ERGOMED

TRANSFORMING DRUG DEVELOPMENT

Preliminary Results 2017

April 2018

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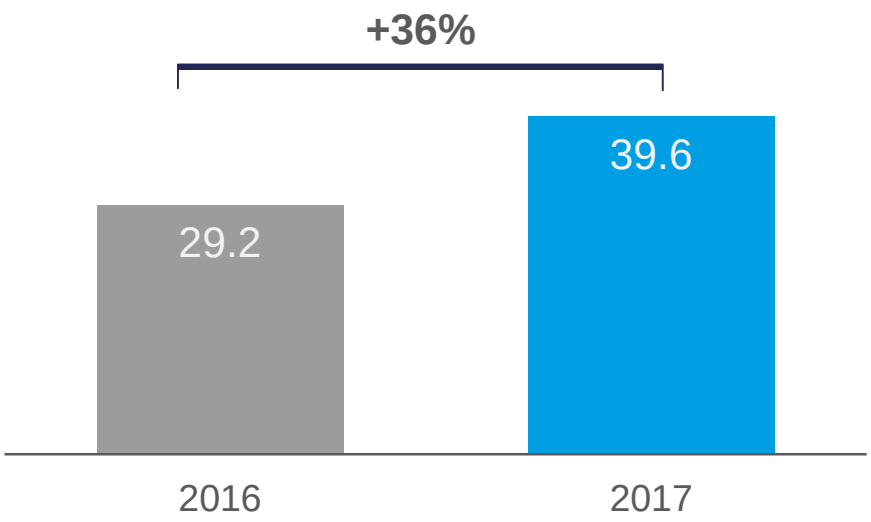
2017 PRELIMS: FINANCIAL HIGHLIGHTS

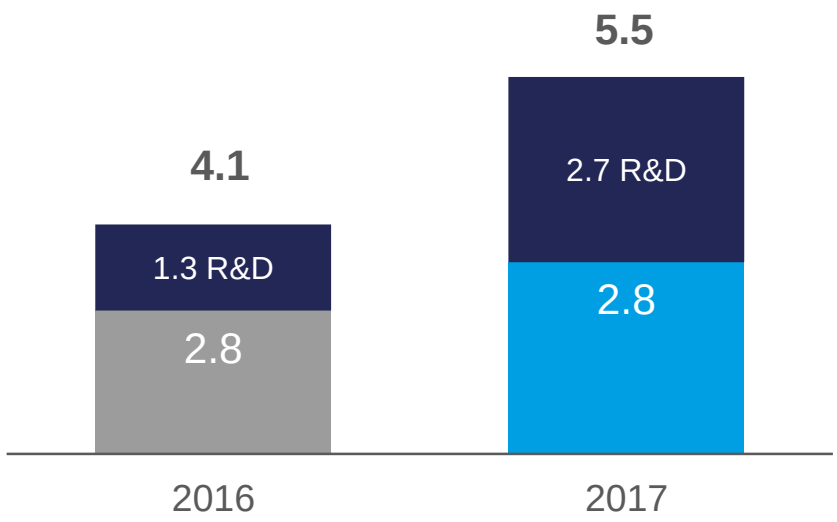
Another year of strong growth

Net service revenue up **36% to £39.6 million** (2016: £29.2 million)	Total revenue up **21% to £47.6 million** (2016: £39.2 million)	Gross profit up **22% to £14.6 million** (2016: £12.0 million)	EBITDA (adjusted) before R&D **£5.5 million** (2016: £4.1 million)	Cash at bank at 31 Dec 2017 **£3.2 million** (2016: £4.2 million)

Net revenue (£m)



Services EBITDA (£m)



2017 OPERATIONAL HIGHLIGHTS

Strong delivery and business outlook

£54 million

of new contracts won through December 2017
(2016: £42 million)

£88 million

of contracted backlog at 31 December 2017
(2016: £70 million)

€5.7 million

acquisition of PSR Group or up to

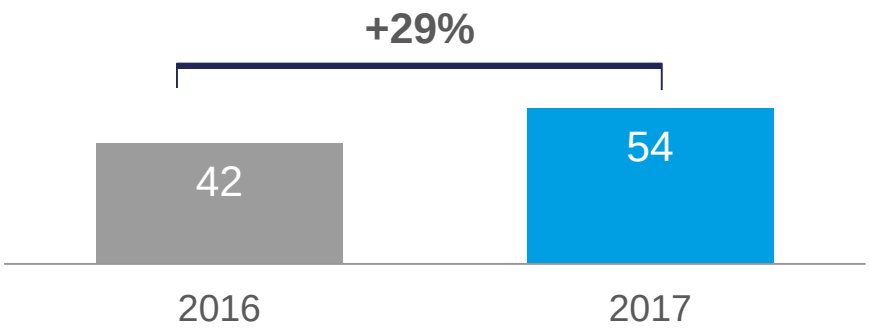
First licensing deal

for Haemostatix products for South Korea

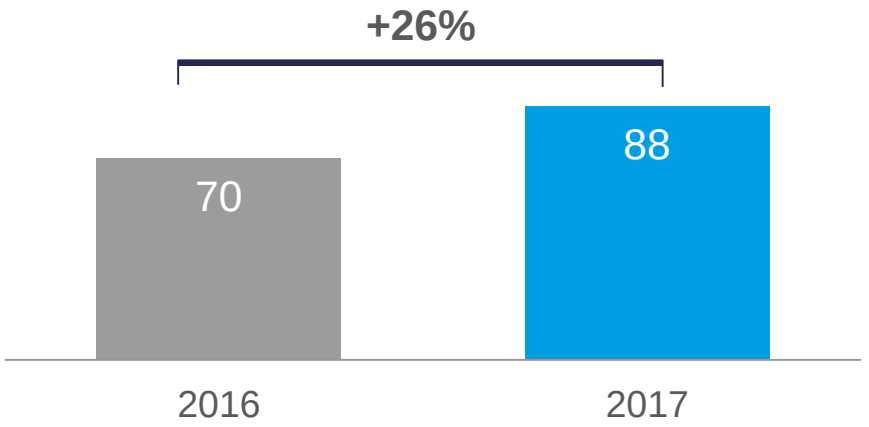
Multiple product

milestones, including PeproStat

New business won (£m)



Contracted backlog (£m)



SERVICES – FAST-GROWING

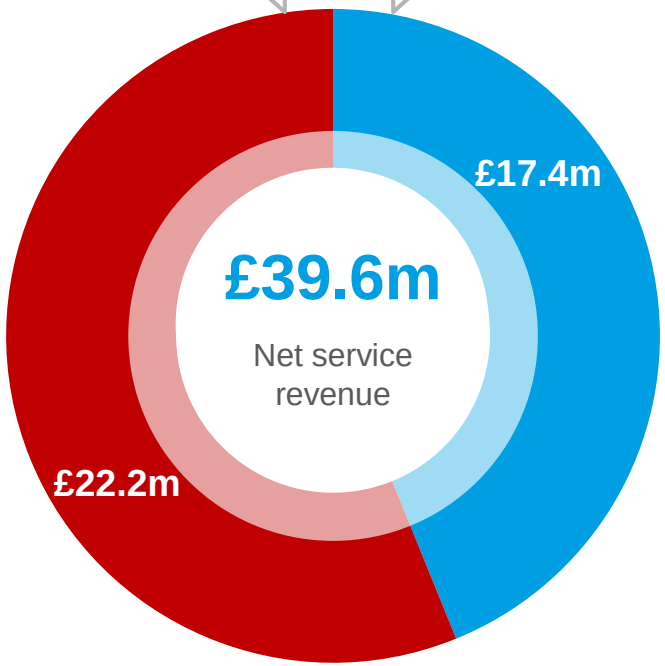
Continuing to out-pace the market with global solutions

Drug Safety & Medical Information

+68% GROWTH

+9% GROWTH

Clinical Research Services



Outsourced PV industry growth

+18%[1]

CRO industry growth

+7.5%[2]

1 Source: Global Market Insights
2 Source: Global Data

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FOCUS ON SPECIALISED SERVICES TO PHARMA

20+ years of profitable growth

COMPLETING THE DEVELOPMENT CIRCLE

OUR MISSION

Building a profitable services business with a focus on .....

global leadership in
pharmacovigilance and
orphan drug development
by 2020

Drug Safety and Medical Information

- Services to international pharma, generic and biotech clients in >100 countries
- 450+ employees and network of 200+ experts
- Senior ex regulators execs on the medic led team
- Covers whole life cycle of benefit-risk management
- Transforming PV using intelligent automation

10 YEARS OF EXCEPTIONAL GROWTH, QUALITY & CLIENT RETENTION

Clinical Research Services

- Global operations platform
- Unique site management model and study physician teams
- Focus on orphan drug development, further key areas: oncology, neurology, immunology
- Effective reach into MENA region

20 YEAR TRACK RECORD OF QUALITY AND DELIVERY

DRUG SAFETY & MEDICAL INFORMATION

Critical business enabler in both developed and emerging markets

Pharmaco-vigilance market

$8bn+
By 2024

50%
contract outsourcing by 2024

18%
PV industry growth

ADRs ↑
Growing number of adverse drug reactions

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

Global Market Insights, Inc.; March 15, 2018

PHARMACOVIGILANCE & MEDICAL INFORMATION SERVICES

Business enabler for biotech and pharma

PRIMEVIGILANCE

£22.5m
Net service revenue

450+
Employees

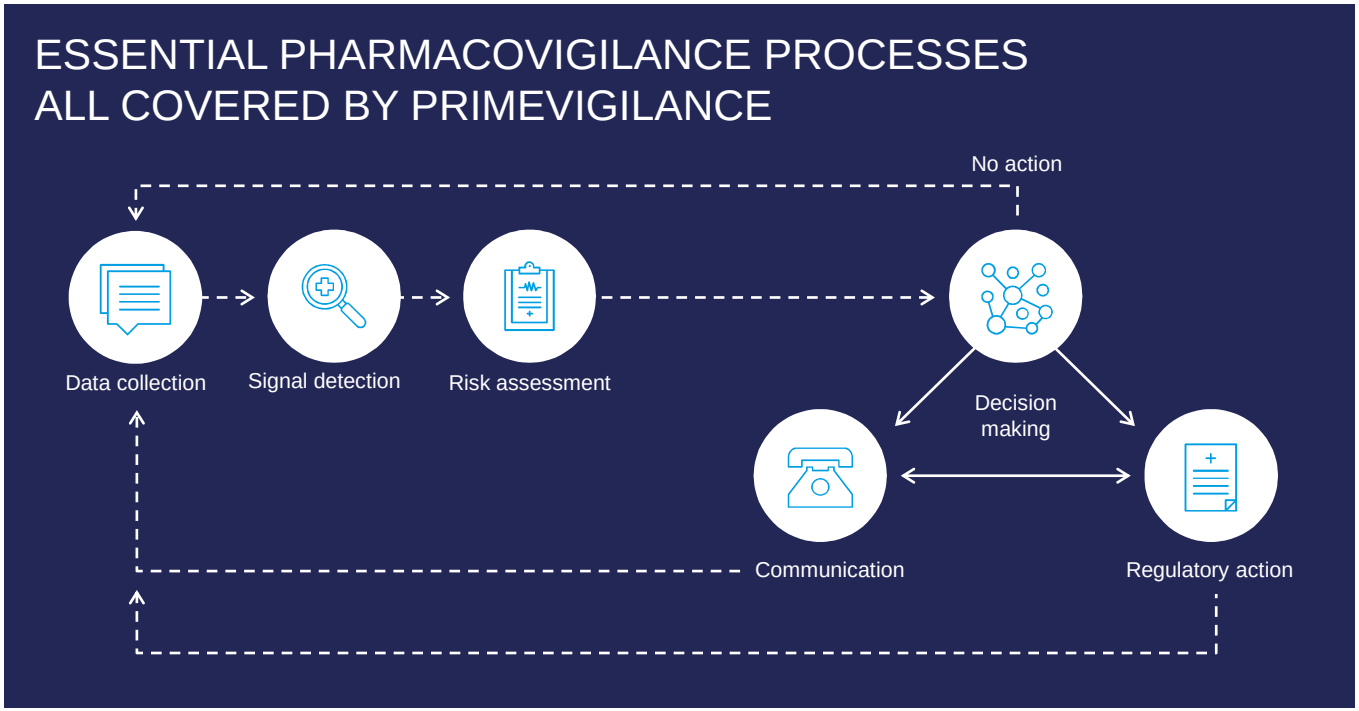
80,000
Adverse event cases processed pa

100+
Customers

Services marketed in
100+
countries

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

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



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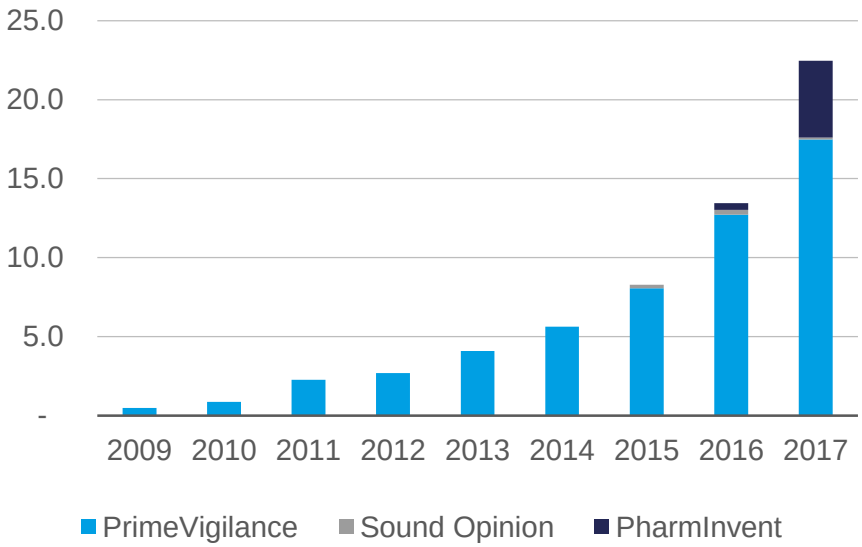
DRUG SAFETY & MEDICAL INFORMATION SERVICES

Vision 2020: world's leading pharmacovigilance provider

- **2008** – Formation of PrimeVigilance in UK
- **2013** – Launch of Medical Information
- **2014** – IPO on AIM
- **2015** – Acquisition of Sound Opinion – UK MI company
- **2016** – Acquisition of PharmInvent – expert regulatory and PV
- **2017**

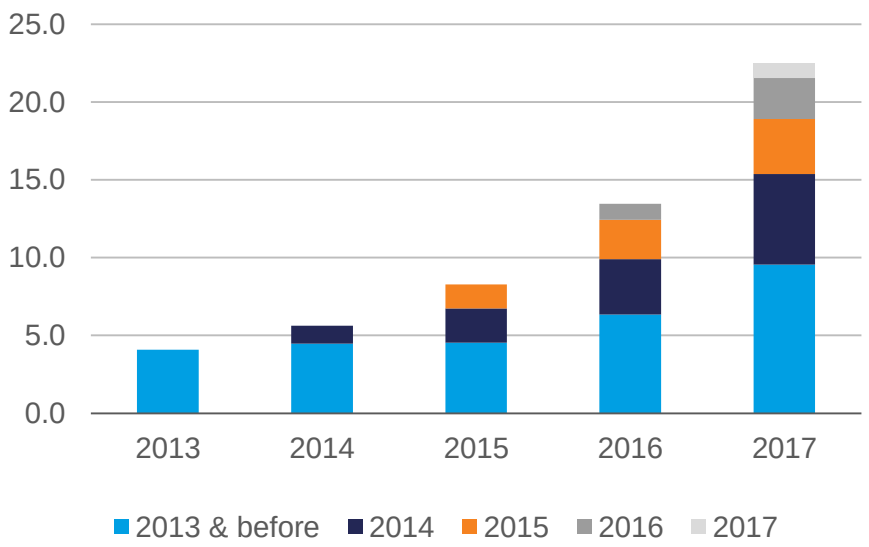
Consistent growth

Revenues (£m)



Exceptional client retention

Revenues by customer cohort (£m)



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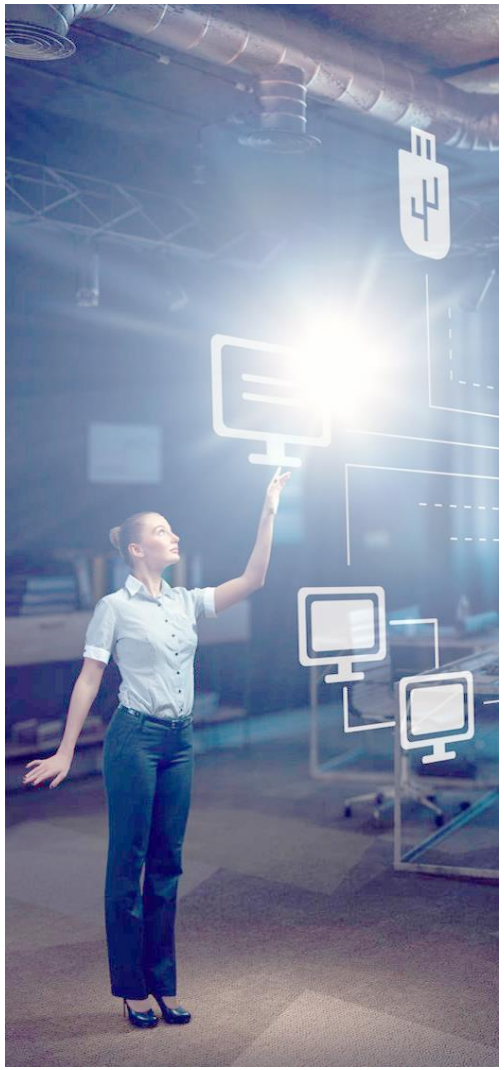
TRANSFORMING PHARMACOVIGILANCE WITH INTELLIGENT AUTOMATION



PrimeVigilance assumptions

- By **2020**, automation is likely to reduce manual **case-processing efforts by over 80%** and **decrease costs by at least 50%.**
- Improving the accuracy, quality, and consistency, creating better audit trails faster, and informing decisions with better evidence.

Investment in technology

- PrimeVigilance has started early deployment of robotic process automation in pharmacovigilance and business operations (e.g., creation of PV trackers, PV operational reports, PV compliance reports, quality assurance, validation etc.)
- PrimeVigilance pilot project has demonstrated how **robotic process automation of selected pharmacovigilance processes** can increase efficiency by up to **400 times**, increasing speed, reducing cost and improving accuracy.
- **Partnerships** with major automation players achieved (Oracle, Automation Anywhere), and more under negotiation.

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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.

£17.4m
Net service revenue

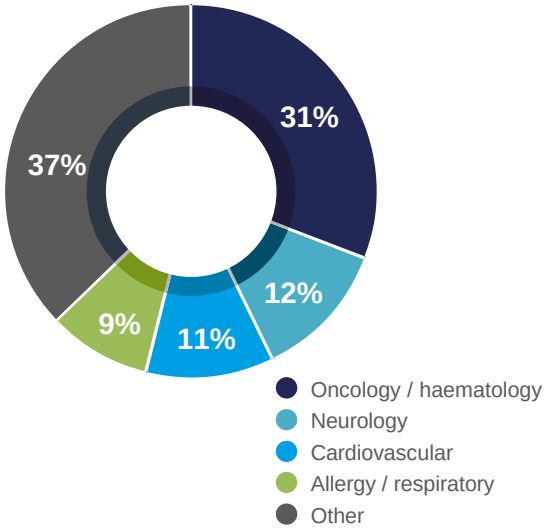
600
Studies (in 20 years)

100+
Active clients

125,000
Patients studied (in 20 yrs)

Clinical trials in
55 countries

Therapeutic Area Expertise



Effective patient recruitment to reduce time & cost of clinical trials

Focusing on patient recruitment with efficient management and control of complex trial protocols

Study Physician Team

- Peer-to-peer support
- Develops best practice across treatment centres
- Provides expertise for particular study designs

Site Management Team

- Enhanced recruitment
- Increased retention
- More evaluable patients

Hospital

- Investigator
- Nurses / Site Staff

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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 Rx

11%
p.a. growth

$200bn
by 2020

30m
people suffer from orphan disease

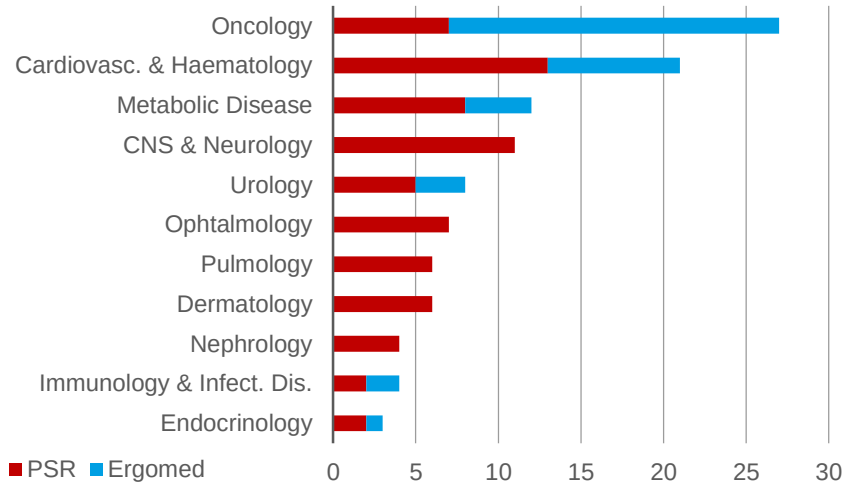
GROWTH DRIVERS

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

PSR ORPHAN EXPERTS

- Leading Orphan Drug CRO in Europe
- Acquired Oct 2017 for up to €5.7m
- Based in The Netherlands, 32 employees
- Experience in ~100 orphan trials

Full Rare Disease Experience per Therapeutic Area



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PEPROSTAT PHASE II RESULTS

Primary endpoint met: 1.6 minutes (p<0.004) reduction in TTH

RANDOMISED, BLINDED, PARALLEL-GROUP, MULTICENTRE CONTROLLED CLINICAL TRIAL

Three surgery types: open liver/soft tissue, vascular, spine

		Time to haemostatis		
		n	Mean	Median
All surgery types	PeproStat + gelatin sponge	110	4.2	3.0
	Standard of care	52	5.8	5.0
	Difference		**1.6**	

80.9% surgeons rated PeproStat (blinded) as good to excellent in controlling bleeding vs **59.6%** for standard of care

93.5% rated the "liquid and sponge" format as easy/very easy to use

Good safety profile:
no treatment-related SAEs

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CO-DEVELOPMENT UPDATE

Multiple milestones in 2017

PARTNERSHIP	STATUS UPDATE
ferrer — Lorediplon / insomnia	• Successful Phase II data reported February 2017 • Ferrer seeking commercial partner(s)
Æterna Zentaris — Zoptrex™ / endometrial cancer	• Phase III data announced May 2017 • Zoptrex did not show treatment benefit over doxorubicin
CEL-SCI — Multikine / head & neck cancer	• Clinical hold on Phase III trial lifted by FDA August 2017 • Study fully recruited, patients being monitored in follow-up phase
Modus — Sevuparin / VOC in sickle cell disease	• Phase II study expanded to 150 patients • Study completion expected by end 2018
ASARINA PHARMA — Sepranolone / PMDD	• Preparatory activities underway • First patient for Phase IIb study expected 1H 18
Allergy Therapeutics — OralVac / allergy desensitization	• New deal signed December 2017 • For up to three Phase I, II and III studies for each of three products

PROFIT AND LOSS ACCOUNT

£000s	FY 2017	FY 2016
Net service revenue	**39,645**	**29,224**
Licence revenue	**370**	**-**
Reimbursement revenue	**7,609**	**10,009**
REVENUE	**47,624**	**39,233**
GROSS PROFIT	**14,621**	**11,994**
Administrative expenses	(15,954)	(10,822)
Other administrative expenses	(9,725)	(8,323)
Amortisation of acquired fair valued intangible assets	(1,167)	(771)
Share-based payment charge	(1,033)	(877)
Deferred consideration for acquisition	(752)	(550)
Revaluation of deferred consideration for acquisition	(2,875)	-
Write-back of deferred consideration for acquisition	-	460
Acquisition costs	(259)	(584)
Exceptional items	(143)	(177)
Research and development	(2,689)	(1,250)
Other operating income	118	127
OPERATING (LOSS) / PROFIT	**(3,904)**	**4 9**
EBITDA (adjusted)	**2,784**	**2,804**

BALANCE SHEET

£000s	31 December 2017	31 December 2016
Goodwill	15,269	12,285
Intangibles	20,229	19,842
Other non-current assets	3,445	2,436
NON-CURRENT ASSETS	**38,943**	**34,563**
Trade and other receivables	19,250	14,958
Other current assets	502	240
Cash and cash equivalents	3,218	4,424
CURRENT ASSETS	**22,970**	**19,622**
TOTAL ASSETS	**61,913**	**54,185**
CURRENT LIABILITIES	**(13,863)**	**(8,592)**
NET CURRENT ASSETS	**9,107**	**11,030**
NON-CURRENT LIABILITIES	**(13,207)**	**(11,195)**
TOTAL LIABILITIES	**(27,070)**	**(19,787)**
NET ASSETS	**34,843**	**34,398**

TRADE AND OTHER RECEIVABLES

£000s	31 December 2017	31 December 2016
Trade debtors	13,390	9,540
Other receivables	1,702	1,025
Prepayments	733	841
Accrued income	2,443	2,538
Corp. tax receivable	982	1,014
TOTAL	**19,250**	**14,958**
DSO (incl. acquisitions)	**92 days**	**89 days**
DSO (excl. acquisitions)	**89 days**	**82 days**

Of 31.12.17 trade debtors, 85% cash received by 9 April 2018[1]

1. Excluding CEL-SCI

STRATEGY FOR ACCELERATED GROWTH

	2017 DELIVERY	STRATEGY
ORGANIC GROWTH	**30%+** top line growth	• Focus on our services growth • Outpace the market

ACQUISITIONS	PSR	• Build out global infrastructure
		• Add specialist skills
		• Goal is global leadership in:
		  • Pharmacovigilance
		  • Orphan Drug development

DEVELOPMENT	Haemostatix	• Optimise Haemostatix value

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QUESTIONS?

SITE MANAGEMENT MODEL

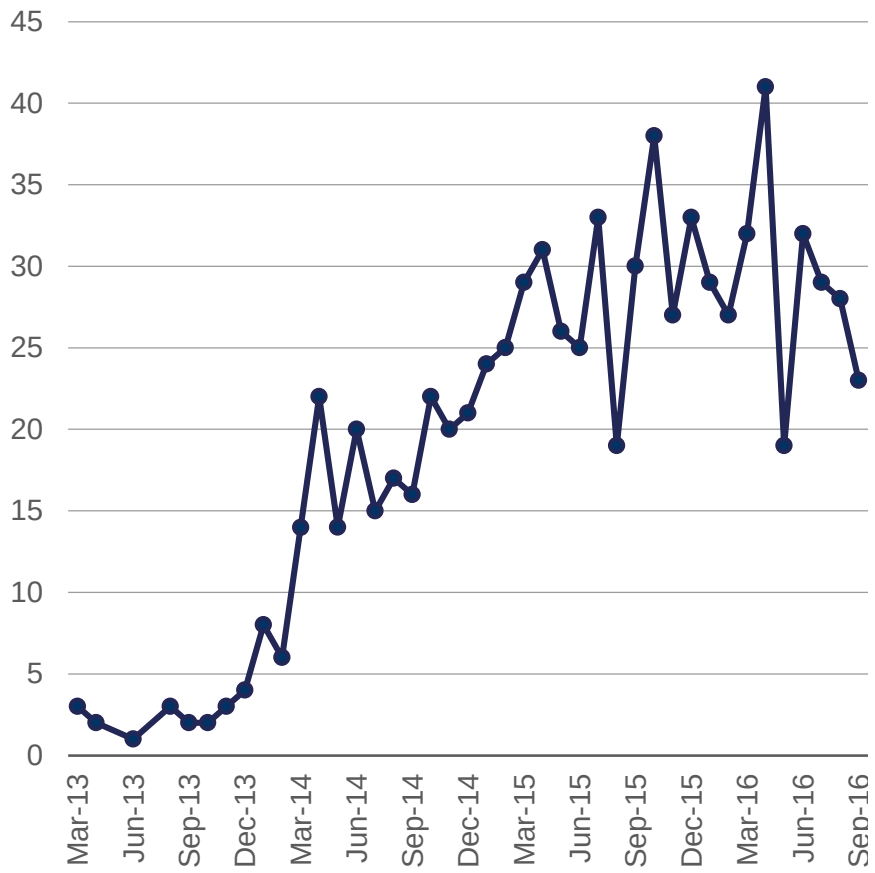
Significantly Increases Study Performance

- Large Phase III Head & Neck Cancer rescue study
- Urgent assistance was required to open sites and enroll patients
- Ergomed's Study Physician program significantly increased study progress:
  - 560% increase in # of patients
  - Enrolment rate per site 4 times higher than prior CRO

Client report from 'The Wall Street Journal' 01 May 2014

'During the past months we have seen very rapid increases in rate of enrollment in this study. We think that increases in the enrollment rate in our trial in recent months are, in part, due to the addition of new centers and the intense site support by our clinical research organization Ergomed.'

Monthly Enrolment Chart

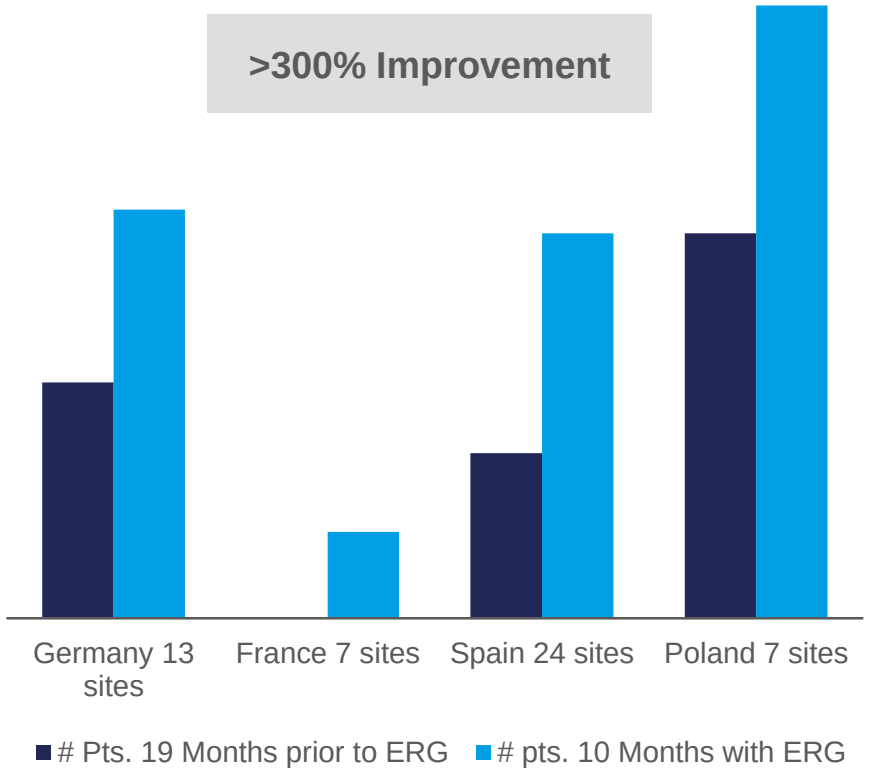


STUDY PHYSICIAN GROUP

Case Study

- Study Physician Support model was used to support a different CRO's enrollment process
- Advanced NSCL Adenocarcinoma study was lagging recruitment goals
- In the 10 months that Ergomed was involved, a 300% improvement in site management and patient enrolment was achieved

of patients enrolled prior to and after Study Physician involvement



EU GOOD PHARMACOVIGILANCE PRACTICE (SINCE JUNE 2012)

GVP Modules on PV Quality Management and Regulatory Aspects	GVP Product- or Population Specific Considerations (PPSC)	GVP Modules on PV Deliverables
I. PV Quality Systems	I. Vaccines for prophylaxis against infectious diseases	V. Risk Management Systems *(Rev 2)*
II. PSMF *(Rev 2)*	II. Biological medicinal products	VI. Management and reporting of ADRs *(Rev 1)*
III. PV Inspections *(Rev 1)*	CHMP guideline on safety and efficacy follow-up, RMP of ATMP	VII. PSURs *(Rev 1)*
IV. PV Audits *(Rev 1)*		VIII. PASS *(Rev 1)* *VIII. Addendum I – MS requirements for PASS submission (Rev 1)*
X. Additional Monitoring		IX. Signal Management
XI. and XIV. - Web references to "EMA Partners and Networks		XV. Safety communication
XII. – Web references to "EMA post-marketing authorisation: regulatory and procedural guidance"		XVI. Risk Minimisation (Rev 2) *XVI. Addendum I – Educational Materials*
XIII. – Web references to "EMA incident management plan"		

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