Innovative Biopharmaceutical Companies Disclose Wide Range of Data on Their Products

Research & Development, Manufacturing and Related Costs

Publicly traded companies, including publicly traded biopharmaceutical firms, make financial disclosures to the public on a quarterly basis[i] regarding costs for research & development (R&D), manufacturing/production, and a range of other business expenses. Specific data reported by biopharmaceutical companies to the federal Securities and Exchange Commission includes:

- **R&D expenses, including clinical development costs, costs of R&D acquired through mergers and acquisitions, as well as information about R&D pipelines.** The R&D costs are provided at the aggregate level and do not reflect the often substantial additional investments that pre-date the clinical phase nor reflect some of the investments that may inform research across a range of therapeutic areas.
- **Aggregate data on cost of manufacturing goods produced and sold,** also referred to as "cost of goods sold" or "cost of sales." This includes the costs of materials that are used to manufacture prescription medicines as well as labor, and overhead costs.
- **Aggregate data on "selling, general and administrative costs" reported by companies,** which includes but is not limited to marketing costs, costs associated with Patient Assistance Programs, and the Affordable Care Act prescription drug fee.

Drug Pricing and Sales Information

A range of information on drug prices and sales are available through a wide range of sources, including:

- **List prices** are widely reported and available through online tools.[ii] However, list or invoice prices do not reflect rebates and other discounts. In addition, pharmacy benefit managers may require patients to pay coinsurance based on the list price rather than on the price paid net of rebates and other discounts.[iii]
- **Rebate and related data at an aggregate level** is included in companies' financial statements. The information can include aggregate information on rebates as well as cash discounts and other deductions.
- **Average sales price paid for drugs covered by Medicare Part B** is publicly reported by the Centers for Medicare & Medicaid Services (CMS).[iv] As a condition of participating in federal healthcare programs, biopharmaceutical companies are required to provide such data.
- **Gross sales** (before rebates, wholesaler chargebacks, and other discounts are considered) **and net sales** (after the rebates and other discounts are taken out) are reported by publicly traded biopharmaceutical companies.[v]
- **Earnings** (also called net income or profit/loss) are reported in publicly traded companies' financial disclosure statements.

Information on Clinical Trials and Related Research

- **Companies regularly make clinical trial data** available through https://www.clinicaltrials.gov/. Biopharmaceutical companies register clinical trials when they begin, provide timely updates, and submit summary results, consistent with Responsible Clinical Trial Data Sharing Principles, which reflect industry's commitment to data sharing requirements and outline additional ways that PhRMA members are voluntarily sharing data with the public and researchers.[vi]
- **Potential adverse events** are submitted by companies and others to the Food and Drug Administration (FDA), which are then included in the FDA's Adverse Event Reporting System. The data base supports the FDA's post-marketing safety surveillance program for all approved prescription medicines.[vii]

Drug Pipeline Information

- **Company-specific drug pipeline information** is reported by publicly traded biopharmaceutical companies as part of their annual reports and other information provided to shareholders.
- **The FDA publishes reports on drugs in development and approved medicines**, including information on investigational new drug applications and breakthrough therapy requests as well as annual reports on approved drugs and biologics.[ix] This information is in addition to information on drugs in development available via https://www.clinicaltrials.gov/.

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[i] The Securities and Exchange Commission (SEC) requires quarterly reporting via 10-Q forms and annually via 10-K forms. Special notices for significant events, e.g., mergers or major acquisitions, are included at http://www.sec.gov/edgar.shtml.
[ii] See, for example, OptumRx's Drug List Price Search; https://www.optumrx.com/RxSolWeb/mvc/discountDrugPricing.do.
[iii] K Begley. "WorldatWork You and Your PBM: Improving Discounts, Fees and Rebates, and Beyond." Aon Hewitt, 2009 Total Rewards Conference & Exhibition.
[iv] Medicare Part B Average Sales Price: Manufacturer reporting of Average Sales Price (ASP) data. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?redirect=/McrPartBDrugAvgSalesPRice/10_VaccinesPricing.asp
[v] Some companies record chargebacks and rebates separately under accrued liabilities.
[vi] See http://phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf.
[vii] See http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm
[viii] MW Rich, RF Nease. "Cost-effectiveness Analysis: The Case of Heart Failure." Arch Intern Med. 1999;159(15):1690-1700.
[ix] See http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/ucm341027.htm; http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/default.htm
[x] See https://www.cms.gov/OpenPayments/index.html