



Edison Healthcare Insight

December 2020

Maxim Jacobs



Max joined Edison's healthcare team in December 2014. Prior to this he worked as a senior analyst at Guidepoint Global. Max has also previously worked as a senior analyst at Ridgemark Capital, a sector head at Broadfin Capital and as a senior analyst at Mehta Partners. He is a CFA charter holder.

Dr Nathaniel Calloway



Nathaniel Calloway joined the healthcare team in December 2015. Before Edison, he performed healthcare investment research for a fund at Bishop Rosen and for Wainscott Capital Partners. Prior to his role as an analyst he performed molecular neuroscience research at Cornell Medical School and holds a PhD in chemistry from Cornell. He has published eight scientific papers on topics ranging from physical chemistry to immunology, and he has been recognised as an American Heart Association fellow and an American Chemical Society Medicinal Chemistry fellow.

Pooya Hemami



Pooya is a licensed optometrist with over five years of experience in life sciences equity research. Prior to joining Edison, he covered the Canadian healthcare sector as a research analyst at Desjardins Capital Markets. He holds a doctor of optometry degree from the University of Montreal, and an MBA (finance concentration) from McGill University. He received his CFA charter in 2011.

Dr John Savin



John is an analyst working on biotech, pharma, medical device and diagnostics companies. As founder CEO of Physiomics, he devised the strategy, raised funds and took the company to AIM in 2004. At Greig Middleton, John was director in charge of the pharma and biotech analyst team and worked with corporate finance on fund-raising, IPOs and corporate restructuring. He has an industry background in sales and marketing with GE Healthcare and AstraZeneca and is a co-author on a number of scientific publications.

Dr Susie Jana



Susie joined the team in September 2015 and has 16 years' experience in the healthcare sector. She is a qualified medical doctor, having studied medicine at UCL. She also holds an intercalated BSc in psychology. After a few years working as a junior doctor in the NHS, Susie joined the investment banking industry for six years on the sell-side covering biotechnology stocks, then midto large-cap pharmaceuticals at Société Générale. Most recently she worked as a buy-side analyst, covering European biotech, pharma and medtech stocks at F&C Investments for five years.

Dr Jonas Peciulis



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

Dr John Priestner



John joined the healthcare team in March 2020. Prior to this he worked at GlaxoSmithKline for four years, where he completed a PhD in medicinal chemistry with a focus on oncology. He holds an integrated master's degree in chemistry from Durham University and is currently studying for the Investment Management Certificate (CFA UK).

Sean Conroy



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



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Prices at 7 December 2020

Published 10 December 2020

Welcome to the December edition of the Edison Healthcare Insight. In this edition we have profiled 48 of our healthcare companies under coverage.

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

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world renowned equity research platform and deep multisector 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 and Maxim Jacobs

Healthcare research



Company profiles

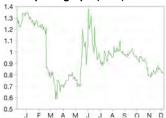
Prices at 7 December

US\$/£ exchange rate: 0.7520 €/£ exchange rate: 0.8966 C\$/£ exchange rate: 0.5779 A\$/£ exchange rate: 0.5514 NZ\$/£ exchange rate: 0.5223 SEK/£ exchange rate: 0.0877 DKK/£ exchange rate: 0.1204 NOK/£ exchange rate: 0.0839 JPY/£ exchange rate: 0.0072 CHF/£ exchange rate: 0.8297 PLN/£ exchange rate: 0.2001



Price: SFK0 79 Market cap: SFK234m NASDAQ OTCQX Market

Share price graph (SEK)



Company description

Abliva (formerly NeuroVive) is a Swedish biopharmaceutical company. Its main focus area is PMDs with lead assets KL1333, a NAD+ modulator (Phase I), and NV354, a succinate prodrug (preclinical). NeuroSTAT is a non-core asset in Phase II for non-core asset in Phase II for neurotrauma

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|--------|--------|
| Actual | (1.1) | (20.1) | (39.2) |
| Relative* | (4.9) | (25.4) | (46.7) |

* % Relative to local index

Analyst

Dr Jonas Peciulis

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|--------|-------------|--------|--------|
| | (1.1) | (20.1) | (39.2) |
| /e* | (4.9) | (25.4) | (46.7) |
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Sector: Pharma & healthcare

€2 35 Price: Market cap: €206m Market **Euronext Brussels**

Share price graph (€)



Company description

Acacia Pharma is a commercial-stage Acada Pharma is a commercial-stage biopharmaceutical company developing and commercialising novel products to improve the care of patients undergoing serious medical treatments such as surgery, invasive procedures or chemotherapy.

BARHEMSYS is launched for PONV in the US and in-licensed asset BYFAVO is approved for PS is approved for PS. Price performance

1m 3m 12m Actual 5.4 13.0 28.4 Relative* (9.0)2.6 36.5

* % Relative to local index

Analyst

Dr Susie Jana

Abliva (ABLI)

INVESTMENT SUMMARY

Abliva is focused on primary mitochondrial diseases (PMD). The core portfolio consists of KL1333 and NV354. KL1333, a small molecule NAD+ modulator used to restore intracellular energy balance, is being developed for PMD, for example due to an m.3243 A>G mutation (eg MELAS, MIDD, PEO). Abliva started a Phase Ia/b study in March 2019 and the first two parts (SAD and MAD) were successfully completed. The third and final part is recruiting patients with PMD. Following positive feedback from the FDA, Abliva intends to start a single pivotal Phase II/III study in H221 following completion of a drug-drug interaction study (healthy volunteers) which initiated in November 2020. NV354 is the second lead drug candidate in Abliva's core portfolio, a succinate prodrug targeting complex I deficiency, such as Leigh syndrome and LHON. IND-enabling studies are ongoing and the Phase I study could start in 2021.

INDUSTRY OUTLOOK

Abliva has a diversified portfolio, with all assets aimed at improving mitochondrial metabolism and function. We feel this puts NeuroVive 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) |
|---------|-------------------|------------------|---------------|-------------------|------------|-------------|
| 2018 | 2.5 | (66.7) | (68.8) | (94.07) | N/A | N/A |
| 2019 | 3.6 | (72.3) | (74.6) | (43.50) | N/A | N/A |
| 2020e | 3.6 | (78.6) | (81.0) | (33.59) | N/A | N/A |
| 2021e | 3.6 | (79.9) | (82.3) | (27.79) | N/A | N/A |

Acacia Pharma (ACPH)

INVESTMENT SUMMARY

Acacia Pharma is focused on commercialising its two approved hospital-based products in the US. Lead product BARHEMSYS (reformulated amisulpride) was launched in August 2020 after receiving FDA approval with a broad label for the management of post-operative nausea and vomiting (PONV). Under the deal with Cosmo Pharmaceuticals, Acacia was assigned the US licence for Paion's sedative BYFAVO (remimazolam), which received FDA approval for procedural sedation (PS) in July 2020 and has been designated as a Schedule IV medicine. Acacia plans to launch BYFAVO shortly and has been building up its US commercial operations in preparation. At 30 June 2020, Acacia had net cash of \$21.9m. A share placing in August that raised €25m gross plus the €45m combined equity investment and loan facility under the Cosmo deal has enabled Acacia to expand its US commercial infrastructure to support both product launches.

INDUSTRY OUTLOOK

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

| Y/E Dec | Revenue (US\$m) | EBITDA (US\$m) | PBT (US\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|--------------------|-------------------|----------------|------------|------------|-------------|
| 2018 | 0.0 | (20.0) | (21.6) | (45.46) | N/A | N/A |
| 2019 | 0.0 | (22.4) | (23.5) | (37.17) | N/A | N/A |
| 2020e | 0.2 | (27.3) | (30.0) | (31.98) | N/A | N/A |
| 2021e | 8.0 | (37.3) | (40.4) | (45.36) | N/A | N/A |



Price: A\$0.02 Market cap: A\$32m Market ASX

Share price graph (A\$)



Company description

Actinogen Medical is an ASX-listed Australian biotech developing lead asset Xanamem, a specific 11beta-HSD1 inhibitor designed to treat cognitive impairment that occurs in chronic neurological and metabolic diseases.

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|--------|--------|
| Actual | 0.0 | (13.7) | (50.1) |
| Relative* | (7.4) | (23.4) | (50.8) |

* % Relative to local index

Analyst

Dr Jonas Peciulis

Sector: Pharma & healthcare

Price: NZ\$4.63 Market cap: NZ\$480m Market NZ\$X

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 drugs to treat a range of conditions and a proprietary nebuliser.

Price performance

| % | 1m | 3m | 12m | | | |
|-----------|--------|--------|------|--|--|--|
| Actual | (10.6) | (11.8) | 34.2 | | | |
| Relative* | (12.7) | (16.7) | 22.2 | | | |

* % Relative to local index

Analyst

Maxim Jacobs

Actinogen Medical (ACW)

INVESTMENT SUMMARY

In October 2020, Actinogen announced that it is expanding the R&D programme and will initiate new Phase II trials in H121: Fragile X syndrome (XanaFX study) and mild cognitive impairment due to Alzheimer's disease (AD) (XanaMIA study). The new plans follow the Phase I XanaHES trial (Xanamem 20mg daily in healthy elderly subjects) designed to assess the safety of high doses and explore the effect on cognition. There were no safety issues and a statistically significant, positive improvement in three of six domains in the Cogstate Cognitive Test Battery was observed. Recall, during the Phase II XanADu trial in AD patients Xanamem was pharmacologically active but other endpoints were not met (dose was half that used in XanaHES). Combined, these data have prompted Actinogen to increase the Xanamem dose to 20mg daily in future trials. The company has also expanded the pipeline to diversify potential routes to market.

INDUSTRY OUTLOOK

The unmet need in chronic neurological and neuropsychiatric disorders (including AD, but also orphan indications such as Fragile X) is high due to limited available treatment options. The orphan indications provide a potentially faster route to market and high pricing of the drug.

| Y/E Jun | Revenue (A\$m) | EBITDA (A\$m) | PBT (A\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|------------|------------|-------------|
| 2018 | 3.3 | (6.0) | (5.9) | (8.0) | N/A | N/A |
| 2019 | 5.1 | (9.5) | (9.4) | (0.9) | N/A | N/A |
| 2020e | N/A | N/A | N/A | N/A | N/A | N/A |
| 2021e | N/A | N/A | N/A | N/A | N/A | N/A |

AFT Pharmaceuticals (AFT)

INVESTMENT SUMMARY

AFT Pharmaceuticals is a profitable New Zealand-based specialty pharmaceutical company that sells 130 prescription specialty generics and OTC products through its own sales force in New Zealand, Australia and SE Asia, and has been expanding its geographic footprint. The company recently reported its results for the first half of FY21. Operating revenue grew 4% year-on-year to NZ\$48.8m driven mainly by 11% growth in Australia and despite the impact of COVID-19 across the business. Reported group operating profit was NZ\$2.4m compared to a normalised NZ\$3.9m last year. Importantly, AFT continues to guide to operating profit of NZ\$14–18m in FY21. Also, the company appears close to FDA approval for Maxigesic tablets. The only major outstanding issue is a manufacturing inspection that was delayed due to the COVID-19 pandemic.

INDUSTRY OUTLOOK

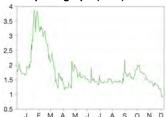
AFT is a multi-product company targeting pharmacy prescription, OTC and hospital markets. Data for Maxigesic offer it a competitive advantage in a fragmented industry.

| Y/E Mar | Revenue (NZ\$m) | EBITDA (NZ\$m) | PBT (NZ\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|--------------------|-------------------|----------------|------------|------------|-------------|
| 2019 | 85.1 | 6.2 | (2.1) | (2.3) | N/A | 46.9 |
| 2020 | 105.6 | 10.9 | 3.4 | 3.3 | 140.3 | 20.5 |
| 2021e | 117.6 | 15.4 | 13.3 | 12.7 | 36.5 | 42.9 |
| 2022e | 139.4 | 27.7 | 25.9 | 21.3 | 21.7 | 25.7 |



Price: SEK0.92 Market cap: SEK183m Market NASDAQ OMX First North

Share price graph (SEK)



Company description

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

lxempra. Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|--------|
| Actual | (34.1) | (44.2) | (51.1) |
| Relative* | (36.6) | (47.9) | (57.2) |

* % Relative to local index

Analyst

Dr Nathaniel Calloway

Allarity Therapeutics (ALLR)

INVESTMENT SUMMARY

Allarity Therapeutics holds the worldwide drug development rights to the drug response predictor (DRP), a microarray technology that examines the expression of a panel of genes to identify potential responders to different cancer therapies. Allarity Therapeutics' goal is to then develop its portfolio of drugs that are active within populations that the DRP can identify. The company recently focused its strategy on three lead assets: the tyrosine kinase inhibitor (TKI) dovitinib, the poly-ADP-ribose polymerase (PARP) inhibitor stenoparib, and the microtubule inhibitor agent Ixempra.

INDUSTRY OUTLOOK

Allarity Therapeutics and the DRP system have the potential to identify the value in drug assets that have otherwise been discontinued by identifying patient populations where these drugs are active. This allows the company to in-license these assets at low cost; it may then out-license them after clinical validation.

| Y/E Dec | Revenue (DKKm) | EBITDA (DKKm) | PBT (DKKm) | EPS (ore) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2018 | 2.1 | (32.3) | (22.5) | (44.00) | N/A | N/A |
| 2019 | 0.8 | (66.5) | (174.9) | (208.11) | N/A | N/A |
| 2020e | 0.9 | (55.0) | (54.4) | (30.51) | N/A | N/A |
| 2021e | 0.9 | (187.1) | (192.8) | (90.62) | N/A | N/A |

Sector: Pharma & healthcare

Price: CHF52.60
Market cap: CHF627m
Market Swiss Stock Exchange

Share price graph (CHF)



Company description

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

Price performance

| % | 1m | 3m | 12m |
|-----------|-----|------|-----|
| Actual | 8.3 | 11.4 | 3.9 |
| Relative* | 7.8 | 10.6 | 4.7 |

* % Relative to local index

Analyst

Dr Susie Jana

Basilea Pharmaceutica (BSLN)

INVESTMENT SUMMARY

Basilea has two approved hospital-based products: Cresemba (severe mould infections) and Zevtera (bacterial infections). Multiple licensing/distribution agreements are in place for Cresemba and Zevtera and should drive top-line growth. Partners include Pfizer and Astellas, which market Cresemba in Europe (ex Nordics) and the US respectively. In August 2019, Basilea reported positive top-line data for Zevtera in the first cross-supportive Phase III study TARGET; top-line data from the ERADICATE study are expected in Q122 and both are required for a US NDA submission. Basilea's oncology pipeline is spearheaded by derazantinib (FGFR inhibitor), which is currently in a Phase II potential registration study for intrahepatic cholangiocarcinoma and two Phase I/II studies in patients with advanced urothelial cancer and advanced gastric cancer. Lisavanbulin (tumour checkpoint controller) is in the expansion phase of a biomarker-driven Phase I/II study for glioblastoma.

INDUSTRY OUTLOOK

There is an ever-increasing need for therapeutic agents that are efficacious against drug-resistant strains of bacteria (eg MRSA), fungus or cancer. Hence, the opportunities for Zevtera, Cresemba and Basilea's oncology pipeline could be significant.

| Y/E Dec | Revenue (CHFm) | EBITDA (CHFm) | PBT (CHFm) | EPS (CHFc) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|---------------|------------|-------------|
| 2018 | 132.6 | (22.3) | (31.0) | (288.15) | N/A | N/A |
| 2019 | 134.4 | (15.6) | (22.2) | (207.16) | N/A | N/A |
| 2020e | 134.3 | (21.4) | (30.4) | (282.93) | N/A | N/A |
| 2021e | 139.2 | (21.4) | (30.8) | (285.80) | N/A | N/A |



Price: NOK33.20 Market cap: NOK2897m Market Oslo

Share price graph (NOK)



Company description

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

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|-------|------|
| Actual | 10.3 | (1.6) | 86.7 |
| Relative* | (0.6) | (9.3) | 93.7 |

* % Relative to local index

Analyst

Dr Susie Jana

BerGenBio (BGBIO)

INVESTMENT SUMMARY

BerGenBio (BGBIO) is a pioneer in AXL biology and the development of AXL inhibitors, and has two clinical stage assets: selective tyrosine kinase inhibitor bemcentinib and functional blocking monoclonal antibody tilvestamab. AXL expression is a negative prognostic marker in most cancers. Its upregulation drives aggressive disease including drug resistant, immune-evasive and metastatic cancers, as well as fibrosis and viral infection. Selective AXL inhibition can prevent and reverse acquired drug resistance and stop immune suppression, potentially augmenting the efficacy of other cancer drug classes. BGBIO's strategy in oncology is to establish bemcentinib's efficacy in proof-of-concept studies to identify opportunities for rapid regulatory approval (relapse AML in combination with LDAC) and concurrently develop line extensions (2L NSCLC in combination with Keytruda). Two ongoing Phase II trials are also exploring its efficacy in COVID-19.

INDUSTRY OUTLOOK

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

| Y/E Dec | Revenue (NOKm) | EBITDA (NOKm) | PBT (NOKm) | EPS (öre) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2018 | 2.3 | (194.3) | (191.7) | (360.0) | N/A | N/A |
| 2019 | 8.9 | (203.6) | (199.3) | (343.0) | N/A | N/A |
| 2020e | 0.0 | (259.7) | (249.1) | (309.0) | N/A | N/A |
| 2021e | 0.0 | (304.8) | (300.9) | (345.0) | N/A | N/A |

Sector: Pharma & healthcare

| Price: | C\$0.32 |
|-------------|---------|
| Market cap: | C\$22m |
| Market . | TSX-V |

Share price graph (C\$)



Company description

Bioasis Technologies is a biopharma company developing the xB3 platform to aid in the delivery of molecules to the brain using receptor mediated transcytosis. The company's lead program is xB3-001, which is in preclinical development for brain metastases in HER2+ metastatic breast cancer patients.

Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|------|
| Actual | (8.6) | (14.7) | 68.4 |
| Relative* | (15.3) | (21.3) | 62.8 |

* % Relative to local index

Analyst

Dr Nathaniel Calloway

Bioasis Technologies (BTI)

INVESTMENT SUMMARY

Bioasis has developed a platform for developing drugs that can pass the blood-brain barrier (BBB) that can be used on small molecules, antibodies and enzymes. The company has licensed this platform to Prothena and Chiesi as well as advancing its internal development project xB3-001 for the treatment of beast cancer brain metastases.

INDUSTRY OUTLOOK

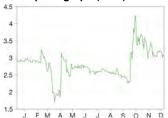
Developing a drug to pass the BBB has historically been difficult and limited to small molecules. By developing a modular platform to solve this problem Bioasis is expanding the potential diseases that can be targeted as well as providing a means to re-purpose previously developed drugs to target the brain.

| Y/E Feb | Revenue (C\$m) | EBITDA (C\$m) | PBT (C\$m) | EPS (fd) (c) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|-----------------|------------|-------------|
| 2019 | 1.4 | (3.8) | (2.4) | (4.29) | N/A | N/A |
| 2020 | 0.6 | (4.0) | (3.4) | (5.50) | N/A | N/A |
| 2021e | 8.7 | (0.2) | (0.2) | (0.27) | N/A | N/A |
| 2022e | 3.7 | (9.8) | (9.8) | (13.34) | N/A | N/A |



Price: DKK3.13 Market cap: DKK834m Market NASDAQ OMX (CPH)

Share price graph (DKK)



Company description

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

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|------|------|
| Actual | (6.6) | 54.0 | 28.5 |
| Relative* | (4.4) | 45.9 | 5.3 |

* % Relative to local index

Analyst

Dr Nathaniel Calloway

BioPorto Diagnostics (BIOPOR)

INVESTMENT SUMMARY

BioPorto's lead strategic goal is development of a test for acute kidney injury (AKI) using the biomarker NGAL. The company is gathering more data for its paediatric urine NGAL 510(k) and expects to submit in H220. For adults using plasma NGAL, the 510(k) will be submitted to the FDA after the submission for paediatric. The NGAL Test is commercially available for research purposes in the US and has been CE marked in Europe. BioPorto also sells a series of other antibodies, ELISA kits and related biologics.

INDUSTRY OUTLOOK

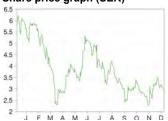
The current standard of care for detecting AKI is serum creatinine, which can take 24 hours or more to detect AKI and can only do so after significant kidney damage. NGAL promises to provide a quicker and more reliable test, allowing early intervention to preserve kidney function.

| Y/E Dec | Revenue (DKKm) | EBITDA (DKKm) | PBT (DKKm) | EPS (ore) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2018 | 26.0 | (42.1) | (42.5) | (24.34) | N/A | N/A |
| 2019 | 26.6 | (68.3) | (71.1) | (39.16) | N/A | N/A |
| 2020e | 23.5 | (63.9) | (70.4) | (31.40) | N/A | N/A |
| 2021e | 82.5 | (30.0) | (31.2) | (10.55) | N/A | N/A |

Sector: Pharma & healthcare

Price: SEK3.02 Market cap: SEK655m Market NASDAQ OMX First North

Share price graph (SEK)



Company description

Brighter is a Swedish healthtech company addressing common welfare challenges of modern society through a group of innovation companies. Its lead solution, Actiste, currently being commercialised, is aimed at helping people with diabetes adhere to care guidelines and achieve treatment goals.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|--------|
| Actual | 16.9 | 21.3 | (42.2) |
| Relative* | 12.4 | 13.3 | (49.3) |

* % Relative to local index

Analyst

Maxim Jacobs

Brighter (BRIG)

INVESTMENT SUMMARY

Brighter is a healthtech company developing solutions for chronic diseases. Its initial strategy is the market introduction of Actiste, a remote monitoring and treatment service for diabetes which received two CE marks (Actiste is regulated under both the EU Medical Devices Directive and the In Vitro Diagnostics Directive) as well as regulatory approvals in Saudi Arabia and the UAE. The service includes a unique patented device that integrates all the essential features for daily diabetes management, a blood glucose meter, a lancer and an insulin injection pen, into a single unit with built-in mobile connection, and a digital platform for analysing and sharing data with family and friends, healthcare providers and other relevant stakeholders.

INDUSTRY OUTLOOK

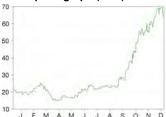
In 2017, costs attributed to diagnosed diabetes and associated complications, such as cardiovascular disease and nephropathy, totalled \$327bn in the US. Patient opinions of treatment burden are heavily correlated with adherence to self-care.

| Y/E Dec | Revenue (SEKm) | EBITDA (SEKm) | PBT (SEKm) | EPS (öre) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2018 | 1.1 | (44.2) | (48.8) | (74.00) | N/A | N/A |
| 2019 | 3.3 | (73.7) | (88.7) | (105.85) | N/A | N/A |
| 2020e | 12.3 | (135.7) | (166.5) | (81.86) | N/A | N/A |
| 2021e | 93.0 | (70.6) | (101.5) | (46.24) | N/A | N/A |



Price: SEK63.60
Market cap: SEK5793m
Market NASDAQ OMX First North

Share price graph (SEK)



Company description

Cantargia is a clinical-stage biotechnology company listed on the Nasdaq Stockholm main market. It is developing CAN04 and CAN10 against IL1RAP, CAN04 is in a Phase IIa clinical trial, CANFOUR, in solid tumours focused on NSCLC and PDAC. It is preparing to file an IND and initiate a trial in the US next year.

Price performance

| % | 1m | 3m | 12m |
|-----------|-----|------|-------|
| Actual | 3.9 | 99.1 | 246.4 |
| Relative* | 0.0 | 85.8 | 203.6 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

Cantargia (CANT)

INVESTMENT SUMMARY

Cantargia is developing antibodies against IL1RAP. Cantargia has provided updated interim data from its Phase IIa CANFOUR trial, reporting new efficacy data from the combination arms of the study investigating CAN04 (anti-IL1RAP) in first-line NSCLC and PDAC. These new Phase IIa data, combined with initial interim data reported in December 2019, continue to support the hypothesis that CAN04 has a synergistic benefit with chemotherapy, in our view. Final analysis and key efficacy data are expected in 2021. Cantargia is preparing to engage with regulators to discuss Phase III development plans. Another tailwind is increasing positive sentiment on Novartis's canakinumab (anti-IL1beta) progressing in its Phase III trials in NSCLC.

INDUSTRY OUTLOOK

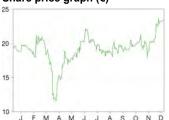
Increasing the understanding of inflammation in malignant processes now includes findings that cytokines are not only produced by the immune cells, but that cancer itself can produce certain cytokines and the associated receptors to escape from the immune response. Therefore, cytokines represent a potentially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

| Y/E Dec | Revenue (SEKm) | EBITDA (SEKm) | PBT (SEKm) | EPS (öre) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2018 | 0.0 | (93.3) | (91.2) | (137.73) | N/A | N/A |
| 2019 | 0.0 | (111.6) | (110.8) | (155.74) | N/A | N/A |
| 2020e | 0.0 | (138.0) | (138.0) | (168.51) | N/A | N/A |
| 2021e | 0.0 | (138.5) | (138.5) | (152.13) | N/A | N/A |

Sector: Pharma & healthcare

Price: €23.35
Market cap: €296m
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. The development process combines the expertise of a wide range of technical and medical experts.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|------|
| Actual | 16.2 | 20.6 | 18.9 |
| Relative* | 3.3 | 9.3 | 24.6 |

* % Relative to local index

Analyst

Maxim Jacobs

Carmat (ALCAR)

INVESTMENT SUMMARY

Carmat continues to make progress in the development of the total artificial heart (TAH). In February, the FDA granted full approval for the company to initiate an early feasibility study (EFS) in 10 patients at seven US centres. Additionally, the company has obtained reimbursement from the Centers for Medicare and Medicaid Services (CMS) for the device and routine care items and services related to the study. The company expects to implant the first TAH in Q121. Additionally, the company is targeting a CE mark by the end of the year.

INDUSTRY OUTLOOK

The Carmat artificial heart is being developed as a permanent replacement or destination therapy for chronic biventricular heart failure or acute myocardial infarction patients who do not have access to a human donor heart. Despite the high EU and US prevalence of stage IV heart failure (c 500,000 patients), the shortfall in donor hearts is such that only about 3,800 human heart transplants were performed in Europe and the US in 2013.

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (fd) (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|-----------------|------------|-------------|
| 2018 | 0.7 | (41.8) | (43.7) | (454.43) | N/A | N/A |
| 2019 | 0.7 | (41.2) | (44.2) | (388.00) | N/A | N/A |
| 2020e | 0.5 | (42.4) | (44.4) | (351.78) | N/A | N/A |
| 2021e | 28.2 | (36.5) | (39.8) | (315.28) | N/A | N/A |



Price: U\$\$2.35 Market cap: U\$\$291m Market NASDAQ

Share price graph (US\$)



Company description

CASI Pharmaceuticals is building a portfolio of drugs it intends to produce for Chinese and worldwide markets including Evomela launched in China, an anti-CD19 CAR-T therapy CNCT19, and the anti-CD38 drug CID-103, among others. The goal is to seek approval through new pathways that have opened in the quickly changing Chinese regulatory environment. Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|--------|
| Actual | 22.4 | 46.0 | (26.8) |
| Relative* | 16.3 | 35.5 | (37.6) |

^{* %} Relative to local index

Analyst

Dr Nathaniel Calloway

CASI Pharmaceuticals (CASI)

INVESTMENT SUMMARY

CASI has a multipronged approach to the entrance into the Chinese pharmaceutical market. In August 2019 it launched Evomela (melphalan) in China via the priority review pathway because it was the first approval in the country for any melphalan product. It is also expanding its development pipeline through collaborations, with the recent licensing of an anti-CD38 drug (CID-103), anti-CD19 CAR-T therapy (CNCT19), and most recently BI-1206, a novel checkpoint inhibitor.

INDUSTRY OUTLOOK

The Chinese regulatory authorities have made a series of substantial changes to their process for drug approval in recent years to improve the availability of new drugs. The Chinese National Medical Products Administration (NMPA, formerly the CFDA) has established new classes of applications for drugs that are previously approved outside of China. Additionally, there is a set of criteria for priority review, which can significantly reduce review times.

| Y/E Dec | Revenue (US\$m) | EBITDA (US\$m) | PBT (US\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|--------------------|-------------------|----------------|------------|------------|-------------|
| 2018 | 0.0 | (19.4) | (20.0) | (23.65) | N/A | N/A |
| 2019 | 4.1 | (37.5) | (36.5) | (38.74) | N/A | N/A |
| 2020e | 14.4 | (33.7) | (31.0) | (28.48) | N/A | N/A |
| 2021e | 25.3 | (22.6) | (23.3) | (17.93) | N/A | N/A |

Sector: Pharma & healthcare

Price: €0.75
Market cap: €16m
Market Euronext Growth

Share price graph (€)



Company description

Deinove is a biotechnology company that discovers, develops and produces high value-added compounds using its state-of-the-art bacterial strain selection, banking, fermentation and screening facilities. The most valuable compounds in the pipeline are novel antimicrobials, with lead asset DNV3837 in a Phase II trial.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|------|
| Actual | 36.4 | 10.6 | 20.0 |
| Relative* | 21.3 | 0.3 | 25.8 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

Deinove (ALDEI)

INVESTMENT SUMMARY

Deinove is running a Phase II study with the novel quinolonyl-oxazolidinone class antibiotic DNV3837 for moderate to severe C. diff infections. This is an open-label study that will be conducted in two parts in 15 centres in the US. Part two of the study will be randomised in up to 30 patients and will include efficacy endpoints. The company also reported multiple developments in its bioactives portfolio. The most recent development was the launch of Luminity, which is a concentrate of neurosporene, an extremely rare carotenoid that contributes to skin vitality and a beautiful complexion. As a metabolic intermediate of the formation of lycopene from phytoene, neurosporene is a carotenoid rarely found in nature, which is now commercially accessible and patent protected. Deinove confirmed Luminity's effects in in vitro, ex vivo and clinical studies. In November, Deinove signed an evaluation and technology development programme with nutrition company DSM for a microbial strain identified in its Color-2B program; deal terms were not disclosed.

INDUSTRY OUTLOOK

Environmentalism will underpin growth in green chemistry and growing antimicrobial resistance to current antibiotics will demand the discovery of new antibiotic structures.

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 0.8 | (9.4) | (10.5) | (61.25) | N/A | N/A |
| 2019 | 0.6 | (10.8) | (12.2) | (58.75) | N/A | N/A |
| 2020e | N/A | N/A | N/A | N/A | N/A | N/A |
| 2021e | N/A | N/A | N/A | N/A | N/A | N/A |



Price: 910.0p Market cap: £443m Market AIM

Share price graph (p)



Company description

Ergomed is a global full-service contract research outsourcing 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 | 13.0 | 42.2 | 142.7 |
| Relative* | 1.8 | 28.0 | 164 2 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

Ergomed (ERGO)

INVESTMENT SUMMARY

Ergomed has proved to be a resilient business in a challenging environment this year, which we attribute to a diversified and well-balanced pharma services offering (pharmacovigilance and CRO). H120 adjusted EBITDA of £9.1m was the main positive surprise for us in Ergomed's full interim report. We have increased our adjusted EBITDA forecasts to £18.3m (up 8.6%) in 2020 and £20.1m (up 6.8%) in 2021. A strong order book (£151.4m, up 22.0% from the end of 2019) with high visibility into 2021, continued overall business growth and a strong balance sheet should allow Ergomed to successfully navigate the COVID-19 pandemic, invest in organic growth and look for potential strategic acquisitions.

INDUSTRY OUTLOOK

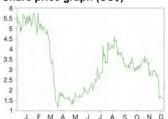
Innovation in healthcare is driving sales and growth in the number of clinical trials being initiated, as pharmaceutical and biotechnology companies continue to invest substantially. Tight operational control and execution will enable Ergomed to drive market share in high-growth orphan drug trials as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

| Y/E Dec | Revenue (£m) | EBITDA (£m) | PBT (£m) | EPS (p) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 54.1 | 2.3 | 1.0 | 1.9 | 478.9 | 389.6 |
| 2019 | 68.3 | 12.5 | 8.6 | 19.8 | 46.0 | 36.0 |
| 2020e | 84.1 | 18.3 | 13.1 | 23.8 | 38.2 | 26.6 |
| 2021e | 96.6 | 20.1 | 16.4 | 27.5 | 33.1 | 28.5 |

Sector: Pharma & healthcare

Price: US\$1.59 Market cap: US\$51m Market NASDAQ

Share price graph (US\$)



Company description

Hepion Pharmaceuticals is a clinical stage biopharmaceutical company focused on developing therapeutics for chronic liver disease. The company's lead asset is CRV431, a cyclophilin inhibitor being developed for the treatment of non-alcoholic steatohepatitis (NASH).

Price performance

| % | 1m | 3m | 12m |
|-----------|----|--------|--------|
| Actual | | (49.2) | (69.4) |
| Relative* | | (52.8) | (73.9) |

* % Relative to local index

Analyst

Dr Nathaniel Calloway

Hepion Pharmaceuticals (HEPA)

INVESTMENT SUMMARY

CRV431 is a non-immunosuppressive cyclosporine derivative that inhibits a class of proteins called cyclophilins. Cyclophilins have been implicated in liver disease specifically stemming from inflammation and fibrosis. Hepion claims that by inhibiting cyclophilins, CRV431 may stall or reverse the progressive deterioration of liver function seen in late stage NASH patients presenting with fibrosis.

INDUSTRY OUTLOOK

There currently are no approved medications for NASH, but a large number of programs in development. Fatty liver disease affects 20% of US and European populations and 20% of these are expected to progress to NASH. We expect CRV431 to be marketed for severe cases (F2 and F4), which we estimate has a market of 1.4 million in the US and Europe.

| Y/E Dec | Revenue (US\$m) | EBITDA (US\$m) | PBT (US\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|--------------------|-------------------|----------------|------------|------------|-------------|
| 2018 | 0.0 | (14.3) | (9.8) | (5587.48) | N/A | N/A |
| 2019 | 0.0 | (7.7) | (7.9) | (432.28) | N/A | N/A |
| 2020e | 0.0 | (16.0) | (16.2) | (191.14) | N/A | N/A |
| 2021e | 0.0 | (12.4) | (12.4) | (143.55) | N/A | N/A |



Price: U\$\$29.28 Market cap: U\$\$4261m Market AIM, NASDAQ

Share price graph (US\$)



Company description

Hutchison China MediTech (HCM) is an innovative China-based biopharmaceutical company targeting the global market for novel, highly selective oral oncology and immunology drugs. Its established commercial platform business continues to expand its outreach.

Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|------|
| Actual | (10.0) | (15.2) | 23.4 |
| Relative* | (14.4) | (21.3) | 5.1 |

* % Relative to local index

Analyst

Dr Susie Jana

Sector: Pharma & healthcare

| Price: | SEK9.46 |
|-------------|---------|
| Market cap: | SEK873m |
| Market . | OMX |

Share price graph (SEK)



Company description

Immunicum is a clinical-stage immuno-oncology (IO) company based in Stockholm, Sweden. It is developing an allogeneic dendritic cell immune primer for use in combination with other anticancer therapies including CPIs in multiple solid tumour indications.

Price performance

| | | - | |
|-----------|-----|-------|--------|
| % | 1m | 3m | 12m |
| Actual | 7.9 | (2.5) | (11.1) |
| Relative* | 3.9 | (9.0) | (22.1) |

* % Relative to local index

Analyst

Dr Jonas Peciulis

Hutchison China MediTech (нсм)

INVESTMENT SUMMARY

HCM has built a substantial pipeline of tyrosine kinase inhibitor drugs. The 2018 launch of Elunate (fruquintinib capsules) in China serves to validate the R&D efforts and its inclusion in China's NRDL significantly increases the addressable market. Key late-stage asset surufatinib met the primary endpoint of PFS in non-pancreatic NET and pancreatic NET, translating into earlier than expected China NDA submissions for both indications (epNET accepted November 2019, pNET accepted September 2020). Surufatinib could be HCM's first unpartnered asset to launch (Q420/Q121). The US FDA has also granted two fast track designations for surufatinib in epNET and pNET (rolling NDA to file shortly). We forecast further product launches in 2021/22, with China launch of savolitinib in MET Exon 14 deletion NSCLC and global launch of savolitinib in MET-positive Tagrisso refractory NSCLC in combination with Tagrisso; timing depends on interim data from the SAVANNAH trial.

INDUSTRY OUTLOOK

HCM's profitable Chinese healthcare business continues to benefit from the fast-growing domestic market, while the clinical, regulatory and technological environments are highly conducive to novel drug development. Longer term, as the oncology pipeline comes to fruition we expect HCM to become a major oncology company globally.

| Y/E Dec | Revenue (US\$m) | EBITDA (US\$m) | PBT (US\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|--------------------|-------------------|----------------|------------|------------|-------------|
| 2018 | 214.1 | (89.0) | (86.7) | (11.3) | N/A | N/A |
| 2019 | 204.9 | (141.3) | (141.1) | (15.9) | N/A | N/A |
| 2020e | 216.8 | (194.5) | (197.4) | (23.3) | N/A | N/A |
| 2021e | 303.9 | (180.8) | (185.1) | (20.6) | N/A | N/A |

Immunicum (IMMU)

INVESTMENT SUMMARY

Immunicum is progressing with the new strategy being implemented by recently appointed CEO Sven Rohmann, who aims to lead the company into a new, commercially oriented phase. GIST and sarcoma type cancers, which are proven indications and orphan diseases, should shorten ilixadencel's path to the market. The Phase Ib/II ILIAD trial, which is a multi-indication study with ilixadencel in combination with checkpoint inhibitors (CPIs), is moving into Phase Ib after no dose-limiting toxicities were seen in the staggered phase. In renal cell carcinoma Immunicum will pursue ilixadencel in a triple combination with PD1 and CTLA4 CPIs. In November, Immunicum announced that it had agreed to acquire the biotech company DCprime (private) which is developing a novel allogeneic dendritic cell vaccine, DCP-001. The most advanced Phase II programme is in AML (data presented at ASH 2020). The proposed merger will be facilitated by the issuance of 73.9k new shares, subject to a decision from an EGM on 18 December 2020.

INDUSTRY OUTLOOK

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

| Y/E Dec | Revenue (SEKm) | EBITDA (SEKm) | PBT (SEKm) | EPS (öre) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2018 | 0.0 | (0.1) | (97.9) | (190.4) | N/A | N/A |
| 2019 | 0.0 | (0.1) | (134.0) | (149.4) | N/A | N/A |
| 2020e | N/A | N/A | N/A | N/A | N/A | N/A |
| 2021e | N/A | N/A | N/A | N/A | N/A | N/A |



Price: C\$4.20 Market cap: C\$29m Market TSX

Share price graph (C\$)



Company description

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

Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|--------|
| Actual | (52.8) | (22.9) | (47.0) |
| Relative* | (56.3) | (28.9) | (48.7) |

* % Relative to local index

Analyst

Maxim Jacobs

InMed Pharmaceuticals (IN)

INVESTMENT SUMMARY

InMed is a pharmaceutical company focused on developing cannabinoid-based medications. Its leading candidates are both based on cannabinol, a minor cannabinoid that has shown evidence of efficacy across indications while having little to no psychoactivity. InMed's programmes include INM-755 for epidermolysis bullosa, a serious orphan indication. The company released data from its first study in healthy volunteers, with no systemic or serious adverse effects seen. Data from a second trial in healthy volunteers is expected in early Q1 CY21. The company is also developing INM-088 for glaucoma and is in preclinical studies. Additionally, InMed recently announced a research collaboration involving its biosysnthesis platform with BayMedica.

INDUSTRY OUTLOOK

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

| Y/E Jun | Revenue (C\$m) | EBITDA (C\$m) | PBT (C\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|------------|------------|-------------|
| 2018 | 0.0 | (5.5) | (5.3) | (3.7) | N/A | N/A |
| 2019 | 0.0 | (9.7) | (9.1) | (5.3) | N/A | N/A |
| 2020e | 0.0 | (14.4) | (14.9) | (8.6) | N/A | N/A |
| 2021e | 0.0 | (14.9) | (16.4) | (9.1) | N/A | N/A |

Sector: Pharma & healthcare

| Price: | A\$1.35 |
|-------------|---------|
| Market cap: | A\$170m |
| Market | ASX |

Share price graph (A\$)



Company description

Kazia Therapeutics' lead asset is paxalisib, a PI3K inhibitor licensed from Genentech that can cross the BBB. It is entering a pivotal study for GBM and is being investigated for other brain cancers such as breast cancer brain metastases.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|-------|
| Actual | 64.6 | 38.8 | 116.7 |
| Relative* | 52.4 | 23.1 | 113.7 |

* % Relative to local index

Analyst

Dr Nathaniel Calloway

Kazia Therapeutics (KZA)

INVESTMENT SUMMARY

Kazia is developing the anti-cancer compound paxalisib (GDC-0084) for glioblastoma multiforme. Paxalisib is a PI3K inhibitor, a well understood class with activity across a wide range of tumor 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. It is in Phase II studies and is expected to enrol its first patients in the pivotal GBM AGILE study in Q1 CY21.

INDUSTRY OUTLOOK

Glioblastoma (GBM) is the most common primary cancer of the brain with 11,500 new cases reported in the US per year. There are currently very limited treatment options for GBM and the disease has a very low survival rate. Paxalisib is currently being developed for use in the adjuvant setting after initial resection and radiation treatment.

| Y/E Jun | Revenue (A\$m) | EBITDA (A\$m) | PBT (A\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|------------|------------|-------------|
| 2019 | 1.6 | (7.4) | (7.4) | (12.8) | N/A | N/A |
| 2020 | 1.1 | (10.8) | (10.8) | (14.8) | N/A | N/A |
| 2021e | 1.4 | (11.4) | (11.4) | (9.7) | N/A | N/A |
| 2022e | 1.5 | (12.0) | (12.0) | (9.0) | N/A | N/A |



Price: €5.08
Market cap: €141m
Market Scale

Share price graph (€)



Company description

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

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|-------|------|
| Actual | 103.2 | 100.8 | 17.3 |
| Relative* | 91.1 | 98.2 | 16.4 |

* % Relative to local index

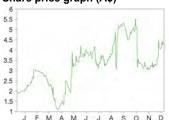
Analyst

Dr Susie Jana

Sector: Pharma & healthcare

| Price: | A\$4.49 |
|-------------|----------|
| Market cap: | A\$2638m |
| Market . | ASX |

Share price graph (A\$)



Company description

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

Price performance

| | • | | |
|-----------|------|--------|-------|
| % | 1m | 3m | 12m |
| Actual | 40.3 | (4.1) | 136.3 |
| Relative* | 29.9 | (14.9) | 133.1 |

* % Relative to local index

Analyst

Maxim Jacobs

MagForce (MF6)

INVESTMENT SUMMARY

MagForce is progressing its strategy to drive uptake and acceptance (in the US and Europe) of its nanoparticle-based therapy NanoTherm, for the treatment of cancerous tumours. It has recently expanded from Germany into Poland and now has four centres in Europe that are commercially capable of treating glioblastoma patients. A loan of up to €35m from the European Investment Bank and access to €15m growth funding via zero interest bearing convertible notes will continue to fund the roll-out. A registrational clinical trial for prostate cancer is ongoing in the US using an FDA-approved one day protocol. Approval and launch are expected in H221. The opportunity in the US will become a significant driver for growth in the long term.

INDUSTRY OUTLOOK

MagForce's NanoTherm therapy is designed to directly target cancerous tissue while sparing surrounding healthy tissue. Magnetic nanoparticles are directly instilled into a tumour or a resection cavity and activated by specialist equipment (NanoActivator). This can either thermally ablate tumours or sensitise them to other treatments (chemotherapy or radiotherapy).

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 0.1 | (6.5) | (8.7) | (32.8) | N/A | N/A |
| 2019 | 0.8 | (5.6) | (7.6) | (28.2) | N/A | N/A |
| 2020e | 0.8 | (6.6) | (8.6) | (30.8) | N/A | N/A |
| 2021e | 2.4 | (5.2) | (7.5) | (26.9) | N/A | N/A |

Mesoblast (MSB)

INVESTMENT SUMMARY

Mesoblast announced that Novartis has signed a partnership with the company to develop remestemcel-L for acute respiratory distress syndrome (ARDS), whether or not the ARDS was caused by COVID-19. This is an important validation of both the platform as well as its application in the treatment of respiratory disease. Novartis will make a US\$25m upfront payment and an additional US\$25m equity investment. Mesoblast may receive a total of US\$505m in development milestones, an additional US\$750m in sales milestones and tiered double-digit royalties. Additionally, Novartis will fully fund global clinical development for all-cause ARDS and potentially other respiratory indications. The Phase III in COVID-19 related ARDS is expected to complete in Q1 CY21 with an interim analysis expected in December.

INDUSTRY OUTLOOK

Mesoblast is a leading mesenchymal stem cell company based in Australia. It has a manufacturing alliance with Lonza. JCR Pharmaceuticals markets Mesoblast's GvHD therapy in Japan; FY19 royalties were US\$5.0m.

| Y/E Jun | Revenue (US\$m) | EBITDA (US\$m) | PBT (US\$m) | EPS (fd) (c) | P/E (x) | P/CF (x) |
|---------|--------------------|-------------------|----------------|-----------------|------------|-------------|
| 2019 | 16.0 | (75.4) | (86.5) | (15.69) | N/A | N/A |
| 2020 | 31.6 | (64.8) | (79.6) | (13.28) | N/A | N/A |
| 2021e | 72.9 | (46.3) | (60.4) | (10.29) | N/A | N/A |
| 2022e | 8.6 | (83.2) | (92.8) | (15.83) | N/A | N/A |



Price: CHF2.19
Market cap: CHF39m
Market Swiss Stock Exchange

Share price graph (CHF)



Company description

Newron Pharmaceuticals is CNS-focused. Xadago for Parkinson's disease (PD) is sold in Europe, Japan and the US. Evenamide, a novel schizophrenia therapy, may start Phase III trials from Q221.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|--------|
| Actual | 23.7 | 13.5 | (70.4) |
| Relative* | 23.1 | 12.6 | (70.2) |

* % Relative to local index

Analyst

Dr John Savin

Newron Pharmaceuticals (NWRN)

INVESTMENT SUMMARY

Newron is focusing on its novel schizophrenia drug, Evenamide (which has a different mechanism of action to other antipsychotic products), and on a further Xadago study. The Evenamide preclinical studies required by the FDA have been successfully completed. A four-week, 120-patient Phase II safety study is now underway to report in Q121; Newron notes that Phase III could start in Q221 with two studies planned. Discussions with Zambon on a Xadago dyskinesia study are progressing. Newron drew down a €7.5m EIB loan in April (a €15m loan facility remains) and had €39.4m cash at end June 2020; the company has cash well into 2022.

INDUSTRY OUTLOOK

Xadago is marketed in key territories as an add-on to levodopa therapy in PD is sold by Supernus Pharmaceuticals. This should benefit Newron since Supernus will have a five-fold larger sales team than the previous partner. Adding a dyskinesia indication will maximise the US potential The former lead, sarizotan, ceased development in H120.

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 4.0 | (14.9) | (15.0) | (84.20) | N/A | N/A |
| 2019 | 7.0 | (20.7) | (20.2) | (113.24) | N/A | N/A |
| 2020e | 5.6 | (13.8) | (14.5) | (81.09) | N/A | N/A |
| 2021e | 6.7 | (19.6) | (20.2) | (113.13) | N/A | N/A |

Sector: Pharma & healthcare

Price: SEK3.74
Market cap: SEK1586m
Market Nasdag FN Premier

Share price graph (SEK)



Company description

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

Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|--------|
| Actual | (9.7) | (25.9) | (14.8) |
| Relative* | (13.1) | (30.8) | (25.3) |

* % Relative to local index

Analyst

Dr Susie Jana

Oasmia Pharmaceutical (OASM)

INVESTMENT SUMMARY

Oasmia Pharmaceutical is focused on developing improved formulations of well-established cancer drugs through its proprietary XR-17 platform. Its 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 cancer indications. Apealea is approved in Europe for second-line ovarian cancer and Elevar is required to complete two new studies before an NDA filing in the US. Oasmia is working on additional nanoparticle formulations, including docetaxel micellar (Phase Ib prostate cancer), and the development of innovative drugs (preclinical stage). Oasmia has an animal health pipeline with two clinical stage assets, Paccal Vet and Doxophos Vet. At 31 October 2020, Oasmia had net cash of SEK249.6m, giving a cash runaway into FY23. Our forecasts are under review.

INDUSTRY OUTLOOK

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

| Y/E Apr | Revenue (SEKm) | EBITDA (SEKm) | PBT (SEKm) | EPS (öre) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2019 | 2.0 | (119.2) | (168.5) | (68.5) | N/A | N/A |
| 2020 | 201.8 | (10.1) | (43.4) | 0.2 | 1870.0 | N/A |
| 2021e | N/A | N/A | N/A | N/A | N/A | N/A |
| 2022e | N/A | N/A | N/A | N/A | N/A | N/A |



Price: €0.76
Market cap: €60m
Market Euronext Paris

Share price graph (€)



Company description

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

Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|------|
| Actual | 15.5 | 10.3 | 44.9 |
| Relative* | 2.7 | 0.0 | 51.9 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

Onxeo (ONXEO)

INVESTMENT SUMMARY

Onxeo's portfolio focuses on its novel platON platform, from which AsiDNA was the first product to enter clinical development. AsiDNA is the only oligonucleotide decoy agonist in development that disrupts and exhausts the tumour DNA damage response mechanism. To date, the only approved similar class of drugs are four commercially successful PARP inhibitors. AsiDNA is now being tested in the Phase Ib part of the DRIIV-1 trial in patients with advanced solid tumours in combination with chemotherapy (the latest interim update in November showed promising data). Another key Phase Ib/II trial, REVOCAN, is recruiting patients and will evaluate AsiDNA's potentially unique ability to reverse tumour resistance to the PARP inhibitor, niraparib. The outcomes of all these events will define AsiDNA's mid- to late-stage development.

INDUSTRY OUTLOOK

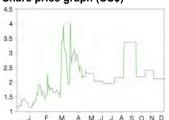
Approval of the first PARP inhibitors has kick-started interest by the scientific community and large pharma in the DNA Damage Response field. Few biotechs are already positioned in this emerging field that has broad potential.

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (fd) (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|-----------------|------------|-------------|
| 2018 | 6.1 | (3.4) | (4.2) | 4.92 | 15.4 | N/A |
| 2019 | 4.3 | (9.1) | (11.5) | (14.98) | N/A | N/A |
| 2020e | 1.1 | 1.0 | 0.4 | (0.62) | N/A | N/A |
| 2021e | 0.0 | (10.1) | (10.8) | (13.78) | N/A | N/A |

Sector: Pharma & healthcare

Price: US\$1.97 Market cap: US\$40m Market NASDAQ

Share price graph (US\$)



Company description

OpGen is focused on revolutionizing the identification and treatment of bacterial infections. Following the merger with Curetis, it has technology platforms 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 | (7.1) | (11.3) | 68.4 |
| Relative* | (11.7) | (17.6) | 43.5 |

* % Relative to local index

Analyst

Maxim Jacobs

OpGen (OPGN)

INVESTMENT SUMMARY

OpGen is a diagnostic company focused on revolutionizing the identification and treatment of bacterial infections. It recently merged with Curetis, a Germany-based molecular diagnostics company with a complementary focus on infectious disease. Curetis has two main business lines: the Unyvero A50 high-plex polymerase chain reaction platform for the diagnosis of infectious disease in hospital patients and the ARES AMR database (ARESdb), which includes data on 55,000 sequenced strains with a focus on resistant pathogens as well as data on over 100 antibiotics.

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) |
|---------|--------------------|-------------------|----------------|------------|------------|-------------|
| 2018 | 2.9 | (13.2) | (13.4) | (4445.18) | N/A | N/A |
| 2019 | 3.5 | (11.7) | (11.9) | (737.57) | N/A | N/A |
| 2020e | 3.9 | (22.3) | (25.7) | (161.79) | N/A | N/A |
| 2021e | 10.5 | (21.2) | (24.7) | (121.14) | N/A | N/A |



Price: €2.77
Market cap: €147m
Market Madrid Stock Exchange

Share price graph (€)



Company description

Oryzon Genomics is a Spanish biotech focused on epigenetics. ladademstat (Phase IIa) is being explored for acute leukaemias and SCLC; vafidemstat, its CNS product, has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder has received approval to start. ORY-3001 is being developed for certain orphan indications.

indications. Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|-------|
| Actual | (1.4) | (1.9) | (7.5) |
| Relative* | (18.2) | (16.1) | 4.9 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

Oryzon Genomics (ORY)

INVESTMENT SUMMARY

Oryzon develops small molecule inhibitors for epigenetic targets. It has completed two PhII and has six ongoing PhII trials with two assets iadademstat (a specific LSD1 inhibitor) and vafidemstat (a CNS-optimised LSD1 inhibitor). In April 2020, Oryzon reported first efficacy data from the PhIIa ETHERAL trial in Alzheimer's disease (AD) (full results in Q221), plus positive data from the PhIIa trial in aggression in AD (REIMAGINE-AD) and announced a new vafidemstat trial in COVID-19 (ESCAPE). In July 2020, Oryzon released final results from its PhIIa REIMAGINE trial with vafidemstat in aggressiveness in psychiatric diseases with improvement in all cohorts (BPD, ADHD and ASD). Oryzon has received approval to start PhIIb PORTICO with vafidemstat in BPD. In September 2020, Oryzon presented final data from its PhIIa CLEPSIDRA trial with iadademstat in SCLC and Oryzon is now considering further steps in this indication. In December 2020, it presented more data from the PhII ALICE trial (iadademstat plus azacitidine) in AML, which continues to impress.

INDUSTRY OUTLOOK

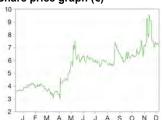
Oryzon is among the leading clinical-stage drug developers with a second generation of epigenetic therapeutics, which have greater selectivity and potentially a favourable safety/efficacy profile than the first generation HDAC inhibitors.

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| | (•, | () | , 3, | (-) | (21) | (2-7 |
| 2018 | 6.8 | (2.8) | (3.7) | (3.37) | N/A | N/A |
| 2019 | 10.3 | (3.7) | (4.6) | (8.81) | N/A | N/A |
| 2020e | 9.9 | (4.1) | (4.7) | (6.51) | N/A | N/A |
| 2021e | 9.9 | (4.1) | (4.2) | (6.38) | N/A | N/A |

Sector: Pharma & healthcare

| Price: | €7.36 |
|-------------|----------------|
| Market cap: | €114m |
| Market . | Furonext Paris |

Share price graph (€)



Company description

OSE Immunotherapeutics is an immunotherapy company based in Nantes and Paris, France and listed on the Euronext Paris exchange. OSE 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 | (20.7) | 17.9 | 101.1 |
| Relative* | (29.5) | 6.9 | 110.8 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

OSE Immunotherapeutics (OSE)

INVESTMENT SUMMARY

OSE Immunotherapeutics focuses on both oncology and immune disorders. Long-term collaborations with top research institutions enable it to identify novel targets in a cost-effective and time-efficient manner. The success of this model is demonstrated by several commercial partnerships, including a deal with Boehringer Ingelheim (BI) for a total value of €1.1bn plus royalties. OSE's most advanced internal programme is Tedopi for NSCLC (Phase III, most recent data update in September 2020). A Phase I study with BI 765063, antagonist of SIRP alpha, in solid tumours is ongoing in partnership with BI with first results expected in H121. Two Phase II trials with OSE-127, an anti-IL-7R alpha antibody, are planned to start by the year end in ulcerative colitis (sponsored by OSE) and Sjögren's syndrome (sponsored by Servier). New project CoVepiT, a potential COVID-19 vaccine, could enter clinical trials Q121. In November, OSE completed a private placement raising €18.6m gross, extending its cash runway until Q122 (from Q321).

INDUSTRY OUTLOOK

OSE has products in development for both immunological diseases and cancer indications. We expect its strong relationships with research institutions and internal expertise to be a significant advantage in continuing to develop pipeline products.

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 24.5 | 5.0 | 4.8 | 38.47 | 19.1 | 57.8 |
| 2019 | 26.0 | (0.9) | (1.2) | (29.55) | N/A | 18.3 |
| 2020e | 9.0 | (13.8) | (13.9) | (65.82) | N/A | N/A |
| 2021e | 9.0 | (14.0) | (14.1) | (94.40) | N/A | N/A |



Price: 820.0p Market cap: £675m Market LSE

Share price graph (p)



Company description

Oxford Biomedica's (OXB) LentiVector technology underpins the company's strategy. OXB generates significant revenue from partners that use its technology and is manufacturing the COVID-19 vaccine candidate AZD1222 for AstraZeneca. OXB is implementing significant capacity upgrades to enable more partnering/jout-licensing agreements. Price performance

| % | 1m | 3m | 12m |
|-----------|-------|--------|------|
| Actual | 0.9 | (3.8) | 30.6 |
| Relative* | (9.2) | (13.4) | 42.1 |

* % Relative to local index

Analyst

Dr Susie Jana

Oxford Biomedica (OXB)

INVESTMENT SUMMARY

Oxford Biomedica (OXB) is a global leader in lentiviral development and manufacturing. It is expanding its manufacturing facilities through Oxbox, a 84,000 sq ft state-of-the-art bioprocessing facility, significantly increasing its production capacity to match increasing demand and to continue growing its platform revenues. In the near term, revenues will continue to be driven by the Novartis partnership for CAR-T Kymriah as the commercial roll-out continues. OXB has several established development and manufacturing partnerships including Novartis, Juno Therapeutics (BMS), Bioverativ (Sanofi), Orchard Therapeutics, Sio Gene Therapies, Boehringer Ingelheim, Santen and Beam Therapeutics. OXB also has a supply agreement with AstraZeneca for the large-scale commercial manufacture of the adenovirus vector-based COVID-19 vaccine candidate AZD1222.

INDUSTRY OUTLOOK

Cell- and gene-therapy is the focus of much industry attention as it can dramatically alter the outcomes of many diseases. OXB's proprietary LentiVector platform has demonstrated promise in many indications.

| Y/E Dec | Revenue (£m) | EBITDA (£m) | PBT (£m) | EPS (p) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 66.8 | 13.5 | 0.3 | 4.3 | 190.7 | 41.5 |
| 2019 | 64.1 | (4.6) | (16.8) | (16.4) | N/A | N/A |
| 2020e | 84.2 | 2.2 | (5.6) | (0.6) | N/A | 512.3 |
| 2021e | 112.4 | 19.9 | 11.7 | 11.6 | 70.7 | 32.3 |

Sector: Pharma & healthcare

Price: NZ\$0.83
Market cap: NZ\$602m
Market NZ\$X

Share price graph (NZ\$)



Company description

Pacific Edge develops and sells a portfolio of molecular diagnostic tests based on biomarkers for the early detection and management of cancer. Tests utilising its Cxbladder technology for detecting and monitoring bladder cancer are sold in the US, New Zealand, Australia and Singapore.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|-------|
| Actual | 16.9 | 29.7 | 564.0 |
| Relative* | 14.2 | 22.5 | 504 6 |

* % Relative to local index

Analyst

Maxim Jacobs

Pacific Edge (PEB)

INVESTMENT SUMMARY

Pacific Edge develops and sells a portfolio of molecular diagnostic tests based on biomarkers for the early detection and management of cancer. Tests using its Cxbladder technology for detecting and monitoring bladder cancer are sold in the US, New Zealand, Australia and Singapore. The company recently reported results for H121, featuring a 46% y-o-y increase in Cxbladder sales to NZ\$3.3m. The US business grew 46% to NZ\$2.9m and was assisted by the inclusion of Cxbladder into a local coverage determination (LCD) enabling reimbursement at US\$760 per test from the US Centers for Medicare and Medicaid Services (CMS) on all tests after 1 July. The outlook for growth in the US business is strong as commercial test orders to Kaiser Permanente, one of the largest non-profit healthcare providers in the US, started in November.

INDUSTRY OUTLOOK

Molecular diagnostics is a growing, but increasingly competitive field. Lead times from the initiation of user programmes to payment can be long.

| Y/E Mar | Revenue (NZ\$m) | EBITDA (NZ\$m) | PBT (NZ\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|--------------------|-------------------|----------------|------------|------------|-------------|
| 2019 | 4.8 | (17.8) | (17.8) | (3.5) | N/A | N/A |
| 2020 | 5.0 | (17.7) | (18.8) | (3.2) | N/A | N/A |
| 2021e | 20.2 | (3.5) | (4.6) | (0.6) | N/A | N/A |
| 2022e | 44.1 | 19.2 | 17.4 | 2.3 | 36.1 | 31.0 |



Price: €2.52
Market cap: €167m
Market FRA

Share price graph (€)



Company description

Paion owns the fast-onset and short-recovery anaesthesia product remimazolam. This is approved in Japan for GA and in the US and China for PS. ByFavo is licensed in the US to Acacia. It is filed in the EU (for PS) and South Korea. A European GA filing is expected in H121.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|-------|------|
| Actual | 17.2 | 0.8 | 29.2 |
| Relative* | 10.2 | (0.5) | 28.2 |

* % Relative to local index

Analyst

Dr John Savin

Paion (PA8)

INVESTMENT SUMMARY

The European Phase III general anaesthesia (GA) trial showed that Remimazolam was as effective as propofol in maintaining anaesthesia in major surgery so met the primary endpoint. More importantly, fewer hypotensive episodes were noted on average in the remimazolam arm; for at risk patients (ASA Class III or IV), this safety gain could be critical in justifying remimazolam's price premium over propofol. In the US, remimazolam (ByFavo) is expected to be launched soon for procedural sedation (PS). It is launched in Japan for GA use as Anerem by Mundipharma. Paion had €24.5m in cash (30 September) after receiving the €15m US approval milestone in Q320. Paion also has an EIB loan facility of up to €20m giving cash until H221.

INDUSTRY OUTLOOK

Paion is considering licensing or acquiring products to make a direct European salesforce economic. Otherwise, there will be a European partnering strategy. In Italy and Belgium, compassionate use of remimazolam is possible to sedate COVID-19 patients.

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 2.8 | (12.5) | (12.4) | (15.9) | N/A | N/A |
| 2019 | 8.0 | (9.2) | (9.3) | (10.8) | N/A | N/A |
| 2020e | 20.3 | 2.4 | 2.4 | 5.9 | 42.7 | 176.2 |
| 2021e | 4.2 | (20.9) | (20.9) | (31.2) | N/A | N/A |

Sector: Pharma & healthcare

Price: US\$2.55 Market cap: US\$291m Market NASDAQ

Share price graph (US\$)



Company description

As of December 2019, PDL BioPharma has ceased to make additional strategic transactions and investments. It is pursuing a formal process to unlock the value of its portfolio by monetizing its assets and ultimately distributing net proceeds to shareholders.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|--------|-------|
| Actual | 13.8 | (18.0) | 14.6 |
| Relative* | 8.2 | (23.9) | (2.4) |

* % Relative to local index

Analyst

Maxim Jacobs

PDL BioPharma (PDLI)

INVESTMENT SUMMARY

After completing a strategic review process, it has decided to cease additional strategic investments and monetize the company's current assets, returning net proceeds to shareholders. PDL has made significant progress so far. Most recently, in October, LENSAR was spun off to PDL shareholders and the previously announced sale of Noden was completed in September. Also, the Kybella, Zalviso and Coflex royalties were sold to SWK Holdings for \$4.35m and a settlement agreement was reached with Wellstat in August. The main assets remaining to be disposed of are the Assertio royalties and the University of Michigan royalties on Cerdelga.

INDUSTRY OUTLOOK

PDL BioPharma has a portfolio of assets (royalties, notes and direct investments) in healthcare covering the medical device and biotechnology sectors.

| Y/E Dec | Revenue (US\$m) | EBITDA (US\$m) | PBT (US\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|--------------------|-------------------|----------------|------------|------------|-------------|
| 2018 | 32.0 | (24.3) | (30.4) | (16.25) | N/A | N/A |
| 2019 | 30.7 | (39.3) | (44.6) | (43.64) | N/A | N/A |
| 2020e | N/A | N/A | N/A | N/A | N/A | N/A |
| 2021e | N/A | N/A | N/A | N/A | N/A | N/A |



Price: €3.45
Market cap: €59m
Market Euronext Paris

Share price graph (€)



Company description

Pharnext is developing new therapies for neurological disorders using its proprietary Pleotherapy platform that unearths new therapeutic effects from drug combinations. Its lead program is PXT3003 for CMT1A, which is entering Phase III. It also has PXT864 for Alzheimer's disease, which has completed Phase IIa.

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|-------|--------|
| Actual | 6.6 | 1.2 | (26.0) |
| Relative* | (5.2) | (8.3) | (22.4) |

* % Relative to local index

Analyst

Dr Nathaniel Calloway

Pharnext (ALPHA)

INVESTMENT SUMMARY

Pharnext's pleotherapy platform uses a combination of in silico prediction of drug effects as well as in vitro screening to find drug combinations that have biochemical effects totally outside of their canonical activities. For instance, the company's lead program 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 results in Phase III for Charcot-Marie-Tooth type 1A (CMT1A) disease.

INDUSTRY OUTLOOK

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

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 6.8 | (17.8) | (21.7) | (183.47) | N/A | N/A |
| 2019 | 3.6 | (19.5) | (23.4) | (161.08) | N/A | N/A |
| 2020e | 3.2 | (14.5) | (17.8) | (95.91) | N/A | N/A |
| 2021e | 1.8 | (23.3) | (26.6) | (138.89) | N/A | N/A |

Sector: Pharma & healthcare

Price: NOK82.50 Market cap: NOK2204m Market Oslo

Share price graph (NOK)



Company description

Photocure specialises in photodynamic therapy. Its bladder cancer imaging product is sold as Hexvix in Europe and Cysview in the US. Photocure handles the marketing in Nordic countries and the US, while Ipsen is its marketing partner in the EU.

Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|-------|
| Actual | (8.0) | (7.0) | (6.5) |
| Relative* | (10.6) | (14.2) | (3.0) |

* % Relative to local index

Analyst

Maxim Jacobs

Photocure (PHO)

INVESTMENT SUMMARY

Photocure is a commercial-stage Norwegian specialty pharmaceutical company that markets Hexvix/Cysview for diagnosing and managing bladder cancer. US sales are a key driver for the company and were up 55% in 2019. As of 1 October, Photocure has re-acquired the rights to Hexvix/Cysview in territories where Ipsen had been marketing the product (primarily the EU). Photocure expects the re-acquisition to be EBITDA accretive in 2021 and beyond. Additionally, the company has announced the ambition of worldwide revenues in the range of NOK1bn in 2023 with approximately 40% EBITDA margin.

INDUSTRY OUTLOOK

Photocure is a photodynamic therapy company focused on bladder cancer. As its products are typically a combination of a drug and a device, hurdles for generics are typically higher than with other therapeutics.

| Y/E Dec | Revenue (NOKm) | EBITDA (NOKm) | PBT (NOKm) | EPS (öre) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2018 | 181.5 | (10.5) | (22.5) | (104.0) | N/A | N/A |
| 2019 | 281.6 | 58.9 | 45.9 | 146.0 | 56.5 | 87.1 |
| 2020e | 168.4 | (46.8) | (60.7) | (312.0) | N/A | N/A |
| 2021e | 266.1 | 39.5 | 38.0 | 117.0 | 70.5 | 89.4 |



Price: €0.84
Market cap: €37m
Market Euronext Paris

Share price graph (€)



Company description

Pixium Vision develops bionic vision systems for patients with severe vision loss. Lead product, Prima, is a wireless sub-retinal implant system designed for dry-AMD. Pixium completed five implantations in an EU feasibility study and recently started a US feasibility study study.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|------|
| Actual | 39.8 | 61.4 | 74.3 |
| Relative* | 24.3 | 46.3 | 82.8 |

* % Relative to local index

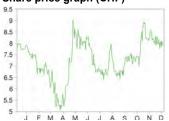
Analyst

Pooya Hemami

Sector: Pharma & healthcare

| Price: | | CHF8.05 |
|-----------|------------|------------|
| Market ca | p: | CHF90m |
| Market | Swiss Stoc | k Exchange |

Share price graph (CHF)



Company description

Polyphor is a development stage company focused on oncology and antibiotics. Its lead programme is balixafortide, a CXCR4 inhibitor currently in Phase III for breast cancer. Data are expected in 2021. It plans to start its Phase I programme of inhaled murepayadin to treat P. aeruginosa infections in CF patients by the year

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|-----|-----|
| Actual | (1.2) | 9.7 | 2.5 |
| Relative* | (1.7) | 8.9 | 3.4 |

* % Relative to local index

Analyst

Maxim Jacobs

Pixium Vision (PIX)

INVESTMENT SUMMARY

Pixium Vision is developing the Prima wireless photovoltaic sub-retinal implant, which transforms images into electrical signals to elicit a form of central visual perception in patients with severe retinal disease. In Q120, positive 18-month data were reported from its EU feasibility study in patients with geographic atrophy associated with dry age-related macular degeneration (GA-AMD), showing continued safety and improvements of between three and seven lines on the Landolt C visual acuity scale versus baseline. Pixium recently received approval to start the PRIMAvera pivotal study in Europe, and it expects to start the trial before year-end 2020.

INDUSTRY OUTLOOK

Pixium completed a €7.3m capital increase in July, which we estimate should enable it to maintain its operations into Q421. Prima is being evaluated in clinical trials as a potential treatment option for patients with decreased vision from GA-AMD, a disease affecting ageing populations and a significant unmet medical need.

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 1.6 | (5.8) | (7.7) | (41.63) | N/A | N/A |
| 2019 | 1.8 | (8.4) | (9.8) | (43.90) | N/A | N/A |
| 2020e | 1.7 | (7.4) | (8.6) | (27.76) | N/A | N/A |
| 2021e | 1.6 | (9.4) | (11.0) | (25.38) | N/A | N/A |

Polyphor (POLN)

INVESTMENT SUMMARY

Polyphor is a development-stage company focused on oncology and antibiotics. Its lead programme is balixafortide, a C-X-C chemokine receptor type 4 (CXCR4) inhibitor currently in a randomised-controlled Phase III trial in 407 previously treated human epidermal growth factor receptor 2 (HER2) negative advanced breast cancer patients. Objective response rate (ORR) data from the trial are expected in Q221 and could allow for an accelerated approval filing in the US. Additionally, it plans to start its Phase I programme of inhaled murepavadin to treat P. aeruginosa infections in cystic fibrosis (CF) patients by the end of the year.

INDUSTRY OUTLOOK

According to the National Cancer Institute, 78% of the estimated 276,480 new cases of breast cancer every year are HER2 negative. For those who are HER2 negative and hormone-receptor positive (68% of breast cancers), chemotherapy remains the standard of care in over 90% of cases once past front-line therapy.

| Y/E Dec | Revenue (CHFm) | EBITDA (CHFm) | PBT (CHFm) | EPS (CHFc) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|---------------|------------|-------------|
| 2018 | 6.5 | (41.6) | (45.6) | (484.0) | N/A | N/A |
| 2019 | 0.0 | (64.9) | (64.2) | (581.0) | N/A | N/A |
| 2020e | 13.7 | (44.9) | (45.1) | (404.0) | N/A | N/A |
| 2021e | 0.0 | (48.6) | (48.8) | (428.0) | N/A | N/A |



Price: €4.78
Market cap: €128m
Market Euronext Paris

Share price graph (€)



Company description

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

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|-------|------|
| Actual | 9.6 | 100.4 | 52.7 |
| Relative* | (2.5) | 81.7 | 60.1 |

* % Relative to local index

Analyst

Maxim Jacobs

Quantum Genomics (ALQGC)

INVESTMENT SUMMARY

Quantum Genomics is investigating brain aminopeptidase A inhibitors, a new class of drug, for the treatment of hypertension and heart failure. Data from the Phase IIb NEW-HOPE trial strongly suggests that firibastat is an efficacious, safe drug. After eight weeks of treatment, patients saw a statistically significant reduction from baseline (p<0.0001) in systolic blood pressure of 9.7mmHg. A pivotal Phase III in 500 resistant hypertension patients has been initiated with results by the end of 2021. Enrolment of the Phase IIb of firibastat in 294 heart failure patients is expected to complete by the end of 2020 with results in H121.

INDUSTRY OUTLOOK

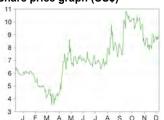
The angiotensin pathway is one of the primary methods of modulating blood pressure and is the target of many anti-hypertensive drugs, including ACEs and ARBs. However, there is a parallel pathway in the brain responsible for the secretion of vasopressin and heart rate that is unaddressed by current drugs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

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 0.0 | (13.6) | (13.6) | (93.94) | N/A | N/A |
| 2019 | 0.0 | (10.8) | (10.8) | (52.69) | N/A | N/A |
| 2020e | 0.0 | (15.6) | (15.6) | (64.07) | N/A | N/A |
| 2021e | 0.0 | (21.6) | (21.6) | (83.78) | N/A | N/A |

Sector: Pharma & healthcare

| Price: | US\$8.66 |
|-------------|----------|
| Market cap: | US\$324m |
| Market | NASDAQ |

Share price graph (US\$)



Company description

RedHill Biopharma focuses on gastrointestinal (GI) and infectious diseases, promoting several GI products in the US. The commercial portfolio includes Movantik (opioid-induced constipation), Talicia (H. pylori eradication) and Aemcolo (TD). RedHill also has a rapidly progressing COVID-19 R&D

programme. Price performance

| % | 1m | 3m | 12m |
|-----------|-------|------|------|
| Actual | (8.0) | 16.4 | 31.6 |
| Relative* | (5.7) | 8.0 | 12.1 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

RedHill Biopharma (RDHL)

INVESTMENT SUMMARY

RedHill is marketing Talicia for H. pylori infection (approved by the FDA in November 2019, launched in March); Movantik for opioid-induced constipation; and Aemcolo, a minimally-absorbed antibiotic approved by the FDA for travellers' diarrhoea (TD). Net revenues were \$20.9m in Q320, in line with Q220. The R&D pipeline includes RHB-204 for pulmonary non-tuberculous mycobacteria infections (Phase III study initiated November); RHB-104 for Crohn's disease (positive top-line results from first Phase III announced in July 2018); BEKINDA for both gastroenteritis (positive results from first Phase III announced in June 2017) and IBS-D (positive final Phase II results announced in January 2018). RedHill is also investigating opaganib for COVID-19 in a US Phase II study (enrolment complete, top-line data in weeks) and a global Phase II/III study (Europe and other territories) which passed the first DSMB review in November (>50% enrolled, futility analysis due in weeks).

INDUSTRY OUTLOOK

RedHill's main focus includes a range of gastrointestinal conditions, but also viral and bacterial infections. Although some of these can be treated with a variety of innovative and established products, in our view, carefully positioned, innovative solutions for the patients will attract attention.

| Y/E Dec | Revenue (US\$m) | EBITDA (US\$m) | PBT (US\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|--------------------|-------------------|----------------|------------|------------|-------------|
| 2018 | 8.4 | (39.2) | (38.8) | (16.8) | N/A | N/A |
| 2019 | 6.3 | (42.0) | (42.1) | (14.2) | N/A | N/A |
| 2020e | 105.0 | 2.5 | 2.3 | 0.5 | 1732.0 | N/A |
| 2021e | 137.0 | 3.4 | 3.2 | 0.6 | 1443.3 | 501.2 |



Price: 81.0p Market cap: £46m Market LSE

Share price graph (p)



Company description

ReNeuron Group is a UK biotech company developing allogeneic cell therapies. Human retinal progenitor cells are the lead Phase I/IIa project for retinitis pigmentosa. There is a strong preclinical technology base in exosomes.

Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|--------|
| Actual | (8.1) | (4.9) | (41.0) |
| Relative* | (17.3) | (14.4) | (35.8) |

* % Relative to local index

Analyst

Dr John Savin

ReNeuron Group (RENE)

INVESTMENT SUMMARY

ReNeuron is focused on human retinal progenitor cell therapy (hRPC) for retinitis pigmentosa (RP). Ongoing Phase IIa data show a stable average gain in visual acuity. A nine-patient continuation Phase IIa study is underway at a higher dose. A placing of £15m and an open offer of up to £2.5m at 70p/share, totalling up to £17.5m before costs, are planned to give at least 18 months' cash to complete the Phase IIa, potentially initiate a pivotal study in H222, and progress preclinical exosome and other cell therapy projects.

INDUSTRY OUTLOOK

hRPC cell therapy could potentially treat any RP patient, giving a big potential commercial advantage; gene therapies only treat a small number of specific mutations. ReNeuron has research agreements to explore uses of the company's proprietary, scalable exosomes to deliver novel therapeutics and as viral vaccines; these can be produced to GMP standard. Preclinical model data may be published in 2021 giving a strong basis for licensing.

| Y/E Mar | Revenue | EBITDA | PBT | EPS | P/E | P/CF |
|---------|---------|--------|--------|---------|-----|------|
| | (£m) | (£m) | (£m) | (p) | (x) | (x) |
| 2019 | 2.7 | (18.1) | (17.2) | (45.34) | N/A | N/A |
| 2020 | 6.2 | (14.0) | (13.9) | (35.85) | N/A | N/A |
| 2021e | 0.2 | (13.8) | (14.4) | (32.85) | N/A | N/A |
| 2022e | 0.2 | (12.9) | (13.3) | (20.55) | N/A | N/A |

Sector: Pharma & healthcare

Price: SEK21.95 Market cap: SEK418m Market SE

Share price graph (SEK)



Company description

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

Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|------|
| Actual | 22.9 | 21.7 | 61.4 |
| Relative* | 10.8 | 12.2 | 67.5 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

RhoVac (RHOVAC)

INVESTMENT SUMMARY

RhoVac is developing RV001, a cancer immunotherapy designed to prevent or limit progression to metastatic disease after curative intent therapy, by activating T-cells against cells with metastatic potential. RV001 contains a fragment of the target protein RhoC, which is overexpressed in cells with metastatic potential across a range of cancers. In November, the FDA granted Fast Track Designation for RV001 in prostate cancer. The existing funding should be sufficient to complete the Phase IIb study in prostate cancer ongoing in Europe and the US (full recruitment expected in Q221 with results expected early-2022, subject to potential pandemic headwinds), as well as covering exploratory preclinical studies in other cancers. RhoVac's strategic aim is to secure a partner for the late-stage development and global launch of RV001 after completion of the Phase IIb study.

INDUSTRY OUTLOOK

Metastatic cancer is the most advanced stage of cancer and is terminal. A large proportion of patients diagnosed with local cancer already have undetectable metastatic cells or micro-metastases that have infiltrated other tissues. Preventing or halting metastasis formation through inhibiting the metastatic cascade or selectively killing cells with metastatic potential could help contribute to a reduction of morbidity and an improved survival.

| Y/E Dec | Revenue (SEKm) | EBITDA (SEKm) | PBT (SEKm) | EPS (öre) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2018 | 0.0 | (20.1) | (20.2) | (195.00) | N/A | N/A |
| 2019 | 6.0 | (36.3) | (35.9) | (155.00) | N/A | N/A |
| 2020e | 12.0 | (38.0) | (37.4) | (219.00) | N/A | N/A |
| 2021e | 8.0 | (42.0) | (41.6) | (261.00) | N/A | N/A |



Price: €38.50
Market cap: €2159m
Market Madrid Stock Exchange

Share price graph (€)



Company description

Laboratorios Farmacéuticos ROVI is a fully integrated Spanish speciality pharmaceutical company that is developing, manufacturing and marketing small molecule and speciality biologic drugs, with expertise in low molecular weight heparin (LMWH). Its drugs pipeline is focused on its proprietary ISM technology.

Price performance

| % | 1m | 3m | 12m |
|-----------|--------|------|------|
| Actual | 4.6 | 25.8 | 57.8 |
| Relative* | (13.1) | 7.7 | 78.9 |

* % Relative to local index

Analyst

Dr Susie Jana

ROVI Laboratorios Farmaceuticos (ROVI)

INVESTMENT SUMMARY

ROVI is a profitable speciality healthcare company that markets ~40 proprietary and in-licensed products across nine core franchises, mainly in its domestic Spanish market. Since obtaining market authorisation for its internally developed enoxaparin biosimilar (Becat) in multiple countries, ROVI has commenced marketing in several European countries and has signed out-licensing agreements that cover 91 countries globally – key drivers for sales and operating growth in the medium term. In September 2019, ROVI announced that it plans to build a new LMWH manufacturing facility over the next three years, doubling its current capacity. R&D progress continues with its proprietary ISM technology. Following positive PRISMA-3 data on DORIA (risperidone ISM), a long-acting injectable for schizophrenia, an MAA was filed with the EMA in January 2020 leading to a potential launch in Europe in 2021. The US NDA was filed in November 2020.

INDUSTRY OUTLOOK

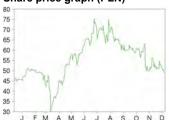
ROVI has a strong presence in the Spanish heparin market (and select international markets through partners), where it has been manufacturing and marketing its flagship product, Hibor (second-generation LMWH), since 1998.

| Y/E Dec | Revenue (€m) | EBITDA (€m) | PBT (€m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 304.8 | 29.5 | 19.2 | 38.45 | 100.1 | 226.7 |
| 2019 | 382.5 | 60.9 | 45.6 | 76.64 | 50.2 | N/A |
| 2020e | 402.6 | 79.9 | 63.3 | 102.55 | 37.5 | 720.0 |
| 2021e | 425.8 | 71.5 | 54.2 | 87.51 | 44.0 | 39.3 |

Sector: Pharma & healthcare

Price: 48.60PLN Market cap: PLN892m Market Warsaw Stock Exchange

Share price graph (PLN)



Company description

Ryvu Therapeutics is an oncology R&D company. The lead asset is wholly owned SEL120, a selective CDK8 inhibitor. SEL24/MEN1703 is a dual PIM/FLT3 kinase inhibitor licensed to the Menarini Group. Ryvu also has a diversified preclinical R&D pipeline.

Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|------|
| Actual | (13.2) | (19.3) | 12.2 |
| Relative* | (24.8) | (26.9) | 18.8 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

Ryvu Therapeutics (RVU)

INVESTMENT SUMMARY

Menarini, Ryvu's licensing partner, is developing SEL24/MEN1703 (a dual PIM/FLT3 kinase inhibitor) in AML and reported positive, preliminary data at ASH 2020 (December) from the dose escalation part of the Phase I/II DIAMOND-01 trial. The dose expansion part of the study is currently recruiting in the US and the EU. In the near term, Ryvu plans to present interim data from its Phase Ib study with wholly owned SEL120 (a selective CDK8 kinase inhibitor) in AML and myelodysplastic syndrome. In addition to clinical-stage assets, Ryvu has a broad R&D pipeline of cutting-edge oncology projects at earlier stages, which have been progressing steadily. In October 2020, the company re-prioritised the preclinical portfolio and discontinued two disclosed programmes and will re-direct the investments into other prospective assets. In July 2020, Ryvu completed a share issue raising \$36m, which ensures funding to progress all R&D projects.

INDUSTRY OUTLOOK

The profiles of SEL24 and SEL120 are potentially unique compared to existing clinical-stage competitors and both candidates may offer efficacy advantages.

| Y/E Sep | Revenue (PLNm) | EBITDA (PLNm) | PBT (PLNm) | EPS (gr) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|-------------|------------|-------------|
| 2018 | 51.7 | (17.3) | (23.0) | (1.49) | N/A | N/A |
| 2019 | 42.6 | (36.1) | (44.4) | (2.26) | N/A | N/A |
| 2020e | 39.5 | (22.5) | (31.2) | (1.95) | N/A | N/A |
| 2021e | 25.0 | (40.0) | (48.7) | (3.05) | N/A | N/A |



Price: 107.0p Market cap: £126m Market AIM

Share price graph (p)



Company description

Shield Therapeutics is a commercial-stage pharmaceutical company. Its proprietary product, Feraccru, is approved by the EMA and FDA for the treatment of iron deficiency. Feraccru is marketed through partners Norgine, AOP Orphan and Ewopharma.

Price performance

| % | 1m | 3m | 12m |
|-----------|--------|--------|--------|
| Actual | (18.0) | (2.3) | (43.8) |
| Relative* | (26.2) | (12.1) | (38.9) |

* % Relative to local index

Analyst

Dr Susie Jana

Shield Therapeutics (STX)

INVESTMENT SUMMARY

Shield Therapeutics is a commercial-stage speciality pharmaceutical company based in the UK. Its primary focus is the commercialisation of Feraccru/Accrufer, approved by the EMA and FDA for the treatment of iron deficiency in adults, with or without anaemia. The commercialisation of Feraccru in Europe, Australia and New Zealand is in the hands of distribution partner Norgine, and the product has been licensed to ASK Pharm in China. Shield is broadening its strategy for commercialisation in the US and will continue ongoing discussions with potential partners and in parallel explore the benefits of marketing Accrufer itself. At 30 November 2020 Shield had an unaudited cash balance of £3.8m, loan facility agreements totalling c £4.4m extend the runway to the end of 2021. Our forecasts are under review

INDUSTRY OUTLOOK

The market for iron deficiency is substantial and Feraccru 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) |
|---------|-----------------|----------------|-------------|------------|------------|-------------|
| 2018 | 11.9 | (2.5) | (5.2) | (1.5) | N/A | N/A |
| 2019 | 0.7 | (6.4) | (9.1) | (7.5) | N/A | N/A |
| 2020e | N/A | N/A | N/A | N/A | N/A | N/A |
| 2021e | N/A | N/A | N/A | N/A | N/A | N/A |

Sector: Pharma & healthcare

| Price: | 453.0p |
|-------------|--------|
| Market cap: | £376m |
| Market . | AIM |

Share price graph (p)



Company description

Silence Therapeutics (SLN) has a portfolio of siRNA drugs in early stage testing. SLN124 for iron overload was recently dosed in the first volunteers of a Phase I study. SLN360 is being developed for cardiovascular disease and recently had its IND approved.

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|--------|--------|
| Actual | 2.7 | (0.4) | (16.1) |
| Relative* | (7.5) | (10.4) | (8.7) |

* % Relative to local index

Analyst

Dr Nathaniel Calloway

Silence Therapeutics (SLN)

INVESTMENT SUMMARY

Silence Therapeutics is a developer of RNA-based therapeutics with some of the foundational intellectual property in the space. The value of its platform has been highlighted with recent licensing deals with Mallinckrodt to develop a complement inhibitor, with Takeda to research undisclosed targets, and recently with AstraZeneca to research cardiovascular, renal, metabolic and respiratory targets. This is in addition to the company's internal pipeline; SLN124 recently entered the clinic in 2020 and SLN360 is planned to enter the clinic in coming months.

INDUSTRY OUTLOOK

RNA therapeutics is an increasingly high-profile sector of the biotechnology industry, now with multiple drug approvals for a range of disorders. We consider the technology in this field to be mature and expect increased interest across the industry to develop new drugs of this class.

| Y/E Dec | Revenue | EBITDA | PBT | EPS (fd) | P/E | P/CF |
|---------|---------|--------|--------|----------|-----|------|
| | (£m) | (£m) | (£m) | (p) | (x) | (x) |
| 2018 | 0.0 | (20.2) | (19.8) | (25.18) | N/A | N/A |
| 2019 | 0.2 | (22.3) | (22.3) | (27.15) | N/A | N/A |
| 2020e | 6.3 | (23.0) | (20.5) | (20.93) | N/A | N/A |
| 2021e | 10.0 | (22.5) | (20.9) | (20.96) | N/A | N/A |



Price: A\$0.04 Market cap: A\$12m Market ASX

Share price graph (A\$)



Company description

SUDA Pharmaceuticals is a drug delivery company focusing on developing oro-mucosal spray versions of established medicines. It has the rights to ZolpiMist, the spray version of Ambien for insomnia, outside of North America.

Price performance

| % | 1m | 3m | 12m |
|-----------|-------|--------|--------|
| Actual | (2.6) | (11.6) | (32.0) |
| Relative* | (9.8) | (21.6) | (33.0) |

* % Relative to local index

Analyst

Maxim Jacobs

SUDA Pharmaceuticals (SUD)

INVESTMENT SUMMARY

SUDA Pharmaceuticals has focused on reformulating established drugs into oro-mucosal spray formulations for better bioavailability. Its lead commercial product is ZolpiMist, an oro-mucosal spray version of Ambien for the treatment of insomnia that is partnered in certain regions with Teva and Mitsubishi Tanabe. SUDA is also working on formulating an oro-mucosal version of anagrelide for the treatment of solid tumours in patients who have high platelet counts. Anagrelide is currently used as an anti-thrombotic agent to reduce elevated levels of platelets in essential thrombocythemia. Additionally, SUDA is working on spray versions of sumatriptan for migraine, cannabinoids for various conditions, as well as other projects.

INDUSTRY OUTLOOK

SUDA is targeting very large markets. ZolpiMist is a spray version of Ambien which has 30m prescriptions in the US. Anagrelide is targeting multiple cancers, including ovarian, pancreatic and lung. Additionally, migraine has a prevalence of 13–15% in the US/EU.

| Y/E Jun | Revenue (A\$m) | EBITDA (A\$m) | PBT (A\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|------------|------------|-------------|
| 2019 | 1.2 | (1.9) | (2.4) | (1.54) | N/A | N/A |
| 2020 | 0.5 | (4.1) | (4.7) | (2.81) | N/A | N/A |
| 2021e | 0.6 | (4.9) | (5.5) | (1.78) | N/A | N/A |
| 2022e | 1.1 | (5.1) | (5.6) | (1.81) | N/A | N/A |

Sector: Pharma & healthcare

Price: ¥377.00 Market cap: ¥13986m Market Tokyo

Share price graph (¥)



Company description

SymBio Pharmaceuticals is a Japanese specialty pharma company focused on oncology and hematology. The Treakisym powder formulation was in-licensed from Astellas in 2005; liquid Treakisym was in-licensed from Eagle Pharmaceuticals in 2017; and brincidofovir was licensed from Chimerix in 2019.

Price performance

| i iioo poiioimanoo | | | | |
|--------------------|-------|--------|--------|--|
| % | 1m | 3m | 12m | |
| Actual | 4.4 | (5.8) | (41.6) | |
| Relative* | (1.6) | (13.8) | (43.2) | |

* % Relative to local index

Analyst

Dr Nathaniel Calloway

SymBio Pharmaceuticals (4582)

INVESTMENT SUMMARY

SymBio is a speciality pharma focused on Asia-Pacific markets and has in-licensed two orphan blood cancer products. Treakisym iv was approved for r/r low-grade NHL/MCL in 2010 and in 2016 for CLL and first-line low-grade NHL/MCL. SymBio has in-licensed liquid formulations for injection that will give Treakisym patent protection to 2031; a clinical trial is underway of the rapid-infusion liquid formulation that would reduce Treakisym infusion time from 60 minutes to 10. A Phase III trial of Treakisym in r/r diffuse large B-cell lymphoma recently reported positive results and the company has filed for a label extension.

INDUSTRY OUTLOOK

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

| Y/E Dec | Revenue (¥m) | EBITDA (¥m) | PBT (¥m) | EPS (fd) (¥) | P/E (x) | P/CF (x) |
|---------|-----------------|----------------|-------------|-----------------|------------|-------------|
| 2018 | 3835.5 | (2621.4) | (2625.8) | (104.91) | N/A | N/A |
| 2019 | 2837.8 | (4263.5) | (4249.5) | (180.46) | N/A | N/A |
| 2020e | 2608.1 | (4754.8) | (4729.1) | (143.00) | N/A | N/A |
| 2021e | 9227.8 | 1465.0 | 1531.3 | 29.86 | 1262.6 | N/A |



Price: NOK9.50 Market cap: NOK822m Market Oslo

Share price graph (NOK)



Company description

Targovax is an immunoncology company headquartered in Oslo, Norway, with an oncolytic virus platform, ONCOS. ONCOS-102 is currently prioritised in several indications including mesothelioma and melanoma. Targovax is also working on mutant RAS peptides and next-gen oncolytic viruses in its

preclinical pipeline. Price performance

| % | 1m | 3m | 12m |
|-----------|------|------|------|
| Actual | 41.8 | 40.3 | 42.2 |
| Relative* | 27.8 | 29.5 | 47.6 |

* % Relative to local index

Analyst

Dr Jonas Peciulis

Targovax (TRVX)

INVESTMENT SUMMARY

Targovax is an immunoncology company specialising in oncolytic viruses. ONCOS-102 is a genetically engineered adenovirus being tested in advanced melanoma, mesothelioma, colorectal and prostate cancer. In November, Targovax announced that an impressive 35% best objective response rate (ORR) was observed in the Phase I study investigating ONCO102 in combination with Keytruda (pembrolizumab) for patients with advanced, PD-1 refractory melanoma. Interestingly, for two patients non-injected lesions completely disappeared implying a systemic effect might have occurred. In June 2020, Targovax reported follow up data from the Phase I/II study (n=31) in mesothelioma. The mPFS for ONCOS-102-treated first-line patients remained at 9.8 months vs 7.6 months in the randomised control arm. In November, the mOS had not yet been reached but will be at least 18.2 months vs 14.2 months in the control arm.

INDUSTRY OUTLOOK

CPIs have gained popularity over the past several years, although a large proportion of patients do not respond to them. Targovax's oncolytic virus technology is designed to prime immune response to cancers, which offers synergies for use in combination with other immunoncology therapies.

| Y/E Dec | Revenue (NOKm) | EBITDA (NOKm) | PBT (NOKm) | EPS (öre) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|--------------|------------|-------------|
| 2018 | 0.0 | (145.8) | (147.3) | (2.79) | N/A | N/A |
| 2019 | 2.3 | (146.2) | (147.9) | (2.43) | N/A | N/A |
| 2020e | 0.0 | (124.5) | (124.5) | (1.79) | N/A | N/A |
| 2021e | 0.0 | (126.3) | (126.3) | (1.66) | N/A | N/A |

Sector: Pharma & healthcare

Price: A\$3.83 Market cap: A\$1053m Market ASX

Share price graph (A\$)



Company description

Telix Pharmaceuticals is a Melbourne-headquartered global biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or molecularly targeted radiation.

Price performance

| % | 1m | 3m | 12m |
|-----------|------|-------|-------|
| Actual | 63.0 | 112.8 | 128.0 |
| Relative* | 50.9 | 88.8 | 124.8 |

* % Relative to local index

Analyst

Dr Nathaniel Calloway

Telix Pharmaceuticals (TLX)

INVESTMENT SUMMARY

Telix is developing diagnostic and therapeutic radiopharmaceuticals for kidney, prostate and brain cancers. It is commercialising TLX591-CDx in the US and Europe and on 24 September 2020 the company announced that it had submitted its NDA to the FDA for approval. Telix expects to fully enrol the ZIRCON Phase III for kidney cancer imaging agent TLX250-CDx in early 2021.

INDUSTRY OUTLOOK

Big pharma has shown keen interest in MTR products. In 2017 Novartis acquired Advanced Accelerator Applications, the developer of the MTR therapeutic Lutathera, for US\$3.9bn. In 2014 Bayer acquired Algeta for ~US\$2.6bn; Algeta had developed Xofigo, a therapeutic radiopharmaceutical for prostate cancer. In December 2018 Novartis acquired prostate cancer radiopharmaceutical developer, Endocyte for US\$2.1bn.

| Y/E Dec | Revenue (A\$m) | EBITDA (A\$m) | PBT (A\$m) | EPS (c) | P/E (x) | P/CF (x) |
|---------|-------------------|------------------|---------------|------------|------------|-------------|
| 2018 | 10.3 | (17.5) | (15.7) | (6.84) | N/A | N/A |
| 2019 | 15.2 | (24.3) | (31.1) | (11.94) | N/A | N/A |
| 2020e | 15.0 | (25.6) | (29.9) | (11.54) | N/A | N/A |
| 2021e | 97.8 | 56.8 | 52.2 | 19.51 | 19.6 | 14.2 |



Company coverage

| Company | Note | Date published |
|---------------------------------|--------------------|--------------------|
| Abliva | Update; Update | 11/03/20; 26/06/20 |
| Acacia Pharma | Update; Update | 21/08/20; 06/11/20 |
| Actinogen Medical | Flash; Update | 08/05/19; 15/10/19 |
| AFT Pharmaceuticals | Update; Update | 21/05/20; 24/11/20 |
| Allarity Therapeutics | Update; Outlook | 04/09/20; 08/12/20 |
| Basilea Pharmaceutica | Update; Update | 20/02/20; 19/08/20 |
| BerGenBio | Initiation | 17/11/20 |
| Bioasis Technologies | Initiation; Update | 16/06/20; 02/07/20 |
| BioPorto Diagnostics | Update; Update | 20/08/20; 19/11/20 |
| Brighter | Update; Update | 29/09/20; 24/11/20 |
| Cantargia | Update; Update | 06/05/20; 30/10/20 |
| Carmat | Outlook; Update | 27/09/19; 04/12/20 |
| CASI Pharmaceuticals | Update; Update | 28/10/20; 23/11/20 |
| Deinove | Update; Update | 16/10/19; 21/02/20 |
| Ergomed | Update; Update | 23/07/20; 22/09/20 |
| Hepion Pharmaceuticals | Update; Update | 07/08/20; 21/08/20 |
| Hutchison China MediTech | ADR update; Update | 10/08/20; 10/12/20 |
| Immunicum | Update; Update | 15/05/20; 03/09/20 |
| InMed Pharmaceuticals | Update; Update | 22/01/20; 20/02/20 |
| Kazia Therapeutics | ADR update; Update | 02/12/20; 10/12/20 |
| Laboratorios Farmacéuticos ROVI | Update; Outlook | 11/11/20; 10/12/20 |
| MagForce | Update; Update | 13/11/20; 30/11/20 |
| Mesoblast | Update; Update | 01/07/20; 30/11/20 |
| Newron Pharmaceuticals | Update; QuickView | 22/09/20; 17/11/20 |
| Oasmia Pharmaceutical | Initiation | 09/09/20 |
| Onxeo | Update; Update | 27/05/19; 18/11/20 |
| OpGen | Update; Update | 19/08/20; 19/11/20 |
| Oryzon Genomics | Update; Update | 15/06/20; 28/09/20 |
| OSE Immunotherapeutics | Update; Update | 08/07/20; 28/09/20 |
| Oxford Biomedica | Flash; Outlook | 08/06/20; 05/10/20 |
| Pacific Edge | Update; Update | 06/01/20; 20/07/20 |
| Paion | QuickView; Update | 15/10/20; 27/11/20 |
| PDL BioPharma | Update; Update | 25/08/20; 17/11/20 |
| Pharnext | Initiation; Update | 29/09/20; 20/10/20 |
| Photocure | Update; Update | 04/03/19; 13/05/20 |
| Pixium Vision | Update; Update | 29/10/20; 25/11/20 |
| Polyphor | Initiation | 05/10/20 |
| Quantum Genomics | Update; Update | 05/10/20; 16/11/20 |
| RedHill BioPharma | Update; QuickView | 26/08/20; 12/10/20 |
| ReNeuron Group | Update; Update | 26/08/20; 08/12/20 |
| RhoVac | Update; Update | 05/10/20; 27/11/20 |
| Ryvu Therapeutics | Update; Update | 23/03/20; 11/05/20 |
| Shield Therapeutics | Flash; Update | 07/08/20; 18/09/20 |
| Silence Therapeutics | Update; Update | 16/04/20; 17/09/20 |
| SUDA Pharmaceuticals | Initiation; Update | 06/07/20; 03/09/20 |
| SymBio Pharmaceuticals | Outlook; Update | 10/09/20; 30/09/20 |



Targovax
Telix Pharmaceuticals

Update; Update Update; Update 22/06/20; 17/09/20 05/11/20; 09/12/20



Glossary

| AACR | American Association for Cancer Research |
|------------------|--|
| AAV | Adeno-associated virus |
| ABSSSI | Acute bacterial skin and skin structure infections |
| Accelerated | Faster FDA approval based on a surrogate endpoint for drugs that fill an unmet medical need for serious |
| approval | conditions. Phase IV confirmatory trial required post-approval to demonstrate clinical benefit |
| ACES | Angiotensin converting enzymes |
| ADC | Alzheimer's disease |
| ADC | Antibody-drug conjugate |
| AdCom ADHD | FDA Advisory Committee meeting Attention deficit hyperactivity disorder |
| ADME | Absorption, distribution, metabolism and excretion |
| Adv | Adenovirus |
| AUV AEs | Adverse events |
| AfDC | Affimer drug conjugates |
| AGvHD | Acute graft vs host disease |
| AKI | Acute grant vs nost disease Acute kidney injury |
| ALL | Acute lymphoblastic leukaemia |
| AM | Alpha-mannosidosis |
| AMF | Alternating magnetic field |
| AMI | Acute myocardial infarction |
| AML | Acute myeloid leukaemia |
| ANDA | Abbreviated new drug application |
| AOBP | Automated office blood pressure |
| APD | Atypical antipsychotic drugs |
| API | Active pharmaceutical ingredient |
| APPA | American Pet Products Association |
| AR | Augmented reality |
| ARBs | Angiotensin receptor blockers |
| ARDS | Acute respiratory distress syndrome |
| ASCO | American Society of Clinical Oncology |
| ASCT | Autologous stem cell transplantation |
| ASD | Autism spectrum disorder |
| AUC | Area under the curve (total drug exposure over time) |
| B-ALL | B-cell acute lymphoblastic leukaemia |
| | Biomedical Advanced Research and Development Authority (US agency that supports research into drugs, |
| BARDA | 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 |
| 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 Perderline percentility disorder |
| BPD DTC | Borderline personality disorder |
| BTC | Biliary tract carcinoma Proakthrough therapy designation (Expediates development and EDA review of drugs intended to treat a serious |
| 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 |
| Cancer stages | Community acquired bacterial pricarrionia |
| I Carreer stayes | The cancer or tumour is small and is still in the place that it started and hasn't spread to nearby tissue |
| | The cancer or tumour is similar and is still in the place that it started and hasn't spread to flearby tissue. The cancer or tumour is larger and may have spread to the surrounding tissue and/or lymph nodes. |
| IV | The cancer has spread to one or more other organs of the body and is considered metastatic |
| CAR-T | Chimeric antigen receptor T cell |
| CBD | Hemp-derived cannabidiol |
| CBN | Cannabinol |
| UDIA | |
| CCRCC | Clear cell renal cell carcinoma |



| CDV | prevention of disease, injury and disability) |
|---------------|--|
| CDK CDMO | cyclin-dependent kinase Contract development and manufacturing organisation |
| CDIVIO CDx | |
| CDX | Companion diagnostic Notified body issued authorisation for medical devices that pass the conformity assessment (health, safety and |
| CE mark | 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 |
| | Centers for Medicare & Medicaid Services (US federal agency that operates the Medicare program and works in |
| CMS | 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 bee |
| CKL | approved for marketing) |
| CRO | Contract research organisation |
| CsA | Cyclosporin A |
| CTA | Clinical trials application (EU version of an IND) |
| CTN | Clinical Trials Notification Scheme (Australian version of an IND) |
| CV | Cardiovascular |
| CXCR4 | C-X-C chemokine receptor type 4 |
| DC | Dendritic cell |
| DCR | Disease control rate |
| DEA | Drug Enforcement Administration (US agency focused on controlled substances) |
| DFS | Disease-free survival |
| DGF | Delayed graft function |
| DIPG | Diffuse intrinsic pontine glioma |
| DLBCL | Diffuse large B-cell lymphoma |
| DLT | Dose-limiting toxicity |
| DMF | Drug master file (submission to FDA to provide confidential, detailed information about facilities or processes |
| | used in the manufacturing, processing, packaging, and storing of human drug products) |
| DMPK | Drug metabolism and pharmacokinetics |
| DoR | Duration of response |
| DRG | Diagnosis-Related Group code |
| Dry-AMD | Dry age-related macular degeneration |
| DSMB | Data safety monitoring board |
| DT | Destination therapy |
| DTC | Direct to consumer |
| EB | Epidermolysis bullosa |
| EBT | External-beam radiation therapy |
| ECM | Extracellular matrix |
| EDL | Essential drug list (list of medicines that must be in stock at public hospitals and clinics in China) |
| EGFR | Epidermal growth factor receptor |
| EMA | European Medicines Agency (European regulator) |
| epNET | Non-pancreatic neuroendocrine tumour |
| ER | Estrogen receptor |
| ESMO | European Society for Medical Oncology |
| EUA | Emergency Use Authorization |
| FDA | Food and Drug Agency (US regulator) |
| FGFR | Fibroblast growth factor receptors |
| FISH | Fluorescence in situ hybridization |
| FL | Follicular lymphoma |
| FTD | Fast Track Designation (Facilitates development and expediates FDA review of drugs to treat serious conditions |
| | and fill an unmet medical need) |
| GA CA | General anaesthesia |
| ga Ga-amd | Geographic atrophy Geographic atrophy associated with dry age-related macular degeneration |
| | |



| GC | Gastric cancer |
|---------------|--|
| G-CSF | Granulocyte colony-stimulating factor |
| 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 |
| GvHD | Graft vs host disease |
| H2H | Head to head |
| HAIs | Hospital-acquired infections |
| HbV | Haemoglobin |
| HBV | Hepatitis B virus |
| HCC HDAC | Hepatocellular cancer Histone deacetylase |
| HDL | How-density lipoprotein (cholesterol) |
| HER | Human epidermal growth factor receptor |
| HF | Heart failure |
| HHT | Human heart transplantation |
| HHV | Human herpesvirus |
| HMAs | Hypomethylating agents |
| HNSCC | Head and neck squamous cell carcinoma |
| hpSCs | Human parthenogenetic stem cells |
| HPV | Human papilloma virus |
| HR | Hazard ratio |
| HR-MDS | Higher-risk myelodysplastic syndrome |
| hRPC HRQoL | Human retinal progenitor cell |
| HSCT | Health-related quality-of-life Hematopoietic stem cell transplant |
| HSIL | High-grade squamous intraepithelial lesion |
| I | The cancer or tumour is small and is still in the place that it started and hasn't spread to nearby tissue |
| IBD | Inflammatory bowel disease |
| IBS-D | Irritable bowel syndrome with diarrhoea |
| iCCA | Intrahepatic cholangiocarcinoma |
| ICU | Intensive care unit |
| ID | Iron deficiency |
| IDA | Iron deficiency anaemia |
| IDMC | Independent Data Monitoring Committee |
| IDN | Integrated delivery network |
| - | The cancer or tumour is larger and may have spread to the surrounding tissue and/or lymph nodes |
| IHC | Immunohistochemistry |
| IIT IMP | Investigator-initiated trials Investigational medicinal product (Australia TGA terminology) |
| IND | Investigational New Drug Application (submission to FDA required to start clinical trials) |
| 10 | Immuno-oncology |
| IOP | Intraocular pressure |
| IPF | Idiopathic pulmonary fibrosis |
| IR | Insulin receptor |
| ITP | Immune thrombocytopenia |
| ITT | Intention-to-treat (analysis includes all patients randomised in the clinical study) |
| IV | The cancer has spread to one or more other organs of the body and is considered metastatic |
| iv, im, sc | Intravenous, intramuscular, subcutaneous |
| KOL | Key opinion leader |
| LAI | Long-acting injectable |
| LCD LDAC | Local coverage determination (MAC decision whether to cover a particular treatment in it's jurisdiction) Low-dose cytarabine |
| LDAC | Low-dose cytarabine Low-density lipoprotein (cholesterol) |
| LDTs | laboratory-developed tests |
| LHON | Leber's hereditary optic neuropathy |
| LMWH | Low molecular weight heparin |
| | Limited population pathway for antibacterial and antifungal drugs (FDA pathway to approval for antibacterial and |
| LPAD | antifungal drugs that treat serious infections in a small population of patients with unmet needs) |
| LPAD | Left pulmonary artery diameter |
| LSC | Leukaemia stem cells |
| LSIL | Low-grade squamous intraepithelial lesions |
| LVEF | Left ventricular ejection fraction |
| LVESV | Left ventricle end systolic volume |
| LVV | Lentiviral vector Marketing Authorication Application (EMA regulatory filing for approval) |
| MAA | Marketing Authorisation Application (EMA regulatory filing for approval) Medicare Administrative Contractor (private insurer that has been awarded geographic jurisdiction to process |
| MAC | claims) |
| MAC | Mycobacterium avium complex |
| MACE | Major adverse cardiac event |
| MAD | Multiple ascending dose |
| | |



| mBC | Metastatic breast cancer |
|------------|---|
| mCDRPC | Metastatic castration and docetaxel resistant prostate cancer |
| MCL | Mantle cell lymphoma |
| mCRC | Metastatic colorectal cancer |
| mCRPC | Metastatic castration-resistant prostate cancer |
| MCS | Mechanical circulatory support |
| MDS | Myelodysplastic syndrome |
| MDSC | Myeloid-derived suppressor cell |
| MES | Molecular epidemiology study |
| MET | Mesenchymal epithelial transition factor |
| MFS | Metastasis-free survival |
| MHRA | Medicines and Healthcare products Regulatory Agency (UK regulator) |
| MI | Myocardial infarctions |
| MM | Multiple myeloma |
| MoA | Mode of action |
| mOS | Median overall survival |
| MPC | Mesenchymal precursor cell |
| mPFS | Median progression-free survival |
| MRI | Magnetic resonance imaging |
| MRP | Mutual recognition procedure (one route of filing in the EU) |
| MRSA | Methicillin-resistant Staphylococcus aureus |
| MS | Multiple sclerosis |
| MSA | Medical savings account (allows owner to withdraw earmarked funds to pay for treatments) |
| MSC | Mesenchymal stem cell |
| MT | Monotherapy |
| MTD | Maximum tolerated dose |
| MTR | Molecularly targeted radiation |
| NAFLD | Nonalcoholic fatty liver disease |
| nAMD | Neovascular age-related macular degeneration |
| NASH | NASH activity score |
| NASH | Non-alcoholic steatohepatitis |
| NCI | National Cancer Institute (US agency for cancer research) |
| NDA | New Drug Application (FDA filing application for approval for chemical/small molecule drugs) |
| NET | Neuroendocrine tumour |
| NGF | Nerve growth factor |
| NGS | Next generation sequencing |
| NHL | Non-Hodgkin's lymphoma |
| NHP | Non-human primate |
| NHSA | National Healthcare Security Administration (China agency that manages medical insurance schemes) |
| NIAID | National Institute of Allergy and Infectious Diseases (US agency for the research of infectious, immunologic and allergic diseases) |
| NICE | g , |
| NK | National Institute for Health and Clinical Excellence (develops clinical guidelines for NHS) Natural killer cell |
| NME | |
| NMIBC | New molecule entity (FDA regulatory pathway) Non-muscle invasive bladder cancer |
| NMPA | Chinese National Medical Products Administration (China regulator) |
| NRDL | National reimbursement drug list (includes drugs reimbursable by public insurance schemes in China) |
| | Non-small cell lung cancer |
| NSCLC | New technology add-on payments (CMS provides additional payment to hospitals for new, high-cost medical |
| NTAP | services and technologies) |
| NTM | Pulmonary non-tuberculous mycobacteria |
| OC | Ovarian cancer |
| 00 | Oncologic Drugs Advisory Committee (makes recommendations to FDA about the safety and effectiveness of |
| ODAC | marketed and investigational oncology drugs) |
| ODAC | Orphan drug designation (provides tax incentives and a period of market exclusivity to treatments targeting rare |
| ODD | 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 |
| 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 |
| | Prescription Drug User Fee Act date (when FDA is expected to approve/not approve NDA or BLA) |
| PDUFA date | |



| PET | Positron emission tomography |
|---|--|
| PFAS | Perfluoroalkyl substances |
| PFS | Progression-free survival |
| 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 Ib | Multiple ascending dose. Patients receive multiple doses of the treatment at the same dose level, and if no adverse side effects are observed, the dose is increased for the next cohort of patients to determine the MTD. Provides preliminary efficacy data. |
| Phase II | Testing of a new treatment in patients with the disease or condition to assess efficacy and side effects. Up to several hundred participants. |
| Phase III | Testing of a new treatment in patients with the disease or condition to assess efficacy and clinical benefit, as well as monitoring adverse reactions (and long-term side effects). Up to several thousand participants. |
| Phase IV | Post-marketing surveillance to assess the safety (rare and long-term side effects) and efficacy of an approved treatment in patients that are prescribed it. |
| PICU | Paediatric intensive care unit |
| PK | Pharmacokinetics |
| PMA | Pre-market approval (FDA approval required for Class III medical devices that support or sustain human life |
| | before marketing) |
| PMC | Pseudomembranous colitis |
| PMDA | Pharmaceutical and Medical Device Agency (Japan regulator) |
| PMDs | Primary mitochondrial diseases |
| pNET | Pancreatic neuroendocrine tumour |
| PoC | Point-of-care |
| PONV | Post-operative nausea and vomiting |
| PP | Per protocol (analysis only includes patients that complied with the clinical study protocol) |
| PPE | Personal protective equipment |
| PR | Partial response |
| PR | Progesterone receptor |
| PRCC | Papillary renal cell carcinoma |
| Preclinical | Testing of drug in non-human subjects, to gather efficacy, toxicity and pharmacokinetic information |
| Priority review | FDA aims to take action on an application within 6 months (compared to 10 months under standard review) |
| PRRT | Peptide receptor radionuclide therapy |
| PS | Procedural sedation |
| PSA | Prostate-specific antigen |
| PSC | Pulmonary sarcomatoid carcinoma |
| Pt | Patient |
| PTCL | Peripheral T-cell lymphoma |
| PV | Pharmacovigilance |
| qd | Once daily |
| QIDP | Qualified infectious disease product designation |
| QoL | Quality-of-life |
| RBC | Red blood cell |
| RCC | Renal cell carcinoma |
| 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 |
| | Refusal to file (allows FDA to inform sponsors of deficiencies in their NDA or BLA as soon as possible, instead of |
| RTF | waiting to issue a CRL) |
| RTK | Receptor tyrosine kinase |
| RT-PCR | Reverse transcriptase polymerase chain reaction |
| Rx | Prescription |
| 11/1 | Severe aplastic anaemia |
| | |
| SAA | |
| SAA SAB | Staphylococcus aureus bacteraemia |
| SAA SAB SAD | Staphylococcus aureus bacteraemia Single ascending dose |
| SAA SAB SAD SAE | Staphylococcus aureus bacteraemia Single ascending dose Serious adverse event |
| SAA SAB SAD SAE SAP | Staphylococcus aureus bacteraemia Single ascending dose Serious adverse event Statistical analysis plan |
| SAA SAB SAD SAE SAP SARS | Staphylococcus aureus bacteraemia Single ascending dose Serious adverse event Statistical analysis plan Severe acute respiratory syndrome |
| SAA SAB SAD SAE SAP SARS SCLC | Staphylococcus aureus bacteraemia Single ascending dose Serious adverse event Statistical analysis plan Severe acute respiratory syndrome Small cell lung cancer |
| SAA SAB SAD SAE SAP SARS SCLC SD | Staphylococcus aureus bacteraemia Single ascending dose Serious adverse event Statistical analysis plan Severe acute respiratory syndrome Small cell lung cancer Stable disease |
| SAA SAB SAD SAE SAP SARS SCLC SD SMA | Staphylococcus aureus bacteraemia Single ascending dose Serious adverse event Statistical analysis plan Severe acute respiratory syndrome Small cell lung cancer Stable disease Spinal muscular atrophy |
| SAA SAB SAD SAE SAP SARS SCLC SD | Staphylococcus aureus bacteraemia Single ascending dose Serious adverse event Statistical analysis plan Severe acute respiratory syndrome Small cell lung cancer Stable disease |



| | Special protocol assessment (FDA process to reach agreement with sponsors on the design and size of certain |
|-------|---|
| SPA | 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 |
| TAH | Total artificial heart |
| TAM | Tumour-associated macrophage |
| TBI | Traumatic brain injury |
| TCM | Traditional Chinese medicine |
| TCR | T-cell receptor |
| TD | Travellers' diarrhoea |
| TEAE | Treatment-emergent adverse event |
| TfR | Transferrin receptor |
| TGA | Therapeutic Goods Administration (Australia regulator) |
| TGF | Transforming growth factor |
| THC | Tetrahydrocannabinol |
| TKI | Tyrosine kinase inhibitor |
| TLR | Toll-like receptor |
| TMAC | Tissue microenvironment-activated conjugates |
| TNBC | Triple-negative breast cancer |
| TNK | Tumour necrosis factor |
| TPS | Tumour proportion score |
| TTP | Time-to-progression |
| TURBT | Transurethral resection of the bladder tumour |
| Tx | Treatment |
| UBC | Umbilical cord blood |
| UC | Urothelial cancer |
| URD | Unrelated matched donor |
| VADs | Visual acuity |
| VADs | Ventricular assistance devices (L = left, R = right and Bi=biventricular) |
| VEGFR | Vascular endothelial growth factor receptors |
| vHC | Viral haemorrhagic cystitis |
| VMIC | Vaccines Manufacturing and Innovation Centre |
| WHO | World Health Organisation |
| WT | g. |
| WT | Wild type |

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