28 November 2019

Diaceutics Plc

Mapping the patient journey via DDPs

A growing pipeline of precision medicines in pharma, together with rising diagnostic testing complexity, are creating a virtuous circle of increasing demand for Diaceutcs' data products. The introduction of DDPs and launch next year of the Nexus platform will enable the business to scale and create significant economic value for shareholders.

- **Growing pipeline.** Diaceutics has identified over 3,000 Phase 2/3 clinical trials supporting approximately 1,000 drug brands which could include a biomarker in their therapy label if they achieve approval. This contrasts with only 173 FDA approved Precision Medicine (PM) drugs currently on the market as at December 2018. PM pipelines are growing rapidly and to a material extent pharmaceutical companies are insufficiently prepared to support the companion diagnostic commercialisation strategies upon which their brands are dependent.
- **Increasing complexity.** The broadening use of diagnostic testing and an increase in the variety of precision diagnostic tests is contributing further to an already complex diagnostic environment. The use of complementary and conduit testing is increasingly supplemental to companion diagnostic testing and the number of testing events on a typical patient journey is rising significantly.
- **A deepening data lake.** Diaceutics had over 126m patient records from multiple sources and key precision testing markets in its data lake as at June. Additionally, the ability to use machine learning to create synthetic records and complete data gaps is enabling high confidence ratio analyses and algorithm based projections about disease progression at a granular level.
- **Introducing DDPs.** These patient level disease journeys are termed Diagnostic Deductive Pathways ™ (DDPs) and Diaceutics has to date researched and developed 37 of these out of the 298 disease areas its data lake covers leveraging proprietary algorithms and machine learning. Uniquely, these DDPs will enable the company's pharmaceutical clients to mine, interrogate, analyse and project the diagnostic pathway in real-time. This places them in a better position to introduce the right therapy to the right patient at the right time. Information on the likely progression of diseases at the patient level is a high value-add, highly defensible proposition.
- **Changing engagement.** DDPs are enabled by the Nexus platform and, as the development of this completes over the next twelve months, customer engagements will progressively change. Already, the delivery of distinct modules is becoming delineated and end-to-end test commercialisation module deployments are becoming the norm. The business is becoming fully productised and the Nexus platform is on track for full commercial delivery in Q4/20E. Buy.

Forecast and Ratios

Y/E December (£m)	2017A	2018A	2019E	2020E
Revenue	7.4	10.4	12.6	15.0
EBITDA	0.9	1.5	1.6	2.6
Adj PBT	0.8	0.9	-0.6	0.9
Adj EPS (p)	3.2	4.0	1.4	1.1
DPS (p)	0.0	0.0	0.0	0.0
EV/Sales (x)	8.6	6.3	4.5	4.0
EV/EBITDA (x)	68.0	43.1	35.8	23.2
Adj PE (x)	28.8	22.8	65.8	81.8
Yield (%)	0.0	0.0	0.0	0.0

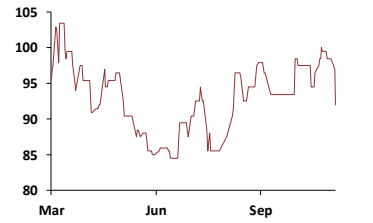
Source: Cenkos Securities estimates, Company data

Brokership Company

BUY

Price at COB 27 Nov 19	94.5p
52-week range	84.5-103.5p
Ticker	DXRX LN

Share Price Performance



Source: Morningstar

Performance	1m	3m	12m
Absolute	(5.6)	0.5	n/a

Stock Data

Market cap (£m)	65.76
Shares outstanding (m)	69.6

Activities

Diaceutics operates as a data analytics and implementation provider. It provides insights generated from its testing data from its worldwide laboratory network to pharmaceutical companies.

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Broadening of pipeline assets and disease areas

Precision medicine market is materially enlarging

Material increase in pipeline assets

The number of precision medicine oncology late stage phase 3 trials with completion dates scheduled from January 2019 to December 2020 currently totals 517. This contrasts significantly with the 173 FDA-approved precision medicine therapies on the market at the end of 2018. Of these 517 trials, 267 of them are expected to complete in 2019 with a further 250 finishing in 2020 (source: Diaceutics Pharma Readiness Report October 2019). Should these trials be successful, the drug brands which will benefit will require a sophisticated diagnostic strategy to assist a successful launch into the marketplace. Testing laboratories are often prepared too late for onboarding these precision testing demands meaning that therapies are only reaching the intended patients years' post drug launch with resulting patient impact and loss of revenue to the pharmaceutical industry. Diaceutics has historically focussed its data products on oncology assets but this is now beginning to broaden.

Developing coverage in non-oncology assets

While the above pipeline statistics are constituted from oncology assets only, there are increasing amounts of precision medicine therapies in the pipeline coming from disease areas such as cardiology, pulmonology, diabetes, genetic and infectious diseases. Diaceutics is adding to its data coverage in these non-oncology disease areas and the Diaceutics data lake has recently been strengthened with the IPO proceeds being deployed in acquiring additional patient records and establishing new partnerships with reference laboratories, academic institutions and data providers. This has specifically broadened the company's data lake in cardiovascular and infectious diseases such as Hepatitis. Further data sets are being constructed and these will become fully developed over the next 24 months to a point where we believe their economic value will be on par with Diaceutics' current oncology assets.

Evolving markets

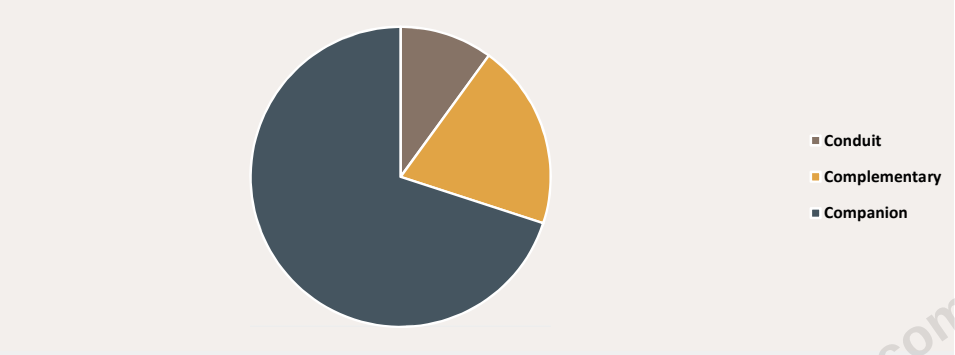
Testing depth is increasing

We see numerous developments in the diagnostic testing industry which should see the number of precision testing events across the healthcare industry rise substantially. Detailed below, these collectively represent higher throughput volumes of testing involved in patient management. In turn, these are placing an unbudgeted and unplanned burden on testing laboratories and are creating an increasingly complex landscape around treatment efficacy. Notably, these developments include:

- **Complementary and conduit testing –** the patient, laboratory, claims and industry data gathered by Diaceutics help it deliver data modules to its pharmaceutical customer base. These modules help pharma companies eliminate the laboratory level testing hurdles for doctors and patients and ensure precision therapies launch successfully with the help of a coherent diagnostic programme. Testing pathways for companion diagnostics are increasingly accompanied by other sets of testing assays where they may be recommended or indicative for patient treatments. Complementary tests are used where the FDA does not make a companion diagnostic mandatory but nevertheless recommends a diagnostic testing event to guide treatment options. More broadly than complementary testing is the emergence of conduit testing which is defined as 'any test which has a role in accelerating a patient to the right drug or right dose of the drug'. Multiple conduit tests can be used in conjunction with complementary and companion tests to manage a patient's disease pathway. These two adjacent markets together are estimated by Diaceutics to be 2-3x greater in volume terms than companion diagnostic testing alone. These are relatively new markets meaning estimates of size are yet to be established but there is already evidence in

non-small cell lung cancer (NSCLC) patients that the number of testing events patients are exposed to is increasing rapidly. This increase in testing intensity comes partly through the need to repeatedly test patients for treatment resistance or relapse, and monitoring patient responses to treatments for any residual disease risk.

Chart 1: Diagnostic test data source (%)



Source: Company actuals

- **Smart screening and referral testing -** We define smart screening as pre-emptive screening for diseases through the analysis of bodily fluids where there are no symptoms of any condition. Smart screening can be a very effective and relatively cost efficient way to identify diseases which are at an early stage of their development. The 'smart' element refers to advances being made in bio-sensing technologies which can automate testing at very high rates of throughput and reduce the unit cost of diagnosis. The facilitation of large scale testing at economically favourable rates is very much in harmony with the prevention is better than cure philosophy in today's healthcare markets. Diagnostic work by clinicians often consists of numerous potential diagnoses which are then narrowed down into a smaller number of likely outcomes. This narrowing process can lead to, for example, patients suspected with Alzheimer's disease that fail a cognitive screening test be onwardly referred to a psychologist or alternate practitioner. The testing events which lead into referrals are highly relevant to the patient journey and therefore form part of the commercial data that Diaceutics gathers in its data lake. Diaceutics has completed project work on disease areas for example in HIV and Alzheimer's where multi-test strategies are appropriate for better treatment targeting purposes.
- **Liquid biopsies -** New roles are emerging for liquid biopsies in the treatment of cancer. Liquid biopsy tests can detect very small amounts of disease in the blood of a patient which can signal an alert for therapeutic intervention without symptoms of the disease being present. These tests identify very small quantities of DNA originating from a tumour are effective for early stage and recurring cancer detection. New assays such as TARgeted Digital Sequencing (TARDIS) have proved their utility in areas such as early stage breast cancer. It is believed that liquid biopsies have applications across the oncology spectrum. Assays such as TARDIS can achieve up to a 100x improvement in cancer detection rates and the personalised nature assays can enable individualised treatment of patients. While liquid biopsies arguably face some accuracy challenges and may require centralised testing laboratories for effective testing, oncology testing companies such as Guardant Health (GH.O) have a role to play in opening up larger numbers of patients to diagnostic testing which might otherwise be painful or problematic to service.
- **Messenger RNA therapies -** diagnostic tests are required in the emerging field of gene silencing. These new drugs can be used to target specific disorders that were previously

untreatable. Messenger RNA sequences which have adverse expressions can be switched off by binding interfering RNA to messenger RNA to effectively switch off the gene's expression. The commercialisation of these medicines is at an early stage but Initial approvals in this field have included Onpattro, developed by Alnylam, which was authorised by NICE for use in the NHS in July 2019 for the treatment of hereditary transthyretin amyloidosis.

Increasing testing complexity

Near exponential increase in testing is expected

With reference to Diaceutics' research, the impact of broader testing in conjunction with multiple therapy treatments is set to increase the number of testing events per patient going forward. This is expected to be further amplified by greater testing for resistance and monitoring such that the number of testing events per patient with NSCLC look set to increase near exponentially:

Table 1: Average number of testing events per NSCLC patient

	2010	2014	2018	2022E	2026E
Average number of testing events per NSCLC patient	0.6	0.8	1.2	4.0	17.0

Source: Diaceutics estimates

Complexity is Diaceutics' friend

The above developments in diagnostic testing depict an environment of multiple and recurring tests and potential application of multiple therapies to support increasingly complex medical indications. Diaceutics analytics and implementation services cater exactly for such an environment and as the patient journey becomes more complicated we see a development roadmap for the company's products which directly address these requirements.

Patient lifecycle

Over 126m patient records in the data lake

As at H1A, the comingled data on diagnostic testing and the healthcare industry in the Diaceutics database covered 126m patient records across 298 disease areas. Approximately 4m patients are being added per quarter on an ongoing basis. There are up to 132 data fields for patient data and gaps are back-filled via machine learning and proprietary algorithms to create synthetic records

High confidence ratio projections

In our view, the true value of this data lake does not lie in any per patient record or number of testing events methodology. The comingling of testing data with other data from patient records, industry, insurance claims, prescription and other sources transforms its value. The output from this comingling reveals information on a patient's pathway through disease management in its entirety. The algorithmic processing of this data facilitates forward projections of pathways at high confidence ratios. This is taking Diaceutics in the direction of covering both current and predictive diagnostic events. Our view is that the natural progression of this will take Diaceutics into the data market for overall outcomes in the patient pathway.

Diagnostic Deductive Pathways (DDP)s

This collective information on a disease pathway is termed a Diagnostic Deductive Pathway ™ (DDP). The establishment of these DDPs is pivotal to the long-term investment case for Diaceutics. The interrogation of this DDP data and its forward projections in real-time by pharmaceutical companies is the heart of the developing value proposition. Of the 298 diseases covered by Diaceutics, 37 DDPs have been sufficiently developed to support commercial analytical applications as at today's date. More importantly, in time these DDPs will enable

Diaceutics' pharmaceutical customers to mine data further to physician testing preferences, analyse and predict disease progression at a micro-level. This granularity at patient level across multiple markets makes for a highly differentiated and defensible product in contrast with population health studies which are widely available. Access to DDPs will be enabled by the Nexus platform which is under development by Diaceutics.

Long term value creation

Given the developments we have outlined, we believe the proprietary data lake underpinning Diaceutics' products and services will only become more valuable to its pharmaceutical clients as patient journeys become increasingly complex. The investment in DDPs therefore represents a significant future growth opportunity. By analysing a disease pathway, scenarios can be created and where diagnostic testing can be introduced at theoretical points of the testing journey and outputs on patient therapy numbers can be projected. Furthermore, the integration of DDPs into the Nexus platform will provide unparalleled levels of client access to real world global precision testing data. This platform will enable the group to scale and drive significant future economic value for shareholders. We expect Nexus to be formally launched in Q4 2020E.

Financials

Table 2: Income Statement

Y/E December (£m)	2017A	2018A	2019E	2020E
Revenue	7.4	10.4	12.6	15.0
% Change YoY	60.6	40.7	21.1	19.6
Cost of sales	-2.5	-3.5	-4.2	-5.0
Gross profit	4.9	6.9	8.3	10.0
Gross margin (%)	66.4	66.3	66.4	66.9
Sales & marketing expenses	0.2	0.1	0.2	0.0
Research & Development	0.0	0.0	0.0	0.0
Administrative expenses	-4.0	-5.1	-6.6	-7.2
EBITDA	**0.9**	**1.5**	**1.6**	**2.6**
EBITDA margin (%)	12.6	14.7	12.5	17.3
Adjusted EBITDA	**1.1**	**1.9**	**1.9**	**2.9**
% Change YoY	-13.2	81.7	-1.8	52.7
Depreciation & amortisation	0.0	-0.1	-0.8	-1.8
Exceptional items	0.0	-0.2	-1.4	0.0
EBIT	0.9	1.2	-0.6	0.8
Net interest	-0.1	-0.3	0.1	0.1
Profit/(Loss) before tax	0.8	0.9	-0.6	0.9
Adj PBT	0.8	0.9	-0.6	0.9
Tax charge	-0.1	-0.2	0.1	-0.1
Profit/(loss) after tax	**0.7**	**0.6**	**-0.5**	**0.8**
Adj PAT	**0.7**	**0.6**	**-0.5**	**0.8**
% Change YoY	-11.2	-4.7	-180.0	-254.7
Profit attributable to company owners	0.7	0.6	-0.5	0.8
Minority interests	0.0	0.0	0.0	0.0
Diluted Basic EPS (p)	**3.2**	**3.0**	**-0.8**	**1.1**
Adj EPS (p)	3.2	4.0	1.4	1.1
% Change YoY	-22.1	26.3	-65.4	-19.5
DPS (p)	0.0	0.0	0.0	0.0
Average shares FD (m)	20.8	20.8	64.0	69.6

Source: Cenkos Securities estimates, Company data

Table 3: Cash Flow

Y/E December (£m)	2017A	2018A	2019E	2020E
EBIT	**0.9**	**1.2**	**-0.6**	**0.8**
Depreciation	0.0	0.0	0.1	0.1
Amortisation (incl. impairments)	0.0	0.1	0.7	1.7
Working capital	0.6	-2.5	-2.0	-1.0
Share based payments	0.1	0.4	0.3	0.3
Other including exceptional costs	0.0	0.0	0.0	0.0
Operating Cash Flow	**1.6**	**-0.8**	**-1.5**	**1.9**
Net Interest	-0.1	-0.3	0.1	0.1
Tax	-0.1	-0.2	0.1	-0.1
Cash flow pre-capex and investment	**1.4**	**-1.3**	**-1.4**	**1.9**
Adj free Cash flow	**1.4**	**-1.3**	**-1.4**	**1.9**
Investment in intangible assets	-0.1	-0.5	-2.8	-3.0
Net capex	-0.2	-0.7	-2.6	-3.1
Acquisitions/disposals	0.0	0.0	0.0	0.0
Financing/other	0.7	1.6	12.6	0.0
Dividends	0.0	-0.3	0.0	0.0
Net Cash Flow	**1.8**	**-1.0**	**5.8**	**-4.2**
Closing Net Cash/(Debt)	**1.0**	**-1.7**	**7.9**	**3.7**

Source: Cenkos Securities estimates, Company data

Table 4: Balance Sheet

Y/E December (£m)	2017A	2018A	2019E	2020E
Fixed Assets	0.0	0.1	0.0	0.0
Goodwill & other intangible assets	0.5	1.2	5.8	10.1
Other long term assets	0.1	0.1	0.0	0.0
Total Fixed Assets	**0.7**	**1.3**	**5.9**	**10.1**
Trade receivables	1.8	4.4	6.9	8.4
Cash	3.1	2.1	7.9	3.7
Total Current Assets	**4.8**	**6.5**	**14.8**	**12.1**
Trade payables	-1.2	-1.0	-1.2	-1.4
Deferred income	-0.3	-0.2	-0.5	-0.8
Other payables	-0.6	-2.7	0.0	0.0
Total Current Liabilities	**-2.1**	**-3.9**	**-1.7**	**-2.2**
Net Current assets	**2.8**	**2.5**	**13.1**	**9.9**
Long term liabilities	-1.6	-1.1	0.0	0.0
Deferred tax liabilities	0.0	0.0	0.0	0.0
Other payables	0.0	-0.2	0.0	0.0
Total Long Term Liabilities	**-1.6**	**-1.2**	**0.0**	**0.0**
Net Assets	**1.9**	**2.6**	**19.0**	**20.0**

Source: Cenkos Securities estimates, Company data

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	Corporate No.	Corporate %	No.	%
Buy	63	95	83	91
Hold	2	3	5	5
Sell	0	0	2	2

Temporary movements by stocks across the boundaries of these categories due to share price volatility will not necessarily trigger a recommendation change. All recommendations are based on 12 month time horizon unless otherwise stated.

Recommendation History

Company	Disclosures	Date	Rec	Price
Diaceutics Plc	2,6,7,8,9,10,11	26 Apr 19	Buy	91p

Source: Cenkos Securities

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