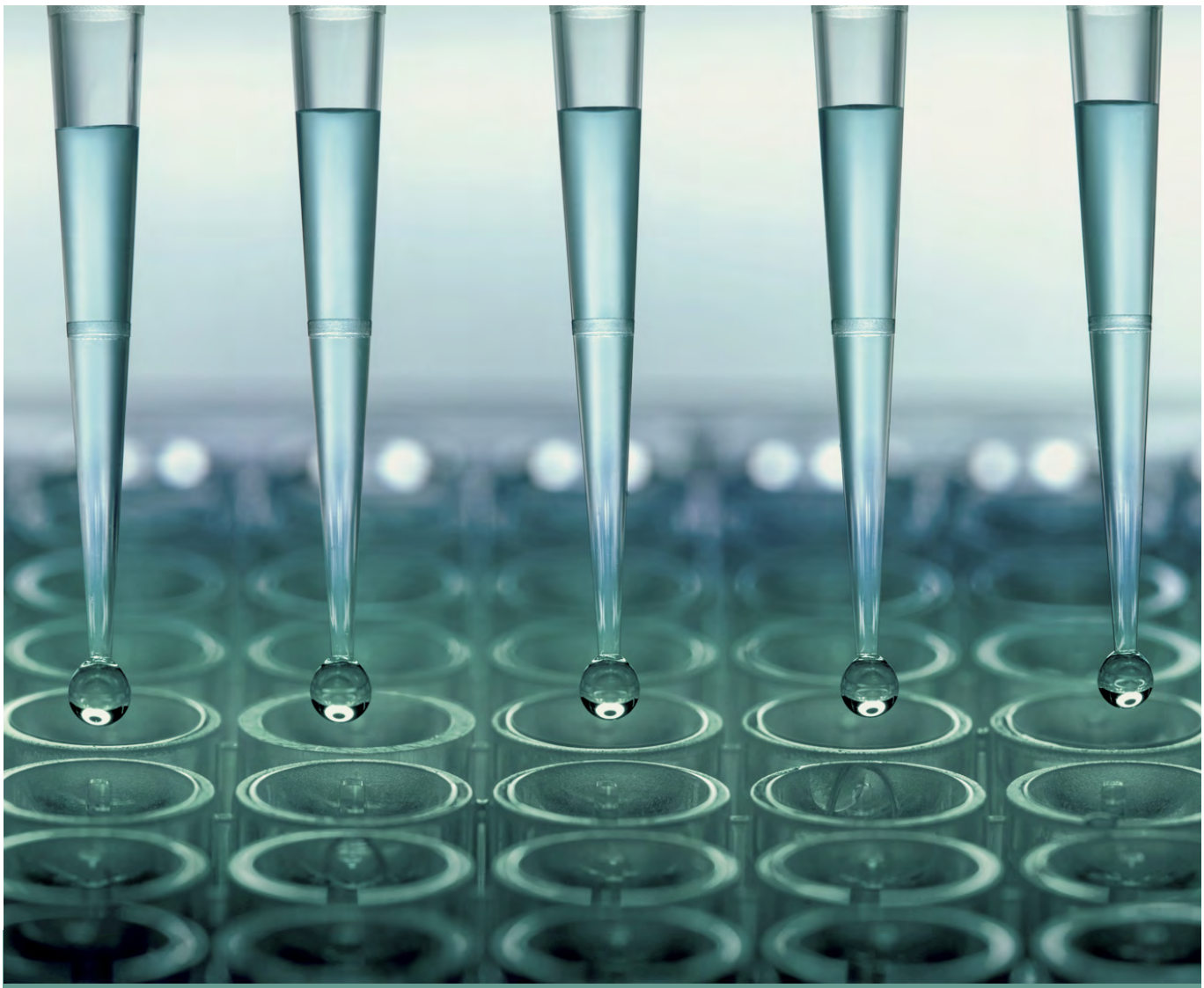
EDISON

BRILLIANT KNOWLEDGE



EDISON HEALTHCARE INSIGHT

February 2022

Published by Edison Investment Research

The Edison healthcare team

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.

Dr Jonas Peciulis

Jonas joined Edison in November 2015. He is a qualified medical doctor with several years of clinical practice. He then moved into equity research as a healthcare analyst at Norne Securities, focused on Norwegian companies, and received two StarMine awards for stock picking in 2013. Most recently, he worked for a London-based life sciences venture capital company before completing his MBA degree.

Sean Conroy

Sean joined Edison's healthcare team in October 2020. He previously worked on the sell-side covering European large-cap pharmaceuticals and biotech stocks at Jefferies. Prior to moving into equity research, Sean worked at Charles River Laboratories performing drug discovery services. He holds a PhD in medicinal chemistry from the University of Nottingham.

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.

Jacob Thrane

Jacob joined the Edison healthcare team in November 2021. He has held roles in product management and corporate development in the healthcare industry and brings several years of equity analysis experience from Standard & Poor's (London) and Baader Bank (Munich) covering pharmaceutical, biotech and medtech stocks. Jacob holds an MSc in biochemistry from the University of Copenhagen and received his executive MBA from Cass Business School in London.

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.

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.

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.

Nidhi Singh

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

Contents

Company profiles	3
Company coverage	24
Glossary	25

Prices at 7 February 2022

Published 10 February 2022

Welcome to the February edition of the Edison Healthcare Insight. In this edition we have profiled 41 of our healthcare companies under coverage.

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

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

We welcome any comments/suggestions our readers may have.

Neil Shah

Director of research

Company profiles

Prices at 7 February 2022

US$/£ exchange rate: 0.7376
€/£ exchange rate: 0.8365
A$/£ exchange rate: 0.5269
NZ$/£ exchange rate: 0.4933
SEK/£ exchange rate: 0.0804
DKK/£ exchange rate: 0.1124
NOK/£ exchange rate: 0.0824
JPY/£ exchange rate: 0.0064
CHF/£ exchange rate: 0.8015

Sector: Pharma & healthcare

Price:	SEK0.52
Market cap:	SEK208m
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 (Phase II/III ready) 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	(7.6)	1.4	(30.8)
Relative*	1.0	9.2	(39.8)

* % Relative to local index

Analyst

Dr Jonas Peciulis

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)
2019	3.6	(72.3)	(74.6)	(43.50)	N/A	N/A
2020	1.9	(55.0)	(57.4)	(23.00)	N/A	N/A
2021e	0.2	(107.9)	(110.4)	(31.58)	N/A	N/A
2022e	0.2	(126.1)	(128.6)	(31.92)	N/A	N/A

Sector: Pharma & healthcare

Price:	€1.40
Market cap:	€141m
Market	Euronext Brussels

Share price graph (€)

Company description

Acacia Pharma is a biopharmaceutical company focused on commercialising novel products to improve the care of patients undergoing serious medical treatments such as surgery, invasive procedures or chemotherapy. Its two assets are launched in the United States: BARHEMSYS for PONV and in-licensed BYFAVO for PS.

Price performance

%	1m	3m	12m
Actual	(5.4)	(14.1)	(56.4)
Relative*	0.9	(6.7)	(58.6)

* % Relative to local index

Analyst

Sean Conroy

Acacia Pharma (ACPH)

INVESTMENT SUMMARY

Acacia Pharma is focused on commercialising its two approved hospital-based products in the US. BARHEMSYS (amisulpride) is approved with a broad label for the management of post-operative nausea and vomiting (PONV) and BYFAVO (remimazolam) is approved for procedural sedation (PS). Both assets have now been launched, BARHEMSYS in August 2020 and BYFAVO in January 2021, and initial focus is on gaining wide formulary access. At 30 September 2021, BARHEMSYS was listed on formulary at 260 institutions (>80% win rate), significantly ahead of schedule to meet guidance for 300 by year end. BYFAVO was listed on 95 accounts (>90% win rate) and is also on track to meet its FY21 target of 150. Acacia is funded into 2022 and at 30 June 2021 had net cash of $17.7m. A share placing in February 2021 that raised €27m gross plus access to a €25m loan facility from Cosmo will continue to fund the commercial roll-out of both products. Our forecasts are under review.

INDUSTRY OUTLOOK

Inadequately treated PONV leads to prolonged stays in post-anaesthesia care unit recovery rooms. Use of BARHEMSYS could reduce patient hospitalisation time and the associated costs. Likewise, BYFAVO can reduce the time required for invasive medical procedures, enabling increased patient throughput for hospitals and surgical centres.

Y/E Dec	Revenue (US$m)	EBITDA (US$m)	PBT (US$m)	EPS (c)	P/E (x)	P/CF (x)
2019	0.0	(22.3)	(21.1)	(0.38)	N/A	N/A
2020	0.2	(27.8)	(28.5)	(0.38)	N/A	N/A
2021e	8.0	(36.0)	(39.9)	(0.40)	N/A	N/A
2022e	39.7	(31.2)	(34.1)	(0.33)	N/A	N/A

Sector: Pharma & healthcare

Price:	A$0.12
Market cap:	A$204m
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 occurs in chronic neurological diseases.

Price performance

%	1m	3m	12m
Actual	(28.1)	(34.3)	325.9
Relative*	(24.6)	(31.1)	308.6

* % Relative to local index

Analyst

Dr Jonas Peciulis

Actinogen Medical (ACW)

INVESTMENT SUMMARY

Actinogen has been expanding its R&D programme lately with the lead asset Xanamem, 11beta-HSD1 inhibitor, now targeting three different CNS indications. The XanaMIA study (n=105) investigates Xanamem in mild cognitive impairment (MCI) due to Alzheimer's disease (AD). It has two parts: Part A – dose ranging (enrolment complete; results are expected in Q222) and Part B – efficacy of Xanamem in patients with MCI due to AD. The second Phase II trial is in Fragile X syndrome (XanaFX study). This is a randomised, placebo-controlled trial, which should soon start enrolling patients, with the results expected in 2023. The third indication is major depressive disorder (MDD), which is based on the rationale that elevated cortisol levels have been associated with depression. A fully funded Phase II trial should start in 2022.

INDUSTRY OUTLOOK

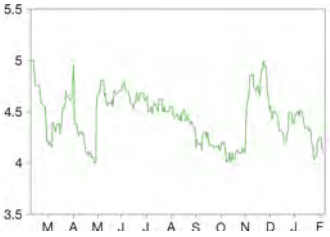
The unmet need in chronic neurological and neuropsychiatric disorders is high due to limited available treatment options. While orphan indications like Fragile X syndrome provide a potentially faster route to market and higher drug pricing, MCI due to AD, as well as MDD, represent much larger markets.

Y/E Jun	Revenue (A$m)	EBITDA (A$m)	PBT (A$m)	EPS (c)	P/E (x)	P/CF (x)
2019	5.1	(9.5)	(9.4)	(0.86)	N/A	N/A
2020	3.6	(4.9)	(4.9)	(0.44)	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:	NZ$4.10
Market cap:	NZ$429m
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	(9.1)	(15.5)	(17.8)
Relative*	(4.0)	(9.7)	(10.5)

* % Relative to local index

Analyst

Nidhi Singh

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% year-on-year 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 compared to 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	124.2	18.1
2021	113.1	11.8	8.2	7.1	57.7	98.7
2022e	130.2	20.5	16.6	15.4	26.6	20.5
2023e	150.3	33.0	29.4	22.3	18.4	12.6

Sector: Pharma & healthcare

Price: SEK1.55
Market cap: SEK626m
Market NASDAQ OMX First North

Share price graph (SEK)

Company description

Denmark-based biopharmaceutical company Allarity Therapeutics' patent-protected mRNA-based DRP platform enables the identification of patients with gene expression likely to respond to treatment. It is advancing the PARP inhibitor stenoparib (2X-121), the TKI dovitinib, and microtubule inhibitor Ixempra.

Price performance

%	1m	3m	12m
Actual	0.0	4.4	101.9
Relative*	9.3	12.4	75.8

* % Relative to local index

Analyst

Karl Egeland

Allarity Therapeutics (ALLR)

INVESTMENT SUMMARY

Allarity Therapeutics holds the worldwide drug development rights to the drug response predictor (DRP), a microarray technology that examines the expression of a panel of genes to discover potential responders to cancer therapies. Lead assets include: tyrosine kinase inhibitor (TKI) dovitinib, poly-ADP-ribose polymerase (PARP) inhibitor stenoparib, and microtubule inhibitor agent Ixempra. In CY Q321 the company's PMA for the dovitinib companion diagnostic agent was accepted by the FDA and in December 2021, the company submitted the respective dovitinib NDA.

INDUSTRY OUTLOOK

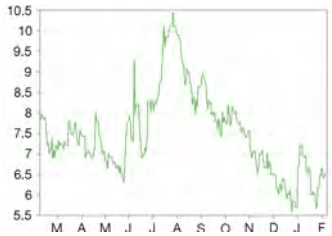
Allarity and the DRP system have the potential to identify the value in drug assets that have otherwise been discontinued by identifying patient populations where these drugs are active. The company has a portfolio of five product candidates. The DRP platform allows the company to identify and in-license assets at low cost; Allarity may then out-license them after clinical validation.

Y/E Dec	Revenue (DKKm)	EBITDA (DKKm)	PBT (DKKm)	EPS (ore)	P/E (x)	P/CF (x)
2019	0.8	(66.5)	(174.9)	(208.11)	N/A	N/A
2020	0.0	(59.0)	(59.1)	(29.22)	N/A	N/A
2021e	0.0	(69.9)	(75.0)	(28.64)	N/A	N/A
2022e	0.0	(247.2)	(248.2)	(91.59)	N/A	N/A

Sector: Pharma & healthcare

Price: SEK6.50
Market cap: SEK245m
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 (symptomatic as well as disease modifying) and pain (neuropathic and osteoarthritic).

Price performance

%	1m	3m	12m
Actual	(6.3)	(8.1)	(16.0)
Relative*	2.4	(1.0)	(26.9)

* % Relative to local index

Analyst

Dr Jonas Peciulis

AlzeCure Pharma (ALZCUR)

INVESTMENT SUMMARY

AlzeCure is a pure play biotech focused on neurological disorders. The pipeline consists of three small-molecule platforms targeting Alzheimer's disease (AD) and pain. The NeuroRestore platform, with lead asset ACD856, is focused on novel symptomatic treatment of AD. The Phase I SAD part with ACD856 has been completed and the MAD part of the trial is 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 (latest data update in June 2021, 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)
2019	0.0	(50.6)	(50.9)	(135.0)	N/A	N/A
2020	0.0	(71.1)	(71.4)	(189.0)	N/A	N/A
2021e	0.0	(75.5)	(75.9)	(201.0)	N/A	N/A
2022e	0.0	(79.2)	(79.8)	(211.0)	N/A	N/A

Sector: Pharma & healthcare

Price:	A$0.04
Market cap:	A$25m
Market	ASX

Share price graph (A$)

Company description

Arovella Therapeutics is a biotechnology company focused on developing therapies to treat cancer and conditions that affect the central nervous system.

Price performance

%	1m	3m	12m
Actual	10.5	2.4	(14.3)
Relative*	15.9	7.5	(17.8)

* % Relative to local index

Analyst

Nidhi Singh

Arovella Therapeutics (ALA)

INVESTMENT SUMMARY

Arovella Therapeutics (ALA) is a biotechnology company focused on developing therapies to treat cancer and conditions that affect the central nervous system. Its most advanced product is ZolpiMist, an oro-mucosal spray version of Ambien for the treatment of insomnia, which is partnered in certain regions with Teva and STADA Pharmaceuticals Australia. ALA recently in-licensed an invariant natural killer T (iNKT) cell therapy platform that can be used in conjunction with chimeric antigen receptors to target blood cancers. There are a number of potential benefits of CAR-iNKT, including the prospect of being an allogeneic 'off-the-shelf' therapy, significantly simplifying the manufacture of the therapy and its delivery to patients. In December 2021, ALA in-licensed patent rights for a monoclonal antibody that targets the Dickkopf-1 (DKK1) peptide, which is expressed in the tumour cells of multiple myeloma and other types of cancer. ALA plans to combine the DKK1 targeting technology with the iNKT cell therapy platform (which is currently at the preclinical stage).

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)	(4.0)	(2.78)	N/A	N/A
2021	0.3	(3.1)	(3.8)	(1.15)	N/A	N/A
2022e	0.5	(6.5)	(7.1)	(1.48)	N/A	N/A
2023e	2.4	(5.4)	(6.1)	(1.25)	N/A	N/A

Sector: Pharma & healthcare

Price:	CHF42.54
Market cap:	CHF550m
Market	Swiss Stock Exchange

Share price graph (CHF)

Company description

Basilea is focused on oncology and infectious diseases. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). The oncology R&D pipeline includes two clinical-stage assets, derazantinib and lisavanbulin.

Price performance

%	1m	3m	12m
Actual	6.4	(0.7)	(19.1)
Relative*	11.6	0.3	(28.7)

* % Relative to local index

Analyst

Jacob Thrane

Basilea Pharmaceutica (BSLN)

INVESTMENT SUMMARY

Basilea has two approved hospital-based products: Cresemba (severe mould infections) and Zevtera (bacterial infections). Multiple licensing/distribution agreements are in place for Cresemba and Zevtera and should drive top-line growth. Partners include Pfizer and Astellas, which market Cresemba in Europe (ex Nordics) and the United States respectively. In August 2019, Basilea reported positive top-line data for Zevtera in the first cross-supportive Phase III study TARGET; top-line data from the ERADICATE study are expected in H122 and both are required for a US NDA submission. Basilea's oncology pipeline is spearheaded by derazantinib (FGFR inhibitor), which is currently in a Phase II potential registration study for intrahepatic cholangiocarcinoma and two Phase I/II studies in patients with advanced urothelial cancer and advanced gastric cancer. Lisavanbulin (tumour checkpoint controller) is in the expansion phase of a biomarker-driven Phase I/II study for glioblastoma. Interim data readouts across the oncology pipeline are expected 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)
2019	134.4	(15.6)	(22.3)	(207.54)	N/A	N/A
2020	127.6	(7.0)	(29.6)	(288.45)	N/A	N/A
2021e	141.4	(13.8)	(23.5)	(184.07)	N/A	N/A
2022e	140.5	(9.4)	(18.4)	(142.51)	N/A	N/A

Sector: Pharma & healthcare

Price:	NOK18.90
Market cap:	NOK1674m
Market	Oslo

Share price graph (NOK)

Company description

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

Price performance

%	1m	3m	12m
Actual	(7.4)	(3.9)	(43.5)
Relative*	(7.7)	(2.3)	(52.2)

* % Relative to local index

Analyst

Sean Conroy

BerGenBio (BGBIO)

INVESTMENT SUMMARY

BerGenBio (BGBIO) is a pioneer in AXL biology and its lead asset bemcentinib is being investigated for AML, NSCLC and COVID-19. AXL is a negative prognostic marker in most cancers, but also implicated in fibrosis and viral infections. AXL inhibition can counter drug resistance, stop immune suppression and potentially augment the efficacy of other drug classes. Initial efficacy data for bemcentinib in relapsed AML look promising and discussions are ongoing with FDA on the design of a potentially pivotal study due to start H222. In NSCLC, data from a Phase II trial are expected in H122 and will provide a better picture of bemcentinib's potential use in the second-line treatment setting. BGBIO will also pursue a first-line opportunity focusing on patients with STK11 mutations and plans to initiate a Phase Ib in H122. For COVID-19, BGBIO will use the EU-SolidAct platform trial to confirm initial efficacy signals observed across two Phase II trials.

INDUSTRY OUTLOOK

Understanding the tumour microenvironment and why even with initial positive response to treatment, cancers often exhibit tumour proliferation, metastasis and treatment resistance is becoming an ever-more critical focus area. The role of AXL is becoming increasingly defined in tumorigenesis, propagation and treatment resistance.

Y/E Dec	Revenue (NOKm)	EBITDA (NOKm)	PBT (NOKm)	EPS (öre)	P/E (x)	P/CF (x)
2019	8.9	(203.6)	(199.3)	(343.40)	N/A	N/A
2020	0.6	(260.4)	(257.0)	(343.07)	N/A	N/A
2021e	0.0	(328.0)	(322.1)	(366.76)	N/A	N/A
2022e	0.0	(336.7)	(335.1)	(380.96)	N/A	N/A

Sector: Pharma & healthcare

Price:	DKK2.38
Market cap:	DKK637m
Market	NASDAQ OMX (CPH)

Share price graph (DKK)

Company description

BioPorto Diagnostics is a diagnostic company focused on the development and commercialisation of biomarker-based assays. The company's portfolio includes The NGAL Test, for the prediction of acute kidney injury, and an extensive antibody library.

Price performance

%	1m	3m	12m
Actual	(15.9)	(27.4)	(61.9)
Relative*	(11.4)	(19.1)	(66.1)

* % Relative to local index

Analyst

Jyoti Prakash

BioPorto Diagnostics (BIOPOR)

INVESTMENT SUMMARY

BioPorto's lead strategic goal is development of a test for acute kidney injury (AKI) using the biomarker NGAL. The company is gathering more data for its paediatric urine NGAL 510(k) and expects to complete the clinical trial by H122, following encouraging interim data. For adults using plasma NGAL, the 510(k) will be submitted to the FDA after the submission for paediatric. The NGAL Test is commercially available for research purposes in the United States and has been CE marked in Europe. BioPorto also sells a series of other antibodies, ELISA kits and related biologics.

INDUSTRY OUTLOOK

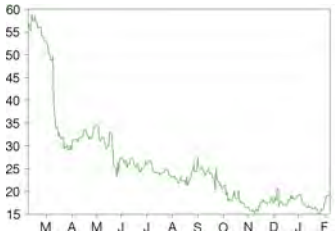
The current standard of care for detecting AKI is serum creatinine, which can take 24 hours or more to detect AKI and can only do so after significant kidney damage. NGAL promises to provide a quicker and more reliable test, allowing early intervention to preserve kidney function.

Y/E Dec	Revenue (DKKm)	EBITDA (DKKm)	PBT (DKKm)	EPS (ore)	P/E (x)	P/CF (x)
2019	26.6	(68.3)	(71.1)	(39.16)	N/A	N/A
2020	23.2	(54.3)	(61.5)	(28.10)	N/A	N/A
2021e	32.2	(71.4)	(74.5)	(25.21)	N/A	N/A
2022e	179.3	68.3	65.2	21.00	11.3	N/A

Sector: Pharma & healthcare

Price: SEK18.42
Market cap: SEK1846m
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	7.2	18.2	(67.5)
Relative*	17.2	27.3	(71.7)

* % Relative to local index

Analyst

Dr Jonas Peciulis

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 latest positive efficacy data update from the PDAC arm of CANFOUR in December 2021, while the latest available data from the NSCLC arm was presented at the ESMO Congress in September 2021. With these data, Cantargia is preparing for the Phase II/III trial in metastatic PDAC in collaboration with PanCAN. Nadunolimab is now being investigated (or about to be) in eight different cancers and in a variety of combinations. The goal of this expansion beyond the original CANFOUR trial is to accumulate a comprehensive data package, which will position Cantargia well to design the next stage development and enter potential partnership negotiations.

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)
2019	0.0	(111.6)	(110.8)	(155.74)	N/A	N/A
2020	0.0	(170.7)	(173.1)	(193.65)	N/A	N/A
2021e	0.0	(347.7)	(347.7)	(347.03)	N/A	N/A
2022e	0.0	(348.5)	(348.5)	(347.88)	N/A	N/A

Sector: Pharma & healthcare

Price: €12.50
Market cap: €192m
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. It received a CE mark in the EU and Carmat is conducting an early feasibility study in the United States.

Price performance

%	1m	3m	12m
Actual	(37.5)	(54.2)	(59.5)
Relative*	(35.4)	(53.5)	(66.4)

* % Relative to local index

Analyst

Jacob Thrane

Carmat (ALCAR)

INVESTMENT SUMMARY

Carmat continues to make progress in the development of its physiologic heart replacement therapy (PHRT). The company recently announced that it has implanted nine of its PHRTs since July, 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, which will be booked in H221. Importantly, due to the PHRT's profile, which features autoregulation, pulsatility and hemocompatibility, additional centres are expected to become commercially active in the coming months, which we believe should help drive revenue growth. FY21 results are due on 16 February.

INDUSTRY OUTLOOK

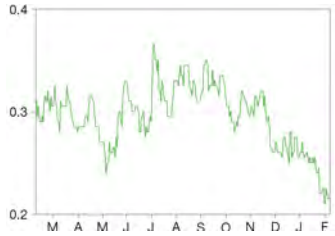
The Carmat artificial heart is being developed as a permanent replacement or destination therapy for chronic biventricular heart failure or acute myocardial infarction patients who do not have access to a human donor heart. Despite the high prevalence of stage IV heart failure in the EU and the United States (c 500,000 patients).

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2019	0.0	(41.9)	(44.3)	(388.95)	N/A	N/A
2020	0.0	(47.7)	(38.7)	(285.32)	N/A	N/A
2021e	4.7	(75.5)	(52.3)	(365.88)	N/A	N/A
2022e	26.9	(63.9)	(65.9)	(502.32)	N/A	N/A

Sector: Pharma & healthcare

Price:	A$0.22
Market cap:	A$48m
Market	ASX

Share price graph (A$)



Company description

Australian-based Chimeric Therapeutics recently went public on the ASX. CLTX CAR T is in Phase I for the treatment of GBM. The technology may have applicability for other tumours such as melanoma. Chimeric recently in-licensed a CDH17 CAR T for use in solid tumours and the CORE-NK platform, which may have broad applicability in cancer.

Price performance

%	1m	3m	12m
Actual	(14.6)	(30.2)	(31.3)
Relative*	(10.4)	(26.7)	(34.0)

* % Relative to local index

Analyst

Jyoti Prakash

Chimeric Therapeutics (CHM)

INVESTMENT SUMMARY

Chimeric Therapeutics is an Australia-based biotechnology company with a focus on oncology that has recently gone public on the ASX. Chimeric is developing CLTX CAR T, currently in Phase I for the treatment of recurrent/progressive glioblastoma (GBM). In July, Chimeric announced that it is licensing a CDH17 CAR T which may have broad applicability in solid tumours. It is expected to enter the clinic in 2022. In December, the company announced that it has entered into an exclusive option agreement to license the CORE-NK platform from Case Western Reserve University, which may vastly expand the pipeline. Four new pipeline programmes are expected to be initiated in 2023 following the completion of the licensure.

INDUSTRY OUTLOOK

GBM (US incidence of around 12,000 per year) accounts for 60% of brain tumours in adults and continues to have a poor prognosis with five-year survival of only 5.1%. The total incidence for the cancers targeted by the CDH17 programme is estimated to be 248,490 in the United States.

Y/E Jun	Revenue (A$m)	EBITDA (A$m)	PBT (A$m)	EPS (c)	P/E (x)	P/CF (x)
2020	0.0	(0.1)	(0.1)	(6200.80)	N/A	N/A
2021	0.0	(14.8)	(14.9)	(8.16)	N/A	N/A
2022e	0.0	(14.0)	(14.0)	(4.19)	N/A	N/A
2023e	0.0	(14.5)	(14.5)	(4.32)	N/A	N/A

Sector: Pharma & healthcare

Price:	158.5p
Market cap:	£287m
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	10.5	4.6	(23.0)
Relative*	10.8	3.1	(32.6)

* % Relative to local index

Analyst

Nidhi Singh

Creo Medical (CREO)

INVESTMENT SUMMARY

Creo Medical is developing and commercialising minimally invasive electrosurgical devices. Its CROMA platform delivers a combination of bi-polar radiofrequency (RF) and microwave energy for the purpose of dissection, resection, ablation and haemostasis of diseased tissue. The initial focus will be on gastrointestinal (GI) procedures but will expand into soft tissues (such as the pancreas) and pulmonology. The company has had all six products within the CROMA platform CE marked and four are also cleared for use by the FDA, with the other two expected to be cleared in the coming months.

INDUSTRY OUTLOOK

Creo Medical products are in a large and lucrative market. Conmed estimates the GI endoscopic technologies market 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:	56.5p
Market cap:	£96m
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	(7.4)	(5.0)	(8.9)
Relative*	(7.1)	(6.4)	(20.2)

* % Relative to local index

Analyst

Nidhi Singh

Diurnal Group (DNL)

INVESTMENT SUMMARY

Diurnal's strategy is to develop useful new medications that address some of the limitations in existing hormone treatments. Efmody, an oral long-acting formulation of hydrocortisone, has been approved in the EU and UK to treat congenital adrenal hyperplasia (CAH) in individuals aged 12 years and older. The company has started the commercial launch of the product in the UK, Germany and Austria. CAH is an orphan disease caused by deficiency of adrenal enzymes. The company's first launched product is Alkindi, a formulation of hydrocortisone intended to treat adrenal insufficiency (AI) in paediatric patients.

INDUSTRY OUTLOOK

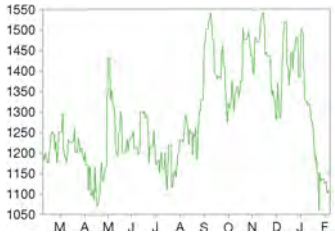
The company's lead products, Alkindi and Efmody, are treatments for deficiencies in the hormone cortisol (aka hydrocortisone). AI affects 250–400 per million individuals in the United States and Europe. A smaller fraction (1/10,000 to 1/18,000 live births) are born with CAH, for which Efmody is approved 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)	(6.6)	N/A	N/A
2022e	7.9	(18.2)	(18.2)	(7.3)	N/A	N/A
2023e	16.1	(13.2)	(13.1)	(5.1)	N/A	N/A

Sector: Pharma & healthcare

Price:	1110.0p
Market cap:	£545m
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	(16.2)	(24.5)	(5.9)
Relative*	(16.0)	(25.6)	(17.6)

* % Relative to local index

Analyst

Dr Jonas Peciulis

Ergomed (ERGO)

INVESTMENT SUMMARY

Ergomed released its 2021 trading update. Total 2021 revenues are expected to be approximately £118.6m, up 37.3% y-o-y (our and the consensus estimate was £119.6m), despite continuing FX headwinds (at constant exchange rates, CER, the growth is expected to be 44.3%). Revenues in the CRO segment increased to £58.1m, up 85.6% (97.4% CER; our estimate was £56.0m) indicating a good rebound in the CRO services industry after it was affected by the COVID-19 pandemic in 2020. Revenues in the PrimeVigilance segment increased to £60.5m, up 9.8% (14.2% CER; our estimate was £63.6m). Ergomed expects adjusted EBITDA to be 'ahead of current market expectations'. Our 2021 adjusted EBITDA stands at £24.0m, marginally above the consensus £23.4m. We therefore keep our estimates and valuation of £751m (1,536p/share) unchanged ahead of the full results.

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 (p)	P/E (x)	P/CF (x)
2019	68.3	12.5	8.6	19.8	56.1	43.9
2020	86.4	19.4	14.4	23.7	46.8	29.8
2021e	119.6	24.0	20.2	34.1	32.6	33.9
2022e	136.9	27.9	24.1	40.5	27.4	25.8

Sector: Pharma & healthcare

Price:	SEK3.18
Market cap:	SEK634m
Market	OMX

Share price graph (SEK)

Company description

Immunicum is a clinical-stage immunoncology (IO) company based in Stockholm, Sweden. It is developing dendritic cell (DC) based therapeutics with two lead therapies in several Phase II trials in multiple cancer indications.

Price performance

%	1m	3m	12m
Actual	(14.1)	(25.6)	(55.8)
Relative*	(6.1)	(19.9)	(61.5)

* % Relative to local index

Analyst

Dr Jonas Peciulis

Immunicum (IMMU)

INVESTMENT SUMMARY

Following the transformational merger with DCprime a year ago, Immunicum now 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. Immunicum will present its pipeline outlook at a shareholder event on 17 February 2022.

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)
2019	0.0	(44.0)	(47.8)	(65.0)	N/A	N/A
2020	0.0	(85.1)	(89.2)	(117.0)	N/A	N/A
2021e	0.0	(134.6)	(137.8)	(75.0)	N/A	N/A
2022e	0.0	(133.1)	(136.3)	(68.0)	N/A	N/A

Sector: Pharma & healthcare

Price:	US$1.19
Market cap:	US$17m
Market	NASDAQ, TSX

Share price graph (US$)

Company description

InMed is a pharmaceutical company focused on developing and manufacturing cannabinoids. Its main pipeline product is INM-755 for EB, a serious, debilitating orphan indication.

Price performance

%	1m	3m	12m
Actual	(7.0)	(19.0)	(72.6)
Relative*	(3.0)	(15.2)	(76.2)

* % Relative to local index

Analyst

Kenneth Mestemacher

InMed Pharmaceuticals (INM)

INVESTMENT SUMMARY

InMed has initiated a Phase II trial for INM-755 in up to 20 epidermolysis bullosa (EB) patients with an anticipated treatment duration of 28 days. Patients with all four subtypes of inherited EB, EB Simplex, Dystrophic EB, Junctional EB and Kindler syndrome will be eligible for the trial. Current expectations are for the trial to enroll in approximately a year. InMed also launched B2B sales of Cannabicitran (CBT), the first of several rare cannabinoids the company plans on launching into the health and wellness sector in H122. Its new acquisition, BayMedica, has received initial orders and commenced commercial sales of the ultra-rare CBT.

INDUSTRY OUTLOOK

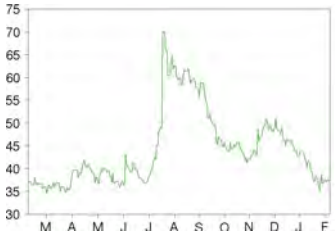
The market for cannabinoids, whether FDA-approved, medical or recreational, is growing at a fantastic rate. Legal cannabis sales in the United States alone were around US$7.5bn in 2017 and we expect them to grow to US$28bn by 2023.

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	0.0	(13.6)	(13.7)	(99.78)	N/A	N/A
2023e	0.0	(11.1)	(12.1)	(83.44)	N/A	N/A

Sector: Pharma & healthcare

Price: SEK36.80
Market cap: SEK1901m
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	(12.4)	(16.7)	(3.7)
Relative*	(4.2)	(10.2)	(16.2)

* % Relative to local index

Analyst

Sean Conroy

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). IRLAB's proprietary in-house-developed ISP research platform is at the heart of its drug discovery engine and has been validated by the progress of its two lead assets, mesdopetam and pirepemat, both of which have novel mechanisms of action. Mesdopetam, an oral D3 antagonist, is currently in a global Phase IIb/III study for levodopa-induced dyskinesias. Top-line data expected in H122 will define the pivotal trials required for approval. A global licensing deal with Ipsen worth up to $363m puts all future clinical development and commercialisation in the hands of a partner, allowing IRLAB to focus on the rest of its pipeline (including preclinical assets IRL942 and IRL1009). Pirepemat is an oral prefrontal cortex (PFC) enhancer currently in development for the treatment of impaired balance and falls in PD. A global Phase IIb study is expected to start shortly. 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	205.6	62.0	97.6	189.0	19.5	32.4
2022e	39.7	(94.6)	(98.6)	(190.0)	N/A	N/A

Sector: Pharma & healthcare

Price: US$7.01
Market cap: US$32m
Market NASDAQ

Share price graph (US$)

Company description

Kazia Therapeutics' lead asset paxalisib, a PI3K inhibitor licensed from Genentech, can cross the BBB. It is entering a pivotal study for GBM and is being investigated for other brain cancers such as breast cancer brain metastases. EVT-801, a VEGFR3 inhibitor, was in-licensed in April 2021 and entered Phase I clinical studies in November 2021.

Price performance

%	1m	3m	12m
Actual	(14.4)	(40.8)	(30.9)
Relative*	(10.7)	(38.0)	(40.1)

* % 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 recently started enrolling patients.

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 (A$m)	EBITDA (A$m)	PBT (A$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	1.1	(10.8)	(10.8)	(14.19)	N/A	N/A
2021	15.2	(4.4)	(4.4)	(3.62)	N/A	N/A
2022e	2.2	(16.3)	(16.3)	(11.53)	N/A	N/A
2023e	2.1	(15.2)	(15.2)	(10.25)	N/A	N/A

Sector: Pharma & healthcare

Price:	€2.35
Market cap:	€69m
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	(17.0)	(30.7)	(48.9)
Relative*	(12.9)	(26.8)	(52.8)

* % Relative to local index

Analyst

Sean Conroy

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 €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$0.13
Market cap:	A$44m
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)	(29.7)	(60.0)
Relative*	(6.0)	(26.3)	(61.6)

* % Relative to local index

Analyst

Dr Jonas Peciulis

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)
2019	8.1	(7.9)	(8.2)	(3.9)	N/A	N/A
2020	5.8	(12.3)	(13.5)	(5.9)	N/A	N/A
2021e	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

Sector: Pharma & healthcare

Price:	A$1.14
Market cap:	A$742m
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	(13.6)	(33.1)	(54.9)
Relative*	(9.4)	(29.9)	(56.8)

* % 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

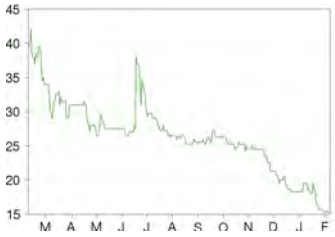
Mesoblast is a leading MSC company based in Australia. It is targeting large indications such as ARDS, congestive heart failure and back pain.

Y/E Jun	Revenue (US$m)	EBITDA (US$m)	PBT (US$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2019	16.0	(75.4)	(86.5)	(15.69)	N/A	N/A
2020	31.6	(64.8)	(79.6)	(13.28)	N/A	N/A
2021e	72.9	(46.3)	(55.7)	(9.06)	N/A	N/A
2022e	8.6	(83.2)	(92.6)	(14.29)	N/A	N/A

Sector: Pharma & healthcare

Price:	15.2p
Market cap:	£15m
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	(21.8)	(37.8)	(61.9)
Relative*	(21.6)	(38.7)	(66.6)

* % 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	(5.2)	(29.6)	(50.0)
Relative*	(0.5)	(28.9)	(55.9)

* % Relative to local index

Analyst

Jacob Thrane

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. H121 results showed Xadago royalties of €2.65m, up 6.5% versus H120. Newron had cash plus loan facilities at end June totalling €36.9m plus Xadago royalties to fund it into 2023.

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: €2.19
Market cap: €95m
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	(20.1)	(30.9)	(52.0)
Relative*	(17.4)	(29.8)	(60.1)

* % 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 90% enrolment and results are expected in Q123. We expect a H225 launch and sales of c €500m in 2031 in the United States and major markets. Nicox had €41.9m gross cash at Q421, 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:	SEK1.74
Market cap:	SEK780m
Market	Nasdaq FN Premier

Share price graph (SEK)

Company description

Oasmia Pharmaceutical 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	(33.0)	(19.2)	(53.9)
Relative*	(26.7)	(13.0)	(59.9)

* % Relative to local index

Analyst

Sean Conroy

Oasmia Pharmaceutical (OASM)

INVESTMENT SUMMARY

Oasmia 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 early 2022. Additional studies are expected to be required before an NDA filing in the United States. Oasmia 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. Oasmia has secured a rights issue that will raise gross proceeds of c SEK151m in Q122 and should alleviate near-term funding requirements.

INDUSTRY OUTLOOK

Despite a slew of novel cancer drugs transforming care for many oncology indications, established chemotherapy regimens remain a cornerstone of treatment. Oasmia'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 Apr / Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2019	2.0	(119.2)	(168.5)	(68.5)	N/A	N/A
2020	201.8	(10.1)	(43.4)	0.2	870.0	N/A
2021e	16.5	(97.1)	(128.1)	(24.0)	N/A	N/A
2022e	46.8	(106.5)	(139.1)	(26.5)	N/A	N/A

Sector: Pharma & healthcare

Price:	€0.39
Market cap:	€36m
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	(10.6)	(21.4)	(48.4)
Relative*	(7.6)	(20.1)	(57.1)

* % Relative to local index

Analyst

Dr Jonas Peciulis

Onxeo (ONXEO)

INVESTMENT SUMMARY

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 that 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$0.88
Market cap:	US$34m
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	(10.1)	(48.1)	(62.8)
Relative*	(6.2)	(45.6)	(67.7)

* % Relative to local index

Analyst

Nidhi Singh

OpGen (OPGN)

INVESTMENT SUMMARY

OpGen is a diagnostic company focused on revolutionising 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; the recently 510(k) cleared Acuitas AMR Gene Panel in bacterial isolates; and the AI-powered AMR database (ARESdb). OpGen's products are differentiated by their short turnaround time, for example, the Acuitas AMR Gene Panel test takes 2.5 hours versus one to four days using traditional methods.

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)
2019	3.5	(11.7)	(11.9)	(737.57)	N/A	N/A
2020	4.2	(22.0)	(25.3)	(157.41)	N/A	N/A
2021e	3.8	(26.2)	(30.9)	(85.48)	N/A	N/A
2022e	8.3	(23.2)	(25.5)	(63.00)	N/A	N/A

Sector: Pharma & healthcare

Price:	€2.92
Market cap:	€155m
Market	Madrid Stock Exchange

Share price graph (€)

Company description

Spanish biotech Oryzon Genomics is focused on epigenetics. Iadademstat (Phase IIa) is being explored for acute leukaemias and SCLC; its CNS product vafidemstat is in Phase IIb trials in BPD, schizophrenia and also being investigated for precision medicine. ORY-3001 is being developed for certain orphan indications.

Price performance

%	1m	3m	12m
Actual	6.4	(7.3)	(20.1)
Relative*	8.8	(1.1)	(23.3)

* % Relative to local index

Analyst

Dr Jonas Peciulis

Oryzon Genomics (ORY)

INVESTMENT SUMMARY

Oryzon develops small molecule inhibitors for epigenetic targets. The two lead drugs are iadademstat for oncology and vafidemstat for 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) 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)
2019	10.3	(3.7)	(4.6)	(8.81)	N/A	N/A
2020	9.5	(4.1)	(4.8)	(6.88)	N/A	N/A
2021e	9.9	(6.8)	(6.9)	(7.37)	N/A	N/A
2022e	9.9	(6.0)	(6.1)	(8.67)	N/A	N/A

Sector: Pharma & healthcare

Price:	€8.23
Market cap:	€152m
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	(12.9)	(4.3)	(31.4)
Relative*	(10.0)	(2.8)	(43.0)

* % Relative to local index

Analyst

Dr Jonas Peciulis

OSE Immunotherapeutics (OSE)

INVESTMENT SUMMARY

OSE focuses on both oncology and immune disorders. Long-term collaborations with top research institutions enable it to identify novel targets in a cost-effective manner, which was particularly evident from the stream of announcements recently when the R&D pipeline expanded significantly. One of last year's positives was the FR104 (a CD28 antagonist) licensing deal signed with Veloxis in the organ transplantation setting for a total of up to €315m in milestones plus royalties. First, positive data from the Phase I study of BI 765063 (SIRPa antagonist) in solid tumours were presented at ASCO and ESMO conferences last year. This asset is partnered with Boehringer Ingelheim in a deal worth €1.1bn plus royalties. Upcoming newsflow from many other projects in the pipeline should provide continued catalysts and hence support the share price.

INDUSTRY OUTLOOK

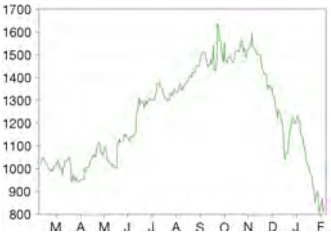
OSE has products in development for both immunological diseases and various cancer indications. As a result, the R&D pipeline is diversified and the outlook does not depend on developments in any specific subsector.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2019	26.0	(0.9)	(1.2)	(29.55)	N/A	20.5
2020	10.4	(18.1)	(18.5)	(101.83)	N/A	N/A
2021e	16.0	(13.6)	(14.1)	(85.30)	N/A	N/A
2022e	0.0	(29.8)	(30.4)	(169.03)	N/A	N/A

Sector: Pharma & healthcare

Price:	830.0p
Market cap:	£756m
Market	LSE

Share price graph (p)



Company description

OXB's strategy is underpinned by its LentiVector technology. It generates significant revenue from a multitude of partners that use its technology and is manufacturing the COVID-19 vaccine Vaxzevria (AZD1222) for AstraZeneca. OXB is implementing significant capacity upgrades to enable more partnering/out-licensing agreements.

Price performance

%	1m	3m	12m
Actual	(26.9)	(45.8)	(17.5)
Relative*	(26.7)	(46.6)	(27.8)

* % Relative to local index

Analyst

Jacob Thrane

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), Sio Gene Therapies, 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)
2019	64.1	(4.6)	(16.8)	(16.4)	N/A	172.5
2020	87.7	8.3	(2.5)	(2.7)	N/A	42.1
2021e	159.1	28.6	18.6	20.3	40.9	N/A
2022e	173.4	39.2	28.0	30.6	27.1	212.8

Sector: Pharma & healthcare

Price:	€0.10
Market cap:	€2m
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 Charcot-Marie-Tooth disease type 1A 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	(34.2)	(30.4)	(97.5)
Relative*	(32.0)	(29.3)	(97.9)

* % 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 instance, 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)
2019	3.6	(19.5)	(23.4)	(161.08)	N/A	N/A
2020	2.8	(18.2)	(21.4)	(117.33)	N/A	N/A
2021e	3.6	(25.2)	(27.7)	(26.80)	N/A	N/A
2022e	3.9	(29.3)	(30.8)	(23.43)	N/A	N/A

Sector: Pharma & healthcare

Price:	€0.71
Market cap:	€41m
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. TThe company started implantations as part of a European pivotal study in early 2021.

Price performance

%	1m	3m	12m
Actual	(16.0)	(31.2)	(32.5)
Relative*	(13.1)	(30.0)	(43.9)

* % Relative to local index

Analyst

Pooya Hemami

Pixium Vision (PIX)

INVESTMENT SUMMARY

Pixium Vision is developing the Prima wireless photovoltaic sub-retinal implant, which transforms images into electrical signals to elicit a form of central visual perception in patients with severe retinal disease. 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 (VA) scale versus baseline, 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 raised €8m in July 2021, which we believe should fund operations through the end of 2022.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2019	1.8	(8.4)	(9.8)	(43.90)	N/A	N/A
2020	2.1	(7.6)	(8.7)	(25.63)	N/A	N/A
2021e	2.6	(9.3)	(10.8)	(22.36)	N/A	N/A
2022e	1.6	(9.6)	(11.0)	(18.85)	N/A	N/A

Sector: Pharma & healthcare

Price:	€4.01
Market cap:	€107m
Market	Euronext Paris

Share price graph (€)

Company description

Quantum Genomics is a biopharmaceutical company developing firibastat, a brain aminopeptidase A inhibitor for treating hypertension and heart failure. Its mechanism is implicated in the 25% of patients resistant to treatment.

Price performance

%	1m	3m	12m
Actual	(4.1)	(1.3)	(12.9)
Relative*	(0.9)	0.3	(27.6)

* % Relative to local index

Analyst

Jacob Thrane

Quantum Genomics (ALQGC)

INVESTMENT SUMMARY

Quantum Genomics is investigating brain aminopeptidase A inhibitors, a new class of drug, for the treatment of hypertension and heart failure. Data from the Phase IIb NEW-HOPE trial suggest that firibastat is an efficacious, safe drug. After eight weeks of treatment patients saw a statistically significant reduction from baseline ($p<0.0001$) in systolic blood pressure of 9.7mmHg. Two pivotal Phase III trials have been initiated. Data from the Phase IIb of firibastat in heart failure patients was recently presented and the trial missed its primary endpoint though with trends in severe patients. The programme is moving forward into Phase III.

INDUSTRY OUTLOOK

The angiotensin pathway is one of the primary methods of modulating blood pressure and is the target of many anti-hypertensive drugs, including ACEs and ARBs. However, there is a parallel pathway in the brain responsible for the secretion of vasopressin and heart rate that is unaddressed by current drugs and that is being targeted by Quantum Genomics.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2019	0.0	(10.8)	(10.8)	(52.7)	N/A	N/A
2020	1.2	(13.9)	(13.9)	(49.9)	N/A	N/A
2021e	0.8	(20.8)	(20.8)	(65.1)	N/A	N/A
2022e	0.0	(22.5)	(22.5)	(67.6)	N/A	N/A

Sector: Pharma & healthcare

Price:	SEK27.40
Market cap:	SEK522m
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	(5.4)	10.3	3.8
Relative*	3.4	18.8	(9.7)

* % Relative to local index

Analyst

Dr Jonas Peciulis

RhoVac (RHOVAC)

INVESTMENT SUMMARY

RhoVac is developing RV001, a cancer immunotherapy designed to prevent or limit progression to metastatic disease after curative intent therapy, by activating T-cells against cells with metastatic potential. RV001 contains a fragment of the target protein RhoC, which is overexpressed in cells with metastatic potential in various cancers. Funding should be sufficient to complete the Phase IIb BRaVac study for prostate cancer and exploratory preclinical studies in other cancers. The trial is now fully enrolled with results expected in H122. The latest interim safety review in July 2021 found no issues. RhoVac aims to secure a partner for the late-stage development and global launch of RV001.

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 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)
2019	6.0	(36.5)	(36.1)	(233.00)	N/A	N/A
2020	6.0	(47.5)	(46.9)	(205.53)	N/A	N/A
2021e	11.0	(39.0)	(38.7)	(162.55)	N/A	N/A
2022e	5.9	(39.1)	(38.9)	(163.83)	N/A	N/A

Sector: Pharma & healthcare

Price:	€6.46
Market cap:	€120m
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	(12.7)	(18.0)	(37.6)
Relative*	(6.9)	(11.0)	(40.8)

* % 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

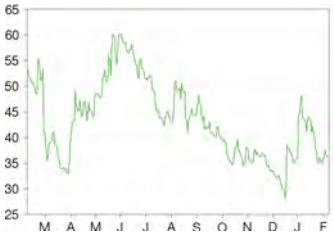
The alfapump is undergoing a pivotal North American registration study (POSEIDON) and is already commercialised in parts of Europe. Sequana completed POSEIDON enrolment in December 2021, and expects to report primary efficacy data in Q422 and submit a US regulatory application for alfapump in mid-2023. 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 December 2021.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2019	1.0	(13.7)	(14.9)	(121.95)	N/A	N/A
2020	1.0	(17.5)	(19.0)	(125.07)	N/A	N/A
2021e	0.5	(22.1)	(22.7)	(125.09)	N/A	N/A
2022e	1.2	(21.4)	(22.8)	(122.17)	N/A	N/A

Sector: Pharma & healthcare

Price:	36.2p
Market cap:	£78m
Market	AIM

Share price graph (p)



Company description

Shield Therapeutics is a commercial-stage pharmaceutical company. Its proprietary product, Feraccru/Accrufer, is approved by the FDA and EMA for the treatment of iron deficiency from any cause. Shield has launched the product itself in the US and partner Norgine is marketing it in Europe.

Price performance

%	1m	3m	12m
Actual	(16.7)	3.6	(29.0)
Relative*	(16.4)	2.1	(37.8)

* % 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 30 June 2021 Shield had an unaudited cash balance of £22.6m. This is sufficient to enable it to establish and expand its US commercial infrastructure to include 30–60 sales reps to support the 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$6.43
Market cap:	US$477m
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.

Price performance

%	1m	3m	12m
Actual	(8.5)	(13.0)	(5.4)
Relative*	(4.6)	(8.8)	(18.0)

* % Relative to local index

Analyst

Kenneth Mestemacher

SIGA Technologies (SIGA)

INVESTMENT SUMMARY

SIGA Technologies is a commercial-stage company focusing on health security. Its lead program is oral TPOXX (tecovirimat), which was approved by the FDA in 2018 for the treatment of smallpox and is active against all orthopoxviruses. Importantly, in 2018 SIGA was awarded a 60-month contract (with options to extend to 2028) of up to $602m from the US Biomedical Advanced Research and Development Authority (BARDA). The bulk of the BARDA contract is related to the oral version of TPOXX in people with smallpox. Additionally, the company recently announced a research collaboration with Bioarchitech to investigate TPOXX in combination with Bioarchitech's oncolytic immunotherapy program in preclinical studies.

INDUSTRY OUTLOOK

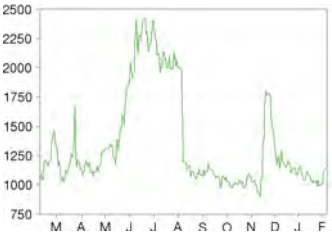
Smallpox is a very serious life-threatening disease caused by the variola virus. The literature suggests a death rate of up to 30% (compared to around 2% for COVID-19). According to CDC forecasts, over 50 million people could be infected in a smallpox outbreak.

Y/E Dec	Revenue (US$m)	EBITDA (US$m)	PBT (US$m)	EPS (c)	P/E (x)	P/CF (x)
2019	26.7	0.0	(15.3)	(15.2)	N/A	N/A
2020	125.0	84.5	82.0	81.8	7.9	7.1
2021e	133.3	87.3	87.4	87.7	7.3	7.4
2022e	124.7	78.0	78.5	80.5	8.0	7.8

Sector: Pharma & healthcare

Price:	¥1120.00
Market cap:	¥43072m
Market	Tokyo

Share price graph (¥)



Company description

SymBio Pharmaceuticals is a Japanese specialty pharma company focused on oncology and hematology. It markets Treakisym (bendamustine) in Japan and in-licensed two liquid formulations from Eagle Pharmaceuticals in 2017; brincidofovir was licensed from Chimerix in 2019.

Price performance

%	1m	3m	12m
Actual	7.6	12.1	25.1
Relative*	11.5	18.8	22.9

* % Relative to local index

Analyst

Jyoti Prakash

SymBio Pharmaceuticals (4582)

INVESTMENT SUMMARY

SymBio is a speciality pharma focused on Asia-Pacific markets and has the Japanese rights to multiple formulations of Treakisym (bendamustine). Treakisym iv was approved for r/r low-grade NHL/MCL in 2010, for CLL and first-line low-grade NHL/MCL in 2016 and for r/r DLBCL in 2021. SymBio has in-licensed liquid formulations for injection that will give Treakisym patent protection to 2031; a clinical trial is underway of the rapid-infusion liquid formulation. The company filed an IND in March 2021 to begin Phase II studies for the anti-viral drug brincidofovir (in-licensed from Chimerix) for pediatric adenovirus infections and received a fast track designation by the US FDA in April 2021.

INDUSTRY OUTLOOK

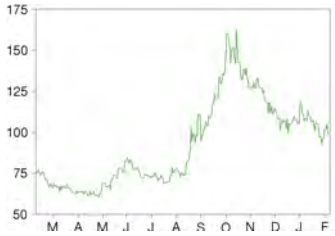
SymBio is focused on in-licensing niche opportunities in hard-to-treat indications often overlooked by big pharma. An in-house screening process to select additional pipeline candidates for development and commercialisation will be key to driving operational leverage.

Y/E Dec	Revenue (¥m)	EBITDA (¥m)	PBT (¥m)	EPS (¥)	P/E (x)	P/CF (x)
2019	2837.8	(4263.5)	(4249.5)	(183.72)	N/A	N/A
2020	2987.1	(4441.4)	(4513.5)	(137.10)	N/A	N/A
2021e	9227.8	1561.2	1508.4	27.02	41.5	N/A
2022e	11483.8	2069.6	2017.5	37.29	30.0	N/A

Sector: Pharma & healthcare

Price:	NOK98.00
Market cap:	NOK3354m
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	(9.4)	(22.8)	27.3
Relative*	(9.8)	(21.6)	7.6

* % Relative to local index

Analyst

Dr Jonas Peciulis

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 ORR 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)
2019	0.0	(64.2)	(61.2)	(267.0)	N/A	N/A
2020	0.0	(121.4)	(120.6)	(398.0)	N/A	N/A
2021e	0.0	(151.2)	(150.0)	(453.0)	N/A	N/A
2022e	0.0	(195.2)	(194.2)	(567.0)	N/A	N/A

Company coverage

Company	Note	Date published
Abliva	Update; Update	27/05/21; 13/01/22
Acacia Pharma	Update; Update	01/04/21; 02/07/21
Actinogen Medical	Flash; Update	08/05/19; 15/10/19
AFT Pharmaceuticals	Update; Update	26/05/21; 22/11/21
Allarity Therapeutics	Update; Update	19/04/21; 08/06/21
AlzeCure Pharma	Flash; Update	27/08/21; 05/01/22
Arovella Therapeutics	Update; Update	23/06/21; 21/12/21
Basilea Pharmaceutica	Update; Update	04/06/21; 29/09/21
BerGenBio	Flash; Update	24/08/21; 31/01/22
BioPorto Diagnostics	Update; Flash	13/05/21; 21/10/21
Cantargia	Flash; Update	10/03/21; 06/04/21
Carmat	Update; Update	11/01/21; 20/09/21
Chimeric Therapeutics	Update; Update	29/07/21; 06/12/21
Creo Medical	Initiation	04/10/21
Diurnal Group	Update; Update	29/03/21; 29/09/21
Ergomed	Update; Update	04/10/21; 03/02/22
Exopharm	Spotlight initiation	28/05/21
Immunicum	Update; Outlook	16/12/20; 14/09/21
InMed Pharmaceuticals	Update; Update	20/09/21; 29/09/21
IRLAB Therapeutics	Update; Update	22/11/21 14/12/21
Kazia Therapeutics	Update; ADR update	13/10/21; 14/10/21
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
Oasmia Pharmaceutical	Update; Flash	06/12/21; 20/01/22
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	28/09/20; 30/04/21
Oxford Biomedica	Outlook; Outlook	05/10/20; 27/05/21
Pharnext	Update; Update	06/12/21; 29/12/21
Pixium Vision	Flash; Update	20/10/21; 15/12/21
Quantum Genomics	Update; Update	12/07/21; 09/09/21
ReNeuron Group	Update; Update	15/07/21; 08/10/21
RhoVac	Update; Outlook	26/04/21; 14/10/21
Sareum Holdings	Update; Flash	23/11/21; 17/12/21
Sequana Medical	Flash; Update	06/12/21; 15/12/21
Shield Therapeutics	Flash; Update	28/05/21; 23/08/21
SIGA Technologies	Update; Update	10/08/21; 09/11/21
SymBio Pharmaceuticals	Update; Update	30/03/21; 27/05/21
Ultimovacs	Update; Update	03/09/21; 13/12/21

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

General disclaimer and copyright

This report has been prepared and issued by Edison. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076960
Schumannstrasse 34b
60325 Frankfurt
Germany

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

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

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