Aide memoire October 2020



To whom it may concern,

This letter sets forth public information previously provided by AstraZeneca and others which may prove helpful in estimating the financial performance of AstraZeneca ahead of year-to-date and third quarter 2020 results.

Sell-side analysts who wish to contribute to company-collected consensus estimates are requested to submit updated numbers by **Tuesday 20 October 2020**; details are provided in the appendix. As usual, those analysts who contribute will automatically receive the consensus data in return.

Following first-half 2020 results, AstraZeneca would like to highlight the following important considerations and prior disclosures (all guidance and indications are at constant exchange rates (CER)):

1. 2020 guidance

Financial guidance for 2020 is unchanged. Total revenue is expected to increase by a high single-digit to a low double-digit percentage and Core EPS is expected to increase by a mid- to high-teens percentage. AstraZeneca recognises the heightened risks and uncertainties from the impact of COVID-19 referred to in the first-half 2020 results announcement. Variations in performance between quarters can be expected to continue.

2. Total revenue

There was only a modest inventory-related benefit to total revenue, reflecting the effects of the ongoing COVID-19 pandemic, in the first half of the year. The table below shows quarterly product sales, collaboration revenue and total revenue since Q1 2019:

\$m	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020
Product sales	5,465	5,718	6,132	6,250	6,311	6,048
Collaboration revenue	26	105	274	414	43	227
Total revenue	5,491	5,823	6,406	6,664	6,354	6,275
Y-o-y % (CER)	11%	18%	22%	5%	17%	11%

3. Product sales

3.1 Oncology

In an broader interview on the heels of the European Society of Medical Oncology in <u>The Times</u> on 24 September 2020, the Company mentioned it has seen a noticeable drop in cancer screenings, cancer diagnosis and initiation of new therapies for cancer patients across the globe during the pandemic period with signs of recovery since the low point while the pandemic has also led to increased patient demand for at-home testing and treatment.

Lynparza & Faslodex

As mentioned in previous results announcements, analysts are reminded that both *Lynparza* and *Faslodex* faced mandated price cuts during the second quarter of 2020 in Japan (14% and 25% respectively).

Enhertu

Daiichi Sankyo books sales of *Enhertu* in the US and <u>forecasts</u> US sales of ¥27bn (~\$251m) in their fiscal 2020 year (ending March 2021). Daiichi Sankyo will also book sales in most European countries

(where it has affiliates). AstraZeneca will book sales in China, Australia, Canada, Russia and some other countries, including many Eastern European countries. Where AstraZeneca does not book sales, it reports its half of gross profits as collaboration revenue. In Japan, Daiichi Sankyo will book sales and pay AstraZeneca a small royalty.

In July, AstraZeneca and Daiichi Sankyo announced a new collaboration, on DS-1062 a TROP2-directed antibody-drug conjugate. AstraZeneca will pay Daiichi Sankyo an upfront payment of \$1bn in staged payments: \$350m was due upon completion, \$325m after 12 months and \$325m after 24 months from the announcement. AstraZeneca will pay additional conditional amounts of up to \$1bn for the successful achievement of regulatory approvals and up to \$4bn for sales-related milestones. Sales of DS-1062 will be booked similar to *Enhertu*.

Calquence

Analysts are reminded that in the chronic lymphocytic leukaemia (CLL) setting, *Calquence* is currently approved in 13 countries including the US (<u>announced</u> on 21 November 2019), Canada and Australia. In the EU, a positive CHMP opinion was announced on 27 July 2020, now awaiting formal approval before any launch and sales booking can take place.

3.2 Cardiovascular, Renal and Metabolism

Roxadustat

In China, the medicine is currently approved in both the dialysis and non-dialysis settings and the FibroGen collaboration has a 50/50 split of gross profit with AstraZeneca booking its share of gross profit as collaboration revenue. FibroGen has previously shared an estimated annual net price in China of approximately \$1,500. AstraZeneca booked \$9m of collaboration revenue in the second quarter of 2020. On 10 July 2020, FibroGen <u>announced</u> an amendment to the collaboration, resulting in AstraZeneca anticipating to book the majority of sales from 2021 (and account for FibroGen's share of gross profits through cost of sales).

In the US, FibroGen has <u>announced</u> regulatory submission acceptance for roxadustat with an action date of 20 December 2020. Upon launch, AstraZeneca will book sales and pay FibroGen a transfer price based on a percentage of net sales in the low- to mid-single digit range and a tiered percentage royalty on net sales in the low 20s.

3.3 Respiratory & Immunology

Pulmicort

In China, the second-quarter 2020 performance of *Pulmicort* continued to be impacted by local COVID-19 pandemic restrictions, with a significant reduction in the number of paediatric patients attending outpatient nebulisation rooms and adult elective procedures, where *Pulmicort* can be used in operative care when oral corticosteroids are unsuitable. However, performance also reflected a particularly benign seasonal influenza in China, resulting in a significantly reduced number of asthma exacerbations. In addition, two generic versions of *Pulmicort* are now approved in China.

<u>Tezepelumab</u>

Amgen recently announced an amendment to the distribution agreement with AstraZeneca with regards to the commercialisation of tezepelumab in severe, uncontrolled asthma. Amgen will be solely responsible for the distribution of tezepelumab in the US (and AstraZeneca will book its share of gross profit as collaboration revenue). Outside the US, AstraZeneca will book product sales (and account for Amgen's share of gross profits in cost of sales).

3.4 Other

Potential COVID-19 vaccine

AstraZeneca and Oxford University recently announced a collaboration agreement on a potential COVID-19 vaccine where AstraZeneca would be responsible for development and worldwide manufacturing and distribution of the potential vaccine. AstraZeneca and Oxford University have communicated that this would be operated on a not-for-profit basis for the duration of the coronavirus

pandemic. In line with IAS 20, any reimbursement received for R&D costs incurred are expected to be booked on the respective P&L line.

FluMist

AstraZeneca <u>announced</u> on 13 August 2020 the first shipment of *FluMist Quadrivalent* for the US 2020-2021 influenza season. In the announcement, the Company detailed a 25% increase in production vs. previously planned volumes.

3.5 China

Volume-based procurement (VBP)

In August 2020, the results from the third round of VBP tenders in China were announced including AstraZeneca medicines *Brilinta*, *Arimidex* and *Losec*. AstraZeneca chose not to compete on price and as a result were not among the winners. However, irrespectively, and as per the current rules, these medicines will be subject to a mandatory 30% price cut. As per normal practice, the Company will need to make accruals for a revaluation of the customer inventory.

National drug reimbursement list (NRDL) guidelines

In August 2020, the official 2020 NRDL guidelines were released stating that new drugs/indications approved by 17 August 2020 are eligible for inclusion in the next update.

4. Collaboration revenue

No transaction generating collaboration revenue has been announced during the third quarter. However, as usual, in addition to *Enhertu* and 2020 roxadustat profit share (see above), an element of non-material royalties will be booked in collaboration revenue. In 2019, these underlying 'other' royalties (including non-material milestones) averaged \$44m per quarter.

5. Other operating income

No transaction generating other operating income has been announced during the third quarter of 2020. The average 'underlying' other operating income in 2019 averaged \$102m per quarter.

6. Outstanding number of shares

The outstanding number of shares is 1,312m.

7. Cash flow

During the first-quarter 2019 results conference call on 26 April 2019, the Company provided the information that, if the impact of the Daiichi Sankyo transaction (i.e. upfront and potential development and approval milestone payments) were excluded, the Company would target dividend coverage in 2020. As mentioned in the Q1 2019 results announcement, half of the \$1.35bn upfront payment was settled in the second quarter of 2019. The remaining payment settled one year later.

On 24 July 2020, AstraZeneca announced US FDA approval for *Breztri Aerosphere* for the maintenance treatment of COPD. The approval triggered a \$150m milestone payment which would have been assumed to be paid during the third quarter of 2020.

In September 2020, Innate Pharma announced an amendment to the agreement with AstraZeneca on monalizumab. Innate now expects to receive a \$50 million payment upon AstraZeneca's dosing of the first patient in a Phase III trial, and a \$50 million payment provided that the interim analysis demonstrates that the treatment meets a pre-defined threshold of clinical activity. Innate expects the Phase III trial to commence in 2020.

8. Currency impact

AstraZeneca's foreign-exchange rate sensitivity analysis is contained within the operating and financial review section of the first-half 2020 <u>results announcement</u>. If foreign-exchange rates for July to December 2020 were to remain at the average of rates seen in the first half of 2020, it is anticipated that there would be a low single-digit adverse impact on Total Revenue and Core EPS, versus the prior year.

If there are any questions, please feel free to contact us.

Sincere regards,

The AZN IR Team

Thomas Kudsk Larsen		+44 203 749 5712
Henry Wheeler	Oncology	+44 203 749 5797
Christer Gruvris	BioPharmaceuticals (Cardiovascular, Metabolism)	+44 203 749 5711
Nick Stone	BioPharmaceuticals (Renal) Environmental, Social and Governance	+44 203 749 5716
Josie Afolabi	BioPharmaceuticals (Respiratory & Immunology)	+44 203 749 5631
Tom Waldron	Other medicines	+44 7385 033 717
Craig Marks	Finance Fixed income	+44 7881 615 764
Jennifer Kretzmann	Corporate access Retail investors	+44 203 749 5824
US toll-free		+1 866 381 72 77

Appendix for contributing sell-side analysts (references are made to an Excel spreadsheet distributed separately)

Guidelines for completing the template

Please enter your data into the orange shaded cells. All other cells will fill in automatically. Please do not alter the format of the template (for example by adding or deleting rows) and wherever possible please submit your information to us in this newly issued template rather than in an historic version.

Tab 1 (Income Statement - AZ Group) should be completed on an as reported basis. We continue to capture the expected currency effects on total revenue and earnings, and the currency assumption of major currencies against USD.

We are again seeking to supplement this with additional data (see details for schedules requested under tabs 2-5). **Tab 2** (Income Statement - Core) should be completed on a Core basis.

Tab 3 (Collaboration Revenue) outlines the partnered medicines for which Collaboration Revenue is expected. Milestone/royalty payments are collected on separate lines.

The costs associated with the AZ restructuring programme should be outlined separately on **Tab 4** (Restructuring). Detailed commentary is always welcome to provide clarity and to reduce the scope for misinterpretation.

Tab 5 (Summary Cash Flow & Balance Sheet) consists of an abbreviated Cash Flow Statement and Consolidated Statement of Financial Position.

Product sales data by both region and medicine should be entered into **Tab 6** (Group product sales). Total product sales are linked from the Income Statement tab in row 9 and is then broken down by region in the reconciliation in rows 11-29. If Rest of World product sales are not currently forecast to the level of detail in the template, please enter a total ROW forecast in row 17.

We continue to collect medicine forecasts by geographic region for a number of medicines. Please complete the rows shaded in orange where regional breakdown of forecasts is available (ROW is a sub-total of Europe, Est. ROW & Emerging Markets).

For some of the medicines in collaboration (*Enhertu* and roxadustat), we are also collecting WW forecasts (rows 440-441, memo lines only). We anticipate this will allow analysts to reflect the appropriate financial treatment of these collaborations as it relates to sales, collaboration revenue and costs of goods sold.

Please note we continue to request information on pipeline risk adjustments and we hope you share our view that this is a valuable addition to the collection: If you use a risk adjusted approach to forecasting pipeline product sales, please enter your product sales forecasts after risk adjustments, as before, but also provide the probability of success % where asked for in the template (i.e. if you include 75% of product sales in your Income Statement, the probability of success is 75%).

If you use a binary approach, please enter 100% next to the included medicines and 0% where you have actively decided to exclude product sales. Please leave blank where you have simply not considered a certain potential medicine (e.g. because of its stage of development).

Peak sales estimates are collected on **Tab 7** (Pipeline peak sales). Please provide the probability of success (POS) if using a risk adjusted approach – if not risk adjusted, please enter 100%.

Please return to christer.gruvris@astrazeneca.com by Tuesday 20 October 2020.

Should you have any queries on how to complete this template, please do not hesitate to contact Christer Gruvris. In return, we will provide a consensus core and reported P&L for AstraZeneca Group, which will give you a good view of market assumptions. We will also provide consensus detail for Collaboration Revenue, Restructuring costs, Summary of Cash Flow & Statement of Financial Position, and product sales split by Region (providing sufficient analysts complete these templates).