15 March 2021

Diaceutics Plc

Recovery into 2021E

Rising patient enrolment volumes and a higher number of late stage assets seeking approval underwrite a recovery in Diaceutics' markets in FY21E. The business is amply funded to capitalise on the growing opportunities now presented. Diaceutics is instrumental in facilitating its pharma customers bringing their precision medicines to market and the importance of the role played here is materially undervalued in the share price in our view.

- **FY20A**. The impact of disrupted clinical trials and reduced prescription related income inevitably fed back up pharma supply chains in 2020. This led Diaceutics to report a lower revenue base last year (-6% YoY) to £12.7m, with the seasonally stronger second half seeing a 19% YoY decline. Restricted site access is telling in the 17% decline in Services income last year. The fixed cost nature of the business meant the revenue decline led to EBITDA margins falling to 4.4% (EBITDA £0.5m). The balance sheet remains robust with £25m of net cash as at 31 December.
- **New platform**. Despite these challenges the DXRX platform was launched on time and on budget. This platform delivers data to stakeholders on an automated basis and is helping reduce the cost of data delivery to clients. The development of a diagnostic ecosystem for the industry is seeing Diaceutics play a central role in ensuring patient access to precision medicines. Six clients saw their data requirements serviced via the platform in Q4A and we expect 20% of all data to be delivered via the platform by the end of FY21E. The proprietary data lake saw significant growth with 365m patient records (+61% YoY) held at the end of FY20A.
- **Material cost savings.** £1.9m of annualised cost savings were secured in Q4A and a £0.4m exceptional cost was declared in support these cost initiatives.
- **New FY21E forecast.** We are cautiously forecasting +7% YoY revenue growth in FY21E, supported by over 40% visibility from backlog and late stage contracts, driven by recovering budgets in 2021. We see the DXRX platform beginning to positively impact gross margins with these rising this year to c81%. The cost savings secured in Q4 reduce the cost base sufficiently to restore EBITDA to £2.0m this year.
- **Oncology driver.** The number of precision medicines coming to market are expected to triple to 450 over the next few years with oncology assets forming a major proportion of this pipeline. This pays to Diaceutics' strength and its role is pivotal in ensuring that the 50% of patients not securing access to suitable therapies find access. On 6x FY21E EV/sales we continue to rate the stock as Buy.

Forecast and Ratios

Y/E December (£m)	2018A	2019A	2020A	2021E
Revenue	10.4	13.4	12.7	13.6
EBITDA	1.5	2.4	0.5	2.0
Adj PBT	0.9	1.8	-0.7	0.2
Adj EPS (p)	4.0	2.7	0.8	1.0
EV/Sales (x)	10.0	6.7	6.0	5.9
EV/EBITDA (x)	67.9	38.0	142.2	39.2
Adj PE (x)	30.0	44.4	147.3	120.9

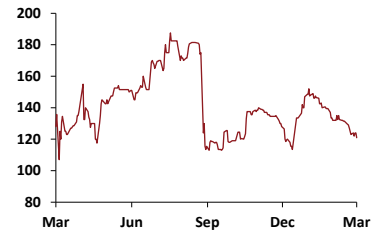
Source: Cenkos Securities estimates, Company data

Brokership Company

BUY

Price at COB 12 Mar 21	121.0p
52-week range	107-187.5p
Ticker	DXRX LN

Share Price Performance



Source: Morningstar

Performance	1m	3m	12m
Absolute	(9.4)	(6.9)	(12.0)

Stock Data

Market cap (£m)	101.7
Shares outstanding (m)	84.1

Activities

Diaceutics operates as a diagnostic commercialisation company. It provides insights generated from its testing data from its worldwide laboratory network to pharmaceutical companies.

Directors

Deborah Davis	Chairman
Peter Keeling	CEO
Ryan Keeling	CIO
Philip White	CFO

Contacts

Simon Strong - Analyst
+44 (0)207 397 1970
sstrong@cenkos.com

Chris Donnellan - Analyst
+44 (0)207 397 1926
cdonnellan@cenkos.com

Julian Morse - Sales
+44 (0)207 397 1931
jmorse@cenkos.com

Michael Johnson - Sales
+44 (0)207 397 1933
mfjohnson@cenkos.com

www.cenkos.com

COVID-19 impact on the pharma industry in 2020

Budgetary and clinical pressures

The impact of COVID-19 pandemic on the pharmaceutical industry was pronounced and caused material disruption to the industry's business model. The impact was felt in several ways:

- declining prescription income which created downward pressure on budgets,
- interruptions to clinical trials which has impacted drug development schedules, and
- disruption to normal working practices.

Focus on later stage assets

The pandemic in 2020 brought about a decline in revenue from on-market drugs across the pharmaceutical industry which necessitated an 'adjustment' period of some 3-6 months as stated by Novartis, amongst others. The response from the industry has been to focus on later stage (Phase III) trials in order to maintain the pipeline of drugs moving to approval. This is having the effect of protecting short term revenues.

Clinical trial interruption

Clinical trials have been impacted by COVID-19 as patients access to clinical trials was severely truncated because of national lockdowns. The impact on trials from this dearth of attendance has not been equal across diseases areas however. Trials for non-acute illnesses saw a substantial drop-off in activity but in areas such as oncology patient volume disruption lasted for no more than two months.

Increasingly digital business model

In-person meetings and entertainment between doctors and sales representatives continue to be significantly curtailed meaning the traditional client engagement model for the pharma industry has been severely challenged. This is creating a pivot to a more virtual operating model across the industry.

Recovery in 2021

Trial and approval recovery

Patient enrolment volumes are reported to be recovering as the industry has moved in 2021 (source: Evaluate Vantage 2021 Review). The volumes of new therapies seeking approval are rising (source: fdatracker.com/trial-tracker/) and Phase III volumes are reported to have recovered to 90% of prior year volumes (source: Evaluate Vantage 2021 Review). This recovery profile should have the effect of protecting or reinstating the budgets in Diaceutics' addressable market.

New forecasts

Focus on predictability

We see no diminution in the longer term opportunity for Diaceutics and we are cautiously forecasting a return to growth in our new FY21E forecasts. The instrumental role that Diaceutics plays in helping pharma bring the right precision medicine to the right person at the right time is immensely valuable to the industry's long term success in our view. We see a return to prior levels of revenue growth as the industry recovers in 2022 and beyond but for FY21E we base our forecasts on the following:

- 7% YoY growth in revenues driven by a recovering industry profile,
- a pipeline of signed backlog and late stage contracts producing over 40% visibility over this revenue figure,
- a further c60% of cover provided by identified opportunities yet to be won,
- further gross margin improvement to 81% as more projects are run on the DXRX platform,
- £1.9m of annualised cost savings enacted in late Q4 2020 with some savings redeployed into DXRX platform marketing expenditure.

Table 1: FY21E forecasts

Dec, £m	FY20A	FY21E	YoY delta %
Revenue	12.7	13.6	7.3
Gross margin (%)	80.6	80.9	0.3
EBITDA	0.5	2.0	280.2
PBT	-0.7	0.2	Nm
Free cash flow	-6.0	-3.8	Nm
Net cash	25.1	21.4	-15.0

Source: Company actuals, Cenkos Securities estimates

Positioned well in the US

It was notable in FY20A that Diaceutics' US activities, which constitute 47% of all revenues, saw less disruption than its European or Asian markets. Revenues in the US rose 7% YoY while those in Europe and Asia fell 6% YoY and 8% YoY respectively. There is still considerable caution in Diaceutics' underlying markets and macro risks still remain. Our cautious approach to forecasting FY21E revenue takes into consideration the potential impact that a third wave of COVID-19 might have on access to European laboratories or on reduced patient prescription rates.

New platform

The launch of the DXRX platform in Q4A plays straight into the evolving digitisation of the pharma industry. The collaborative nature of the DXRX platform places Diaceutics at the heart of a developing digital ecosystem. The automated flow of testing data from over 2,500 laboratories is driving increased efficiency internally and the company is reporting +30% increases in like-for-like pricing for data delivered via the platform. The comingling of proprietary diagnostic, claims and demographic data delivered via a subscription based, automated and secure platform transforms the value of the data lake and is we believe a unique proposition.

Expanded module base

The traditional delivery of the four data modules is being supplanted by 12 new modules on the platform which will deliver much broader functionality to clients as per the table below. This expanded offering and subsequent end-to-end commercialisation of the diagnostic journey is helping underwrite the rise in the collective information on disease pathways know as Diagnostic Deductive Pathways (DDPs). These DDPs to our mind are Diaceutics' real value proposition because of the longitudinal insight and predictive nature of the underlying data. The number of DDPs currently stand at 49 (versus 37 in Q4 2019) and the integration of these into the DXRX platform will enable Diaceutics to scale and drive future economic value for shareholders.

Table 2: DXRX modules

Conventional modules	DXRX platform modules
Landscape	Data subscription
Planning	Lab mapping
Implementation	Physician mapping
Tracking	Testing dashboard
	Test quality assessment
	Test educational awareness
	Test report optimisation
	Lab training
	Lab support
	Lab standardisation
	Test regulation
	Network access fee

Source: Company

Biopharma and diagnostics

In this chapter of the note, we aim to illustrate the increasing extent of the biopharmaceutical industry's reliance on the timely and accurate provision of companion diagnostics. As the prescription of an increasing number of pharmaceuticals becomes dependant upon a precision diagnostic, this relationship will likely increase.

We explain that:

- The increasing use or precision medicine is reliant upon the availability of both the precision therapeutic itself and the provision of an associated companion diagnostic to identify suitable patients to treat.
- The biopharmaceutical industry is increasingly moving towards precision medicine, particularly in oncology, and therefore we can expect an increasing number of precision medicine products on the market.
- The sale of precision medicines is expected to generate multiple $bn of revenues for the biopharmaceutical industry in the coming decade, all of which will be reliant upon the identification of patients with appropriate companion diagnostic testing.

What is precision medicine?

Precision medicine aims to tailor a patient's disease therapy specifically to their individual condition. There are two key elements to precision medicine, the therapeutic developed specifically for a sub-group of patients within a broader disease population and the companion diagnostic that identifies those patients by detecting a specific biomarker.

Precision medicines

It remains the case that for many healthcare conditions or diseases 'one-size fits all' therapies are the mainstay of treatment. The majority of patients therefore are treated with drugs or biological therapies that have been developed to treat the entire patient population suffering from a particular disease.

The biopharmaceutical industry's focus on one-size fits all likely reflects a combination of factors, including:

- **Disease knowledge** – previously limited understanding of biomarkers markers and the genetic drivers of disease.
- **Technical capabilities** – limited ability to identify biomarkers and to test potential patients in a timely and economical manner.
- **Market drivers** – the biopharmaceutical industry's aim to maximise investment returns by treating the broadest possible patient population.

However, with an increased understanding of the underlying causes of certain diseases and particularly their genetic drivers, previously broadly categorised conditions can be sub-divided into smaller populations based upon the different disease drivers.

With this new information, the biopharmaceutical industry is increasingly developing medicines targeted at specific sub-populations of patients. These medicines offer the hope of improved patient outcomes, reduced side effects and lower development risk and cost in the form of precision medicine.

There a many benefits associated with the development and increased use of precision medicines, for patients, healthcare systems and the biopharmaceutical industry. These include:

- Potential for improved efficacy as the precision medicine is targeted at a specific disease driver which is known to be present.
- Reduced population-level side effects as patients who will not benefit (ie do not have the specific biomarker) will not be treated with a drug and therefore avoid any side effect risk.
- Reduced healthcare costs as expensive therapies are not given to patients who will not respond to them.
- Reduced cost of development as smaller, targeted populations can be tested in drug trials.

The FDA defines precision medicine as *'an innovative approach to tailoring disease prevention and treatment that takes into account differences in people's genes, environments, and lifestyles. The goal of precision medicine is to target the right treatments to the right patients at the right time.'*

Companion diagnostic

To accurately identify the subset of patients who may respond to a precision medicine, specific diagnostic tests are required to identify the specific biomarker which defines the sub-group of patients within the broader disease classification. These diagnostic tests are termed companion diagnostics (CDx).

- **Biomarkers** – combining the words 'biological' and 'marker', a biomarker is defined as '*a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention*' by the National Institutes of Health Biomarkers Definitions Working Group.
- **Types of CDx** – there are many types of companion diagnostic that can identify a range of different biomarkers including single gene mutations or alterations in the structure or expression of a protein.

The FDA defines a companion diagnostic as an '*in vitro diagnostic device or an imaging tool that provides information that is essential for the safe and effective use of a corresponding therapeutic product.*'

Precision medicine in practice

To sum up, a precision medicine is targeted at patients who have a specific biomarker, with a companion diagnostic required to identify this sub population of patients. In many cases, the precision medicine cannot be prescribed unless a patient has been classified using the applicable companion diagnostic.

For example, in oncology, which is at the forefront of precision medicine, many new therapeutics are targeted at specific gene mutation drivers of a specific cancer. Therefore, unless the patient has the specific mutation the 'precision medicine' is unlikely to work and if used in the absence of the biomarker could expose the patient to un-necessary risk of side effects.

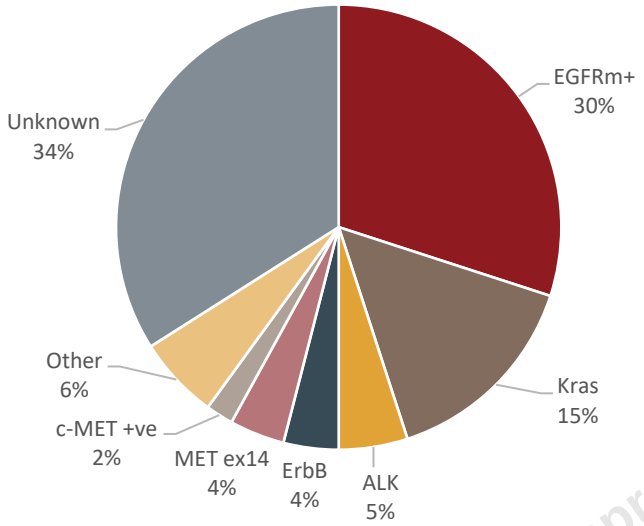
Therefore, identifying patients with the specific biomarker identifies a subset of patients most likely to benefit from treatment with the precision medicine.

Case study: Non-small cell lung cancer (NSCLC)

With an increasing 'academic' understanding of the genetic mutations that drive specific cancers, the biopharmaceutical industry is able to develop therapies that specifically and precisely target the specific mutation.

For example, the chart below shows the main genetic mutation drivers of non-small cell lung cancer (NSCLC).

Chart 1: NSCLC mutation drivers – treatment naïve patients



Source: Hutchison China Meditech R&D Briefing 2017

As shown, ahead of treatment, approximately two thirds of patients have an identifiable genetic mutation driver of their cancer. Further, for specific mutations there are specific therapeutic options – precision medicines.

The table below shows the range of precision medicines available to treat NSCLC associated with a specific gene mutation. Prior to prescribing any of these drugs, a patient's mutation status needs to be assessed to ensure the correct drug is used for the most suitable patients.

Table 3: Precision medicines for NSCLC

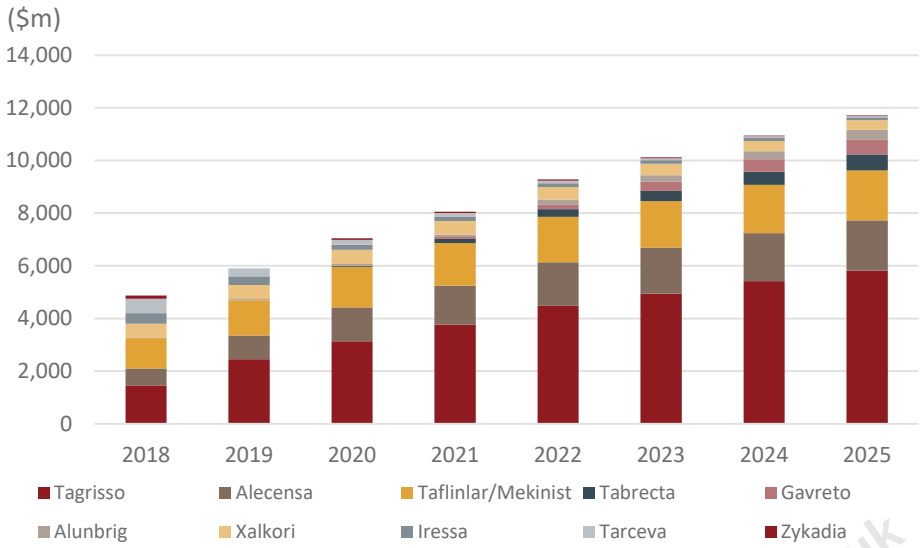
NSCLC mutation	Therapeutic options
EGFRm+	Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib), Tagrisso (osimertinib), Vizimpro (dacomitinib)
Kras	sotorasib (currently in Phase 3. Amgen AMG 510)
ALK	Xalkori (crizotinib), Zykadia (ceritinib), Alecensa (alectinib), Alunbrig (brigatinib), Lorbrena (lorlatinib)
MET	Tabrecta (capmatinib), Tepmetko (tepotinib)
ROS1	Xalkori (crizotinib), Zykadia (ceritinib), Lorbrena (lorlatinib), Rozlytrek (entrectinib)
BRAF	Taflinlar/Mekinist (dabrafenib/trametinib)
RET	Retevmo (selpercatinib), Gavreto (pralsetinib)
NTRK	Vitrakvi (larotrectinib), Rozlytrek (entrectinib)

Source: American Cancer Society

The sales potential of the drugs listed in the table above is estimated at least $12bn by 2025 (FactSet), as shown in the chart below. Note that estimates for all drugs are not available, and therefore this represents a subset as shown in the legend.

As such, in just this limited group of precision medicines indicated for NSCLC, there is expected to be over $12bn of revenues dependent upon correctly identifying patients with the specific mutations relevant to each drug.

Chart 2: Revenue estimates for NSCLC precision medicines



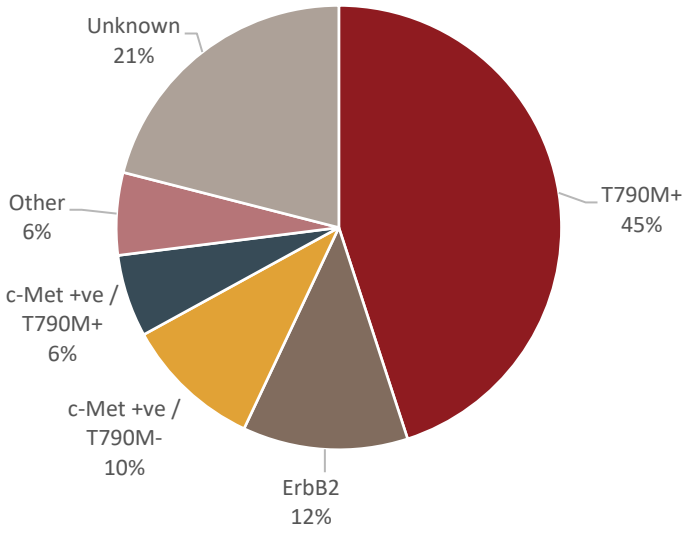
Source: FactSet

Second line NSCLC

NSCLC is not a stable condition and after several months of even successful treatment with an EGFR inhibitor, most patients will develop additional mutations and become refractory to their first line therapy.

In these situations, a further assessment of the tumour mutation can be undertaken and a new precision medicine potentially prescribed. The chart below shows the distribution of genetic mutation drivers in patients with EGFR inhibitor refractory second line NSCLC.

Chart 3: NSCLC mutation drivers – EGFRi refractory



Source: Hutchison China Meditech R&D Briefing 2017

Precision medicine approvals

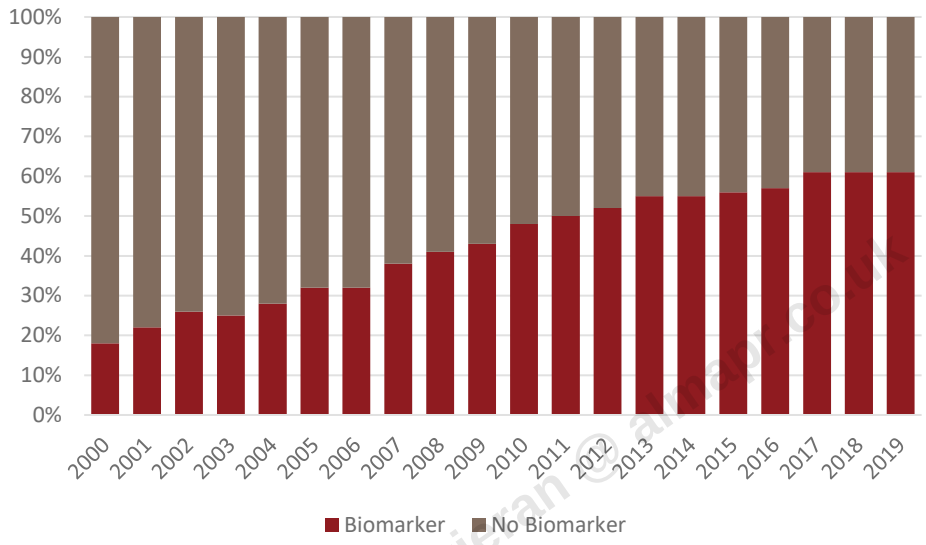
Biomarkers in clinical trials

The availability of precision medicines to treat patients has its beginnings in the clinical development of drugs targeted at a defined sub-group of patients with a specified biomarker.

As shown in the chart below, the use of biomarkers in trials for pipeline oncology products has steadily increased since the year 2000. As such, by 2019, over 60% of drug trials for cancer treatments incorporated a biomarker, up from less than 20% in 2000.

This increase in the use of biomarkers in clinical trials for oncology products will almost certainly lead to an increase in the requirement to use biomarkers in the treatment of cancer patients in the future.

Chart 4: Use of biomarkers in oncology clinical trials

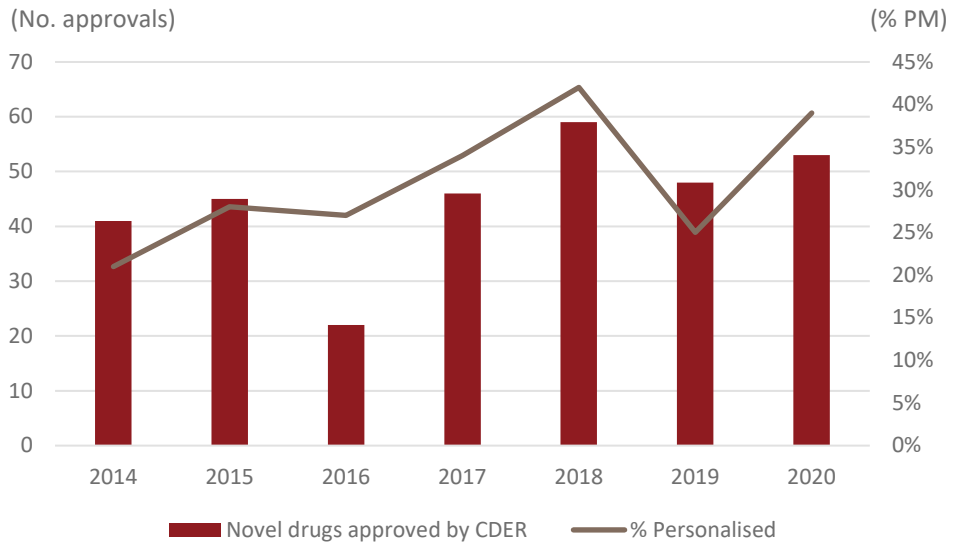


Source: The Personalized Medicine Report: 2020 - Opportunity, Challenges, and the Future. Personalized Medicine Coalition

Precision medicine FDA approvals

With the increasing trends in the use of biomarkers in clinical trials, an increase in the proportion of FDA approved drugs defined a precision medicines is apparent, as shown in the chart below.

Chart 5: FDA NDA approvals and % defined as precision medicines

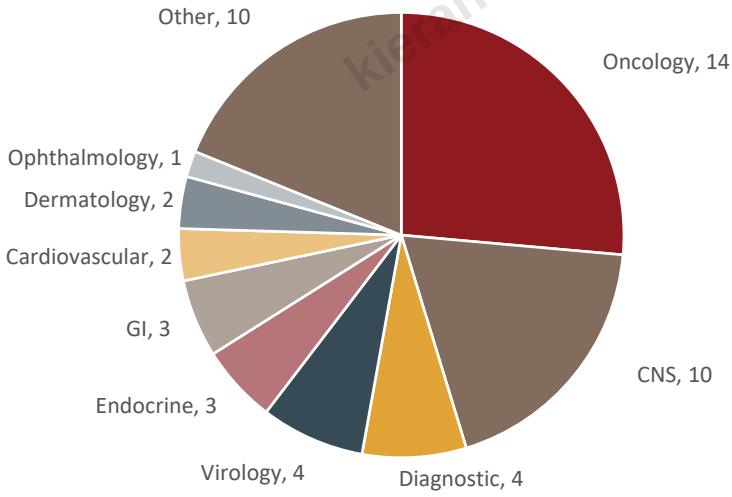


Source: Statista.com. Personalized Medicine At FDA. Personalized Medicine Coalition

2020 FDA approvals

In 2020, the FDA approved 53 novel drugs (new drug applications - NDAs) often representing innovative products to treat medical unmet needs. The active ingredients associated with these NDAs will not have been previously approved for use in the US.

Chart 6: FDA 2020 NDAs by therapeutic area



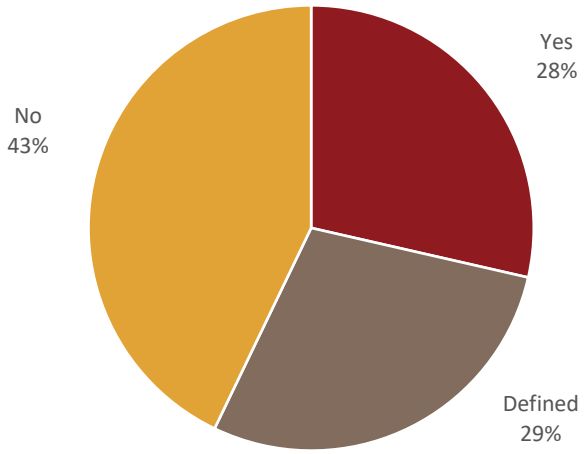
Source: FDA. Cenkos Securities estimates

While precision medicine encompasses a broad range of therapeutic areas, oncology remains the most important precision medicine market. Focusing specifically on oncology, the FDA approved 14 NDAs for oncology products, of which:

- four product labels (Prescribing Information) had specific reference to requiring a diagnostic test prior to prescribing, for example '*detected by an FDA-approved test*'.
- four product labels referenced treating patients with a specific tumour mutation, for example '*metastatic HER2-positive breast cancer*' indicating the requirement for a diagnostic test prior to use.

- six drug labels did not directly reference the requirement for a pre-treatment test.

Chart 7: Pre-prescription diagnostic test requirement, 2020 oncology NDA approvals



Source: FDA. Cenkos Securities estimates

The table below details the 14 oncology NDA approvals received in 2020 and the associated testing statements taken from the individual approved drug label (Prescribing Information).

Table 4: 2020 oncology FDA approved NDAs

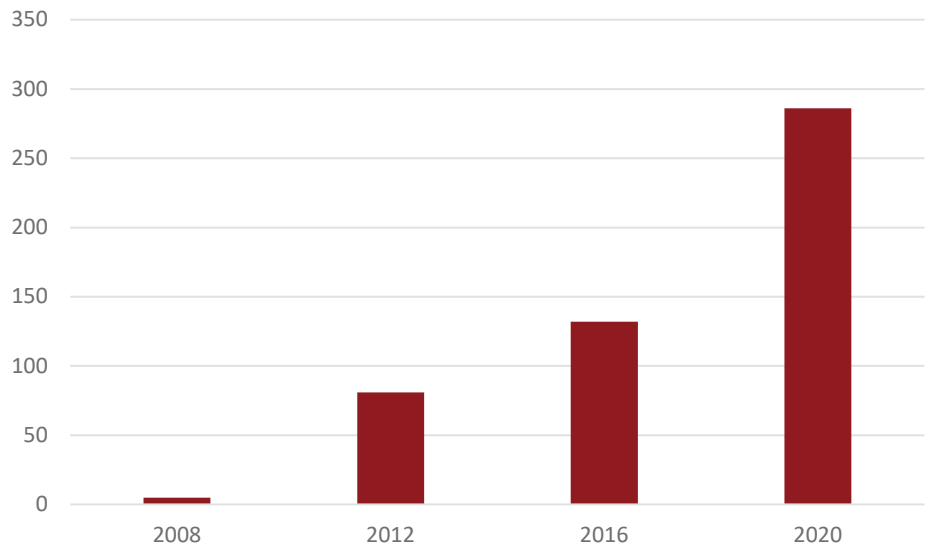
Brand	Generic	Testing requirement
Tazverik	tazemetostat	Positive for an EZH2 mutation as detected by an FDA-approved test
Sarclisa	isatuximab	n/a
Tukysa	tucatinib	Advanced unresectable or metastatic HER2-positive breast cancer
Pemazyre	pemigatinib	FGFR2 fusion or other rearrangement as detected by an FDA-approved test
Trodelvy	sacituzumab govitecan-hziy	Metastatic triple-negative breast cancer (mTNBC)
Tabrecta	capmatinib	Mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
Retevmo	selpercatinib	Metastatic RET fusion-positive non-small cell lung cancer
Zepzelca	lurbinectedin	n/a
Monjuvi	tafasitamab-cxix	n/a
Blenrep	belantamab mafodotin-blmf	n/a
Gavreto	pralsetinib	RET fusion-positive non-small cell lung cancer as detected by an FDA approved test
Margenza	margetuximab	Metastatic HER2-positive breast cancer
Orgovyx	relugolix	n/a
Danyelza	naxitamab-gqgk	n/a

Source: FDA. Drug specific prescribing information

Precision medicines on the market

The on-going approval of new precision medicines is therefore leading to a cumulative increase in the number of precision medicines available on the market, as shown in the chart below. The Precision Medicine Coalition estimate that in 2020 there were 286 precision medicines available in the US.

Chart 8: No. of personalised medicines on the US market



Source: The Personalized Medicine Report: 2020 - Opportunity, Challenges, and the Future. Personalized Medicine Coalition

FDA pharmacogenomic markers

Pharmacogenomic prescribing requirements

The FDA provides a list of 431 instances of pharmacogenomic information being present on a therapeutic's product label (prescribing information), with some drug labels containing multiple references in different sections of the label[1].

Pharmacogenomics is the study of how a person's genotype affects their response to a drug treatment. Genetics can identify potential responders and non-responders, screen for patients most likely to have an adverse reaction to a drug and allow optimisation of drug dosage. Increasingly the genetic contribution to a disease can direct treatment towards a precision medicine option that has been developed to target the specific genetic mutation.

In total there are c300 individual therapeutics listed whose prescribing information includes pharmacogenetic information and over 100 individual pharmacogenomic markers mentioned.

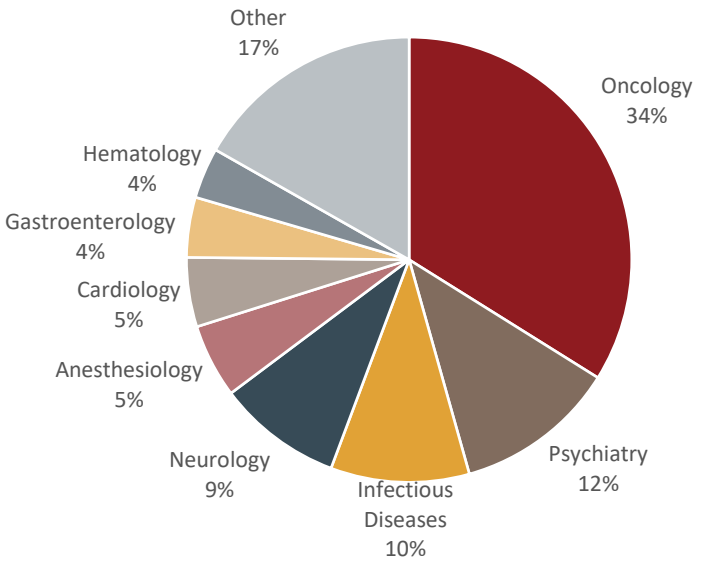
By therapeutic area

As shown in the chart, and perhaps unsurprisingly, oncology therapeutics most commonly have pharmacogenomic information listed in their prescribing information, with over 100 individual pharmacogenomic references (34%).

Other significant therapeutic areas referencing pharmacogenomic information on prescribing labels include psychiatry (35 / 12%), infectious diseases (30 / 10%) and neurology (27 / 9%).

[1] https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling

Chart 9: Pharmacogenomic drug label information, by indication



Source: FDA

By genomic marker

There are over 100 specific pharmacogenomic biomarkers referenced in the c300 individual therapeutics pharmacogenetic information referenced on their labels. We highlight the most commonly reference pharmacogenomic biomarkers in the table below along with the frequency with which they are mentioned.

Table 5: Common pharmacogenomic markers on FDA approved drug labels

Pharmacogenomic marker	Frequency
CYP isoforms	112
G6PD	39
ERBB2 (HER2)	18
ESR, PGR (Hormone Receptor)	15
EGFR	12
IFNL3 (IL28B)	12
Chromosome alterations	11
ALK	10
BCR-ABL1 (Philadelphia chromosome)	10
Nonspecific (Congenital Methemoglobinemia)	10
UGT1A1	10
RAS	9
BRAF	8
BRCA	6
CD274 (PD-L1)	6
ESR (Hormone Receptor)	6
HLA-B	6
Other	131

Source: FDA

Most commonly referenced are CYP genotypes, including CYP1A2, CYP2B6, CYP2C19, CYP2C9, CYP2D6 and CYP3A5. Cytochrome P450 (CYP450) enzymes are a family of human proteins expressed largely in the liver and gut that are commonly involved in the metabolism of drugs, clearing these compounds from the blood stream.

Different isoforms (genetic variants) of CYP450 enzymes result in individuals breaking down drugs either faster or slower than the general population. This could result in a 'normal' dose of a drug resulting in either and over or and under dosage, depending upon specific expression.

As such identification of a patient's CYP450 genetics is important prior to prescribing a wide range of drugs, including commonly prescribed products such as statins, anti-depressants and blood thinners.

It is estimated that 70% of drugs are metabolised by one of four CYP450 enzymes, 3A4/5, 2D6, 2C9 and 2C19.

By genomic marker - oncology

There are 184 pharmacogenomic information references to 62 individual pharmacogenomic biomarkers across the c100 oncology therapeutics with pharmacogenomics mentioned in their labels.

The table below shows the most commonly reference pharmacogenomic biomarkers mentioned across the 184 total references.

Table 6: Common pharmacogenomic markers on FDA approved oncology drug labels

Pharmacogenomic biomarker	Frequency
ERBB2 (HER2)	18
ESR, PGR (Hormone Receptor)	15
EGFR	12
ALK	10
BCR-ABL1 (Philadelphia chromosome)	10
RAS	9
BRAF	8
Chromosome alteration	8
BRCA	6
CD274 (PD-L1)	6
ESR (Hormone Receptor)	6
UGT1A1	6
CYP isoforms	5
G6PD	4
Microsatellite Instability, Mismatch Repair	4
FLT3	3
ROS1	3
Other	51

Source: FDA

Companion diagnostics in the US

FDA approved companion diagnostics devices

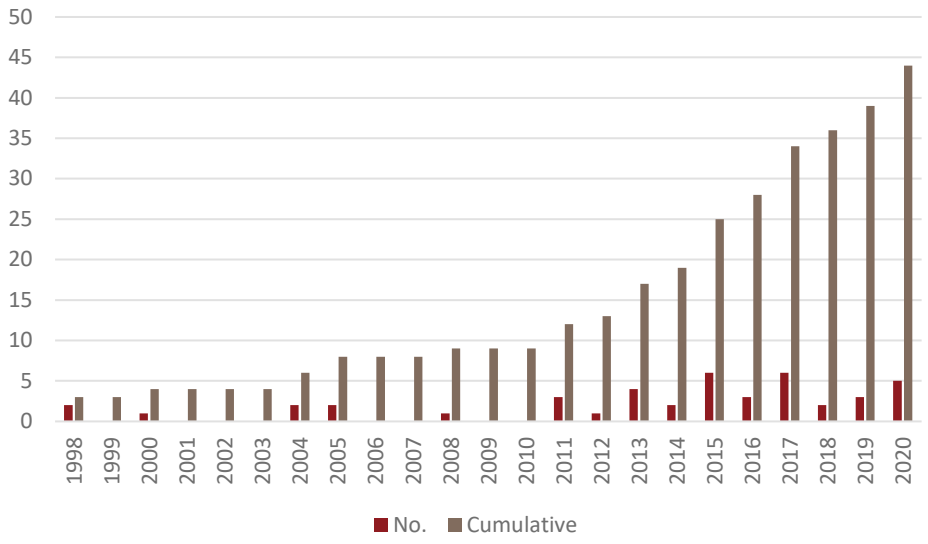
As noted earlier, the FDA defines a companion diagnostic as an *'in vitro diagnostic device or an imaging tool that provides information that is essential for the safe and effective use of a corresponding therapeutic product.'*

To date, the FDA has approved 44 companion in vitro diagnostic devices (IVDs) associated with specifically identified oncology therapeutics. As such, these oncology drugs, for example Lynparza, will have a specific reference to the use of an FDA-approved companion diagnostic prior to use. The companion diagnostic tests cover 44 separate drugs or drug combinations.

The FDA states that '*the use of an IVD companion diagnostic device is stipulated in the labeling of the therapeutic product, as well as in the labeling of any generic equivalents and biosimilar equivalents of the therapeutic product.*'

IVDs are products that contain all the relevant reagents to undertake a diagnostic test and, as noted, are regulated by the FDA as medical devices.

Chart 10: Companion diagnostic approvals by the FDA



Source: FDA. https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

FDA approved nucleic acid based tests

Alongside the specifically defined companion diagnostics discussed above, the FDA also approves nucleic acid-based tests which can be used in the process of prescribing precision medicines.

The FDA defines these tests as able to '*analyze variations in the sequence, structure, or expression of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) in order to diagnose disease or medical conditions, infection with an identifiable pathogen, or determine genetic carrier status.*'

To date, the FDA has cleared 133 nucleic acid tests, which are used for a range of diagnostic functions, as shown in the table below.

Table 7: FDA approved nucleic acid tests

Disease/Use	No. approvals
Breast Cancer	17
Drug Metabolizing enzymes	14
Coagulation Factors	13
Cystic Fibrosis	12
Colorectal Cancer	8
Tumour Profiling	8
Acute Myeloid Leukaemia	6
Chromosome abnormalities	6
Non-Small Cell Lung Cancer	6
Other	43

Source: FDA. https://www.fda.gov/medical-devices/vitro-diagnostics/nucleic-acid-based-tests#human

Laboratory developed tests (LDTs)

As noted, there are 44 FDA approved invitro diagnostic tests and 133 nucleic acid tests on the market in the US, however the majority of tests used in precision medicine are laboratory developed tests (LDTs) rather than approved invitro diagnostic kits (IVDs). As noted below there are over 260,000 recognised laboratories in the US covered by regulations that allow them to develop LDTs.

LDTs are diagnostic tests that are designed and performed by the single specific laboratory in which they are used. Relatively few LDTS have received FDA approval, instead the laboratories are covered by the Clinical Laboratory Improvement Amendment (CLIA) regulations. The CLIA regulations are administered by the Centers for Medicare and Medicaid Services (CMS).

CMS estimates that CLIA covers approximately 260,000 laboratory entities in the US, as defined in the table below. We note that the 'Independent' category includes laboratories operated by for-profit business such as US listed, Laboratory Corp. of America (LabCorp), a $23bn company.

Table 8: Laboratories by Type of Facility

Category	Number
Physician Office	121,125
Skilled Nursing/Nursing Facility	14,985
Home Health Agency	13,091
Pharmacy	12,534
Hospital	9,108
End Stage Renal Disease Dialysis	7,229
Community Clinic	6,714
Independent	6,577
Ambulatory Surgery Center	6,481
Other	68,672

Source: CMS

Precision medicines market

In this section, we discuss significant companies and therapeutic markets that are at the forefront of precision medicine and are therefore dependent upon the accurate and timely provision of a companion diagnostic to identify patients ahead of prescribing the specific drug.

The table below is based upon the list of FDA approved drugs that also have a specific FDA approved companion diagnostic (IVD). As shown, these drugs generated over $45bn of revenues in 2019 and are expected to generate over $80bn of revenues by 2025E.

Table 9: Revenue estimates for branded drugs with an FDA approved IVD CDx ($m)

Company	Brand	Generic	2019A	2025E
Agios	Tibsovo	ivosidenib	0	160
Amgen	Vectibix	panitumumab	744	647
Astellas	Xospata	gilteritinib	n/a	n/a
AstraZeneca	Iressa	gefitinib	325	115
AstraZeneca	Lynparza	olaparib	921	3,247
AstraZeneca	Tagrisso	osimertinib	2,450	5,816
Bayer	Vitrakvi	larotrectinib	n/a	n/a
Boehringer Ingelheim	Gilotrif	afatinib	n/a	n/a
Bristol Myers Squibb	Idhifa	enasidenib	13	100
Bristol Myers Squibb	Opdivo/Yervoy	nivolumab/ipilimumab	n/a	n/a
	Opdivo[1]	nivolumab	7,204	12,102
	Yervoy[1]	ipilimumab	1,489	2,415
Clovis	Rubraca	rucaparib	143	370
Epizyme	Tazverik	tazemetostat	n/a	n/a
GlaxoSmithKline	Zejula	niraparib	297	1,487
Incyte	Pemazyre	pemigatinib	0	156
J&J	Balversa	erdafitinib	n/a	n/a
Lilly	Erbitux[2]	cetuximab	543	357
Merck & Co	Keytruda	pembrolizumab	11,084	25,656
Novartis	Exjade	deferasirox	975	233
Novartis	Gleevec	imatinib	1,263	582
Novartis	Tafinlar/Mekinist	trametinib/dabrafenib	1,338	1,900
Novartis	Piqray	alpelisib	0	1,224
Novartis	Rydapt	midostaurin	0	900
Novartis	Tasigna	nilotinib	1,880	580
Novartis	Tabrecta	capmatinib	0	606
Novartis	Zykadia	ceritinib	0	15
Pfizer	Braftovi	encorafenib	n/a	n/a
Pfizer	Talzenna	talazoparib	n/a	n/a
Pfizer	Vizimpro	dacomitinib	n/a	n/a
Pfizer	Xalkori	crizotinib	530	364
Roche	Alecensa	alectinib	905	1,909
Roche	Cotellic	cobimetinib	59	131
Roche	Gavreto	pralsetinib	0	570
Roche	Herceptin	trastuzumab	6,236	1,414
Roche	Kadcyla	trastuzumab emtansine	1,439	2,631
Roche	Perjeta	pertuzumab	3,637	6,146
Roche	Tarceva	erlotinib	308	49
Roche	Tecentriq	atezolizumab	1,936	6,484
Roche	Venclexta	venetoclax	802	2,034
Roche	Zelboraf	vemurafenib	0	371
Takeda	Alunbrig	brigatinib	47	364
Total estimated revenues			**46,568**	**81,131**

Source: Company data. FactSet. 1- individual drug revenue estimates. 2 – Eli Lilly revenues only.

The drugs listed above will generally have a statement in their specific prescribing information documents relating to the use of an 'FDA-approved test'. We note the following examples in the labels of the therapeutics that are expected to generate significant revenues in 2025.

- **Keytruda** – 'as a single agent for the first-line treatment of patients with NSCLC expressing PD-L1 [Tumor Proportion Score (TPS) ≥1%] as determined by an FDA-approved test'
- **Opdivo** – 'adult patients with metastatic non-small cell lung cancer expressing PD-L1 (≥1%) as determined by an FDA-approved test'
- **Perjeta** – 'HER2 testing: Perform using FDA-approved tests by laboratories with demonstrated proficiency'

- **Tagrisso** – 'the first-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test'
- **Lynparza** – 'Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza'
- **Alcensa** – 'for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test'

Precision medicine revenue by company

Given precision medicine at present is very focused on oncology, we have limited the subsequent review to the oncology space and note that this discussion is not an exhaustive review of precision medicine market expectations. As such a larger market exists beyond the specific companies discussed below.

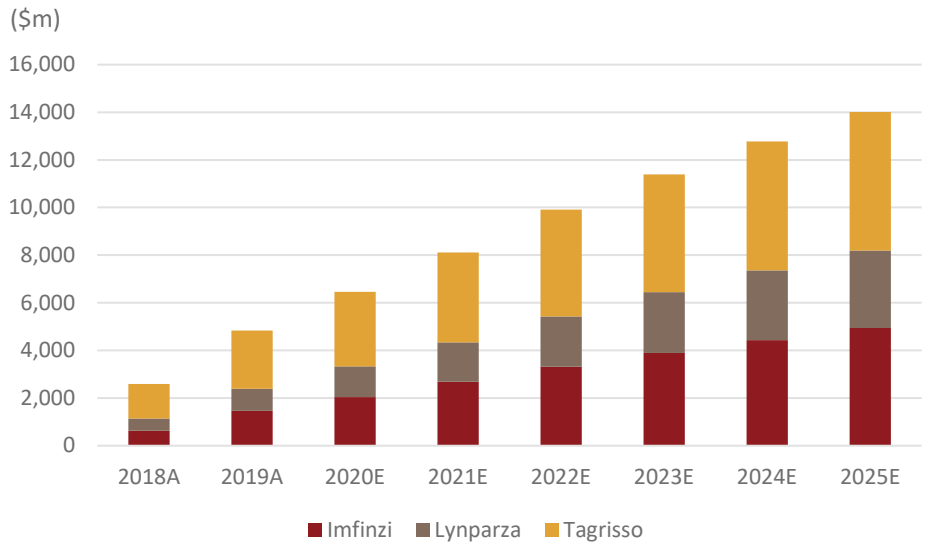
AstraZeneca

AstraZeneca has actively targeted precision medicine in recent years and now has, in our opinion, some of the most exciting precision medicine products on the market.

- Imfinzi – an anti-PD-L1 antibody indicated for NSCLC and small cell lung cancer.
- Lynparza – a PARP inhibitor approved for a range of cancers, particularly those with BRCA mutations.
- Tagrisso – an EGFR inhibitor, specifically developed to target the T790M mutation.

Consensus analyst expectations are for these three drugs to generated revenues of c$9bn for AstraZeneca by 2025E.

Chart 11: Revenue forecasts for specific precision medicines, AstraZeneca



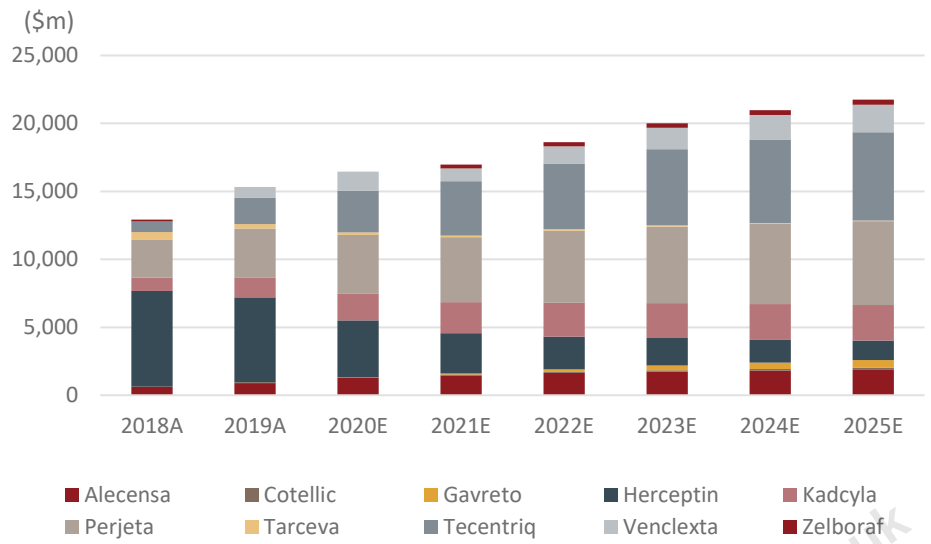
Source: FactSet

Roche

Roche can probably be considered as the market leader in precision medicine, being the company that developed what is considered the first precision medicine, Herceptin for treating HER2 positive breast cancer.

As shown in the chart below, analyst expectations are for the drugs shown (key precision medicines) to generate over $20bn of revenues for Roche by 2025E.

Chart 12: Revenue forecasts for specific precision medicines, Roche

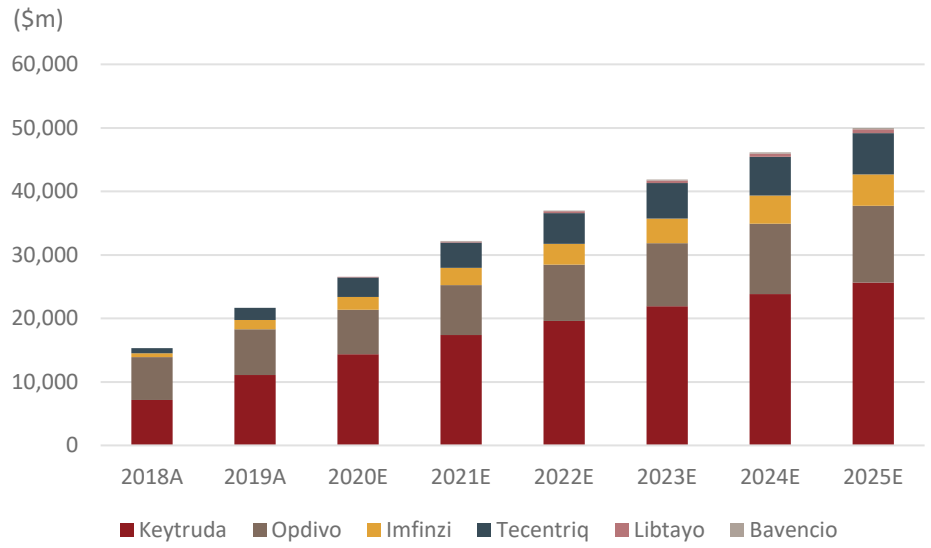


Source: FactSet

PD-1 / PD-L1 inhibitors

At a therapeutic level, the chart below shows analyst expectations for the group of PD-1 / PD-L1 targeting antibodies which have been developed by a number of pharmaceutical companies. As shown, these six therapeutics are expected to generate $50bn in revenues by 2025E, with Merck & Co's Keytruda expected to generate $25bn in 2025E alone.

Chart 13: Revenue forecasts for specific checkpoint inhibitors



Source: FactSet

Laboratory testing market

As noted earlier there are over 260,000 laboratories operating under the CMS' CLIA regulations. Within these are c6,000 independent laboratories including those operated by private and public companies such as LabCorp.

LabCorp estimates that the US '*clinical laboratory testing industry generated revenues of more than $80 billion'* in 2020.

Grand View Research estimate the global clinical laboratory service market was worth $200bn in 2020 and expect it to grow at a rate of 4.7% from 2021 to 2028 reaching c$290bn in size. The market is expected to be driven by the increasing prevalence of chronic diseases and demand for early diagnosis of disease.

Research and Markets forecast the global oncology companion diagnostic market reaching $5.7bn in 2027, based on a growth rate of 12.7% from 2020. Growth is expected to be driven by the number of companion diagnostic tests being used in clinical trials which should deliver marketed CDx use in the future.

Financials

Table 10: Income Statement

Y/E December (£m)	2018A	2019A	2020A	2021E
Revenue	10.4	13.4	12.7	13.6
% Change YoY	40.7	29.6	-5.6	7.2
Cost of sales	-3.5	-3.1	-2.5	-2.6
Gross profit	6.9	10.3	10.2	11.0
Gross margin (%)	66.3	76.7	80.6	80.9
Other operating income	0.1	0.2	0.3	0.2
Research & Development	0.0	0.0	0.0	0.0
Administrative expenses	-5.1	-8.1	-9.7	-8.5
EBITDA	**1.5**	**2.4**	**0.5**	**2.0**
EBITDA margin (%)	14.7	17.7	4.2	15.0
Adjusted EBITDA	**1.9**	**2.4**	**0.8**	**2.7**
% Change YoY	81.7	24.2	-65.4	228.0
Depreciation & amortisation	-0.1	-0.3	-0.8	-1.8
Exceptional items	-0.2	-1.3	-0.4	0.0
EBIT	1.2	0.7	-0.7	0.2
Net interest	-0.3	-0.2	0.0	0.0
Profit/(Loss) before tax	0.9	0.5	-0.7	0.2
Adj PBT	0.9	1.8	-0.7	0.2
Tax charge	-0.2	-0.1	0.9	0.6
Profit/(loss) after tax	**0.6**	**0.4**	**0.2**	**0.8**
Adj PAT	**0.6**	**0.4**	**0.2**	**0.8**
% Change YoY	-4.7	-37.1	-37.5	238.3
Profit attributable to company owners	0.6	0.4	0.2	0.8
Minority interests	0.0	0.0	0.0	1.0
Diluted Basic EPS (p)	**3.0**	**0.6**	**0.3**	**1.0**
Adj EPS (p)	4.0	2.7	0.8	1.0
% Change YoY	26.3	-32.4	-69.9	21.9
DPS (p)	0.0	0.0	0.0	0.0
Average shares FD (m)	20.8	64.1	77.5	84.1

Source: Cenkos Securities estimates, Company data

Table 11: Cash Flow

Y/E December (£m)	2018A	2019A	2020A	2021E
EBIT	**1.2**	**0.7**	**-0.7**	**0.2**
Depreciation	0.0	0.0	0.0	0.2
Amortisation (incl. impairments)	0.1	0.2	0.8	1.6
Working capital	-2.5	-1.5	0.5	-1.0
Share based payments	0.4	0.0	0.3	0.7
Other including exceptional costs	0.0	0.0	-0.2	0.0
Operating Cash Flow	**-0.8**	**-0.5**	**0.7**	**1.7**
Net Interest	-0.3	-0.2	0.0	0.0
Tax	-0.2	-0.2	-0.4	0.6
Cash flow pre-capex and investment	**-1.3**	**-0.9**	**0.3**	**2.3**
Adj free Cash flow	**-2.4**	**-3.8**	**-6.0**	**-3.8**
Investment in intangible assets	-0.5	-1.1	-3.2	-3.5
Net capex and capitalised development	-0.7	-1.8	-3.1	-2.6
Acquisitions/disposals	0.0	0.0	0.0	0.0
Financing/other	1.6	13.4	19.6	0.0
Dividends	-0.3	0.0	0.0	0.0
Net Cash Flow	**-1.0**	**9.6**	**13.5**	**-3.8**
Closing Net Cash/(Debt)	**-1.7**	**11.6**	**25.1**	**21.4**

Source: Cenkos Securities estimates, Company data

Table 12: Balance Sheet

Y/E December (£m)	2018A	2019A	2020A	2021E
Fixed Assets	0.1	0.1	0.2	0.2
Goodwill & other intangible assets	1.2	3.8	9.4	13.7
Other long term assets	0.1	0.1	0.3	0.3
Total Fixed Assets	**1.3**	**4.0**	**9.9**	**14.2**
Income tax receivable	0.0	0.0	2.3	0.0
Trade receivables	4.4	6.7	6.1	7.6
Cash	2.1	11.7	25.3	21.5
Total Current Assets	**6.5**	**18.4**	**33.6**	**29.1**
Trade payables	-1.0	-1.7	-2.3	-2.5
Deferred income	-0.2	-0.5	0.0	-0.3
Other payables	-2.7	-0.1	-0.6	-0.1
Total Current Liabilities	**-3.9**	**-2.2**	**-2.9**	**-3.0**
Net Current assets	**2.5**	**16.2**	**30.7**	**26.1**
Long term liabilities	-1.1	0.0	0.0	0.0
Deferred tax liabilities	0.0	0.0	0.0	0.0
Other payables	-0.2	0.0	-0.4	0.0
Total Long Term Liabilities	**-1.2**	**0.0**	**-0.4**	**0.0**
Net Assets	**2.6**	**20.1**	**40.2**	**40.3**

Source: Cenkos Securities estimates, Company data

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	Corporate No.	Corporate %	No.	%
Buy	58	80	72	81
Hold	1	1	3	3
Sell	0	0	0	0
Under review	13	18	13	14

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.

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Company	Disclosures	Date	Rec	Price
Diaceutics Plc	2,6,7,8,9,10,11	07 Sep 20	Hold	175p
		13 Jan 20	Buy	102p

Source: Cenkos Securities

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