

ERGOMED

TRANSFORMING DRUG DEVELOPMENT

Preliminary Results 2018
10 April 2019



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OUR VISION

GLOBAL LEADERSHIP

In **Pharmacovigilance**
and **Orphan Drug Development**



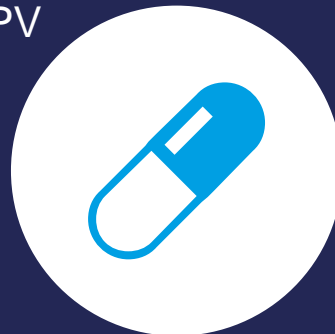
ERGOMED: 2018 SCORECARD

**Focused on
pharmacovigilance & orphan
drug development**

Service fee growth of 18% driven by PV
growth 23%

**Significant 2H18 turnaround
in profitability underlines
operational improvements**

EBITDA (adj.) pre-R&D in 2H18 of
£4.2m vs
£0.5m in 1H18



**Orphan drug strategy
gaining traction; overlap with
PV offers cross-selling
potential**

37% of CRO new business won in
2018 was orphan drug related

**2019 growth targets
underpinned**

Contracted backlog of £109m
at 31 Dec 2018

ADOPTION OF ACCOUNTING STANDARDS

IFRS 15 – REVENUES – ADOPTION 1 JANUARY 2018

	£m	IAS 18 Reporting	IFRS 15 Impact	As adjusted	
ADAPTION IMPACT	BACKLOG At 31 Dec 2017	Backlog	88.2	2.2	90.4
	BALANCE SHEET At 31 Dec 2018	Accrued Income	2.4	0.4	2.8
		Deferred Income	(1.0)	(2.6)	(3.6)
		Retained Earnings	(0.7)	(2.2)	(2.9)
REPORTING IMPACT	PROFIT & LOSS 2018 Year	Total Revenue	54.9	(0.8)	54.1
		Gross Profit	20.1	(0.8)	19.3
		Loss after Tax	(8.1)	(0.9)	(9.0)
		Adjusted EBITDA	3.1	(0.8)	2.3

Cumulative effect transition impact is to increase backlog

Cumulative effect transition impact is to adjust accrued / deferred income and reduce retained earnings

On the portfolio of 73 projects in 2018 the impact is to reduce revenue on profitability measures

IFRS 16 – LEASES – ADOPTION 1 JANUARY 2019

Balance Sheet	Profit & Loss	EBITDA
<ul style="list-style-type: none"> 1 January 2019 implementation Right-of-Use Asset ~ £7m Lease Liability ~ £7m No prior period restatement 	<ul style="list-style-type: none"> Neutral over term of lease Minor timing differences through mortgage principal amortisation over lease term 	<ul style="list-style-type: none"> Lease expenses removed from operating profit Replaced by depreciation and interest – excluded from EBITDA Expect ~ £1.7m EBITDA improvement in 2019

2018 PRELIMS: FINANCIAL HIGHLIGHTS

Growth in-line with expectations

Total revenue of **£54.1m**
(£54.9m equiv.)
up 15% equiv.
(2017: £47.6m)

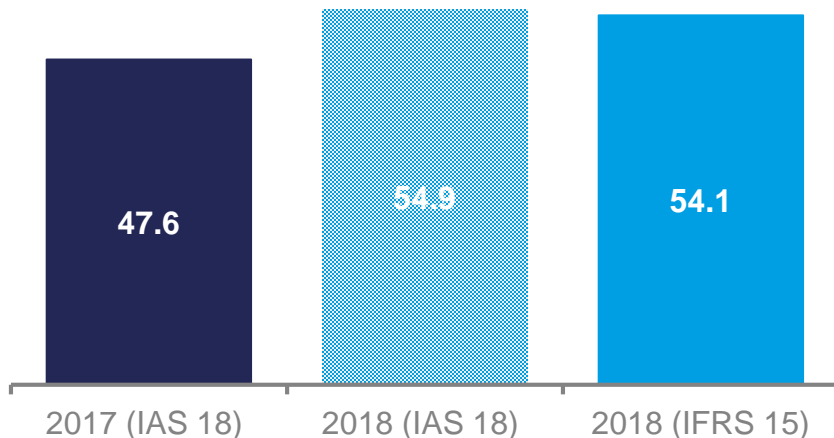
Gross profit was **£19.3m**
(£20.1m equiv.)
up 14% equiv.
(2017: £17.6m)

PV business
Strong performance with **23% growth YOY**

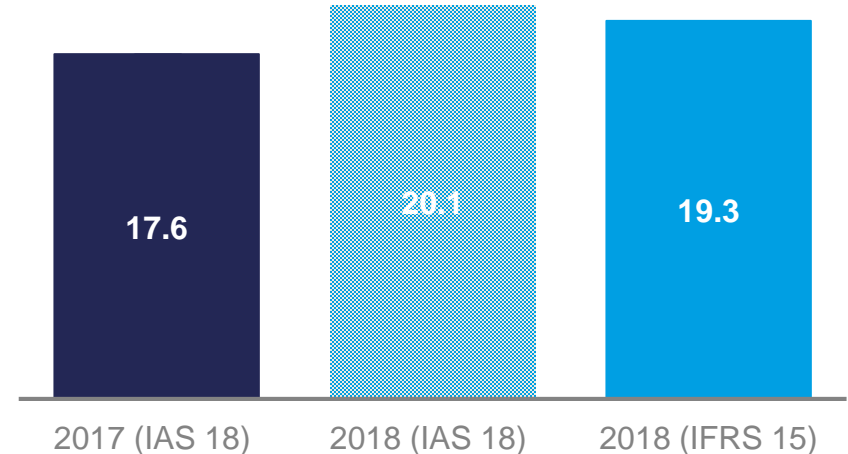
CRO business
Orphan drug development gaining traction
now over 32% of CRO revenue

Results for 2018 include IFRS 15 impact. 2017 results do not, as no restatement is required under the chosen adoption method. % comparisons are made between IAS18 numbers.

Revenue (£m)



Gross profit (£m)



2018 PRELIMS: FINANCIAL HIGHLIGHTS

Strong contracted backlog and re-aligned cost base

Adjusted EBITDA of **£2.3 m** (£3.1m equiv.) **up 11% equiv.** (2017: £2.8m)

Significant turnaround in profitability in 2H18; adjusted EBITDA of **£2.3 million** (1H18: £(0.0)m)

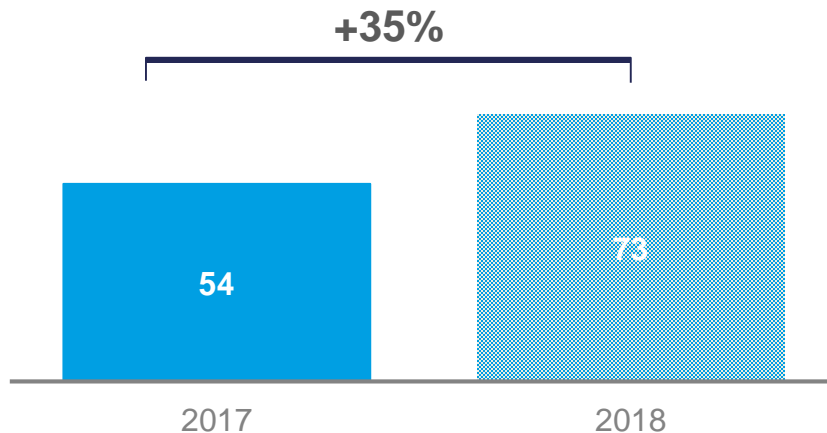
Cost reduction programme benefits of approx. **£1.2m** for 2018

£109m of contracted backlog at 1 January 2019 (£106m equiv.) (1 Jan. 2018: £88m)

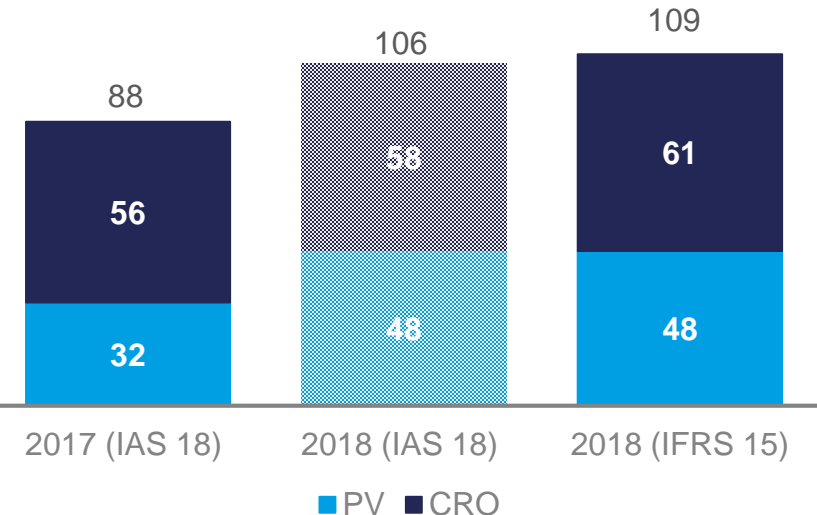
£73m new contracts won in 2018 (2017: £54m)

Results for 2018 include IFRS 15 impact.. 2017 results do not, as no restatement is required under the chosen adoption method. % comparisons are made between IAS18 numbers.

New business won (£m)



Contracted backlog equivalent (£m)



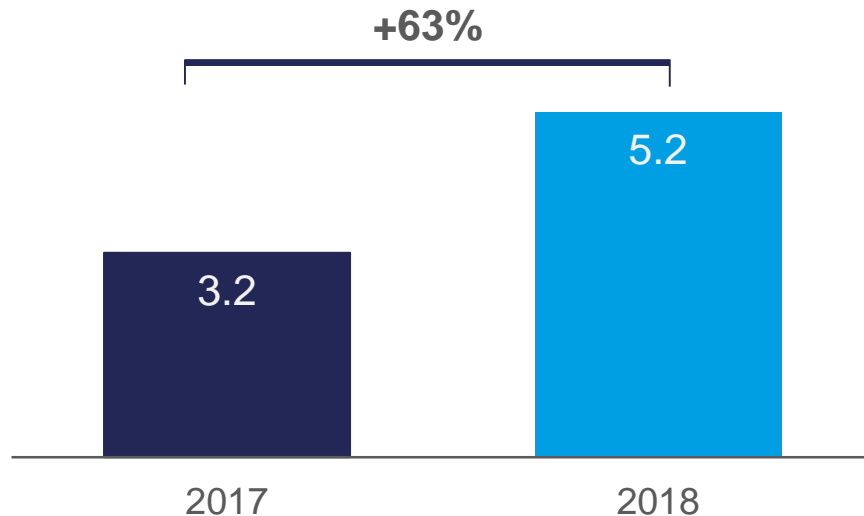
2018 PRELIMS: FINANCIAL HIGHLIGHTS

Improved cash position

Cash and cash equivalents at 31 Dec 2018
£5.2m
(2017: £3.2m)

➤ Comfortable base for investing and financing activities

Cash at bank (£m)



Improved cash position

Receivables

- Successful management of CEL SCI receivable risk
- DSO at year end was 78 days, 79 equivalent (2017:97 days)

Financing Activities

- £3.7m net proceeds from the issue of 2,029,971 shares in February 2018

Investing Activities

- Paid £0.7m in respect of PharmInvent earn-out
- Further £0.5m systems upgrade

GLOBAL PLATFORM – FULL SERVICE

16
offices worldwide

700+
employees

300+
Contractors

Clinical trials
in 53 countries

Supporting products in
100+ countries



ERGOMED

\$70m+
PV / CRO revenue

Combined PV /
specialized CRO

~20%
growth

Public / AIM-
listed
(LSE: ERGO)

Biotech / small
pharma

EXPLOITING POTENTIAL IN THE CRO MARKET

Ergomed - mid-tier specialist CRO within reach

LARGE

Characteristics

- \$2Bn+ CRO revenue
- Global
- 10,000+ employees
- Multi-divisional

Dynamic

- Mostly publicly owned-US
- Single-digit growth
- Consolidating
- Big pharma orientated

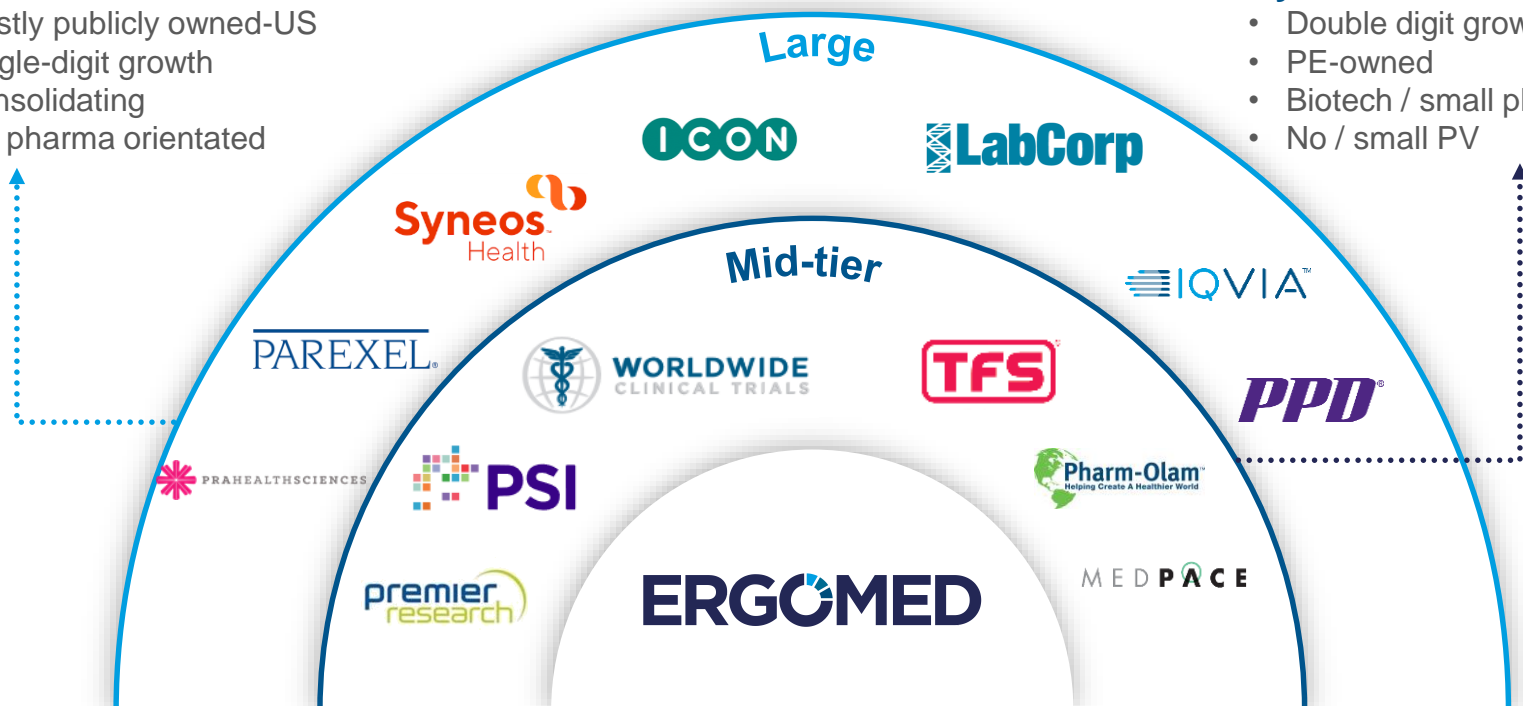
MID-TIER

Characteristics

- \$100m+ CRO revenue
- Global (excl Asia)
- 1,000+ employees
- Pure CRO models

Dynamic

- Double digit growth
- PE-owned
- Biotech / small pharma
- No / small PV



PV & MEDICAL INFORMATION SERVICES

Business enabler for biotech and pharma



**Pharmaco-
vigilance market**

\$8bn+

By 2024

50%

contract outsourcing by
2024

18%

PV industry growth

ADRs ↑

Exponential growth of
data in the system,
including adverse drug
reactions

PV:

Ensuring drugs get on the market quicker & stay there, even if benefit-risk profile is challenged by regulators. Automation accelerated growth.

Medical Information:

Multi-lingual call centres for enquiries of healthcare professionals, receipt of safety information and product quality complaints, other customer-specific services

ESSENTIAL PHARMACOVIGILANCE PROCESSES ALL COVERED BY PRIMEVIGILANCE



Global Market Insights, Inc.; March 15, 2018

PHARMACOVIGILANCE (PV) SERVICES

Critical business enabler in both developed and emerging markets



£27.5 m

Revenue in 2018

450+

Employees

>23%

growth in sales,
majority new business
won

130+

Customers

Services marketed in

100+

countries

Pharmacovigilance

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects, or any other drug related problem.
(WHO, 2002)

Essential	Intermediate	Premium
Case processing	Signal management	Pharmaco-epidemiology
Aggregate reports	Risk management	Additional risk minimisation
PSMF + SOPs + business continuity	EU QPPV Local QPPVs	PV referral procedures
Internal audits	External audits and inspections	Strategic consultancy

Expertise / experience

Technology / automation

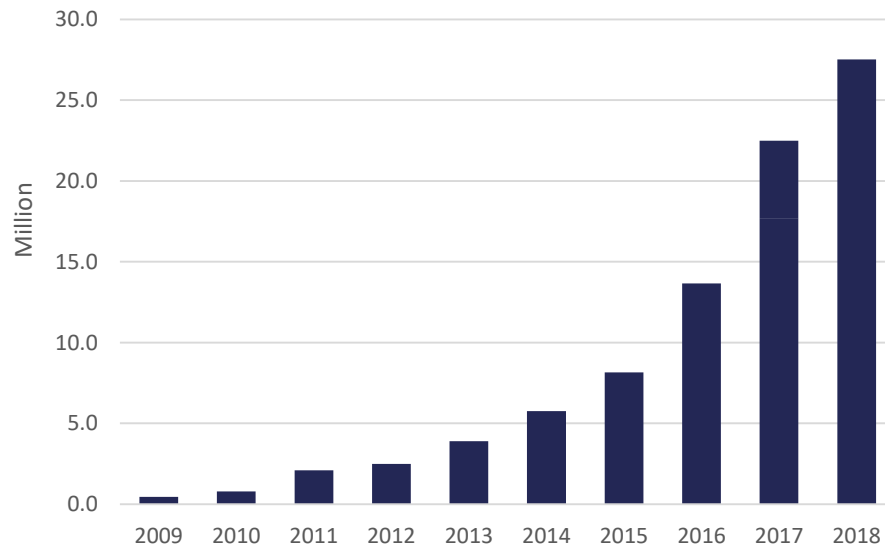
PHARMACOVIGILANCE (PV) SERVICES

Reinforcing our position in orphan drug development services.



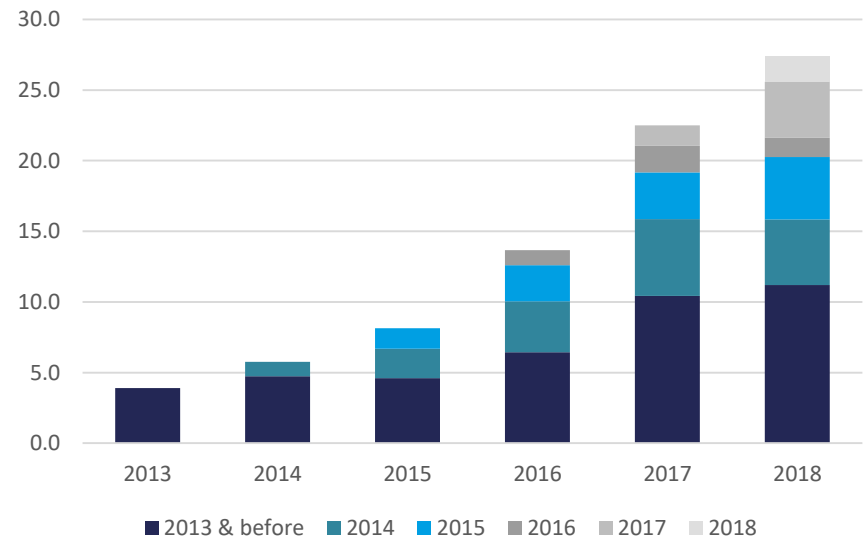
Consistent growth

Revenues (£m)



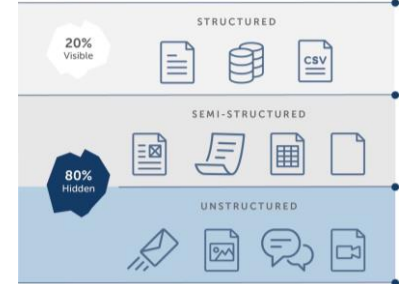
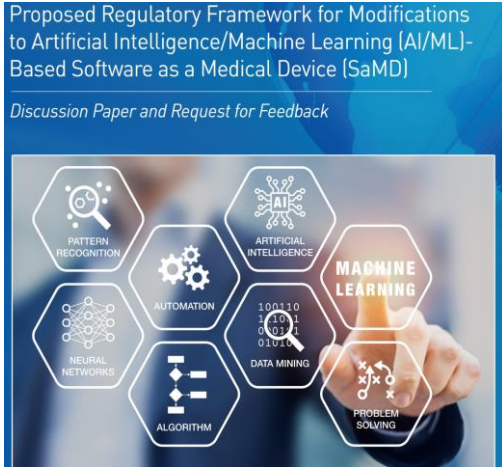
Good client retention

Revenues by customer cohort (£m)



DIGITAL TRANSFORMATION

Validated RPA platform, 9 automation solutions in use, 8 under validation



Basic Process Automation

- Automates a workflow that involves multiple roles
- Continuous Metrics Collection
- Reporting and Dashboards

Robotic Process Automation

- Reduces or Eliminates a Manual Task

Cognitive Automation

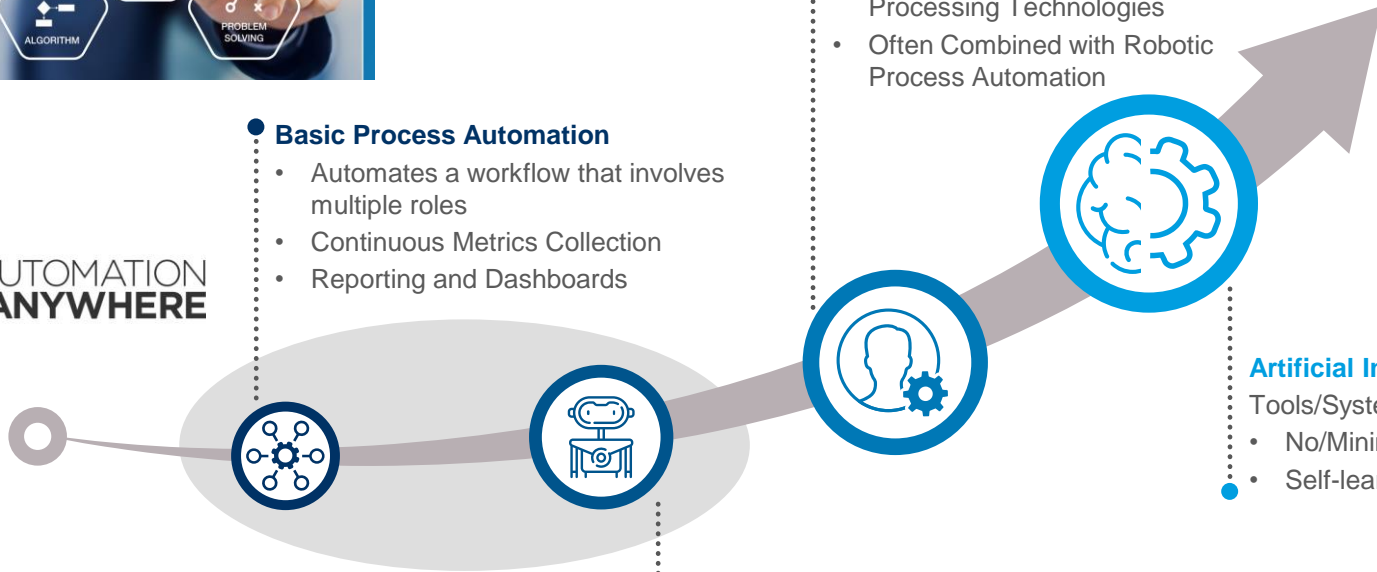
Tools/Systems that:

- Engage in Human Interaction
- Leverage Natural Language Processing Technologies
- Often Combined with Robotic Process Automation

Artificial Intelligence

Tools/Systems that:

- No/Minimal Human Interaction
- Self-learns through experience



CRO DIGITAL TRANSFORMATION

Leveraging opportunities from digitalization in CRO services

End-to-end Evidence
Management

Advanced Data Analytics

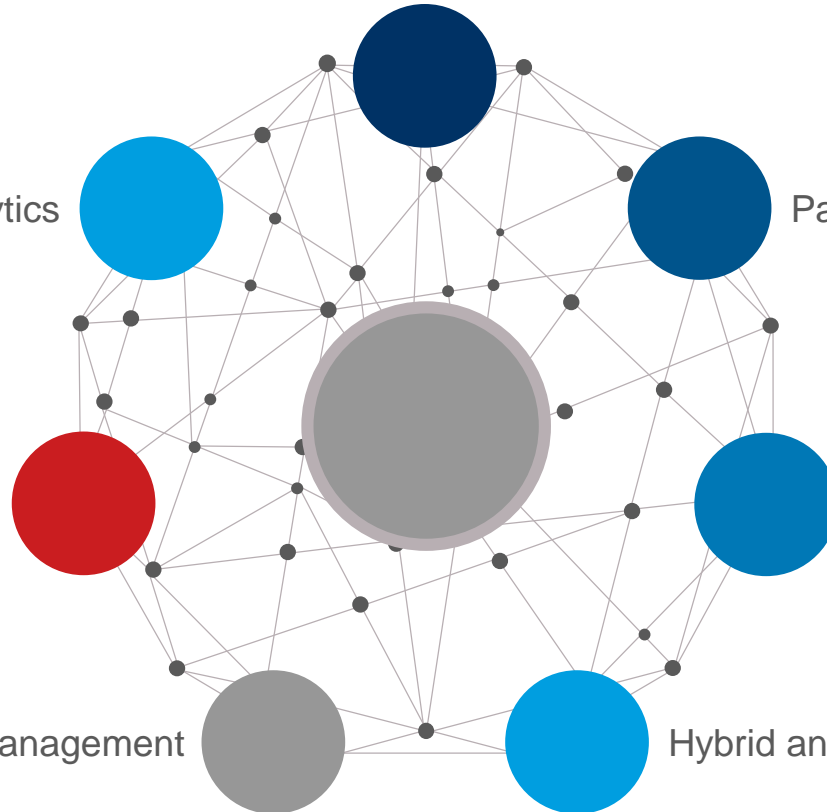
Patient-Centric RWE Platform

Patient-Sourced Data and
Outcomes

Integrated Wearables

Predictive Risk Management

Hybrid and Virtual Trial Designs



CLINICAL RESEARCH SERVICES

Efficient management and control of complex trial protocols

In its **Clinical Research Services** division, Ergomed undertakes on behalf of our clients all facets of clinical trial management and execution from Phase I to IV.

£26.6 m

Revenue in 2018

111

Active studies

59

Active clients

300+

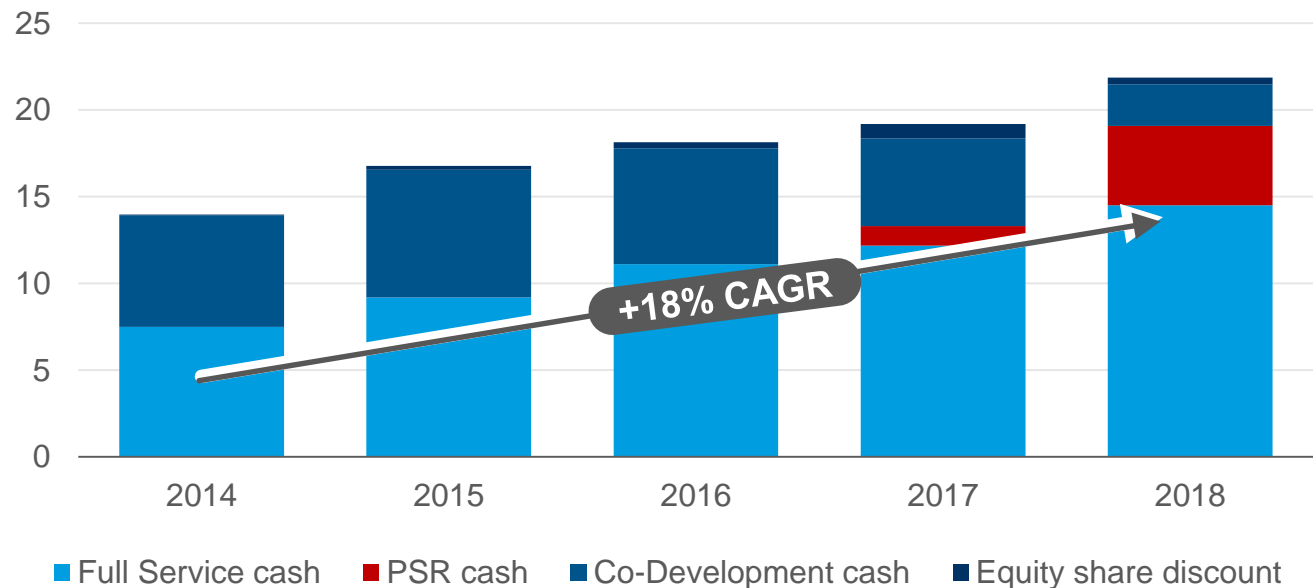
Employees and consultants

Clinical trials in

53

countries

Ergomed CRO – Service Fee (€m)



The underlying CRO revenue has been growing at 18% CAGR over the past 5 years, excluding revenue attached to Co-Development projects and acquisitions

CLINICAL RESEARCH SERVICES

Focus: global leadership in Orphan Drug development

Orphan Drug trials are complicated by the nature and types of therapy and **patient recruitment**.

Specialist knowledge combined with tailored recruitment and **site management** required for optimal outcomes.

ORPHAN DRUG MARKET

21%
of all prescription

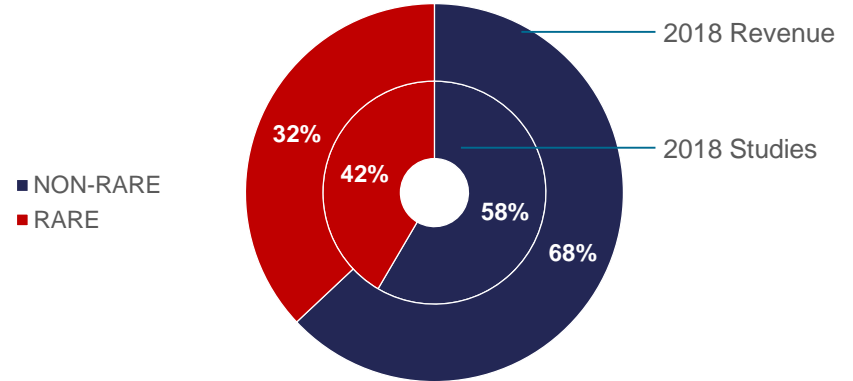
11%
p.a. growth

\$200bn
by 2020

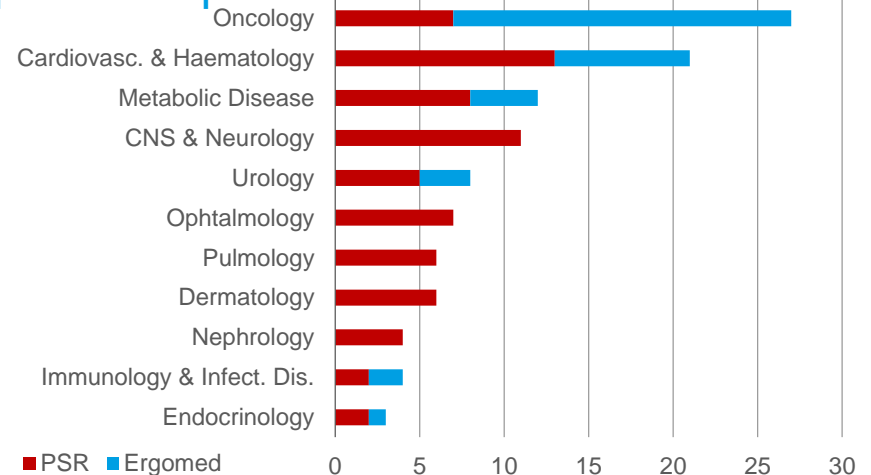
30m
people suffer from orphan disease

GROWTH DRIVERS

- ✓ Personalised medicine
- ✓ Regulatory framework
- ✓ Speed to market
- ✓ Exclusivity
- ✓ Pricing



Full Rare Disease Experience per Therapeutic Area



DRUG DEVELOPMENT UPDATE

Co-Development pipeline continues to offer upside potential as programmes progress

PROGRAMME

Modus

Sevapurin
Sickle Cell Disease



ASARINA
PHARMA

Sepranolone /
PMDD



CEL·SCI

Multikine
Head and neck
cancer



STATUS UPDATE

- Phase II recruitment completed in January 2019
- Results expected in May 2019

- Recent IPO on NASDAQ First North exchange – Ergomed holding valued at £0.9 million
- Phase II results expected before end of 2019

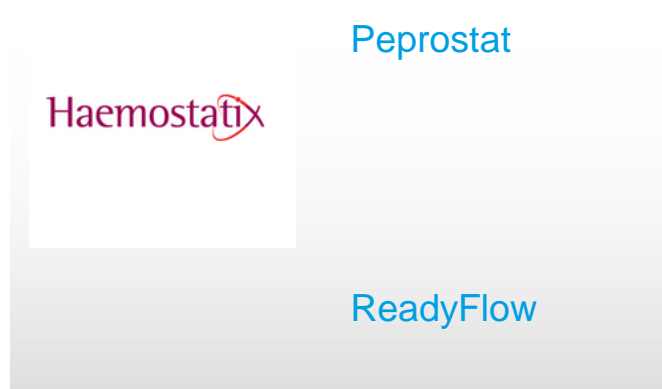
- Continuing Ergomed contribution in 2019 until trial completion
- Phase III expected to finish 1H19

> In line with focus on services, no new co-development partnerships signed during 2018

HAEMOSTATIX

Protecting intellectual property whilst maintaining readiness for Phase III

STATUS UPDATE



- > • Phase III ready - all necessary stability studies and preparation for Phase III drug production completed and prepared
- Continuous incremental investments during 2018 to protect IP and maintain readiness for Phase III trials
- Appointment of external advisers to find a partner/partners to fund Phase III trials and manufacturing scale-up and prepare for commercial launch
- > • The experimental formulation of the follow-on product, ReadyFlow, did not yet produce the desired results and will require further development work.

Haemostatix impairment

- Negotiation for Haemostatix deal not sufficiently advanced to support current carrying values leading to impairment of net assets
- Haemostatix assets fully impaired in line with continued focus on services businesses and ongoing partnering discussions
- As a consequence of this impairment, certain onerous contract costs committed as of 31 December 2018 amounting to £0.2 million
- Upside potential in case of licensing deal or partnership

ABBREVIATED PROFIT & LOSS ACCOUNT

Figures in £ millions, unless otherwise stated	31 December 2018 IFRS 15 basis	31 December 2018 IAS 18 basis	31 Dec 2017 IAS 18 basis as reported
Total Revenue	54.1	54.9	47.6
Cost of Sales & Reimbursable	(34.8)	(34.8)	(30.0)
Gross Profit	19.3	20.1	17.6
Gross Margin %	36%	37%	37%
Selling, General & Administrative	(16.7)	(16.7)	(13.6)
Research & Development	(1.6)	(1.6)	(2.7)
Exceptional & Other Items	(11.4)	(11.4)	(5.2)
Operating Loss	(10.4)	(9.6)	(3.9)
Depreciation/Amortisation	2.5	2.5	1.6
Exceptional & Other Items	10.2	10.2	5.1
Adjusted EBITDA	2.3	3.1	2.8

Principal movements in the year:

Revenue	Revenue growth of 15% (on a comparable basis) driven by 23% growth in PV revenues, complemented by 9% growth from Clinical Research Organisation Services
Selling, General and Administrative (excluding exceptional and other items)	Increase driven by £0.6m of additional overhead in acquisitions, £0.5m recruitment costs, £0.7m increase in depreciation of internally generated software, £0.5m in increased premises costs across the group and £1.4m increase in support functions, offset by a £0.6 million movement in foreign exchange
Exceptional & Other Items	Includes Haemostatix impairment of £18.2m, offset by the release of deferred consideration for Haemostatix of £11.6m, cost-reduction programme of £0.7m

ABBREVIATED CASHFLOW

Figures in £ millions, unless otherwise stated	31 December 2018	31 Dec 2017
Adjusted EBITDA	2.3	2.8
Adjustments	(3.9)	(2.7)
Changes in working capital	2.5	0.4
Taxation received/(paid)	0.1	(0.4)
Net cash inflow from operating activities	1.0	0.1
Translation	(0.1)	-
Investing activities	(2.7)	(3.9)
Financing activities	3.8	2.7
Net cash generated in the period	2.0	(1.1)
Cash and cash equivalents at year end	5.2	3.2

Principal movements in the year:	
Adjustments	Equity investments received in exchange for services £(1.1)m, Restructuring costs £(1.7)m, Other provisions £(0.2)m, Acquisition-related contingent consideration £(1.0)m, Other £0.1m
Changes in Working Capital	Reduction in accounts receivable as a result of the Cel-Sci share-sales
Investing Activities	Tangible fixed assets of £0.8m, intangible fixed assets (software under development) of £0.8m, PharmInvent earn-out cash payments of £0.7m, and Net cash flows on acquisitions of £0.4m
Financing Activities	Share placing in February 2018 net of expenses

ABBREVIATED BALANCE SHEET 31 DECEMBER 2018

Figures in £ millions, unless otherwise stated	31 December 2018 IFRS 15 basis	31 December 2018 IAS 18 basis	31 Dec 2017 IAS 18 basis as reported
Non-current Assets	21.4	21.4	38.9
Current Assets	25.5	24.8	23.0
Current Liabilities	(17.2)	(13.4)	(13.9)
Non-current Liabilities	(1.3)	(1.3)	(13.2)
Total Net Assets	28.4	31.5	34.8
Total Equity	28.4	31.5	34.8

Principal movements in the year:

Non-current Assets	A decrease in goodwill and intangibles of £1.6 million and £16.5 million respectively, and deferred taxes of £2.8 million, primarily due to the impairment of the Haemostatix assets
Current Assets	An increase in accrued income of £1.4 million and an increase in deferred revenue of £4.7 million, reflecting the impact of adopting IFRS 15. An increase in cash and cash equivalents of £2.0 million
Non-current Liabilities	A decrease in contingent consideration due to the revaluation of the contingent consideration relating to the Haemostatix acquisition

ERGOMED: STRATEGIES FOR GROWTH

Focus on driving top-line services growth through integrated commercial organization

Continue path to leadership positions in pharmacovigilance and orphan drug development



Carry operational and financial improvements into 2019

Drive efficiencies and competitive advantage through digital transformation

APPENDIX

ABBREVIATED PROFIT AND LOSS ACCOUNT FOR 2018

SHOWING EFFECT OF IFRS 15

Unaudited (Figures in £ millions, unless otherwise stated)	Results under IAS 18	Effect of IFRS 15	Results under IFRS 15
Total Revenue	54.9	(0.8)	54.1
Cost of Sales	(26.7)		(26.7)
Reimbursable expenses	(8.1)		(8.1)
Gross Profit	20.1	(0.8)	19.3
Administrative and Other Expenses	(28.2)		(28.2)
Research & Development	(1.6)		(1.6)
Other operating income	0.1		0.1
Operating (Loss) / Profit	(9.6)	(0.8)	(10.4)
Finance Costs & Other Income	(0.4)		(0.4)
(Loss) / Profit Before Taxation	(9.9)	(0.8)	(10.8)
Taxation	1.8	0.0	1.8
(Loss) / Profit After Taxation	(8.1)	(0.9)	(9.0)
Adjusted EBITDA (after exceptional and other items)	3.1	(0.8)	2.3
Exceptional Items	(20.1)		(20.1)
(Loss) / Earnings Per Share (pence)*	(18.2)p		(20.0)p

*Adjustments are made to EPS for amortisation of acquired fair valued intangible assets, share-based payment charge, deferred consideration for acquisitions relating to post acquisition remuneration, acquisition costs and exceptional items.

ABBREVIATED PROFIT AND LOSS ACCOUNT FY 2018

Figures in £ millions, unless otherwise stated	FY 2017 (IAS 18)	FY 2018 (IAS 18)	FY 2018 (IFRS 15)	Delta to FY 2017 under IAS 18	Delta to FY2018 under IAS 18
PV revenue	22.5	27.5	27.5	+ 23%	--
CRO revenue	25.2	27.4	26.6	+ 6%	(3)%
TOTAL REVENUE	47.6	54.9	54.1	+ 15%	(1)%
GROSS MARGIN	17.6	20.1	19.3	+ 10%	(4)%
Gross margin %	37%	37%	36%		
ADJUSTED EBITDA	2.8	3.1	2.3	(19)%	(26)%
EPS – basic and diluted	(11.0)p	(18.2)p	(20.0)p		