr Shefali Agarwal. Onxeo's portfolio focuses on its novel platON platform with AsiDNA as the lead drug candidate. AsiDNA is the only oligonucleotide decoy agonist in development that disrupts and exhausts the tumour DNA damage response mechanism. To date, the only approved similar class of drugs are several commercially successful PARP inhibitors. AsiDNA has completed the Phase Ib part of the DRIIV-1 trial in patients with advanced solid tumours in combination with chemotherapy, demonstrating a favourable safety profile. Another key Phase Ib/II trial, REVOCAN, is recruiting patients and will evaluate AsiDNA's potentially unique ability to reverse tumour resistance to the PARP inhibitor, niraparib. The outcome will define AsiDNA's mid- to late-stage development.

INDUSTRY OUTLOOK

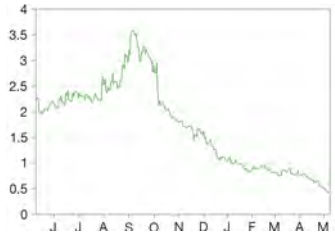
Approval of the first PARP inhibitors has kick-started interest by the scientific community and large pharma in the DNA damage response field. Few biotechs are already positioned in this emerging field, which has broad potential.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2019	4.3	(9.1)	(11.5)	(14.98)	N/A	N/A
2020	1.8	(7.2)	(8.2)	(12.26)	N/A	N/A
2021e	N/A	N/A	N/A	N/A	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	US$0.38
Market cap:	US$17m
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	(48.3)	(58.3)	(83.8)
Relative*	(41.8)	(52.1)	(82.8)

* % Relative to local index

Analyst

Jyoti Prakash

OpGen (OPGN)

INVESTMENT SUMMARY

OpGen is a diagnostic company focused on the identification and treatment of bacterial infections. It has a broad product portfolio of molecular diagnostic tests including the Unyvero platform with five CE-IVD-marked tests and two cartridges cleared by the FDA; Ares Genetics' next-generation antimicrobial resistance (AMR) testing services; 510(k) cleared Acuitas AMR Gene Panel in bacterial isolates; and ARESdb (AI-powered AMR database). OpGen's products are differentiated by their short turnaround time, large range of pathogen detection and AMR profiling. OpGen reported FY21 revenues of $4.3m (ahead of our expectations) and management is guiding for 25–50% year-on-year growth from products and services in FY22.

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	(22.0)	(25.3)	(157.41)	N/A	N/A
2021	4.3	(20.4)	(35.7)	(97.00)	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:	€2.11
Market cap:	€112m
Market	Madrid Stock Exchange

Share price graph (€)

Company description

Spanish biotech Oryzon Genomics is 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	(18.2)	(29.3)	(40.4)
Relative*	(13.5)	(23.2)	(33.7)

* % 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 lysine-specific demethylase 1A, or LSD1, inhibitors). The company's R&D strategy has been to select indications where there is a scientific rationale for intervention with an epigenetic therapy and then conduct quick and relatively small trials, but with patient sample sizes still sufficient to obtain proof-of-concept data. With this strategy, Oryzon has completed multiple trials over the last several years. Importantly, insights from the data have allowed the company to design the next phase of development. At least two new trials with iadademstat (FRIDA in acute myeloid leukaemia and STELLAR in small cell lung cancer, SCLC) could potentially be pivotal.

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 (c)	P/E (x)	P/CF (x)
2020	9.5	(4.1)	(4.8)	(6.88)	N/A	N/A
2021	10.6	(6.9)	(7.0)	(8.51)	N/A	N/A
2022e	9.9	(6.0)	(6.1)	(8.67)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	€6.31
Market cap:	€117m
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	(23.6)	(23.6)	(42.6)
Relative*	(18.1)	(11.1)	(39.2)

* % 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 is now aiming to discuss the data with regulators. 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)	(1.02)	N/A	N/A
2021	26.3	(13.6)	(16.5)	(0.89)	N/A	N/A
2022e	5.0	(38.2)	(38.8)	(1.89)	N/A	N/A
2023e	0.0	(43.6)	(44.2)	(2.42)	N/A	N/A

Sector: Pharma & healthcare

Price:	485.0p
Market cap:	£466m
Market	LSE

Share price graph (p)

Company description

OXB's LentiVector technology supports its internal initiatives and allows it to generate significant revenue from a multitude of partners. OXB is implementing significant capacity upgrades to improve efficiency and support more partnering/out-licensing agreements. AAV growth is projected to offset anticipated declines in vaccine revenues.

Price performance

%	1m	3m	12m
Actual	(26.3)	(39.9)	(52.6)
Relative*	(21.3)	(35.5)	(51.7)

* % Relative to local index

Analyst

Soo Romanoff

Oxford Biomedica (OXB)

INVESTMENT SUMMARY

Oxford Biomedica (OXB) is a global leader in lentiviral development and manufacturing. It is expanding its manufacturing facilities through Oxbox, a 84,000 sq ft state-of-the-art bioprocessing facility, significantly increasing its production capacity to match increasing demand and to continue growing its platform revenues. In the near term, revenues will continue to be driven by Novartis and AstraZeneca as 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, Santen, Beam Therapeutics and PhoreMost. OXB also has a supply agreement with AstraZeneca 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.

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	24.6
2021	142.8	33.2	19.9	22.2	21.8	13.9
2022e	173.4	39.2	28.0	30.6	15.8	124.4
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	€0.03
Market cap:	€1m
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.

Price performance

%	1m	3m	12m
Actual	(56.5)	(68.0)	(99.2)
Relative*	(53.4)	(62.8)	(99.1)

* % Relative to local index

Analyst

Jyoti Prakash

Pharnext (ALPHA)

INVESTMENT SUMMARY

Pharnext's pleotherapy platform uses a combination of in silico prediction of drug effects as well as in vitro screening to find drug combinations that have biochemical effects totally outside of their canonical activities. For example, the company's lead programme PXT3003 is a triple combination of an anti-opiate (naltrexone), a drug for spasms (baclofen), and the sweetener sorbitol, but the combination has shown positive interim results in Phase III for Charcot-Marie-Tooth type 1A (CMT1A) disease.

INDUSTRY OUTLOOK

The power of the pleotherapy platform lies in its ability to predict gene expression patterns as a result of different drug combinations. This provides a way of addressing diseases of a genetic origin like CMT (and potentially other types of disease) that may not be amenable to other treatments like enzyme replacement therapy.

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	N/A
2021	3.6	22.2	30.6	(100.66)	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:	€0.49
Market cap:	€28m
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	(15.3)	(34.4)	(60.4)
Relative*	(9.2)	(23.7)	(58.0)

* % 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

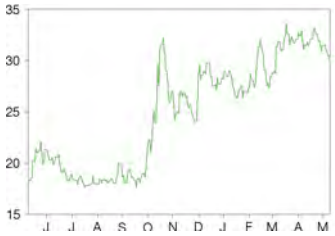
Pixium started the PRIMAvera European pivotal study in Q420 and plans to complete enrolment by year end 2022, which we believe could lead to top-line data being reported in late 2023 or early 2024. GA-AMD is a leading cause of blindness in older adults, affecting over 2.5 million persons in the United States and Europe, and there is no approved treatment. Pixium reported €10.4m gross cash on 31 March 2022, which we believe should fund operations into 2023.

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)	(11.1)	(22.94)	N/A	N/A
2022e	1.6	(10.0)	(11.5)	(19.46)	N/A	N/A
2023e	0.8	(13.8)	(16.2)	(27.12)	N/A	N/A

Sector: Pharma & healthcare

Price:	SEK29.70
Market cap:	SEK566m
Market	SE

Share price graph (SEK)



Company description

RhoVac is an immunotherapy company listed on the Spotlight stock market in Sweden, with a 100%-owned subsidiary in Denmark. It is developing a peptide-based immunotherapy, RV001, which aims to train the immune system to specifically target cancer cells with metastatic potential.

Price performance

%	1m	3m	12m
Actual	(5.6)	2.2	65.0
Relative*	9.9	26.1	96.0

* % Relative to local index

Analyst

Soo Romanoff

RhoVac (RHOVAC)

INVESTMENT SUMMARY

RhoVac's Phase IIb BRaVac trial has been fully enrolled since September 2021. The study reached Database Lock on 10 May and primary outcome in anticipated at end May or early June 2022, which is the most significant catalyst of the investment case so far. RhoVac's lead asset is RV001 (onilcamotide), a tissue-agnostic cancer immunotherapy. It contains a fragment of the target protein RhoC, which is overexpressed in cells with metastatic potential in various cancers. The BRaVac trial investigates RV001 in prostate cancer patients with localised disease who have relapsed after treatment with curative intent. The latest interim safety review (December 2021) found no issues.

INDUSTRY OUTLOOK

Metastatic cancer is the most advanced stage of cancer and forms the bulk of the current prostate cancer therapy market. RhoVac's target group is focused on non-metastatic patients with biochemical failure and patients in this group are several times more prevalent than metastatic patients. Preventing or halting metastasis formation in this group of patients by inhibiting the metastatic cascade or killing cells with metastatic potential could reduce morbidity and improve survival.

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (fd) (öre)	P/E (x)	P/CF (x)
2020	6.0	(47.5)	(46.9)	(205.53)	N/A	N/A
2021	10.2	(61.9)	(61.5)	(283.46)	N/A	N/A
2022e	5.9	(39.1)	(38.9)	(163.84)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	€5.84
Market cap:	€126m
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	(12.8)	(9.0)	(32.1)
Relative*	(5.3)	(3.9)	(29.3)

* % 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 its initial commercial opportunity is for treating fluid overload (ascites) resulting from liver disease including non-alcoholic steatohepatitis. DSR technology adds a complementary method for removing excess fluid that is spread all over the body and the combined approach, alfapump DSR, is being advanced as a therapy for HF patients affected by congestion (fluid overload).

INDUSTRY OUTLOOK

The alfapump is undergoing a pivotal North American registration study (POSEIDON) and is already commercialised in parts of Europe. Sequana recently completed POSEIDON implantations and expects to report primary efficacy data in Q422 and submit a US regulatory application for alfapump in mid-2023. The alfapump DSR system was shown in the RED DESERT study to sustainably improve diuretic response and cardio-renal status, and Sequana reported positive interim data in the SAHARA DESERT alfapump DSR study in decompensated HF patients in Q421.

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	0.6	(22.5)	(23.3)	(98.23)	N/A	N/A
2023e	0.7	(21.0)	(22.8)	(95.55)	N/A	N/A

Sector: Pharma & healthcare

Price:	15.0p
Market cap:	£32m
Market	AIM

Share price graph (p)

Company description

Commercial-stage pharmaceutical company Shield Therapeutics' proprietary product Feraccru/Accrufer is approved by the FDA and EMA for the treatment of iron deficiency from any cause. Shield launched the product itself in the United States and partner Norgine is marketing it in Europe.

Price performance

%	1m	3m	12m
Actual	(25.9)	(56.7)	(68.8)
Relative*	(20.9)	(53.4)	(68.1)

* % Relative to local index

Analyst

Karl Egeland

Shield Therapeutics (STX)

INVESTMENT SUMMARY

Shield Therapeutics is a commercial-stage speciality pharmaceutical company based in the UK. Its primary focus is 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. The commercialisation of Feraccru in Europe, Australia and New Zealand is in the hands of distribution partner Norgine, and the product has been licensed to ASK Pharm in China, Korea Pharma in South Korea, and KYE Pharmaceuticals in Canada. Shield is commercialising Accrufer itself in the United States and launched the product in July 2021. At 31 December 2021 Shield had an unaudited cash balance of £12.1m. This is sufficient to enable it to establish and expand its US commercial infrastructure to include 30–60 sales reps to support the initial product launch.

INDUSTRY OUTLOOK

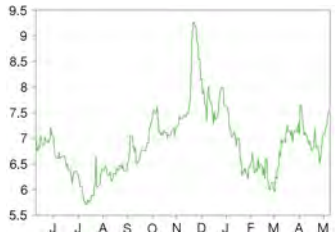
The market for iron deficiency is substantial and Feraccru/Accrufer is a unique oral formulation of iron developed to overcome the side-effect profile of salt-based oral iron therapies and provides an alternative treatment to intravenously administered iron.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2019	0.7	(6.4)	(9.1)	(7.5)	N/A	N/A
2020	10.4	0.6	(1.9)	(2.2)	N/A	N/A
2021e	3.9	(21.6)	(23.6)	(11.7)	N/A	N/A
2022e	19.3	(11.1)	(13.0)	(5.1)	N/A	N/A

Sector: Pharma & healthcare

Price:	US$7.61
Market cap:	US$551m
Market	NASDAQ

Share price graph (US$)



Company description

SIGA Technologies is a commercial-stage health security company focused on the treatment of smallpox and other orthopoxviruses. It has contracts with both the US and Canadian governments for TPOXX, its treatment for smallpox, and is looking to expand internationally.

Price performance

%	1m	3m	12m
Actual	7.9	15.3	3.8
Relative*	21.4	32.5	10.1

* % Relative to local index

Analyst

Kenneth Mestemacher

SIGA Technologies (SIGA)

INVESTMENT SUMMARY

SIGA has reported Q122 revenues of $10.5m, up 119% y-o-y, driven by the first IV TPOXX deliveries to the US government. It also achieved key milestones in its product and international expansion strategies, including EMA approval for oral TPOXX, the first TPOXX contract in the Asia-Pacific (APAC) region, and a Canadian contract increased by $5m. The PEP trials are making progress, with the active phase planned to complete in Q322, and the DOD announced its intent for a single-source contract for TPOXX. We raise our valuation to $9.17 per share, up from our previous $8.80.

INDUSTRY OUTLOOK

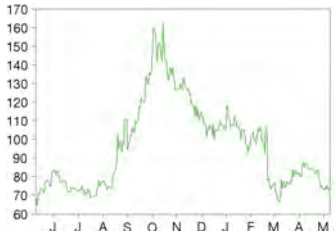
Smallpox is a very serious life-threatening disease caused by the variola virus. The literature suggests a death rate of up to 30% (compared to around 2% for COVID-19). According to CDC forecasts, over 50 million people could be infected in a smallpox outbreak.

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	9.4	8.4
2021	133.7	89.7	89.1	90.61	8.4	49.7
2022e	125.0	63.5	63.0	65.86	11.6	19.8
2023e	121.3	60.5	60.0	66.16	11.5	10.6

Sector: Pharma & healthcare

Price:	NOK71.00
Market cap:	NOK2430m
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 (hTERT), 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	(17.6)	(32.9)	6.6
Relative*	(9.9)	(31.2)	(0.6)

* % 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 over 85% 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 2022–24, all within cash reach. In October 2021, the latest update of data from a Phase I trial of UV1 in advanced melanoma in combination with Keytruda continued to show an impressive objective response rate benefit.

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	(195.2)	(194.2)	(567.0)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

Sector: Pharma & healthcare

Price:	SEK1.00
Market cap:	SEK536m
Market	Nasdaq FN Premier

Share price graph (SEK)

Company description

Vivesto is a Swedish speciality pharma company focusing on its proprietary XR-17 technology platform 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	(38.9)	(42.7)	(71.1)
Relative*	(28.9)	(29.3)	(65.7)

* % Relative to local index

Analyst

Jyoti Prakash

Vivesto (VIVE)

INVESTMENT SUMMARY

Vivesto is focused on developing improved formulations of well-established cancer drugs through the application of its proprietary XR-17 platform. 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 H122. Additional studies are expected to be required before an NDA filing in the United States. Vivesto is working on additional nanoparticle formulations, including docetaxel micellar (Phase Ib prostate cancer) and the development of innovative drugs (preclinical stage). In-licensed asset Cantrixil is expected to start Phase II development in ovarian cancer. In March, Vivesto completed a rights issue raising gross proceeds of c SEK151m, our forecasts are under review.

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 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	201.8	N/A	(57.5)	(13.0)	N/A	N/A
2021	26.2	N/A	(132.7)	(30.0)	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

Company coverage

Company	Note	Date published
Abliva	Update; Update	27/05/21; 13/01/22
Actinogen Medical	Flash; Update	08/05/19; 15/10/19
AFT Pharmaceuticals	Update; Update	26/05/21; 22/11/21
AlzeCure Pharma	Flash; Update	27/08/21; 05/01/22
Arovella Therapeutics	Update; Flash	05/04/22; 04/05/22
Basilea Pharmaceutica	Flash; Outlook	28/04/22; 04/05/22
BerGenBio	Flash; Flash	31/01/22; 05/05/22
Cantargia	Update; Update	06/04/21; 09/05/22
Carmat	Update; Update	11/01/21; 20/09/21
Chimeric Therapeutics	Update; Update	29/07/21; 06/12/21
Context Therapeutics	Update; Update	08/0422; 22/04/22
Creo Medical	Initiation; Flash	04/10/21; 29/04/22
Diurnal Group	Update; Flash	21/04/22; 26/04/22
Ergomed	Update; Update	03/02/22; 27/04/22
Exopharm	Spotlight initiation	28/05/21
Immunicum	Outlook; Flash	14/09/21; 11/05/22
InMed Pharmaceuticals	Update; Update	29/09/21; 16/02/22
IRLAB Therapeutics	Update; Update	28/02/22; 30/03/22
Kazia Therapeutics	ADR update; ADR update	14/10/21; 28/03/22
MagForce	Scale update; QuickView	10/11/21; 10/11/21
Medlab Clinical	Initiation; Update	12/07/21; 27/01/22
Mesoblast	Update; Update	30/11/20; 15/03/21
Midatech Pharma	Spotlight initiation; Flash	17/09/21; 18/01/22
Newron Pharmaceuticals	Update; QuickView	27/09/21; 01/11/21
Nicox	Flash; Update	02/12/21; 16/12/21
Onxeo	Update; Update	27/05/19; 18/11/20
OpGen	Update; Update	18/08/21; 17/11/21
Oryzon Genomics	Update; Outlook	15/06/21; 09/02/22
OSE Immunotherapeutics	Update; Update	30/04/21; 03/05/22
Oxford Biomedica	Outlook; Outlook	05/10/20; 27/05/21
Pharnext	Update; Update	06/12/21; 29/12/21
Pixium Vision	Update; Update	15/12/21; 07/03/22
ReNeuron Group	Update; Update	15/07/21; 08/10/21
RhoVac	Outlook; Update	14/10/21; 28/02/22
Sareum Holdings	Update; Flash	19/03/22; 14/04/22
Sequana Medical	Update; Update	08/04/22; 27/04/22
Shield Therapeutics	Flash; Update	28/05/21; 23/08/21
SIGA Technologies	Update; Update	05/04/22; 09/05/22
Ultimovacs	Update; Update	03/09/21; 13/12/21
Vivesto	Flash; Flash	20/01/22; 25/02/22

Glossary

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
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
AI	Adrenal insufficiency
AKI	Acute kidney injury
ALL	Acute lymphoblastic leukaemia
AM	Alpha-mannosidosis
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
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)
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
BVS	Bionic vision system
CABP	Community-acquired bacterial pneumonia
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
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
CHMP	Committee for Medicinal Products for Human Use (a committee of the EMA)
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
COPD	Chronic obstructive pulmonary disease
CPI	Checkpoint inhibitor
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 trials application (EU version of an IND)
CTN	Clinical Trials Notification Scheme (Australian version of an IND)
CV	Cardiovascular
CXCR4	C-X-C chemokine receptor type 4
DC	Dendritic cell
DCR	Disease control rate
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
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
DRG	Diagnosis-related group code
Dry-AMD	Dry age-related macular degeneration
DSMB	Data safety monitoring board
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
ESMO	European Society for Medical Oncology
EUA	Emergency Use Authorization
FDA	Food and Drug Agency (US regulator)
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)
GA	General anaesthesia
GA	Geographic atrophy
GA-AMD	Geographic atrophy associated with dry age-related macular degeneration
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
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
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
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
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
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
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
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
mBC	Metastatic breast cancer
MC	Mast cell
mCDRPC	Metastatic castration and docetaxel resistant prostate cancer
MCI	Minimal cognitive impairment
MCL	Mantle cell lymphoma
mCRC	Metastatic colorectal cancer
mCRPC	Metastatic castration-resistant prostate cancer
MCS	Mechanical circulatory support
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
MTR	Molecularly targeted radiation
NAFLD	Nonalcoholic 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)
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)
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)
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
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
PTCL	Peripheral T-cell lymphoma
PV	Pharmacovigilance
qd	Once daily
QIDP	Qualified infectious disease product designation
QoL	Quality-of-life
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
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
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
SMA	Spinal muscular atrophy
SMC	Safety monitoring committee
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
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
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
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
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
WHO	World Health Organisation
WT	Wild type

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