EDISON

Ergomed

Initiation of coverage

Resilient global pharma services specialist

Healthcare services

We are initiating coverage on specialist pharmaceutical services provider Ergomed. We believe it should prove relatively resilient during the COVID-19 crisis and has the fundamentals in place to execute its growth strategy. Ergomed announced impressive audited numbers for FY19, with revenue up 26% to £68.3m and EBITDA up 5.5x to £12.5m. The FY19 announcement is effectively Ergomed's fourth profit upgrade for FY19 and a small beat on recently reset FY19 expectations. Ergomed trades at a discounted EV/EBITDA of 10.1x vs the contract research outsourcing (CRO) sector average of 11.5x (FY20). We value Ergomed at £186m or 399p/share. Ergomed's strong organic growth is benefiting from a clear strategic focus on high growth pharma sectors, margin control and order book growth (up 15% to £125m in FY19, giving 90% visibility to 2020).

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/18	54.1	1.0	1.9	0.0	N/A	N/A
12/19	68.3	8.6	19.8	0.0	16.5	N/A
12/20e	84.8	13.7	24.9	0.0	13.1	N/A
13/21e	100.3	16.5	28.9	0.0	11.3	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Tackling COVID-19 crisis with efficient platform

We believe Ergomed is well positioned to maintain a steady course through the economic crisis caused by the onset of the COVID-19 pandemic. Its services in both its CRO and pharmacovigilance divisions are provided under long-term contracts to meet the needs of essential medical research as well as mandated pharmacovigilance (PV) requirements. Both CRO and pharmacovigilance services are delivered remotely and Ergomed has announced it has seen no decline in its business volumes since the start of the crisis. If necessary, the company can adjust the cost of its external contractor labour and discretionary costs.

Focused strategy providing improved returns

Ergomed enjoys relatively low customer concentration with its top five clients representing 24.8% of FY19 revenues. Clients are generally well financed and good payers, with >85% of debtor ageing current or under 30 days. The contracted order book of £124.1m (up 14% over 2018) together with the strong pipeline and significant recent wins give over 90% visibility to 2020 revenue. The company's recently signed new credit facility, on which it has now drawn £15m to add to its own cash pile of over £10m, provides additional resilience. Finally, Ergomed is likely to play a role in the expected increase in COVID-19 research, as can be seen from recent announcement of an important new study and contracts with EUSA Pharma/ Bergamo Papa Giovanni XXIII hospital.

Valuation: £186m or 399p/share

We value Ergomed on an EV/EBITDA multiple based on our FY20 forecasts using a FY20e sector average ratio of 11.5x. We believe Ergomed's strengthened management, focus on growing segments (oncology, orphan drugs and pharmacovigilance) and potential resilience in responding to the coronavirus crisis support our valuation.

25 March 2020

Price	**327p**
Market cap	**£155m**

Net cash (£m) at 31 December 2019	14.3
Shares in issue	47.3m
Free float	67%
Code	ERGO
Primary exchange	AIM
Secondary exchange	Frankfurt Xetra

Share price performance

%	1m	3m	12m
Abs	(27.3)	(18.6)	92.2
Rel (local)	10.2	26.3	177.8
52-week high/low		464p	166p

Business description

Ergomed is a global full-service contract research outsourcing (CRO) business with a core focus on the US and EU. It provides Phase I–III clinical services in addition to post-marketing pharmacovigilance (Phase IV) services through its PrimeVigilance division. The company is predominantly focused on oncology, orphan drugs or rare diseases and pharmacovigilance.

Next events

FY19 full results	March 2020
H120 results	September 2020

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Edison profile page

Ergomed is a research client of Edison Investment Research Limited

Investment summary

Company description: Operational control

Founded in 1997, Ergomed is a full-service pharmaceutical services company. Its two divisions are CRO, which provides Phase I to III clinical trial services and PrimeVigilance, which provides post-marketing pharmacovigilance (Phase IV) services. The company has expertise across all common disease areas but is predominantly focused on oncology and rare diseases/orphan drugs. It has made numerous acquisitions over its lifespan; the most recent acquisitions were PSR Orphan Experts (PSR) in 2017, which expanded its rare disease expertise, and Ashfield Pharmacovigilance in January 2020, which broadens the geographical reach (in the US) of its PrimeVigilance business. The company was listed on the AIM market of the London Stock Exchange in 2014. At 31 December 2019, Ergomed employed over 850 people and 300 contractors across 16 offices globally, had completed 600 studies with 125,000 patients enrolled across 60 countries and was supporting products in over 100 countries. The company has 220 active clients (including those of the recently acquired PrimeVigilance USA) and low client concentration.

Valuation: £186m or 399p/share

We value Ergomed on an EV/EBITDA multiple based on FY20e numbers using an average ratio of 11.5x, which is the average multiple of comparative public peers including Syneos Health, PRA Health Sciences, ICON and Medpace. We use Ergomed's adjusted EBITDA in our calculations. These peer companies are predominantly focused on clinical services and while they are significantly larger than Ergomed, we believe they represent suitable comparators. As comparators for future order book and revenue forecasts we use Ergomed's FY19 book-to-bill ratio of c 1.22x, historical net order book (+ new contracts – revenue – calculated cancellations) growth and past order book burn rates (the percentage of the order book converted to revenue in a period).

Financials: Focused strategy demonstrating benefits

Ergomed's 2019 results demonstrate strong organic growth year-on-year. Revenue was £68.3m, driven by a growing order book of £124.1m. Although revenues increased substantially, costs remained under control as utilisation rates increased and synergies improved. FY19 costs of sales were £29.8m vs £26.8m in FY18, while SG&A expenses decreased to £23.5m vs £28.2m in FY18 (mainly due to exceptional costs in that year relating to Haemostatix impairment and business reorganisation costs). FY19 gross margin was 43% vs 36% in FY18. We forecast FY20 adjusted EBITDA of £14.9m (adjusted EBITDA was £12.5m in FY19), as the transition from a co-development model to a services model completed during 2019 continues to benefit profit margins. We forecast this trend to continue on an adjusted EBITDA basis (FY21e: £17.6m). We forecast a FY20 net profit of £10.2m (versus £5.6m in FY19). Cash at 31 December 2019 was £14.3m.

Sensitivities: Reputation is everything

Ergomed is reimbursed on a time and materials basis as a services company and not based on study outcome; as such it is not associated with the usual biotech and drug development risks, including clinical development delays or failures, regulatory risks, competitor successes or partnering setbacks. However, it is subject to business risks that include loss of key clients (although concentration is low and falling with total revenue generated by the top five clients in FY19 at under 25% vs 28% in FY18 and 40% in FY17), changing costs and increased competition. Ergomed relies on its reputation; any failure to deliver on contractual obligations with current clients could affect its ability to win new contracts. It is sensitive to pressure around clinical trials, notably around patient enrolment, where actual timelines and costs could drastically differ from a proposal if the correct planning is not undertaken.

CROs: A sector on the rise

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 to remain ahead of competition. In hand with an increasing number of trials being initiated globally, the complexity of the trials is increasing, substantially driven by multiple innovation factors (page 9). As a result, the operation of clinical trials in their entirety and on a day-to-day basis is beyond the expertise of many pharmaceutical and biotechnology organisations and especially newly spun-out biotechnology companies. CROs can provide the expertise when the industry needs it. This need has led to increasing demand for CRO services and an industry, which is expected to grow at 5.1% CAGR to $70bn by 2027, according to Ergomed.

Industry-wide consolidation has created several large (>£5bn market cap) CROs (eg, Covance, IQVIA, LabCorp, Syneos and Parexel) with global capabilities. While these CROs can provide a full range of services, expertise in any one specific technology, disease or geography will vary on a company-by-company basis. Opportunity exists for smaller CROs that can offer specific expertise. Ergomed aims to grow its market share by its focus on oncology, rare diseases, pharmacovigilance and its core geographies of the EU and US.

The success of a CRO relies on management's ability to operationally execute on multiple metrics. However, few of those are as key to a CRO's success as the continued growth of the order book. The order book is typically defined as anticipated future net service revenue plus pass-through costs billed on to clients (included in revenues since the advent of IFRS15). There is no industry standard for what can be included in the order book, but Ergomed follows best practice by only including revenues that are contractually committed. Revenue and cancellations will reduce the order book while new orders will increase it. Therefore, a growing order book is positive and a sign of momentum, in contrast to a shrinking order book. In addition to order book growth, attention should be paid to the book-to-bill ratio, which is the ratio of new contracts signed net of cancellations to revenue recognised in the period. A book-to-bill ratio of greater than 1.0x denotes growth while a book-to-bill ratio greater than 1.20x is typically considered healthy for a CRO business.

Ergomed is strongly focused on ensuring each project is well managed, costs are controlled, utilisation rates are high and every project is profitable with sufficient margins. Tight operational control and execution will enable Ergomed to drive market share in high-growth orphan drug trials as well as in larger indications including oncology and in pharmacovigilance services, enabling order book growth through increased pricing, new contracts and growth of market share.

Ergomed management key to its potential success

In our view, Ergomed has a strong management team comprised of industry veterans who are aware of the opportunities and challenges of operating within CROs and have a track record of delivering high growth (both organic and inorganic).

Of the new management team in place, CFO Richard Barfield, COO Lewis Cameron and NED Dr Jim Esinhart were previously part of the management team at Chiltern International and drove its growth before its acquisition by LabCorp in September 2017 for $1.2bn. Under their management, between 2013 and 2017 Chiltern grew its revenue from $160m to $560m, increased its EBITDA from $22m to $97m and grew its order book from $200m to $1.2bn.

Additional new hires include Roy Ovel as Chief Commercial Officer (previously at ICON, TFS and Worldwide), Sally Amanuel as Head of Regulatory and Clinical Delivery (previously at Worldwide, PPD) and Jon West as President of PrimeVigilance (first employee of PrimeVigilance in 2008). We

note founder Dr Miroslav Reljanović has returned as Executive Chairman, following previous CEO Stephen Stamp stepping down due to health reasons in early 2019. In addition to Dr Jim Esinhart, Rolf Soderstrom (former CFO of BTG) and Ian Johnson (serial founder, CEO and chairman of life sciences businesses) have joined the board as Non-Executive Directors. Alongside Michael Spiteri (Global COO of Digital, Data and Development at HSBC), who has been a NED for two years, this makes for a seasoned NED team to support the executive management team.

The strengthened team has laid out its key strategic goals for Ergomed:

- **Integration of recent acquisitions and realisation of CRO/PV synergies**. The global business development (BD) team is focused on gaining and retaining clients throughout the development and commercial lifecycle of a product. This was recently evidenced by the award from a CRO client of a £4.8m contract for global post-marketing pharmacovigilance services.
- **Targeted acquisitions**. Ergomed will continue to assess potential acquisitions, which would be earnings accretive, add additional services, increase the customer base and continue the focus on rare diseases and oncology.
- **Develop strong organic growth in both CRO and PV**. The acquisition of PSR in 2017 is now complete, with CRO growth driven by organic means in FY19 (up 24% to £32.8m in FY19 from £26.6m in FY18). Additionally, strong client retention in PrimeVigilance continues to drive growth (up 29% to £35.4m in FY19 from £27.5m in FY18) as demonstrated by existing clients from 2013 providing £11.2m in revenue in 2018 out of a total £27.5m.
- **Full focus on a profitable services business model, termination of co-development strategy and a significant reduction in R&D spend**. Net profit in FY19 was £5.6m (versus a loss of £9.0m in FY18). R&D spend on co-development reduced from £1.6m in 2018 to £0.5m in 2019 and is expected to be minimal in 2020.
- **Maintain positive cash flow and build strong cash position**. Cash generated from operating activities increased in FY19 to £11.7m (versus £0.9m in FY18). Substantial cash flow generation was evident by the acquisition of Ashfield in cash only ($10m). The company has now prudently drawn £15m cash on its recently announced new credit facilities, to bolster its already strong cash position in the face of the COVID-19 crisis.
- **Focus on oncology and rare disease indications**. In FY19, 45% of CRO revenue was focused on rare diseases.. Oncology (including rare and non-rare cancers) represents Ergomed's largest indication and was responsible for over 25% of revenue in FY19. These trends have continued with over 70% of new business in 2020 YTD focused on rare diseases and oncology.

We believe the strengthened management team and board, a core focus on oncology, rare diseases and pharmacovigilance, a renewed BD team and a strong balance sheet and cash flows should ensure resilience through the COVID-19 crisis and are all positive to Ergomed's near-term returns potential.

Ergomed CRO: A full-service offering

Ergomed is a full-service CRO, offering a full suite of clinical services to enable, if desired, clinical development from first patient through regulatory approval to post-marketing studies. Services offered include but are not limited to clinical trial and project management, medical writing, regulatory affairs, quality management and pharmacovigilance. A typical full-service clinical trial contract would consist of the CRO organising all aspects of a clinical trial, including the creation of an internal team to run the trial (including project directors, project managers, clinical team manager, monitors and clinical trial administrators), recruitment of relevant medical experts, the setup of patient centres and the recruitment of local teams (who are natives and familiar with the local healthcare system, language(s) and customs), the creation of study documents (eg protocols, patient information leaflets and final clinical reports), the implementation of standard operating

procedures and database creation for tracking adverse events. Additionally, the team will ensure regulatory compliance and maintain relevant interactions with regulatory authorities.

A CRO contract is typically signed a couple of months before a clinical trial is expected to start. Revenue is recognised over the life of the contract when hours are billed and targets are met (eg patients are enrolled). Tight control over these margins is critical to ensuring profitability. An internal team at Ergomed tracks every project on an ongoing basis to ensure study targets are being met and, when divergences from the plan happen, to quickly recognise, assess and solve any problems.

How effectively a CRO uses its billable employees is key to driving both revenue and profit. Allowing for holidays, sick leave and training, utilisation rates are typically expected to be around 80%. A poor understanding by senior management of how its employees are being utilised will result in missed targets, higher costs (potentially though rework or overwork) and damaged reputation, while good control of this will enable a management team to push margin and revenue growth. As a CRO grows, its strong operational gearing should allow SG&A to increase minimally and be spread over a larger number of employees (billable hours), resulting in increasing margins.

Additionally, effective delivery of trials enables a CRO to increase prices as its premium service offerings are recognised. For Ergomed this is particularly relevant as its focus on oncology and rare diseases requires expert capabilities and could enable it to drive higher margins through price expansion.

Pharmacovigilance: Long-term drug safety and real-world evidence

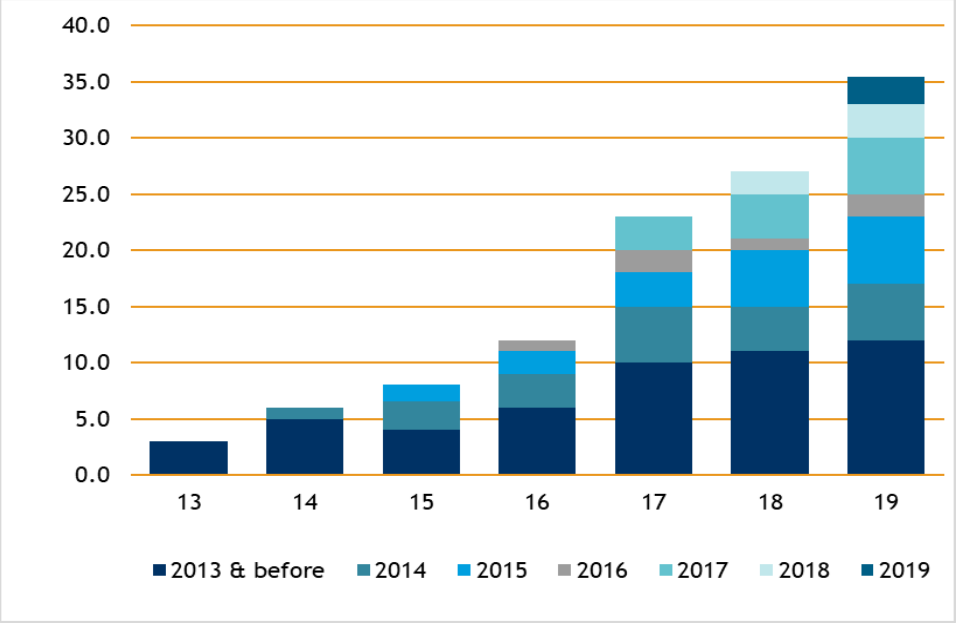
PrimeVigilance is Ergomed's key pharmacovigilance division and represented 52% of total revenues in 2019 (£35.4m). Established in 2008, the division focuses on pharmacovigilance work across the globe. Once a drug is approved and marketed, regulators require pharma companies to track the safety of their drug to ensure no unforeseen risks arise. This originally involved tracking of any adverse events that patients experience but has evolved to cover a whole suite of lifecycle management options including medical information and its Qualified Person Responsible for Pharmacovigilance (QPPV) network.

Revenue from the division continues to grow. PrimeVigilance revenue grew 29% in FY19 to £35.4m from £27.5m in FY18. Order book grew in FY19 by 11.9% to £54.6m. FY19 order book across PrimeVigilance and CRO was £124.1m. Post period end, the PrimeVigilance order book has benefited from the addition of the Ashfield order book, which was $9.8m. Gross margins across PrimeVigilance and the CRO businesses are similar once pass-through costs have been accounted for. In FY19, gross service fee margin for the CRO business was 46.4% and 52.2% for PrimeVigilance.

In 2018, North America represented the largest market for Ergomed's PrimeVigilance division. Strict regulatory requirements in the region mean post-approval pharmacovigilance work is a necessity and continues to drive a strong market for Ergomed. To bolster its capabilities in the region, Ergomed has acquired US-based Ashfield Pharmacovigilance from UDG Healthcare for $10m. The addition adds over 40 new clients to PrimeVigilance and an order book (contracted future revenues) of $9.8m. In the year to 30 September 2019, Ashfield reported $11.6m in revenue and $0.9m in adjusted EBITDA. This deal will be immediately accretive to earnings in FY19.

We note that Ergomed's capabilities in pharmacovigilance are highlighted by its high number of repeat clients (Exhibit 1).

Exhibit 1: PrimeVigilance client retention – revenues (£m) by customer cohort



Source: Ergomed

Co-development strategy fully closed down

Under the previous strategy, which Ergomed decided to terminate in FY18 and fully exited in FY19, Ergomed shared the cost of running clinical trials with the drug developers to take a share of any potential upside. Ergomed has re-confirmed that there will be no further co-development partnerships and there will be no further financial commitments to existing ones. Under its co-development strategy, Ergomed had planned to derive potential upside in a product through equity or future financial incentives (eg royalties). However, the high risk of drug development (only one in 10 drugs that are tested in humans receive regulatory approval) and long development times (c 10 years from start of clinical development to potential approval) meant Ergomed did not realise any upside to its co-development deals. Management strongly committed that it was in the best interests of the company to wind this strategy down completely and focus on making every project profitable within a services model. Margin control and pricing became the clear focus for Ergomed's growth with the elimination of potential shared ownership risk downside on contracts, and it is clear from FY19's significant improvement in profitability that the costs and low margins in prior years of the now closed co-development projects potentially have masked the underlying profit generation of the business. Ergomed's previous partnerships and exit status are found in Exhibit 2 below.

Exhibit 2: Co-development partners

Company	Product	Status
Haemostatix	PeproStat and ReadyFlow	Fully impaired. Awaiting Phase III trial, seeking financial/licence partner. No carrying value on Ergomed balance sheet.
Modus	Sevuparin in sickle cell disease	Negative Phase II data. New funding being sought for new indication; Ergomed will not contribute. Commitments 100% complete at 31 December 2019. Fully impaired. No carrying value on Ergomed's balance sheet.
Asarina	Sepranolone in premenstrual dysphoric disorder	Recruitment completed and Phase IIa results expected in H120. Ergomed has a c 1.6% shareholding. Commitments 98% complete at 31 December 2019. We forecast minimal commitments left (<5%).
Cel-Sci	Multikine in head and neck cancer	Awaiting Phase III results. Trial is at an advanced stage. Ergomed continues to support with minimal cash exposure. No carrying value on Ergomed's balance sheet.

Source: Ergomed, Edison Investment Research

Business development renewed as Ergomed looks to US expansion

With the co-development strategy now definitively exited, management has made a renewed push to capitalise on internal capacity by significantly increasing its BD activities. It now has a full BD team in place in the US with teams being expanded in key markets in Europe (Exhibit 3).

Exhibit 3: Renewed BD activities

Source: Ergomed

The substantial growth in the order book in FY19 (up 14% from £109m in FY18 to £124.1m in FY19), highlights Ergomed's success in the investment in its BD teams. Recent key wins include a £2.5m contract (over three years) for a full-service global Phase II in a rare disease for a West Coast biotech (new client), a £4.8m contract (over three years) for pharmacovigilance automation for a large Asia-Pacific pharma (existing client) and a £17m contract for a global full-service Phase III in 1,400 patients with a European biotech.

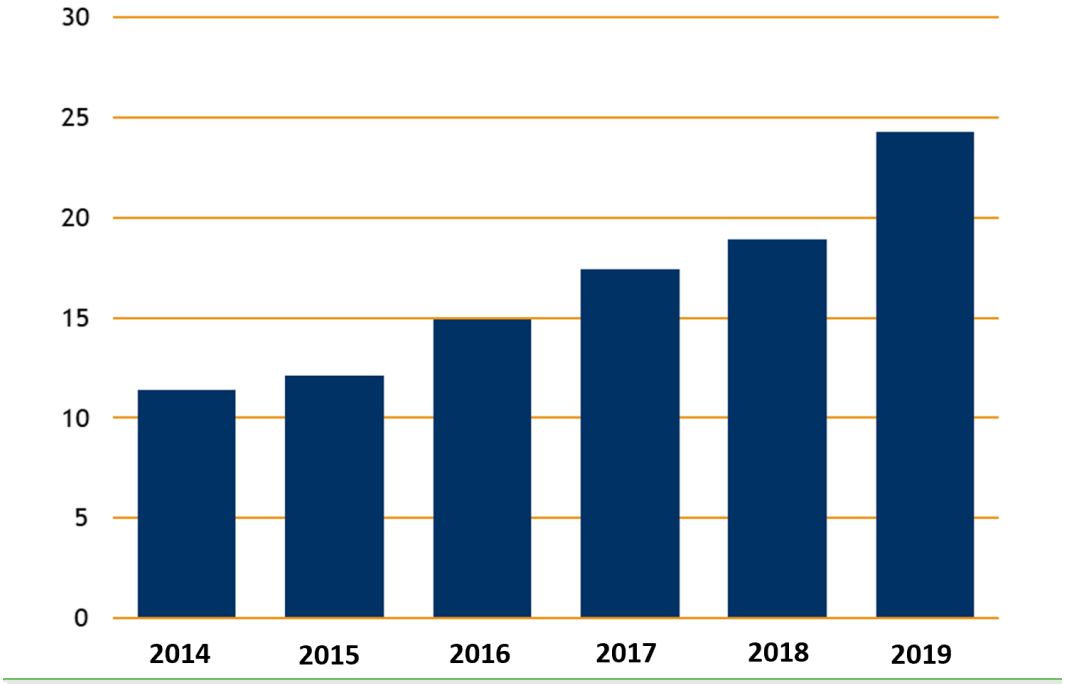
With the completion of its expanded US BD team, the addition of the BD team from the recently acquired Ashfield and key hires in Europe now complete, we expect that Ergomed will continue to be able to successfully attract new business and increase its win rate and book-to-bill ratio.

Rare diseases: Regulatory incentives match innovation

Ergomed's focus on rare diseases has enabled it to drive internal expertise and market a unique capability to orphan drug developers. Rare disease trials are complex and many orphan drug developers lack the clinical expertise to take a product into what is often a difficult patient population. Low patient numbers can result in lengthy enrolment times. Combine this with fewer clinicians who are likely to be familiar with the particular rare disease, complex inclusion criteria and often very sick patients, and a rare disease clinical trial can be difficult to run if a CRO does not have the required expertise, experience or geographical coverage. As a result, CROs such as Ergomed that have the required capabilities also have a competitive advantage and may be able to charge a premium to less-capable competitors.

With a focus on rare diseases, Ergomed has grown its expert understanding of how to undertake orphan drug trials (through the acquisition of PSR and growth of its internal team), a global network of specialist investigator centres (so enrolment can happen where the biggest needs exist) and an experienced network of contacts that can run trials. In 2017, Ergomed acquired PSR for its expertise in orphan drug development services, for €5.7m. Since the acquisition, Ergomed has been able to drive its CRO revenues and increase its commitment to rare disease trials (Exhibit 4).

Exhibit 4: Ergomed CRO service fee growth



Source: Ergomed

The number of rare disease therapies in development has risen rapidly in the last decade. This has been driven by regulatory incentives that have enabled a faster path to market and lengthy exclusivity periods, in addition to the technology to diagnose the specific cause of a disease and the capabilities to treat it.

Rare disease definitions differ from region to region, but it is typically a disease with a prevalence of no more than five in 10,000. The US defines a rare disease as a disease with no more than 200,000 patients in the US. Approved orphan drugs in the US receive seven years of marketing exclusivity (compared with five years for a new chemical entity for a non-orphan disease), while those in the EU have 10 years of marketing exclusivity (compared with eight for a new chemical entity for a non-orphan disease), as well as an additional two years for completion of a paediatric investigation plan (to test and confirm the drug is appropriate for children).

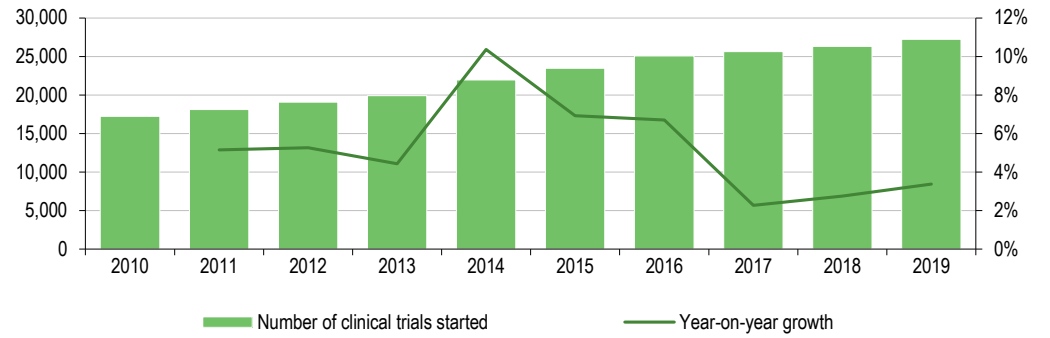
As well as exclusivity periods, governments offer numerous incentives including tax credits, R&D grants, fee waiving and regulatory incentives that include orphan designation, fast-track designation, breakthrough therapy designation and accelerated approval (all FDA) and PRIME (EU).

Profiting from pharma industry innovation

Technology advances, patient-centric clinical trials tailored to personalised medicine, a proliferation of biotech companies globally, blockbuster (>$1bn) drug sales from new immunooncology assets and a sector-wide orphan drug focus have all generated a boom in demand for CRO services.

This innovation in healthcare is driving sales and growth in the number of clinical trials being initiated (Exhibit 5) as biopharma companies continue to invest substantially to remain ahead of competition.

Exhibit 5: Number of clinical trials initiated globally each year



Source: Edison Investment Research, Clinicaltrials.org

Over the last decade this revolution in healthcare has been driven on multiple fronts by:

- An evolving understanding of the role and the importance of the immune system in cancer. Notably the invention of PD-(L)1 immune checkpoint inhibitors has revolutionised treatment in many cancers. They are seen to 'take the brakes off the immune system' and enable a patient's immune cells to recognise a cancer. Keytruda (Merck), the leading PD-L1 inhibitor, is on track to surpass $10bn in sales in 2019. This has caused intense competition in the space, with **record numbers of clinical trials initiated in cancer.**
- Precision medicine. There have been improvements in accuracy and a reduction in the cost of genomic sequencing (it now routinely costs <$1,000 a genome compared to first genome costs of c $3bn) and diagnostics (commercial systems available can detect a range of genomic or protein mutations). This has enabled patients to be treated for the specific driver of their disease rather than as part of a larger, more homogenous group. This is resulting in a **larger number of new clinical trials looking to enrol patients** with only specific disease drivers.
- Innovation and validation of techniques that enable the genetic modification of cells (viral vectors, CRISPR, zinc fingers, mRNA). It is now possible to make single or multiple gene edits with a new wave of drugs being approved (eg Luxturna, Zolgensma). This has proven successful in (often orphan/rare) diseases where single mutations are responsible for the disease. This has enabled **clinical trials to initiate in previously untreated diseases**.
- Increased regulatory incentives. Regulatory bodies over the last decade have enabled the industry to move drugs quickly to the market if they demonstrate substantial clinical efficacy (eg fast-track designation, priority review, breakthrough therapy designation, accelerated approval). As a result, **drug developers are willing to invest substantially to complete clinical trials quickly and effectively**.
- Improvements in classical drug modalities and enabling of combinations. All the top five drugs by sales are antibodies. However, until recently there has been limited innovation in antibody technology beyond selecting new targets. New technologies including antibody drug conjugates, bi/tri-specifics and improvements to affinity and specificity are leading to a new wave of improved therapies (eg Enhertu and Kadcyla). Additionally, improvements in small molecule technology are enabling their development for once undruggable targets. New modalities have brought safer drugs, allowing drugs to be combined to more effectively treat a disease. **Clinical trials focused on new drug combinations have grown substantially** as a result.

The CRO sector: Low drug developer R&D ROIs aid growth

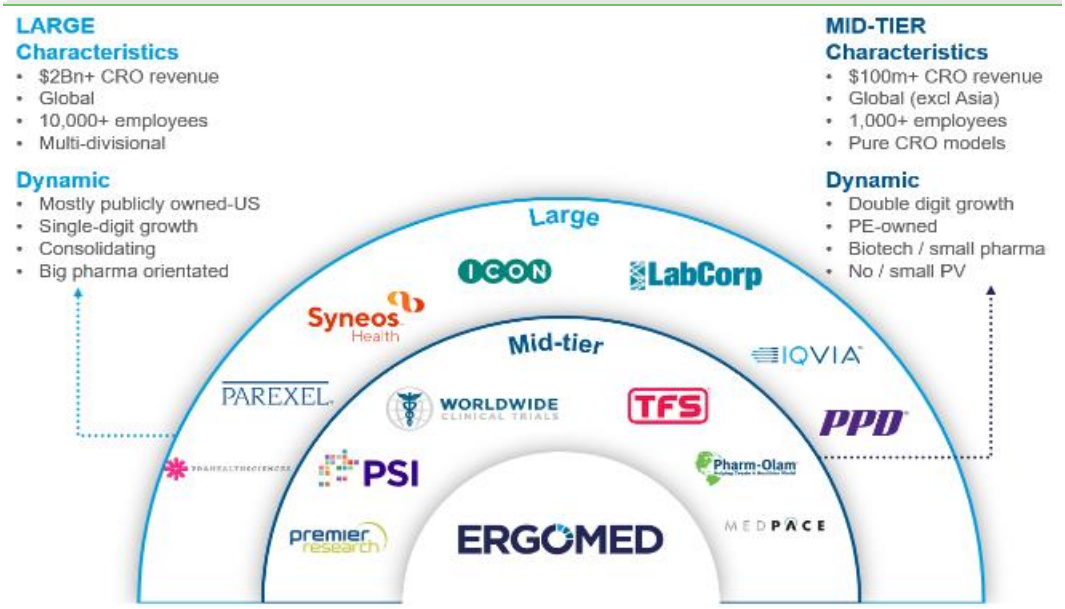
Driven by rising development costs (complexity of drugs, targets, patient populations and trials) and flat success rates (one in 10 drugs to enter human clinical trials will succeed), the R&D return on

investment (ROI) is at historic lows. To counter this, pharmaceutical and biotech companies are increasingly outsourcing non-critical services; clinical trials have been key, enabling the CRO sector to grow to a c $27bn market globally according to Ergomed.

The CRO industry is broadly split into companies that offer pre-clinical services or clinical services. Pre-clinical work is defined as work that involves pre-discovery work (finding new targets and causes of disease), drug discovery (finding a promising lead compound) and pre-clinical research (testing lead compounds in cellular and animal models). The pre-clinical CRO market is dominated by Charles River Laboratories (which was involved in 85% of the drugs approved by the FDA in 2018).

In the clinical CRO sector, companies are broadly focused on delivering human clinical trials through Phase I, II and III, in addition to post-approval studies (Phase IV) and support. As the return on investment for biopharma continues to drop, CROs continue to be attractive as they offer an expert but flexible cost structure. The services provided continue to broaden but typically involve trial management, data analysis and regulatory advice. Multiple large CROs exist, notably Covance, IQVIA, Syneos and Parexel (Exhibit 6).

Exhibit 6: The CRO industry



Source: Ergomed

Sensitivities: Execution is key

Ergomed is reimbursed on a time and materials basis as a services company and not based on study outcome; as such, it is not associated with the usual biotech and drug development risks, including clinical development delays or failures, regulatory risks, competitor successes or partnering setbacks. However, it is subject to business risks that include the loss of key clients (total revenue generated by the top five clients in FY19 was under 25% versus 28% in FY18 and 40% in 2017), changing costs and increased competition. Critically, failure of commercial execution or quality control could adversely affect Ergomed's reputation. Ergomed relies on its reputation; any failure to deliver on contractual obligations with current clients could affect its ability to win new contracts. It is sensitive to pressure around clinical trials, notably around patient enrolment, where ultimate timelines and costs could drastically differ from a proposal if the correct planning is not undertaken. The COVID-19 pandemic could have some impact on clients' clinical trial recruitment; however, so far Ergomed has not been affected by this. Additionally, Ergomed is susceptible to

financial risks that could arise from changes in the market or its operational outlook. Changing foreign exchange rates could adversely affect or benefit cash generation.

Valuation: £186m or 399p/share

We value Ergomed at £186m or 399p/share on an EV/EBITDA multiple based on our forecast FY20 numbers using an average ratio of 11.5x, which is the average multiple of comparative public peers (Exhibit 7) including Syneos Health, PRA Health Sciences, ICON and Medpace. Although these companies are significantly larger than Ergomed, we believe they represent suitable comparators. We use Ergomed's current book-to-bill ratio of approximately 1.22x, historic net order book (+ new contracts – revenue – calculated cancellations) growth and past order book burn rates (a % order book is converted to revenue) as comparators for future order book and revenue forecasts.

Ergomed trades at a discounted FY20e EV/EBITDA of 9.3x value against a current CRO sector average of 10.5x. We believe this discount to peers related to its historic co-development partnership which masked Ergomed's potential. Many CROs are private, so as a result there are limited public comparables. We have included companies with a pure focus on clinical research within the mid-cap range and do not include IQVIA or Labcorp (as they are significantly larger with services that span outside clinical CRO).

Exhibit 7: Comparable companies

	EV ($m)	EV/EBITDA (x)	EV/sales (x)	P/E (x)	P/book (x)
Market consensus forecast/actual FY19					
Syneos Health	6,613	10.25	1.41	12.22	1.35
PRA Health Sciences	5,571	10.45	1.82	13.85	4.17
ICON	6,477	13.09	2.31	18.15	4.14
Medpace	2,343	15.66	2.72	22.71	3.41
Average	**5,251**	**12.36**	**2.06**	**16.73**	**3.27**
IQVIA	29,432	12.26	2.65	15.17	3.10
LabCorp	17,426	8.52	1.51	10.43	1.52
FY20e					
Syneos Health	6,613	9.69	1.35	11.06	1.25
PRA Health Sciences	5,571	9.84	1.72	12.64	3.80
ICON	6,477	12.11	2.16	16.51	4.41
Medpace	2,343	14.30	2.48	21.26	3.19
Average	**5,251**	**11.48**	**1.93**	**15.37**	**3.16**
IQVIA	29,432	11.43	2.49	13.44	3.25
LabCorp	17,426	8.14	1.45	9.92	1.48
FY21e					
Syneos Health	6,613	8.85	1.27	9.77	1.14
PRA Health Sciences	5,571	8.89	1.60	11.20	3.21
ICON	6,477	11.06	2.01	14.74	3.88
Medpace	2,343	12.23	2.17	18.19	2.82
Average	**5,251**	**10.26**	**1.76**	**13.48**	**2.76**
IQVIA	29,432	10.46	2.31	11.66	3.28
LabCorp	17,426	7.83	1.40	9.22	1.37

Source: Refinitiv. Note: Prices at 24 March 2020.

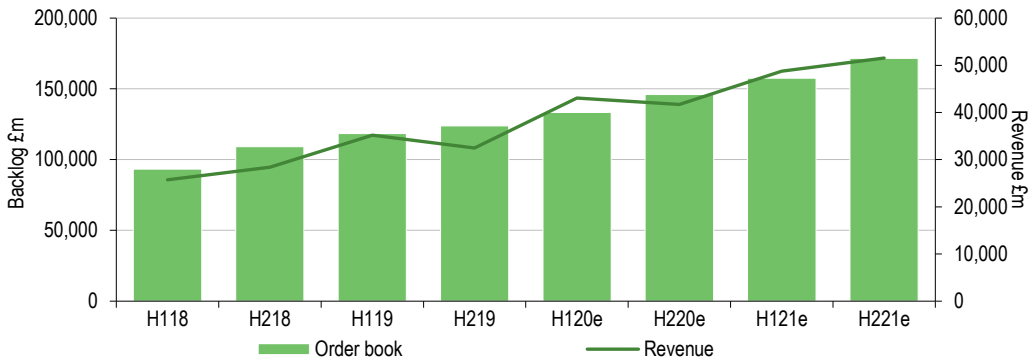
Financials: Cash generative

Ergomed is benefiting from a clear strategic focus (oncology, rare diseases and pharmacovigilance, order book growth and margin control) and strong sector fundamentals (6% pa growth) as shown by its strong organic growth in FY19 (revenue up 26% to £68m).

Driven by a growing order book (FY19: £124.1m) and the accretive acquisition of Ashfield, we forecast sustained revenue growth in FY20 to £84.8m. Our revenue forecasts (Exhibit 8) are driven

by forecast order book growth, revenue consumption and book-to-bill ratios comparable to Ergomed's historical performance. We assume a group book-to-bill ratio of approximately 1.2x.

Exhibit 8: Forecast order book and revenue growth



Source: Ergomed, Edison Investment Research

Although revenues increased substantially, costs remained under control as utilisation rates increased and synergies (with the integration of PSR) improved. FY19 costs of sales came in at £29.8m vs £26.8m in FY18, while SG&A expenses decreased to £23.5m vs £28.2m in FY18 (mainly due to exceptional costs in that year relating to Haemostatix impairment and business reorganisation costs). FY19 gross margin was 43% vs 36% in FY18.

We forecast FY20 adjusted EBITDA of £14.9m (adjusted EBITDA of £12.5m in FY19), as the transition from a co-development model to a services model benefits revenue generation at higher gross margin levels. We forecast this trend to continue on an adjusted EBITDA basis (forecast FY21: £17.6m). We forecast a FY20 net profit of £10.2m (versus £5.6m in FY19). Cash at 31 December 2019 was £14.3m.

Margins comparable across divisions

Gross margins for the CRO and PrimeVigilance divisions were 34.4% and 51.5%, respectively, in FY19. However, the CRO division's gross margin was affected by high pass-through costs, which once stripped out reveal margins of 46.5% for CRO and 52.1% for the PrimeVigilance division (Exhibit 9).

Exhibit 9: Net service revenue and gross margins (less pass-through costs)

	2017	2018	2019
CRO			
CRO net service (£m)	17.4	19.7	24.3
COGS (£m)	10.6	12.2	13.0
Gross margin (£m)	6.8	7.5	11.3
Gross margin %	39.1%	38.1%	46.5%
PrimeVigilance			
PrimeVigilance net service (£m)	22.3	27.1	34.9
COGS (£m)	11.8	14.6	16.7
Gross margin (£m)	10.5	12.5	18.2
Gross margin %	47.1%	46.1%	52.1%

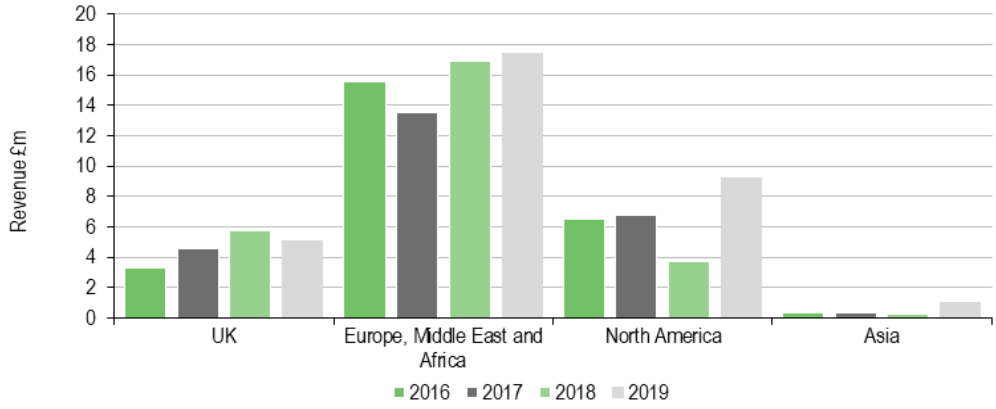
Source: Edison Investment Research, Ergomed

CRO: Co-development cessation benefits margins

We forecast CRO revenue (including pass-through costs) of £35.2m in FY20 and £42.3m in FY20. In the CRO business, the strong growth in revenue in FY19 was driven by the ongoing implementation of studies from the existing order book and by significant new contract wins in the period. The acquisition of PSR (an orphan drug-focused CRO) in 2017 continues to demonstrate benefits with around half of all CRO revenue and new awards in FY19 focused on orphan diseases.

Adjusted gross margin (stripped of reimbursement costs) demonstrated substantial growth in FY19 (52.2%) from FY18 (38.8%) as result of the complete exit from the co-development strategy and using billable staff on fee-paying clients. We forecast a maintained margin; however, the utilisation rate of staff is an area of increasing focus and improvements to this margin could be achieved (if utilisation rates are able to go higher) or it could be lower (if additional staff need to be hired at lower utilisation rates). Historically the company's strength has been in Europe where it has a significant presence and generates most of its revenue (Exhibit 10). However, it is noteworthy that the highest level of growth by geography was in North America, where revenue increased by 77% over FY18, underlining Ergomed's commitment to build its business rapidly (as demonstrated by the recent Ashfield Pharmacovigilance acquisition in January 2020) in the largest and most dynamic global pharmaceutical market.

Exhibit 10: CRO revenues by geography



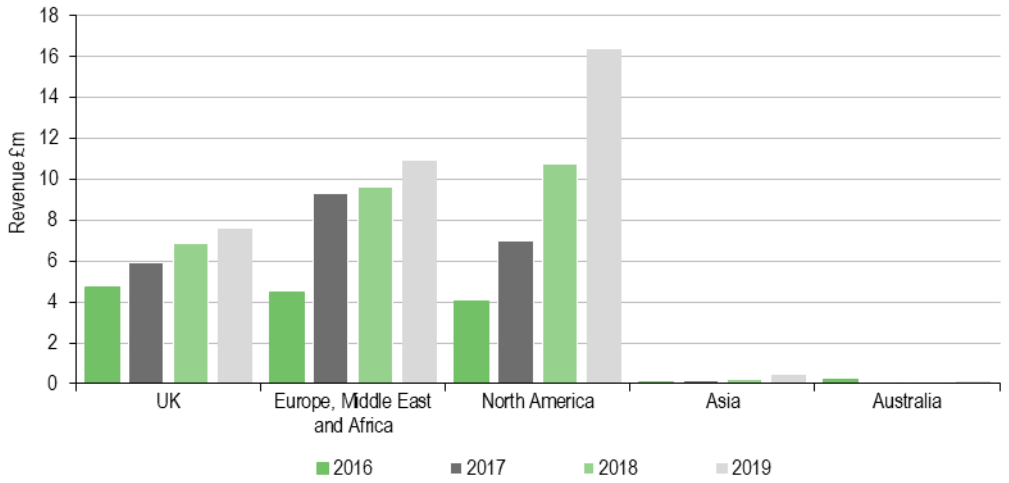
Source: Ergomed

PrimeVigilance: Customer retention drives order book

Strong customer retention in addition to new clients continues to drive growth in PrimeVigilance. The US remains PrimeVigilance's key market (Exhibit 11) and will be bolstered by the recent acquisition of Ashfield Pharmacovigilance Inc. New contracts in the period came from across its pharmacovigilance, medical information and QPPV network services.

Adjusted gross margin (stripped of reimbursement costs) increased slightly in FY19 (52.2%) from FY18 (46.1%). We forecast PrimeVigilance revenue (including pass through costs) of £49.6m in FY20 and £58.0m in FY21.

Exhibit 11: PrimeVigilance revenues by geography

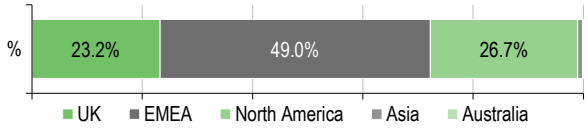


Source: Ergomed

Exhibit 12: Financial summary

Accounts: IFRS, year end 31 December (£000s)	2017A	2018A	2019A	2020E	2021E
INCOME STATEMENT					
Total revenues	47,624	54,112	68,255	84,779	100,288
Cost of sales	(22,398)	(26,788)	(29,790)	(39,401)	(47,679)
Reimbursable expenses	(7,609)	(8,070)	(8,940)	(8,200)	(9,292)
Gross profit	17,617	19,254	29,525	37,177	43,318
Gross margin %	37%	36%	43%	44%	43%
SG&A (expenses)	(19,784)	(28,152)	(23,513)	(24,169)	(27,620)
R&D costs	(2,689)	(1,578)	(545)	(485)	(495)
Other income/(expense)	952	30	51	0	0
Exceptionals and adjustments	5,062	10,165	3,265	957	957
Reported EBITDA	(2,278)	(7,912)	9,230	13,973	16,662
Depreciation and amortisation	1,626	2,534	3,712	1,451	1,460
Reported EBIT	(3,904)	(10,446)	5,518	12,522	15,203
Finance income/(expense)	(543)	(599)	(245)	(205)	(156)
Other income/(expense)	0	277	(286)	0	0
Reported PBT	(4,447)	(10,768)	4,987	12,318	15,046
Income tax expense (includes exceptionals)	(57)	(89)	583	(2,139)	(3,009)
Reported net income	(4,504)	(8,980)	5,570	10,178	12,037
Basic average number of shares, m	41.1	44.7	46.6	46.6	46.6
Basic EPS (p)	(11.0)	(20.1)	12.0	21.8	25.8
Adjusted EBITDA	2,784	2,253	12,495	14,930	17,619
Adjusted EBIT	1,158	(281)	8,783	13,479	16,160
Adjusted PBT	1,782	960	8,637	13,725	16,463
Adjusted EPS (p)	4.2	1.9	19.8	24.9	28.9
Adjusted diluted EPS (p)	4.2	1.9	19.8	24.9	28.9
Order book	88,200	109,200	125,000	146,068	171,527
BALANCE SHEET					
Property, plant and equipment	1,078	1,344	1,110	1,100	1,090
Right-of-use assets	-	-	5,171	5,171	5,171
Goodwill	15,269	13,659	13,380	21,080	21,080
Intangible assets	20,229	3,740	2,755	2,304	1,845
Other non-current assets	2,367	2,646	2,616	2,666	2,716
Total non-current assets	38,943	21,389	25,032	32,321	31,902
Cash and equivalents	3,218	5,189	14,259	31,530	43,257
Trade and other receivables	16,807	16,429	14,359	18,439	22,789
Other current assets	2,945	3,857	5,665	5,665	5,665
Total current assets	22,970	25,475	34,283	55,635	71,711
Lease liabilities	0	0	3,716	3,716	3,716
Long term debt				15,000	15,000
Other non-current liabilities	13,201	1,314	635	635	635
Total non-current liabilities	13,207	1,314	4,351	19,351	19,351
Trade and other payables	10,717	10,989	10,373	13,836	17,455
Lease liabilities	0	0	1,718	1,718	1,718
Other current liabilities	3,134	6,192	6,053	6,053	6,053
Total current liabilities	13,863	17,187	18,144	21,607	25,226
Equity attributable to company	34,843	28,363	36,820	46,998	59,035
CASH FLOW STATEMENT					
Profit before tax	(4,447)	(10,768)	4,987	12,318	15,046
Cash from operations (CFO)	425	898	11,664	13,101	15,726
Capex	(1,425)	(1,587)	(996)	(1,000)	(1,000)
Acquisitions & disposals net	(1,932)	(398)	(107)	(7,690)	10
Other investing activities	(559)	(751)	(930)	0	0
Cash used in investing activities (CFIA)	(3,916)	(2,736)	(2,831)	(8,690)	(990)
Net proceeds from issue of shares	2,676	3,790	1,427	0	0
Movements in debt	10	(12)	(1,677)	15,000	0
Other financing activities	(2)	(4)	0	0	0
Cash from financing activities (CFF)	2,684	3,774	(250)	15,000	0
Increase/(decrease) in cash and equivalents	0	0	0	0	0
Currency translation differences and other	(44)	(111)	363	0	0
Cash and equivalents at start of period	4,424	3,218	5,189	14,259	31,530
Cash and equivalents at end of period	3,218	5,189	14,259	31,530	43,257
Net (debt) cash	3,200	5,183	14,259	16,530	28,257

Source: Ergomed accounts, Edison Investment Research

Contact details	Revenue by geography
1 Occam Court The Surrey Research Park Guildford, Surrey, GU2 7HJ United Kingdom +44 (0)1483 503 205 www.ergomedplc.com	

Management team

Executive Chairman: Dr Miroslav Reljanović

Miro is a medical doctor and a board-certified neurologist who founded Ergomed in 1997 and co-founded PrimeVigilance in 2008. Miro led Ergomed through its IPO onto the AIM market of the London Stock Exchange in July 2014 and the subsequent completion of five acquisitions and a secondary offering. Miro is a director of Asarina Pharma (listed on the Nasdaq First North exchange) and Modus Therapeutics Holding, both Swedish-incorporated companies in which Ergomed plc has an equity stake through co-development arrangements. Miro brings to the board his in-depth experience in clinical development and the operational execution of drug development, as well as a detailed knowledge of the group and its operations.

Chief Financial Officer: Richard Barfield

Richard joined Ergomed as Chief Financial Officer in June 2019. Since qualifying as a chartered accountant, Richard has gained more than 25 years' experience at Chief Financial Officer level in the healthcare, technology and business services sectors in US multinational companies as well as in UK-listed and PE-backed businesses. Richard has proven experience within the contract research sector, having most recently been Chief Financial Officer at Chiltern International, a leading global mid-tier private CRO, from July 2013 to March 2018. During his five years at Chiltern, Richard was instrumental in transforming the corporate finance and strategy of the business, enabling it to grow revenues from $160m to $560m and deliver significant returns to its investors.

Chief Operating Officer: Lewis Cameron

Lewis joined Ergomed in January 2020. He was previously Head of Global Clinical Development at Covance (CRO division of LabCorp) between 2017 and 2019 where they achieved $4.2bn in revenue in 2018. Prior to that, he was Executive Vice President of Oncology and General Manager for CEE and APAC regions at Chiltern International from 2014 to 2017. Previous roles include CEO of biotech Avillion LLP and CEO of Clearstone Central laboratories.

Chief Commercial Officer: Roy Ovel

Roy has a wealth of experience with more than 30 years in international business development with some of the leading global CROs. He has experience of working globally with large pharma across the drug development continuum. His reputation as a leader with strong commercial acumen focused on working with customers to meet their needs is key in an environment where customers' demands on pharmaceutical and biotech continues to grow. Roy has worked for both small, local CROs and larger CROs like ICON, TFS and Worldwide Clinical Trials.

Principal shareholders	(%)
Miroslav Reljanović	22.6
BlackRock	10.4
Hardwood Capital	9.8
Slater Investments	7.5
GVQ Investment Management	5.1
Gresham House Asset Management	4.9
Octopus Investments	4.1
Premier Miton Investors	3.4
Rathbones	3.3
Danske Bank Asset Management	3.2

Companies named in this report

ICON (ICLR), IQVIA (IQV), Labcorp (LH), Medpace (MEDP), PRA HealthSceinces (PRAH), Syneos Health (SYNH).

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