



#### Soo Romanoff: Head of content, healthcare



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

#### Pooya Hemami



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

## **Harry Shrives**



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

## Jyoti Prakash



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

#### **Adam McCarter**



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

# Nidhi Singh



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



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Prices at 12 September 2022

Published 15 September 2022

Welcome to the September edition of the Edison Healthcare Insight. In this edition we have profiled 33 of our healthcare companies under coverage.

Readers wishing more detail should visit our website, where reports are freely available for download (<a href="www.edisongroup.com">www.edisongroup.com</a>). 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 12 September 2022

US\$/£ exchange rate: 0.8535 €/£ exchange rate: 0.8551 A\$/£ exchange rate: 0.5862 NZ\$/£ exchange rate: 0.5253 SEK/£ exchange rate: 0.0803 NOK/£ exchange rate: 0.0866 CHF/£ exchange rate: 0.8835 DKK/£ exchange rate: 0.1150



Price: SEK0.22 Market cap: SEK232m Market NOMX Sweden Small Cap

## Share price graph (SEK)



#### Company description

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

#### Price performance

%	1m	3m	12m
Actual	(18.4)	(40.5)	(63.0)
Relative*	(14.4)	(39.8)	(53.5)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# Abliva (ABLI)

#### **INVESTMENT SUMMARY**

Abliva is focused on primary mitochondrial diseases (PMD). The core portfolio consists of KL1333 and NV354. KL1333 is a small molecule NAD+/NADH modulator used to restore intracellular energy balance. With the investigational new drug (IND) application approved by the FDA, Abliva is getting ready for the pivotal Phase II/III FALCON trial with KL1333 and is expected to start screening patients in H222. Abliva is also progressing with its other core asset, NV354, as a systemic treatment for Leigh syndrome, with preparations ongoing for a Phase I start. In June Abliva completed a c SEK200m funding (SEK150m private placement and SEK50m rights issue), which is expected to provide the company with a 24-month cash runway through to mid-2024.

#### **INDUSTRY OUTLOOK**

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

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (fd) (öre)	P/E (x)	P/CF (x)
2020	1.9	(55.0)	(57.4)	(23.00)	N/A	N/A
2021	0.2	(117.9)	(120.4)	(34.44)	N/A	N/A
2022e	0.2	(128.2)	(128.9)	(17.67)	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

#### Sector: Pharma & healthcare

Price: NZ\$3.54
Market cap: NZ\$371m
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	(1.7)	(13.2)	(17.7)
Relative*	(1.8)	(17.6)	(6.3)

\* % Relative to local index

# Analyst

Soo Romanoff

# **AFT Pharmaceuticals (AFT)**

# INVESTMENT SUMMARY

AFT Pharmaceuticals is a profitable New Zealand-based specialty pharmaceutical company that sells 130 proprietary branded and generic products through its own sales force in New Zealand and Australia, with offices in SE Asia and Europe to handle its growing export business. Despite COVID-19 headwinds, operating revenue in FY22 grew strongly by 15.2% y-o-y to NZ\$130.3m, mainly aided by new product launches, solid recovery in Australia and sustained growth in New Zealand. Reported group operating profit almost doubled to NZ\$20.4m in FY22 versus NZ\$10.7m in the same period a year ago. AFT has given FY23 guidance for operating profit in the range of NZ\$27–32m. In July 2022, AFT expanded its product reach into China following registration under the country's Cross Border E-Commerce OTC platform. In September, AFT announced that along with partner Hyloris Pharmaceuticals, it will initiate additional studies to address the FDA queries (raised in July 2022) related to Maxigesic IV's packaging, with completion expected by CY23.

#### **INDUSTRY OUTLOOK**

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

Y/E Mar	Revenue (NZ\$m)	EBITDA (NZ\$m)	PBT (NZ\$m)	EPS (c)	P/E (x)	P/CF (x)
2021	113.1	11.8	8.2	7.1	49.9	N/A
2022	130.3	21.4	18.9	19.2	18.4	30.2
2023e	155.9	30.6	27.0	20.4	17.4	20.2
2024e	194.2	47.1	43.5	30.0	11.8	10.9



Price: A\$0.02 Market cap: A\$15m Market ASX

# Share price graph (A\$)



#### Company description

Arovella Therapeutics focuses on oncology and CNS diseases through its cell therapy and legacy OroMist platforms. It is developing a CAR-iNKT programme for haematological malignancies and a DKK1 antibody with potential in multiple myeloma and solid tumours. The OroMist platform focuses on oromucosal spray versions of established medicines. Price performance

%	1m	3m	12m
Actual	(17.9)	(14.8)	(57.4)
Relative*	(16.9)	(15.6)	(54.5)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# **Arovella Therapeutics (ALA)**

#### **INVESTMENT SUMMARY**

Arovella Therapeutics is focused on the immunoncology space (in particular cell therapies) following the in-licensing in CY21 of two chimeric antigen receptor (CAR) based immunotherapies (both in preclinical stage). The first was an invariant natural killer T (iNKT) cell therapy platform in-licensed from Imperial College London in July 2021. The platform can be combined with CARs to target blood cancers, with a potential of being an allogeneic 'off-the-shelf' therapy. This was followed by the in-licensing of a novel monoclonal antibody targeting a Dickkopf-1 (DKK1) peptide from MD Anderson Cancer Center in December 2021. Arovella plans to combine the DKK1 targeting technology with the iNKT cell therapy platform in future. In addition, the company also reformulates established drugs into oro-mucosal spray formulations (via its legacy OroMist platform) for better bioavailability. The FY22 year-end cash balance of A\$6.1m should provide a 12-month runway based on the current run rate, but we estimate the need to raise another A\$5m in FY24.

#### INDUSTRY OUTLOOK

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

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (c)	P/E (x)	P/CF (x)
2021	0.3	(3.1)	(3.4)	(1.15)	N/A	N/A
2022	0.3	(7.0)	(7.4)	(1.42)	N/A	N/A
2023e	2.4	(5.2)	(5.6)	(0.87)	N/A	N/A
2024e	6.2	(1.8)	(2.1)	(0.35)	N/A	N/A

#### Sector: Pharma & healthcare

Price: CHF40.80
Market cap: CHF530m
Market Swiss Stock Exchange

# Share price graph (CHF)



#### Company description

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

#### Price performance

%	1m	3m	12m
Actual	(6.0)	22.9	(11.0)
Relative*	(4.8)	23.9	(2.4)

\* % Relative to local index

# Analyst

Soo Romanoff

# Basilea Pharmaceutica (BSLN)

# INVESTMENT SUMMARY

In February Basilea announced a strategic refocusing of its core anti-infective business in 2022, which it is separating out from its oncology assets for which it is exploring strategic options. Strong FY21 results were driven by key anti-infective assets, Cresemba and Zevtera, which contributed 65% of the year's non-deferred revenue growth. Global Cresemba sales were over US\$300m in FY21 resulting in significantly increased royalty and milestone payments. Basilea has secured a CHF75m senior secured loan from Athyrium Capital Management (a US-based asset management company), which along with cash on books will be used to repay the outstanding convertible bonds due in December 2022 and is anticipated to bridge the company until expected operational profitability in FY23. Positive results from the ERADICATE study of Zevtera in bloodstream infections, reported in June 2022, complete the data package needed for NDA submission, paving the way for entry to the US antibiotic market.

# **INDUSTRY OUTLOOK**

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

Y/E Dec	Revenue (CHFm)	EBITDA (CHFm)	PBT (CHFm)	EPS (CHFc)	P/E (x)	P/CF (x)
2020	127.6	(7.0)	(29.6)	(288.45)	N/A	N/A
2021	148.1	1.9	(6.6)	(56.90)	N/A	N/A
2022e	110.0	(21.0)	(29.5)	(249.47)	N/A	N/A
2023e	128.8	23.1	14.5	164.57	24.8	N/A



Price: NOK7 90 Market cap: NOK700m Market Oslo

## Share price graph (NOK)



#### Company description

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

# Price performance

%	1m	3m	12m
Actual	(42.3)	(33.5)	(65.6)
Relative*	(40.8)	(32.7)	(67.4)

\* % Relative to local index

#### **Analyst**

Pooya Hemami

# **INDUSTRY OUTLOOK**

BGBIO plans to initiate a Phase Ib/IIa study in 1L NSCLC with STK11m in H222. For COVID-19, BGBIO is using the EU-SolidAct platform trial to confirm initial efficacy signals observed across its Phase II ACCORD2 study. The Phase IIb trial arm studying bemcentinib in hospitalised COVID-19 patients began recruitment in Q322 and is designed to enrol 500 patients across European sites.

BerGenBio (BGBIO) is a pioneer in AXL biology and following a recent business strategy update, it will focus lead asset bemcentinib in first-line (1L) non-squamous non-small cell

lung cancer (NSCLC) patients with STK11 mutations (STK11m), and also in hospitalised COVID-19 patients. AXL is a negative prognostic marker in most cancers, but also implicated in fibrosis and viral infections. AXL inhibition may counter drug resistance, stop immune suppression and potentially augment the efficacy of other drug classes, particularly immunotherapies. The company's Phase II BGB008 study in 2L NSCLC has already shown

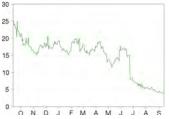
some efficacy in STK11m patients when combined with pembrolizumab.

Y/E Dec	Revenue (NOKm)	EBITDA (NOKm)	PBT (NOKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.6	(260.4)	(257.0)	(343.07)	N/A	N/A
2021	0.8	(313.1)	(309.4)	(351.72)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

#### Sector: Pharma & healthcare

Price: SFK3 83 Market cap: SEK639m Market NASDAQ OMX First North

### Share price graph (SEK)



# Company description

Cantargia is a clinical-stage 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 Relative*		(72.3) (72.0)	(81.2) (76.3)
Relative	(29.1)	(12.0)	(10.5)

\* % Relative to local index

# Analyst

Soo Romanoff

# Cantargia (CANT)

BerGenBio (BGBIO)

**INVESTMENT SUMMARY** 

# **INVESTMENT SUMMARY**

Cantargia is developing antibodies against IL1RAP. Data from its Phase IIa CANFOUR trial, investigating nadunolimab in first-line non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC), support the hypothesis that nadunolimab has a synergistic benefit with chemotherapy. At the ASCO Annual Meeting in June, Cantargia presented promising interim results for nadunolimab from a Phase I/IIa in PDAC and a Phase IIa trial in NSCLC. The company is now preparing for the Phase II/III trial in metastatic PDAC in collaboration with PanCAN. A second programme, CAN10, is being developed for treatment of myocarditis and systemic sclerosis. New supportive preclinical data were recently presented and Phase I clinical trials are planned for early 2023. Nadunolimab is being investigated across eight different cancers in different combinations. The company had an estimated cash and short-term investment position of SEK575.2m at end-August 2022.

# **INDUSTRY OUTLOOK**

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

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.0	(170.7)	(173.1)	(193.65)	N/A	N/A
2021	0.0	(366.8)	(370.3)	(369.55)	N/A	N/A
2022e	0.0	(390.4)	(393.8)	(294.78)	N/A	N/A
2023e	0.0	(364.0)	(367.5)	(220.06)	N/A	N/A



Price: €13.50
Market cap: €266m
Market Euronext Growth

## Share price graph (€)



#### Company description

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

# Price performance

%	1m	3m	12m
Actual	(0.9)	13.8	(55.7)
Relative*	2.7	11.9	(52.7)

\* % Relative to local index

#### **Analyst**

Pooya Hemami

# Carmat (ALCAR)

#### **INVESTMENT SUMMARY**

Carmat continues to implement controls to improve quality and safety of its Aeson physiologic heart replacement therapy, in response to defects identified in two components that were the root cause of issues affecting some of its prostheses. The company voluntarily suspended Aeson implantations in Q421 once the issues were identified and it is regular contact with regulatory agencies. The company expects to resume Aeson availability in October 2022. Carmat recorded €2.3m in FY21 revenue from the sale of seven Aeson devices in Germany and Italy and three in the US as part of an early feasibility study. In April 2022, Carmat raised €40.5m in gross proceeds, extending its cash runway until March 2023

#### INDUSTRY OUTLOOK

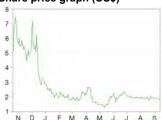
The Aeson artificial heart is being developed as a permanent replacement or destination therapy for chronic biventricular heart failure or acute myocardial infarction patients who do not have access to a human donor heart.

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

### Sector: Pharma & healthcare

Price:	US\$1.82
Market cap:	US\$29m
Market .	NASDAQ

# Share price graph (US\$)



# **Company description**

Context Therapeutics is a clinical-stage women's oncology company. Lead candidate ONA-XR is a 'full' PR antagonist currently being evaluated in three Phase II clinical trials in hormone-driven breast, endometrial and ovarian cancer. Preliminary data from at least one trial are expected in H222.

#### Price performance

%	1m	3m	12m
Actual	(7.1)	(4.7)	N/A
Relative*	(3.3)	(9.6)	N/A

\* % Relative to local index

# Analyst

Soo Romanoff

# **Context Therapeutics (CNTX)**

# INVESTMENT SUMMARY

Nasdaq-listed Context Therapeutics is developing novel therapeutics focused on women's oncology indications. Lead programme onapristone extended release (ONA-XR) is a potential first-in-class progesterone receptor (PR) antagonist being evaluated in several mid-stage clinical programs in advanced HR+/HER2- breast as well as hormone-driven endometrial and ovarian cancer, all areas with significant unmet need and most expected to release preliminary data in 2022. CLDN6xCD3, a novel bi-specific monoclonal antibody, was acquired in April 2021 is being assessed in endometrial and ovarian cancers. In August 2022, Context announced a collaboration with the Menarini Group to study ONA-XR in combination with elacestrant, an oral SERD for the treatment of second/third-line HR+/HER2- metastatic breast cancer (mBC). The Phase Ib/II study will commence in Q422.

### **INDUSTRY OUTLOOK**

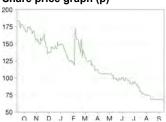
According to the American Cancer Society, there were an estimated 284,200 breast cancer cases, 66,570 endometrial cancer cases and 21,410 ovarian cancer cases in the United States in 2021 (more than 70% of these are hormone-driven). Long-term survival rates remain low (c 30% for HR+/HER2- mBC) despite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

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	0.0	(2.6)	(3.2)	(928.15)	N/A	N/A
2021	0.0	(10.5)	(10.6)	(373.72)	N/A	N/A
2022e	0.0	(21.9)	(21.9)	(137.12)	N/A	N/A
2023e	0.0	(34.2)	(34.2)	(214.13)	N/A	N/A



Price: 68.0p Market cap: £123m Market AIM

# Share price graph (p)



#### Company description

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

%	1m	3m	12m
Actual	(0.7)	(31.3)	(63.0)
Relative*	0.3	(32.4)	(63.5)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# Creo Medical (CREO)

#### **INVESTMENT SUMMARY**

Creo Medical is developing and commercialising minimally invasive endoscopic electrosurgical devices. Its CROMA platform delivers a combination of advanced bi-polar radiofrequency (RF) and microwave energy for the purpose of dissection, resection, ablation and haemostasis of diseased tissue. The initial focus is on gastrointestinal (GI) procedures expanding into soft tissues (such as the pancreas) and pulmonology. The company has had all six products within the CROMA platform CE marked, with four cleared for use by the FDA and the other two expected to be cleared in the coming months. Creo's first commercially available device, Speedboat Inject, is now used across the globe. In H122, Creo reported first licensing income from its May 2022 multi-year collaboration with robotics market leader, Intuitive and has agreed heads of terms with further potential future partners as interest grows in its Kamaptive technology.

#### **INDUSTRY OUTLOOK**

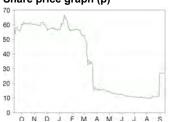
Creo Medical products are in a large and lucrative market. Conmed estimates the GI endoscopic technologies market alone is approximately \$3.0–3.2bn with the RF energy based surgical device market at \$2.7–2.9bn per year. Entering the robotics and laparoscopic markets further increases the scale of opportunity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

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2020	9.4	(21.4)	(23.0)	(12.7)	N/A	N/A
2021	25.2	(26.7)	(29.7)	(15.0)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

#### Sector: Pharma & healthcare

Price:	26.9p
Market cap:	£46m
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 Al in the US and EU. Efmody is approved for the treatment of CAH in the EU and UK.

# Price performance

%	1m	3m	12m			
Actual	136.0	138.7	(52.6)			
Relative*	138.4	135.1	(53.2)			

\* % Relative to local index

# Analyst

Soo Romanoff

# Diurnal Group (DNL)

# INVESTMENT SUMMARY

Diurnal Group is mainly focused on developing new formulations of hormone-based products for the treatment of endocrine disorders. Diurnal recently announced that it has agreed to an acquisition by Neurocrine Biosciences (US-based biopharmaceutical player) for a cash consideration of £48.3m or 27.5p per share. The proposed acquisition consideration is a c 144% premium to the closing price of 11.25p on 26 August. Although the acquisition is subject to shareholder approval by both companies, the transaction is likely to close by late October or early November.

# INDUSTRY OUTLOOK

For the purposes of the Takeover Code, Edison is deemed to be connected with Diurnal Group as a provider of paid-for research. Under Rule 20.1 Edison must not include any profit forecast, quantified financial benefits statement, asset valuation or estimate of other figures key to the offer, except to the extent that such forecasts, statements, valuations or estimates have been published prior to the offer period (as defined in the Takeover Code) by an offeror or the offeree company (as appropriate) in accordance with the requirements of the Code. Consequently we have removed our estimates until the offer period ends.

Y/E Jun	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (fd) (p)	P/E (x)	P/CF (x)
2020	6.3	(5.2)	(5.1)	(4.1)	N/A	N/A
2021	4.4	(11.1)	(11.1)	(7.0)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A



Price: 1240.0p Market cap: £619m 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	(8.0)	24.6	(15.9)
Relative*	0.2	22.7	(17.0)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

#### Sector: Pharma & healthcare

Price:	US\$4.91
Market cap:	US\$254m
Market	NASDAQ

### Share price graph (US\$)



#### Company description

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

% 1m 3m 12m Actual 1.9 (12.3) N/A Relative\* 6.1 (16.8) N/A

\* % Relative to local index

Analyst

Soo Romanoff

# Ergomed (ERGO)

#### **INVESTMENT SUMMARY**

Ergomed's H122 trading update re-emphasised its robust business model and resilient growth despite the challenging macro environment. Revenues grew 24.8% y-o-y to £69.9m, underpinned by strong and sustained demand for both the clinical research services (CRO) and pharmacovigilance (PV) segments. The order book, a leading indicator of forthcoming sales potential, remained robust at £284.5m, up 18.7% from end December 2021 and 24.9% from H121 (ahead of our estimates) Ergomed recently acquired ADAMAS Consulting Group. ADAMAS is a UK-based quality assurance services provider and will diversify revenue sources (its offerings do not overlap with Ergomed's). The acquisition should also immediately be accretive to earnings, according to management. The company has been shortlisted for three awards at the 2022 European Mediscience Awards. Ergomed will publish its H122 results on 27 September.

# INDUSTRY OUTLOOK

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

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (fd) (p)	P/E (x)	P/CF (x)
2020	86.4	19.4	14.4	22.8	54.4	33.2
2021	118.6	25.4	21.6	39.6	31.3	32.2
2022e	140.3	28.1	26.3	42.6	29.1	28.7
2023e	156.3	31.6	29.8	48.1	25.8	26.0

# Incannex Healthcare (IXHL)

# INVESTMENT SUMMARY

Incannex Healthcare specializes in the development of treatments for chronic conditions through a unique approach. Specifically, the company is investigating the use of cannabinoids and psychedelics, leveraging its synergistic combination intellectual property. Most recently, it has achieved proof-of-concept in Australia for IHL-42X, its lead asset for the treatment of obstructive sleep apnea. Incannex intends to file an investigational new drug application with the FDA (in CY Q422) following positive Phase II results from its Australian clinical trial data. It is also progressing development of its (Australian) Phase II clinical asset, psilocybin in combination with psychotherapy in generalized anxiety disorder.

#### **INDUSTRY OUTLOOK**

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

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	0.8	N/A	(4.7)	(0.69)	N/A	N/A
2021	2.0	N/A	(8.2)	(0.83)	N/A	N/A
2022e	0.9	N/A	(9.7)	(0.82)	N/A	N/A
2023e	0.1	N/A	(14.9)	(1.01)	N/A	N/A



Price: SEK33.00
Market cap: SEK1709m
Market NASDAQ OMX First North

## Share price graph (SEK)



## **Company description**

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

# and falls). Price performance

%	1m	3m	12m
Actual	(2.9)	(13.3)	(35.3)
Relative*	1.8	(12.2)	(18.5)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# **IRLAB Therapeutics (IRLABA)**

#### **INVESTMENT SUMMARY**

IRLAB Therapeutics is focused on developing novel, potential first-in-class treatments for the symptoms of Parkinson's disease (PD) and other CNS disorders. Its proprietary ISP discovery platform has been validated by the progress of its two lead assets, pirepemat and mesdopetam, which have novel mechanisms of action. Pirepemat is an oral prefrontal cortex enhancer in a phase IIb trial for the treatment of impaired balance and falls in PD. Mesdopetam is an oral D3 antagonist has just completed recruitment in a Phase IIb trial for levodopa-induced dyskinesias (PD-LIDs) and top line data are anticipated at the year end. In 2021 Ipsen acquired a global licence (worth up to \$363m plus royalties) for the future clinical development and commercialisation of mesdopetam. In addition to pirepemat IRLAB is developig a preclinical pipeline of drug candidates (IRL942 and IRL757) for the non motor symptoms of PD and a potential one a day treatment for PD without complications (P003). The company remains well funded in the medium term.

#### INDUSTRY OUTLOOK

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

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.4	(89.2)	(91.4)	(192.0)	N/A	N/A
2021	207.9	56.1	91.1	176.0	18.8	N/A
2022e	62.1	(109.1)	(112.9)	(218.0)	N/A	N/A
2023e	0.3	(118.9)	(122.7)	(237.0)	N/A	N/A

#### Sector: Pharma & healthcare

Price: US\$1.47 Market cap: US\$21m Market NASDAQ

### Share price graph (US\$)



#### Company description

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

Price performance

Price performance

%	1m	3m	12m
Actual	(17.9)	(75.6)	(86.2)
Relative*	(14.5)	(76.9)	(85.0)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# Kazia Therapeutics (KZIA)

# INVESTMENT SUMMARY

Kazia is developing the anti-cancer compound paxalisib (GDC-0084) for glioblastoma (GBM). Paxalisib is a PI3K inhibitor, a well understood class with activity across a wide range of tumour types and multiple previously approved drugs. Paxalisib, unlike other drugs of this class, can cross the blood brain barrier (BBB), opening the potential to treat cancers of the brain. Paxalisib has not progressed to stage 2 of the Phase III GBM AGILE study, however the data from this, expected in the second half of CY23, may still support registration. Kazia is also developing paxalisib in a range of different brain cancer indications.

#### **INDUSTRY OUTLOOK**

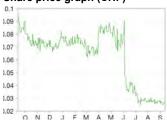
GBM is the most common primary cancer of the brain with c 12,500–13,000 new cases reported in the United States per year. There are very limited treatment options for GBM and there is a very low survival rate. Paxalisib is currently being developed for use in the adjuvant setting after initial resection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

Y/E Jun	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2021	10.5	(3.1)	(3.1)	(0.25)	N/A	N/A
2022	0.0	(14.6)	(14.6)	(1.08)	N/A	N/A
2023e	0.0	(18.6)	(18.6)	(1.23)	N/A	N/A
2024e	10.6	(16.8)	(16.8)	(1.11)	N/A	N/A



Price: CHF0.03
Market cap: CHF29m
Market Swiss Stock Exchange

# Share price graph (CHF)



#### Company description

Kinarus Therapeutics is a clinical-stage biopharmaceutical company focused on bringing novel treatments to patients suffering from viral, respiratory, and ophthalmic diseases.

# Price performance

%	1m	3m	12m
Actual	(9.2)	(30.3)	(74.2)
Relative*	(8.0)	(29.7)	(71.7)

\* % Relative to local index

#### **Analyst**

Pooya Hemami

# Kinarus (KNRS)

#### **INVESTMENT SUMMARY**

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

#### **INDUSTRY OUTLOOK**

Subject to funding, Kinarus plans to start a Phase II study in wet AMD before year end 2022, backed by preclinical data suggesting potential benefit in reducing choroidal neovascularisation lesions. Having shown in vitro antiviral activity against many COVID-19 variants, KIN001 is being assessed in two ongoing Phase II COVID-19 studies, with interim data from the KINETIC Phase II study in hospitalised patients expected in Q322.

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

#### Sector: Pharma & healthcare

Price: A\$12.11
Market cap: A\$28m
Market ASX

### Share price graph (A\$)



#### Company description

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

#### Price performance

%	1m	3m	12m
Actual	9.9	17.0	(55.1)
Relative*	11.1	16.0	(52.0)

\* % Relative to local index

# Analyst

Soo Romanoff

# Medlab Clinical (MDC)

# INVESTMENT SUMMARY

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

# INDUSTRY OUTLOOK

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

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (c)	P/E (x)	P/CF (x)
2021	8.1	(11.4)	(12.4)	(627.0)	N/A	N/A
2022	6.0	(7.4)	(8.4)	(314.0)	N/A	N/A
2023e	7.7	(7.9)	(8.8)	(384.3)	N/A	N/A
2024e	7.7	(8.6)	(9.6)	(417.5)	N/A	N/A



Price: SFK2 02 Market cap: SEK404m OMX Market

## Share price graph (SEK)



# Company description

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

# Price performance

%	1m	3m	12m
Actual	(20.6)	(14.2)	(56.3)
Relative*	(16.7)	(13.1)	(45.0)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

## treatment for gastrointestinal stromal tumours (GIST). The treatment is currently in preparations to start a Phase II trial in GIST, which we expect to begin later this year.

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.

Following the transformational merger with DCprime, Mendus aims to become a global leader in off-the-shelf, allogeneic cell therapies, using its expertise in DC biology. It has two

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

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. Readouts from

DCP-001's use in AML and ovarian cancer are expected in Q422 and October 2022

respectively. Ilixadencel has been granted orphan drug designation by the FDA as a

cancer relapse after standard of care. DCP-001 is currently in two clinical trials: Phase II in

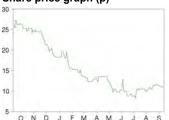
advanced clinical-stage pipeline products, addressing both solid tumours and

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (fd) (öre)	P/E (x)	P/CF (x)
2020	0.0	(85.1)	(89.2)	(117.1)	N/A	N/A
2021	0.0	(130.1)	(133.4)	(73.0)	N/A	N/A
2022e	1.9	(121.2)	(126.0)	(63.2)	N/A	N/A
2023e	0.0	(124.4)	(128.9)	(64.6)	N/A	N/A

### Sector: Pharma & healthcare

Price:	11.0p
Market cap:	£11m
Market	AIM

### Share price graph (p)



#### Company description

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

#### Price performance

%	1m	3m	12m
Actual	4.8	10.0	(57.7)
Relative*	5.8	8.3	(58.2)

\* % Relative to local index

**Analyst** 

Soo Romanoff

# Midatech Pharma (мтрн)

# **INVESTMENT SUMMARY**

Mendus (IMMU)

**INVESTMENT SUMMARY** 

INDUSTRY OUTLOOK

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. In June 2022, the company received the US FDA fast-track designation for MTX110 in glioblastoma and an EMA orphan drug designation for the treatment of gliomas.

### **INDUSTRY OUTLOOK**

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

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



Price: CHF1.44
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 add-on therapy, is involved in a Phase II/III trial programme targeting schizophrenia.

# Price performance

%	1m	3m	12m
Actual	0.0	(11.7)	(31.8)
Relative*	1.3	(10.9)	(25.1)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

#### Sector: Pharma & healthcare

Price:	€2.00
Market cap:	€86m
Market	Euronext Paris

### Share price graph (€)



# **Company description**

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

### Price performance

		•	
%	1m	3m	12m
Actual	0.7	9.9	(46.2)
Relative*	4.4	8.0	(42.7)

\* % Relative to local index

#### **Analyst**

Pooya Hemami

# Newron Pharmaceuticals (NWRN)

#### **INVESTMENT SUMMARY**

Newron is developing evenamide (30mg twice per day) as an add-on to treat poorly managed and resistant schizophrenia. A potentially pivotal Phase II/III study (008A) is underway and could report by Q422. Further US studies will be needed. Newron hopes to partner evenamide for larger indications and to sell the product directly for clozapine-resistance. FY21 results showed Xadago royalties of €5.8m, up 9.4% versus FY20. Newron had cash, equivalents and other of €34.6m at the end of December 2021.

#### **INDUSTRY OUTLOOK**

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

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2020	5.3	(16.4)	(18.2)	(109.0)	N/A	N/A
2021	5.8	(12.1)	(14.1)	(79.0)	N/A	N/A
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

# 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 (DED) 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 completed patient screening and results are expected in Q422. The company is also developing a DED development strategy for NCX-4251. Nicox had  $\in$ 31.6m gross cash at 30 June 2022 and has guided that it is financed to Q423, based on the development of NCX-470 alone.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	14.4	(5.3)	(10.2)	(0.30)	N/A	N/A
2021	8.6	(16.5)	(15.5)	(0.32)	N/A	N/A
2022e	5.3	(17.1)	(18.7)	(0.43)	N/A	N/A
2023e	7.0	(18.1)	(19.8)	(0.44)	N/A	N/A



Price: U\$\$0.43 Market cap: U\$\$21m 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	(30.9)	(24.8)	(86.8)
Relative*	(28.0)	(28.6)	(85.6)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# OpGen (OPGN)

#### **INVESTMENT SUMMARY**

OpGen is a diagnostics company focused on the identification and treatment of bacterial infections. Its portfolio of molecular diagnostic tests includes Unyvero platform with five CE-IVD-marked tests and two cartridges cleared by FDA; Ares Genetics' next-generation antimicrobial resistance (AMR) testing services; 510(k) cleared Acuitas AMR Gene Panel in bacterial isolates; and ARES Genetics (NGS and bioinformatics platform). OpGen's products are differentiated by their short turnaround time, large range of pathogen detection and AMR profiling. In H122, OpGen signed two commercial contracts for Acuitas AMR Gene Panel. In August, next-generation sequencing services were launched in the US at OpGen's new Rockville-based service laboratory. OpGen's adjusted FY22 guidance is for around 25% y-o-y growth from product revenues versus the previous 25–50%.

#### INDUSTRY OUTLOOK

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

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2020	4.2	(19.6)	(24.7)	(157.43)	N/A	N/A
2021	4.3	(20.4)	(35.7)	(117.12)	N/A	N/A
2022e	4.6	(18.5)	(24.0)	(49.73)	N/A	N/A
2023e	7.7	(16.3)	(21.4)	(44.36)	N/A	N/A

#### Sector: Pharma & healthcare

Price:		€2.43
Market c	ap:	€131m
Market	Madrid S	Stock Exchange

### Share price graph (€)



#### Company description

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

# Price performance

i ilee periormanee							
%	1m	3m	12m				
Actual	(5.4)	(13.5)	(29.4)				
Relative*	(3.1)	(11.5)	(25.0)				

\* % Relative to local index

# Analyst

Soo Romanoff

# **Oryzon Genomics (ORY)**

# INVESTMENT SUMMARY

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

# INDUSTRY OUTLOOK

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

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2020	9.5	(4.1)	(4.8)	(6.90)	N/A	N/A
2021	10.6	(6.9)	(7.2)	(8.83)	N/A	N/A
2022e	9.9	(6.8)	(7.0)	(10.28)	N/A	N/A
2023e	10.0	(7.2)	(7.3)	(10.01)	N/A	N/A



Price: €7.22
Market cap: €134m
Market Euronext Paris

## Share price graph (€)



#### Company description

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

# Price performance

%	1m	3m	12m
Actual	0.5	8.7	(36.4)
Relative*	4.1	6.8	(32.1)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# **OSE Immunotherapeutics** (OSE)

#### **INVESTMENT SUMMARY**

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

#### **INDUSTRY OUTLOOK**

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

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2020	10.4	(18.1)	(18.5)	(1.02)	N/A	N/A
2021	26.3	(13.6)	(16.5)	(0.89)	N/A	N/A
2022e	5.0	(38.2)	(38.8)	(1.89)	N/A	N/A
2023e	0.0	(43.6)	(44.2)	(2.42)	N/A	N/A

### Sector: Pharma & healthcare

Price:	455.0p
Market cap:	£438m
Market .	LSE

### Share price graph (p)



#### Company description

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

# Price performance

p	•		
%	1m	3m	12m
Actual	(9.5)	(6.4)	(68.7)
Relative*	(8.6)	(7.8)	(69.1)

\* % Relative to local index

# Analyst

Soo Romanoff

# Oxford Biomedica (OXB)

# INVESTMENT SUMMARY

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

# INDUSTRY OUTLOOK

Cell and gene therapy is the focus of much industry attention as it can dramatically alter the outcomes of many diseases. OXB's proprietary LentiVector platform has demonstrated promise in many indications. On 7 September OXB announced a new licence and supply agreement with an undisclosed US-based late-stage cell and gene therapy company.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2020	87.7	8.3	(2.5)	(2.7)	N/A	23.1
2021	142.8	33.2	19.9	22.2	20.5	13.0
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A



Price: €0.00
Market cap: €1m
Market Euronext Paris

# Share price graph (€)



#### Company description

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

#### Price performance

%	1m	3m	12m
Actual	(61.1)	(90.4)	(99.9)
Relative*	(59.7)	(90.6)	(99.9)

\* % Relative to local index

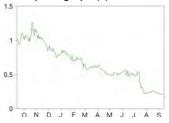
#### **Analyst**

Soo Romanoff

#### Sector: Pharma & healthcare

Price:	€0.21
Market cap:	€13m
Market	Euronext Paris

### Share price graph (€)



#### Company description

Pixium Vision develops bionic vision systems for patients with severe vision loss. Its lead product, Prima, is a wireless sub-retinal implant system designed for dry-AMD. The company started implantations as part of a European pivotal study in early 2021.

### Price performance

i iloo polioimanoo							
%	1m	3m	12m				
Actual	(14.4)	(59.7)	(76.7)				
Relative*	(11.3)	(60.4)	(75.2)				

\* % Relative to local index

#### **Analyst**

Pooya Hemami

# Pharnext (ALPHA)

#### **INVESTMENT SUMMARY**

Pharnext's pleotherapy platform uses a combination of in silico prediction of drug effects as well as in vitro screening to find drug combinations that have biochemical effects totally outside of their canonical activities. For example, the company's lead programme PXT3003 is a triple combination of an anti-opiate (naltrexone), a drug for spasms (baclofen), and the sweetener sorbitol, but the combination has shown positive interim results in Phase III for Charcot-Marie-Tooth type 1A (CMT1A) disease. The company recently announced first patient enrolment in the open-label extension study of the ongoing pivotal Phase III PREMIER trial, PREMIER-OLE. In August, Pharnext announced a €2.5m short-term bridge loan from Neovacs. In the event the companies enter a broader financing agreement, the funding will translate to a convertible instrument, possibly giving Neovacs access to one-third of Pharnext's capital.

#### **INDUSTRY OUTLOOK**

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

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

# Pixium Vision (PIX)

# INVESTMENT SUMMARY

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

# INDUSTRY OUTLOOK

Pixium started the PRIMAvera European pivotal study in Q420 and plans to complete enrolment by year end 2022, which we believe could lead to top-line data being reported in late 2023 or early 2024. GA-AMD is a leading cause of blindness in older adults, affecting over 2.5 million persons in the United States and Europe, and there is no approved treatment. Pixium reported €7.2m gross cash on 30 June 2022, and subsequently raised €5.5m in notes with a US-based healthcare investor as part of a convertible notes financing arrangement (for up to €30m). Pixium expects its current cash position to maintain operations to the end of Q123.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	2.1	(7.6)	(8.7)	(25.58)	N/A	N/A
2021	2.7	(9.7)	(10.9)	(22.56)	N/A	N/A
2022e	1.8	(12.1)	(12.3)	(21.71)	N/A	N/A
2023e	0.8	(16.2)	(18.2)	(28.62)	N/A	N/A



Price: €3.00
Market cap: €104m
Market Euronext Paris

#### Share price graph (€)



#### Company description

Quantum Genomics is focused on the research and development of novel cardiovascular medicines. Lead asset firibastat is in two Phase III trials for the treatment of TRH and is also being investigated to treat post-MI HF. Readouts from the TRH programme, expected in Q422 and mid-2023, represent the most significant pear-term catalysts.

		-	
%	1m	3m	12m
Actual	2.0	70.9	(40.9)
Relative*	5.8	68 O	(36.9)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# **Quantum Genomics (ALQGC)**

#### **INVESTMENT SUMMARY**

Quantum Genomics is focused on the development of new classes of cardiovascular medicines. Lead asset Firibastat is in development for the management of treatment-resistant hypertension (TRH) and post-myocardial infarction heart failure. In the near term, readouts from two Phase III trials in TRH are the main catalysts. In our view, firibastat's unique mechanism of action offers the potential for significant differentiation in the sizeable cardiovascular drug market. If Phase III results are positive, the company could file an NDA with the FDA by end-2023. With a handful of licensing deals already in place, we see the timely signing of licensing deals in the US and EU5 as essential to maximising the commercial success of firibastat. We estimate that, post the capital raise, end April net cash was c €20.5m, providing a runway into Q223.

#### INDUSTRY OUTLOOK

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

Y/E Dec	Revenue	EBITDA	PBT	EPS	P/E	P/CF
	(€m)	(€m)	(€m)	(c)	(x)	(x)
2020	4.0	(13.1)	(14.7)	(72.0)	N/A	N/A
2021	6.2	(14.9)	(15.4)	(58.0)	N/A	N/A
2022e	8.3	(19.9)	(20.2)	(62.0)	N/A	N/A
2023e	54.3	30.0	29.8	86.0	3.5	3.7

#### Sector: Pharma & healthcare

Price: SEK6.00
Market cap: SEK244m
Market Nasdaq First North

### Share price graph (SEK)



#### Company description

Scandion Oncology is focused on the development of add-on therapies to reverse chemotherapy resistance in oncology. Lead asset SCO-101 is in a Phase II trial for mCRC and a Phase Ib trial for pancreatic cancer. Proof-of concept data, expected in Q322, will be crucial in shaping management's future development plans.

# Price performance

%	1m	3m	12m
Actual	(18.4)	(32.7)	(67.3)
Relative*	(14.4)	(31.9)	(58.8)

\* % Relative to local index

# Analyst

Soo Romanoff

# Scandion Oncology (SCOL)

# INVESTMENT SUMMARY

Scandion Oncology is a biotechnology company focused on the development of add-on therapies to reverse chemotherapy resistance in oncology. The company's lead asset SCO-101 is currently in a Phase II trial for metastatic colorectal cancer (mCRC) and a Phase Ib trial for pancreatic cancer. Proof-of concept data from the CORIST study in mCRC (expected in Q322) will be crucial in shaping management's future development plans. In H222 management undertook a rights issue, raising c SEK75m gross, mainly to fund the expansion of the SCO-101 clinical development programme to target second-line mCRC patients and those harbouring RAS mutations. Assuming proof-of-concept is met, we view the positioning of SCO-101 in higher lines of mCRC treatment as essential to maximising value. We estimate that the company is funded into FY24, past key readouts in FY22 and FY23. We value Scandion Oncology at SEK609.5m or SEK15.0 per share.

# INDUSTRY OUTLOOK

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

Y/E Dec	Revenue (DKKm)	EBITDA (DKKm)	PBT (DKKm)	EPS (ore)	P/E (x)	P/CF (x)
2020	1.0	(23.5)	(21.5)	(53.0)	N/A	N/A
2021	0.8	(54.8)	(57.2)	(161.0)	N/A	N/A
2022e	0.8	(64.0)	(64.9)	(166.0)	N/A	N/A
2023e	0.8	(82.0)	(82.4)	(189.0)	N/A	N/A



Price: €5.70 Market cap: €123m 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	(3.7)	0.4	(8.9)
Relative*	(0.6)	1.6	2.2

\* % Relative to local index

#### **Analyst**

Pooya Hemami

# Sequana Medical (SEQUA)

#### **INVESTMENT SUMMARY**

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

#### **INDUSTRY OUTLOOK**

The alfapump is undergoing a pivotal North American registration study (POSEIDON) and is already commercialised in parts of Europe. Sequana recently completed POSEIDON implantations and expects to report primary efficacy data in Q422 and submit a US regulatory application for alfapump in H223. Following encouraging data including sustained improvements in diuretic response from its Phase IIa SAHARA DSR study in HF patients with persistent congestion, the company plans to start the MOJAVE US Phase Ib/IIa study in H123 using its second-generation product (DSR 2.0) in a similar patient population.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	1.0	(17.5)	(19.0)	(125.07)	N/A	N/A
2021	0.4	(23.4)	(24.4)	(136.37)	N/A	N/A
2022e	0.8	(24.3)	(26.3)	(111.64)	N/A	N/A
2023e	0.8	(23.0)	(25.1)	(105.06)	N/A	N/A

### Sector: Pharma & healthcare

Price:	11.8p
Market cap:	£30m
Market	AIM

### Share price graph (p)



#### Company description

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

#### Price performance

%	1m	3m	12m
Actual	35.5	(17.8)	(72.0)
Relative*	36.8	(19.1)	(72.4)

\* % Relative to local index

# Analyst

Soo Romanoff

# Shield Therapeutics (STX)

# INVESTMENT SUMMARY

Shield Therapeutics is a UK-headquarted commercial-stage speciality pharmaceutical company focused on the commercialisation of Feraccru/Accrufer (oral ferric maltol), approved by the EMA and FDA for the treatment of iron deficiency in adults, with or without anaemia. Shield launched the product in the US in July 2021 and recently reported a 87% q-o-q increase in total prescriptions in Q222. The commercialisation of Feraccru in Europe, Australia and New Zealand is managed by distribution partner Norgine, and the product has been licensed to ASK Pharm in China, Korea Pharma in South Korea and KYE Pharma in Canada. Shield had a net cash balance of £2.4m at end-June 2022 and raised US\$10m in convertible debt from its largest shareholder in August. This should be sufficient to support its ongoing US commercial roll-out through the end of 2022.

### **INDUSTRY OUTLOOK**

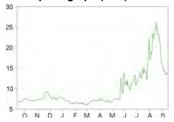
The market for iron deficiency is substantial and Feraccru/Accrufer is a unique oral formulation of iron developed to overcome the side-effect profile of salt-based oral iron therapies and provides an alternative treatment to intravenously administered iron.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2020	10.4	0.6	0.8	0.1	118.0	N/A
2021	1.5	(17.9)	(17.5)	(8.4)	N/A	N/A
2022e	5.8	(20.2)	(20.0)	(8.3)	N/A	N/A
2023e	15.9	(16.3)	(17.9)	(6.5)	N/A	N/A



Price: US\$13.84 Market cap: US\$1011m Market NASDAQ

#### Share price graph (US\$)



# **Company description**

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

# Price performance

%	1m	3m	12m
Actual	(44.1)	31.1	112.9
Relative*	(41.8)	24.4	131.0

\* % Relative to local index

#### **Analyst**

Soo Romanoff

#### Sector: Pharma & healthcare

Price: NOK65.20 Market cap: NOK2234m 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

p	•		
%	1m	3m	12m
Actual	(5.9)	(9.4)	(40.2)
Relative*	(3.5)	(8.2)	(43.3)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# SIGA Technologies (SIGA)

#### **INVESTMENT SUMMARY**

SIGA Technologies announced FDA approval for its intravenous formulation of tecovirimat (TPOXX), an antiviral drug for the treatment of smallpox. The formal decision expands the company's addressable market to those who are unable to take the oral formulation (which was approved by the FDA in 2018). This follows on the heels of strong Q122 results and recent milestones, including EMA approval for oral TPOXX, the first contract for TPOXX in the Asia-Pacific region and increases in the Canadian oral TPOXX contract. The company has received \$56m in international procurement orders (year to date) from six jurisdictions, five of which are new customers. Of this, SIGA expects to deliver \$26m in orders by end-September 2022. We expect this new delivery medium, international expansion and the ongoing clinical study (on post-exposure prophylactic) to remain the key upcoming catalysts for SIGA shares.

### 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% and according to CDC forecasts, over 50 million people could be infected in a smallpox outbreak.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2020	125.0	88.6	81.5	80.97	17.1	15.3
2021	133.7	89.7	89.1	90.61	15.3	90.3
2022e	N/A	N/A	N/A	N/A	N/A	N/A
2023e	N/A	N/A	N/A	N/A	N/A	N/A

# **Ultimovacs** (ULTI)

# INVESTMENT SUMMARY

Ultimovacs is a biotechnology company focused on developing a next generation cancer vaccine with virtually universal potential. Lead asset, UV1, activates the immune system to recognise cancer cells that express human telomerase reverse transcriptase (hTERT, or telomerase), which is present in up to 90% of all cancer types. For this reason, UV1 has broad potential in a variety of cancers and in combination with other treatments. Ultimovacs' R&D strategy is to combine UV1 with checkpoint inhibitors due to an expected treatment synergy. The broad R&D programme includes five Phase II trials in different solid tumours, which will enrol more than 600 patients in total. Readouts are expected over 2023–24, all within cash reach. In H122, the INITIUM Phase II trial in malignant melanoma completed enrolment in June, after the company reported positive two-year survival data from a previous Phase I trial in the same indication.

# INDUSTRY OUTLOOK

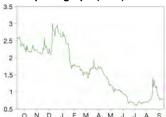
Novel drug projects in oncology comprise the lion's share of total R&D investments in the industry. Around 85% of all cancer types express high levels of hTERT, which means that UV1 has a broad potential in a variety of different settings, including combinations with other cancer treatments.

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



Price: SEK0.76
Market cap: SEK411m
Market Nasdaq FN Premier

# Share price graph (SEK)



#### Company description

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

# Cantrixil. Price performance

%	1m	3m	12m
Actual	(13.3)	(10.6)	(71.8)
Relative*	(9.1)	(9.5)	(64.4)

\* % Relative to local index

#### **Analyst**

Soo Romanoff

# Vivesto (VIVE)

#### **INVESTMENT SUMMARY**

Vivesto is developing improved formulations of well-established cancer drugs through the application of its proprietary XR-17 and XR-18 platforms. This solubility enhancing technology has received validation though a global partnership deal for lead asset Apealea (Cremophor-free paclitaxel) with Elevar Therapeutics across a variety of cancers. Apealea is approved in Europe for 2nd-line ovarian cancer and will be launched by Inceptua in H222. Additional studies are expected to be required before a US NDA filing. Vivesto is working on additional nanoparticle formulations, including docetaxel micellar (Phase Ib prostate cancer). In-licensed asset Cantrixil is expected to start Phase II development in ovarian cancer. In March, Vivesto completed a rights issue raising gross proceeds of c SEK151m and interim results in August confirmed the company is well capitalised. In July it announced it has wound down its Russian operations and appointed Christer Nordstedt as acting CEO.

#### **INDUSTRY OUTLOOK**

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

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2020	0.5	(102.6)	(140.3)	(24.8)	N/A	N/A
2021	26.2	(99.8)	(132.7)	(24.6)	N/A	N/A
2022e	18.3	(95.2)	(120.6)	(19.2)	N/A	N/A
2023e	66.3	(125.1)	(148.7)	(23.8)	N/A	N/A



# **Company coverage**

Company	Note	Date published
Abliva	Update; Update	27/05/21; 13/01/22
AFT Pharmaceuticals	Flash; Flash	02/09/22; 07/09/22
Arovella Therapeutics	Flash; Update	01/08/22; 05/09/22
Basilea Pharmaceutica	Flash; Flash	08/09/22; 09/09/22
BerGenBio	Flash; Flash	05/05/22; 25/05/22
Cantargia	Flash; Update	23/06/22; 31/08/22
Carmat	Update; Update	11/01/21; 20/09/21
Chimeric Therapeutics	Update; Update	29/07/21; 06/12/21
Context Therapeutics	Update; Update	02/08/22; 12/08/22
Creo Medical	Flash; Update	04/08/22; 14/09/22
Diurnal Group	Flash; Flash	27/07/22; 31/08/22
Ergomed	Update; Flash	27/04/22; 27/07/22
Incannex Healthcare	QuickView; Initiation	08/08/22; 30/08/22
IRLAB Therapeutics	Flash; Flash	08/09/22; 13/09/22
Kazia Therapeutics	ADR Update; ADR Update	08/08/22; 05/09/22
Kinarus Therapeutics	Flash; Flash	31/08/22; 05/09/22
Medlab Clinical	Flash; Update	02/08/22; 02/09/22
Mendus	Update; Update	24/06/22; 26/08/22
Midatech Pharma	Flash; Flash	13/06/22; 21/06/22
Newron Pharmaceuticals	QuickView; Flash	01/11/21; 07/06/22
Nicox	Flash; Flash	07/06/22; 21/07/22
OpGen	Update; Flash	12/08/22; 26/08/22
Oryzon Genomics	Flash; Flash	25/07/22; 26/07/22
OSE Immunotherapeutics	Flash; Flash	19/05/22; 08/06/22
Oxford Biomedica	Outlook; Flash	27/05/21; 05/07/22
Pharnext	Flash; Flash	23/08/22; 12/09/22
Pixium Vision	Flash; Flash	04/08/22; 14/09/22
Quantum Genomics	Initiation	30/08/22
ReNeuron Group	Update; Update	15/07/21; 08/10/21
Sareum Holdings	Flash; Flash	29/07/22; 13/09/22
Scandion Oncology	Flash; Update	22/08/22; 26/08/22
Sequana Medical	Outlook; Update	15/08/22; 12/09/22
Shield Therapeutics	Update; Update	22/07/22; 08/09/22
SIGA Technologies	Flash; Flash	08/08/22; 11/08/22
Ultimovacs	Update; Flash	19/08/22; 13/09/22
Vivesto	Flash; Update	25/02/22; 27/06/22



# **Glossary**

AACD	American Accociation for Concor Deceases
AACR	American Association for Cancer Research
ARCCCI	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
105	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
Al	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
ARR	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  Particular percentility disorder
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	
l	The cancer or tumour is small and is still in the place that it started and hasn't spread to nearby tissue
11-111	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
IV	The cancer has spread to one or more other organs of the body and is considered metastatic



CADT	Objection and a contract to all
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
DMPK	processes used in the manufacturing, processing, packaging, and storing of human drug products)
DMT	Drug metabolism and pharmacokinetics Disease modifying therapy
DoR	Disease modifying therapy  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
1 1311	i idorescence in situ nyondization



FL	Follicular lymphoma
FTD	Fast Track Designation (facilitates development and expediates FDA review of drugs to treat seriou
	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
npSCs	Human parthenogenetic stem cells
HPV	Human papilloma virus
HR HD MDS	Hazard ratio
HR-MDS	Higher-risk myelodysplastic syndrome
hRPC HRQoL	Human retinal progenitor cell
HSCT	Health-related quality-of-life 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)
0	Immuno-oncology
IOP	Intraocular pressure
IPF	Idiopathic pulmonary fibrosis
R	Insulin receptor
TP	Immune thrombocytopenia
TT	Intention-to-treat (analysis includes all patients randomised in the clinical study)
v, 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)
	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) Myocardial infarctions
MIGS	
MM	Minimally invasive glaucoma surgeries  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 NHP	Non-Hodgkin's lymphoma  Non-human primate
NHSA	
NHSA	National Healthcare Security Administration (agency in China that manages medical insurance schemes)
NIAID	schemes)  National Institute of Allergy and Infectious Diseases (US agency for the research of infectious,
MAID	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
NTM OAG	Pulmonary non-tuberculous mycobacteria Open-angle glaucoma



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 la	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 lb	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
Phase IV	participants.  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 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
SAA	Prescription  Source palestic appearie
SAB	Severe aplastic anaemia 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 TD	T-cell receptor 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
Тх	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 WHO	Vaccines Manufacturing and Innovation Centre
WT	World Health Organisation
VV I	Wild type

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