Advanced Explanation for Transactions with Roche

CHUGAI PHARMACEUTICAL CO., LTD.

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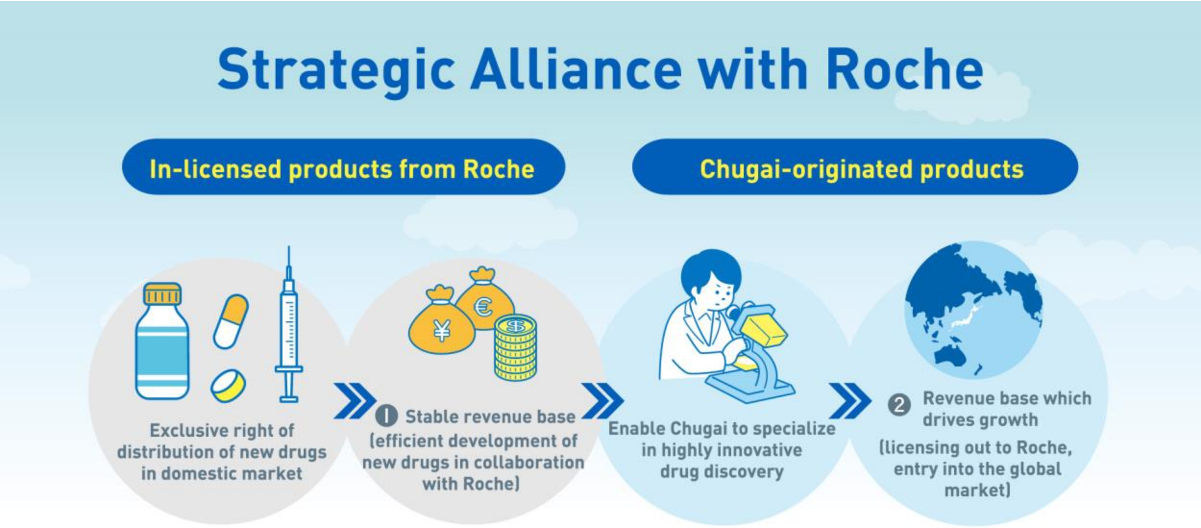
TABLE OF CONTENTS

Introduction

In 2002, Chugai started a strategic alliance with the Swiss company Roche, one of the world's leading pharmaceutical companies. Under its unique business model, Chugai has realized its continuous growth.

The financial impact of transactions with Roche under the strategic alliance will be explained in detail in line with the drug development phase. Specifically, we will look at "out-licensing of in-house products to Roche" and "in-licensing of products from Roche."



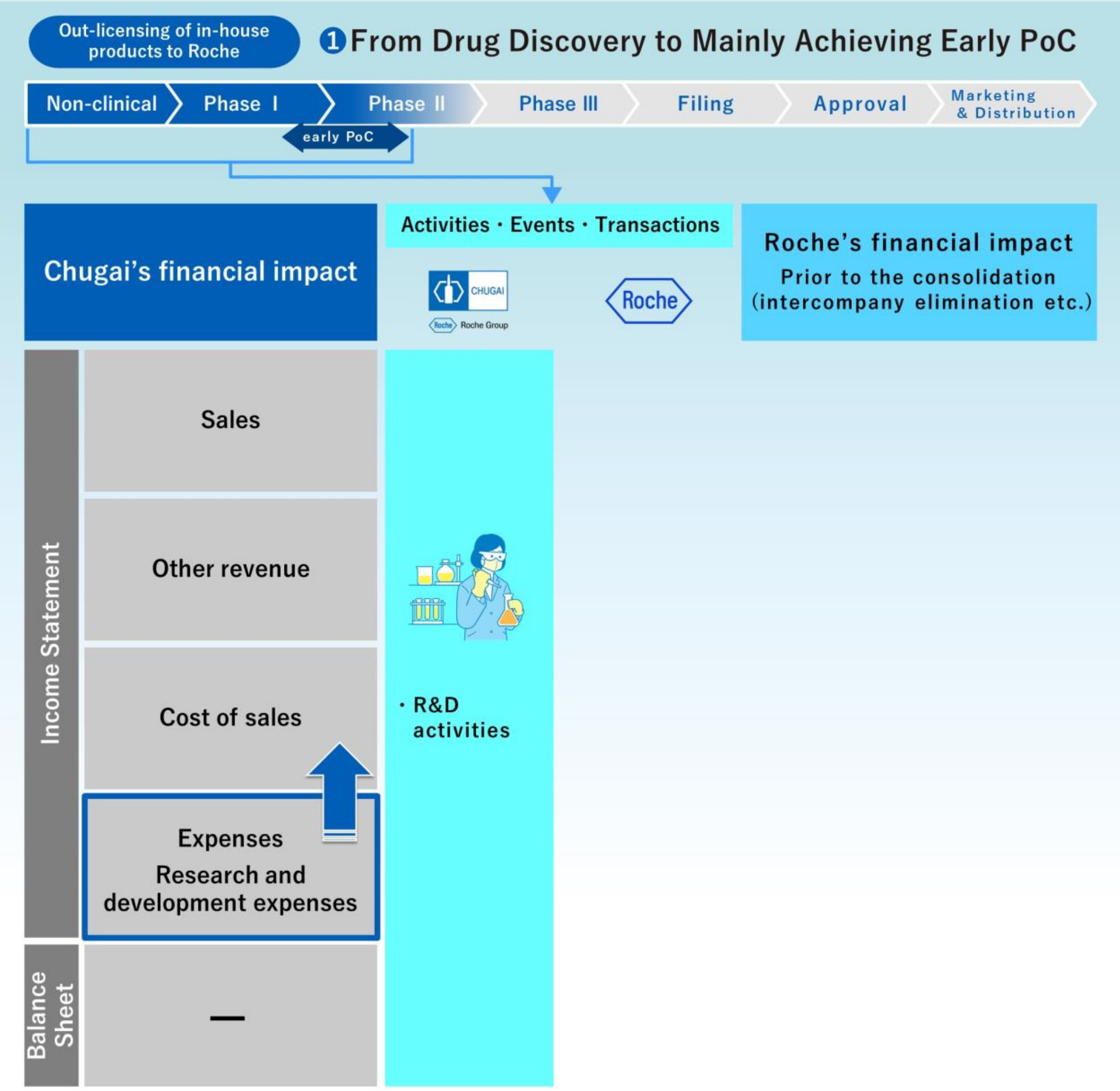
[Out-Licensing of In-House Products to Roche]

Out-licensing in-house products to Roche gives us access to global markets through Roche's infrastructure, which provides a revenue stream that drives our company's growth and allows us to reinvest to create our next innovative products.

[In-Licensing of Products from Roche]

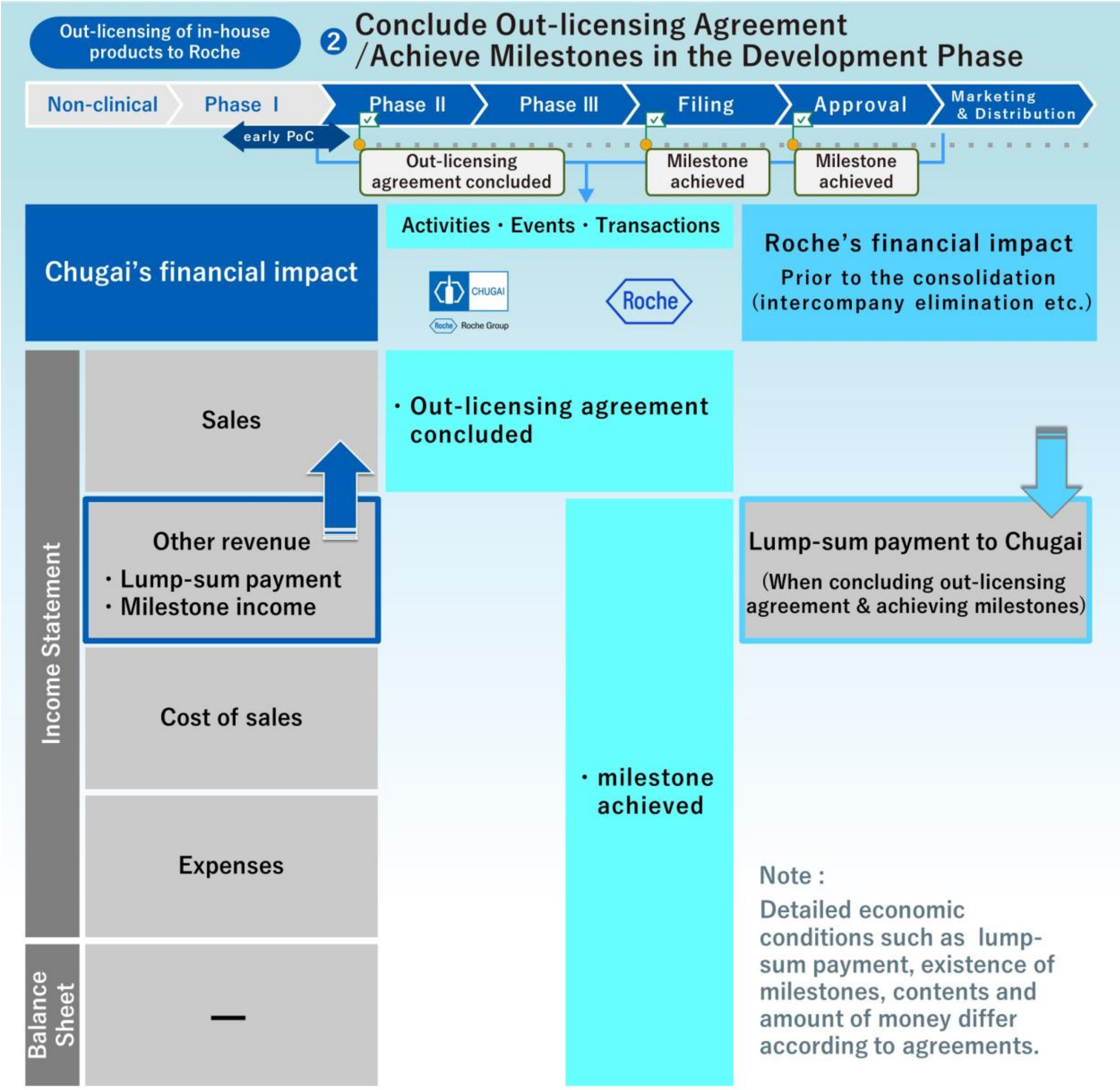
Chugai owns exclusive rights to develop and market new drugs from the Roche Group in Japan. Chugai can efficiently advance new drug development because it is able to consider and make decisions on drug introduction based on the results of early clinical trials. This stable revenue base enables Chugai to focus its investments in highly innovative proprietary technologies and drug discovery.

Out-Licensing of In-House Products to Roche



In principle, proposals for out-licensing Chugai products to Roche are made at the time of obtaining early Proof of Concept (PoC). Early PoC refers to the stage where safety, signs of efficacy, and/or pharmacological effects are confirmed in a limited number of patients and is usually conducted in the latter half of Phase I or the first half of Phase II clinical studies.

Until early PoC is achieved, Chugai will solely be engaged in R&D activities and incur the full costs. Costs associated with research and development activities are reported in the income statement as "Research and development expenses."



After achieving early PoC, Chugai will offer out-licensing of in-house products to Roche. When Roche exercises first refusal rights with respect to development and marketing overseas (excluding South Korea and Taiwan), Chugai will enter into an out-licensing agreement with Roche. Once the agreement is concluded, Chugai will receive a lump-sum payment from Roche.

After that, Chugai will receive one-time income (milestone income) associated with reaching predetermined milestones. The amount and timing of the lump-sum payment and milestone income are specified in the contract for each product under development and are determined in consideration of multiple factors such as the development status of in-house products at the time of out-licensing.

Lump-sum payment and milestone income are reported as “Other revenue” in the income statement.

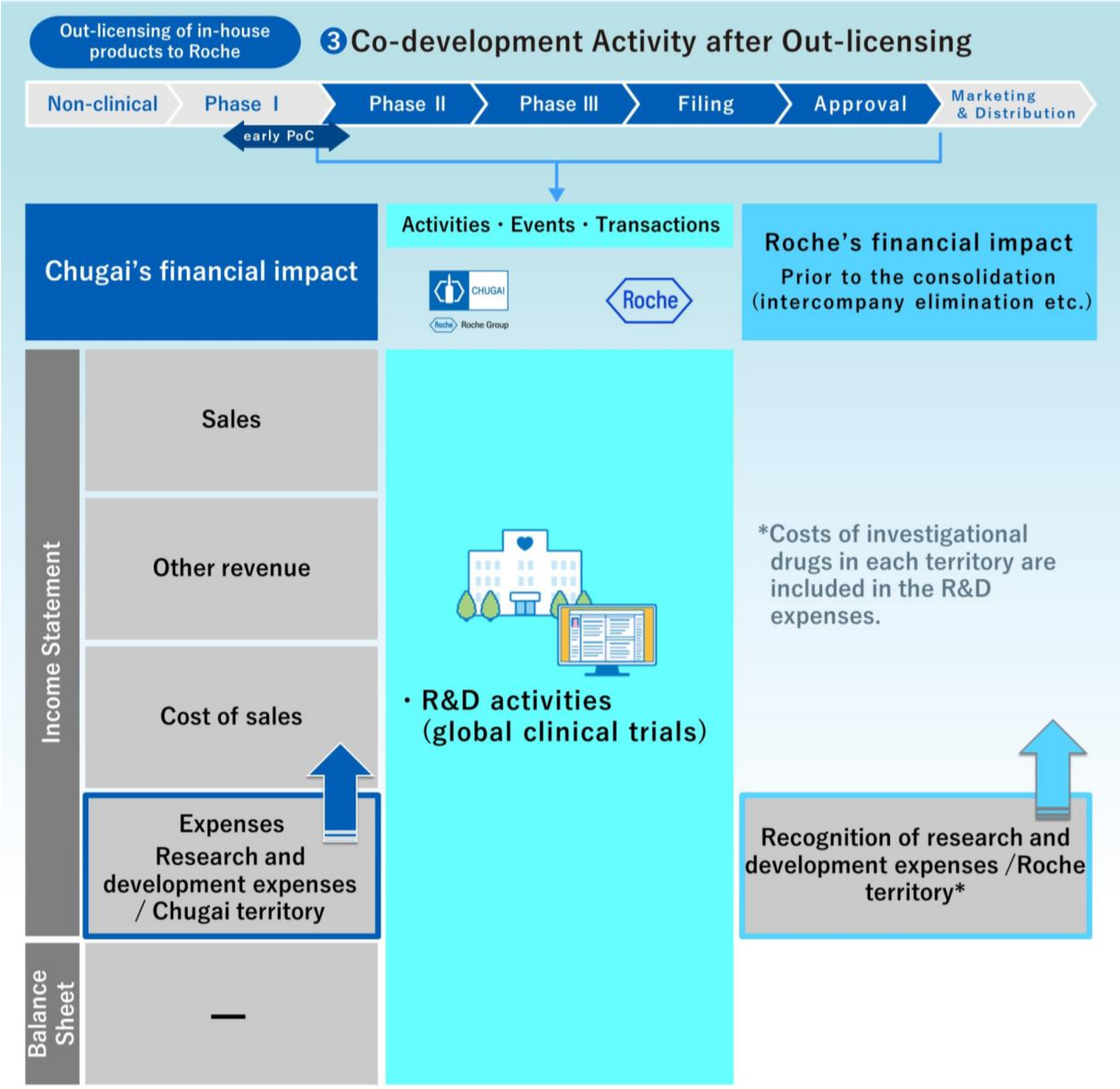
Although specific milestones for each development product are not disclosed, multiple milestones may be set during the clinical development stage, regulatory application stage, and after launch.

Example:

Clinical development phase: Phase transition, confirmation of study results, etc.

Regulatory application stage: Approval application, regulatory approval, etc.

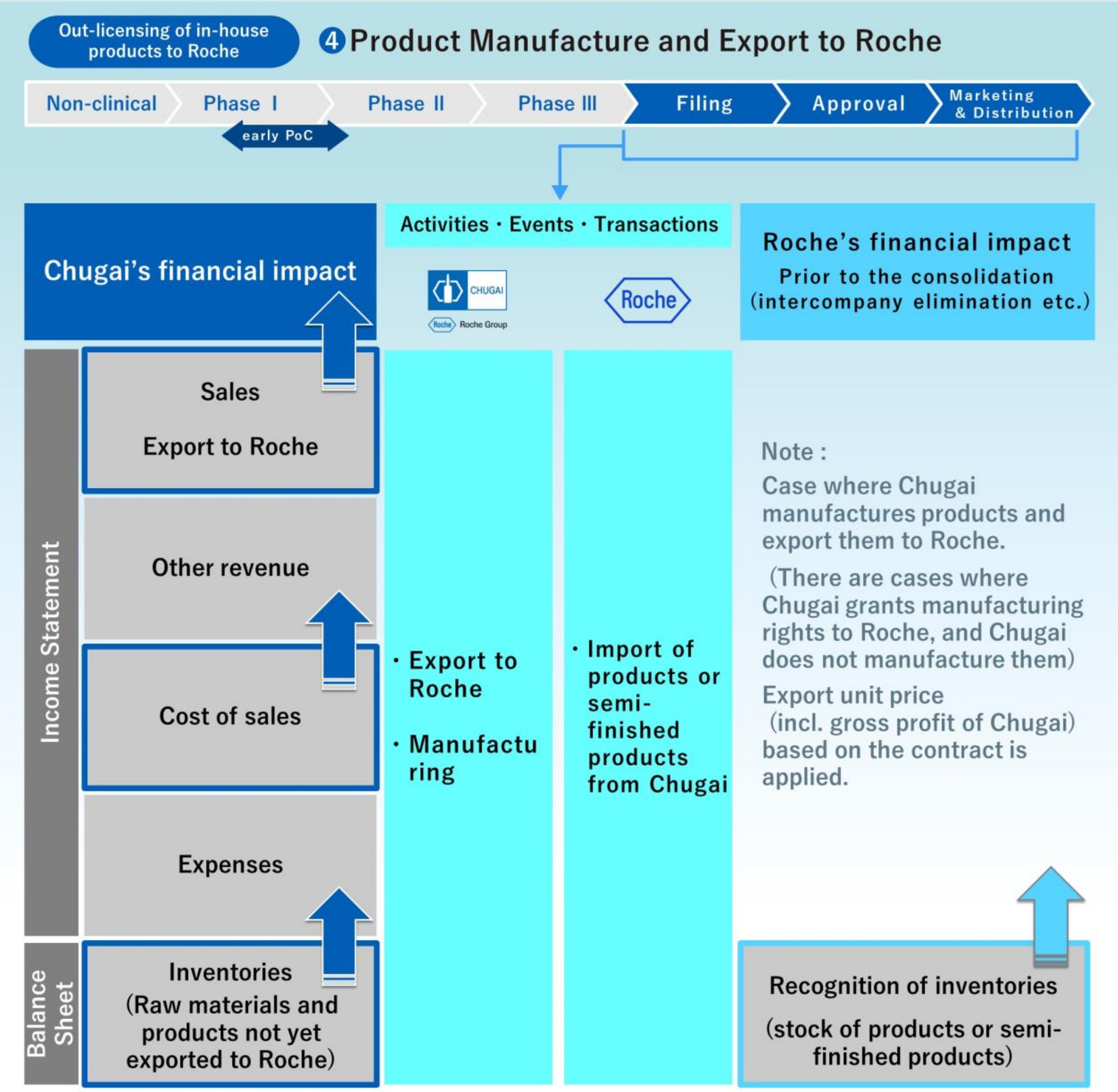
After launch: Launch, achievement of predetermined sales, expansion of indications, etc.



After out-licensing to Roche, global clinical trials including Japan will be led by Roche.

Roche and Chugai will incur research and development expenses for their respective territories. Chugai will incur expenses for clinical studies primarily in countries and regions in the Chugai territory (Taiwan and South Korea) including Japan, which enables efficient global development.

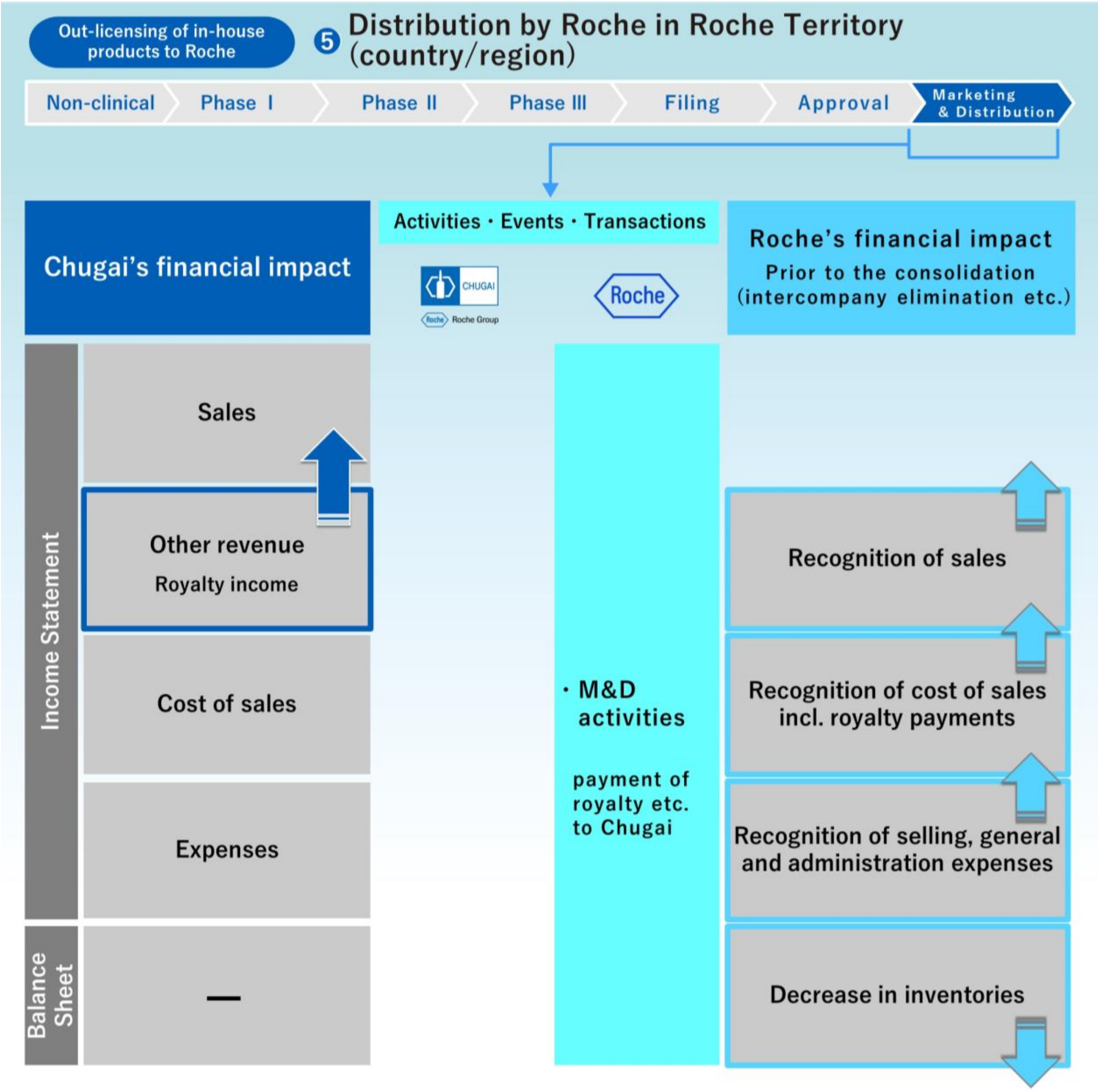
These costs are reported in the income statement as research and development expenses. Research and development expenses include the cost of investigational products used in clinical trials in the Chugai territory.



In the case where Chugai has the right to manufacture its in-house products, we will start commercial production of the products and export them to Roche in preparation for approval and distribution in the countries and regions of the Roche territory.

Sales from exports to Roche are recorded in the income statement as "Sales." Export sales are calculated using the export unit price based on the out-licensing agreement, which includes Chugai's margin (gross margin).

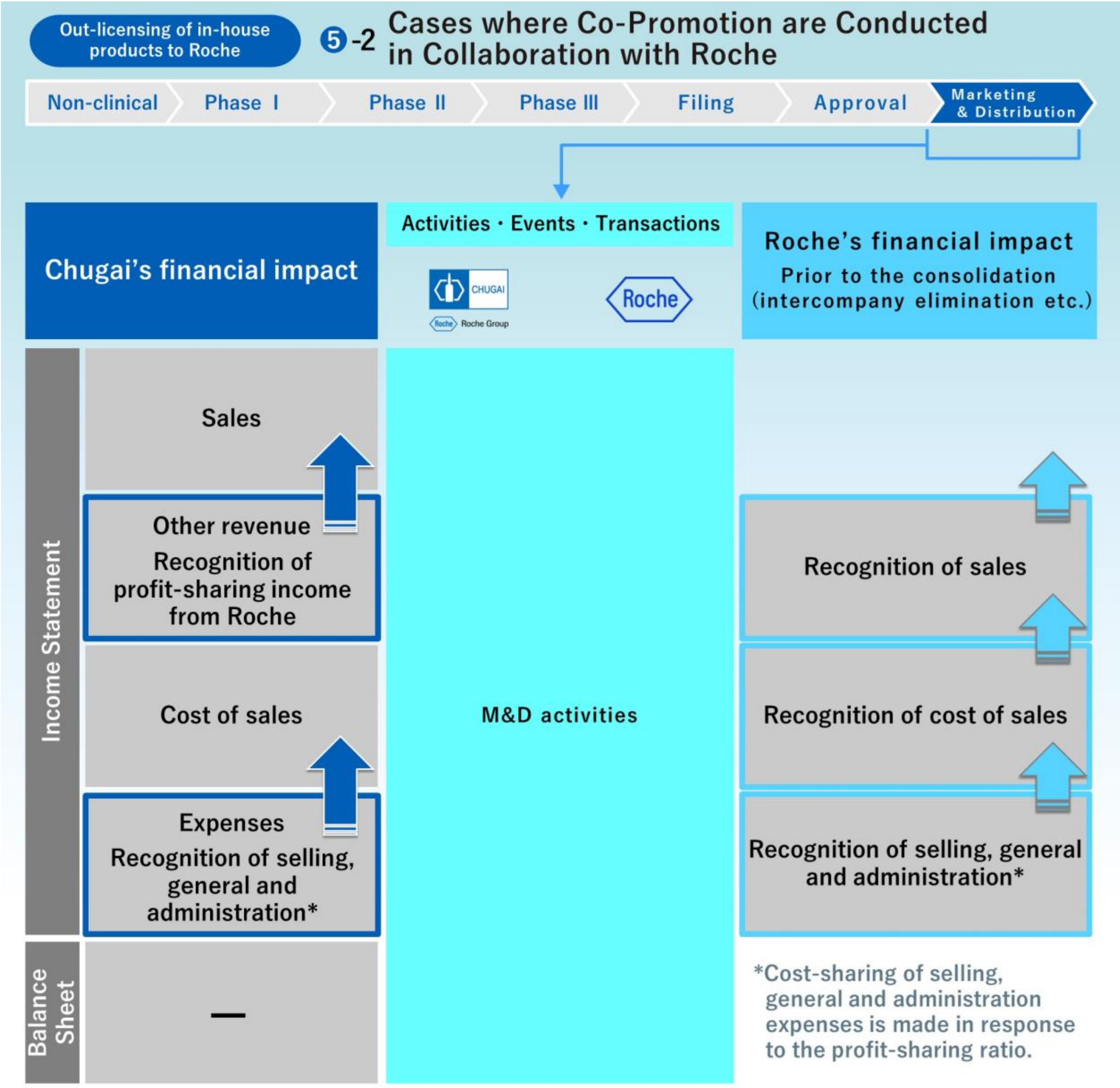
Manufacturing costs for exports are recorded as "Cost of sales" in the income statement, and raw materials and unexported products are recorded as "Inventories" in the balance sheet.



Sales of in-house products in the Roche territory are recorded as "Sales" in Roche's income statement.

Chugai receives a royalty based on Roche sales. The royalty income is calculated by multiplying Roche's worldwide sales by the royalty rate. The specific calculation method is specified in the contract and varies for each product.

Royalty income received from Roche is recorded in the income statement as "Other revenue."



Revenue Chugai receives from Roche includes, in some cases, profit-sharing income in addition to royalty income. Chugai co-promotes certain products with Roche's local affiliates in the Roche territory such as the United Kingdom, France, Germany, and China. Expenses associated with marketing activities in these countries will be borne by both companies, and based on product sales and cost of sales, Chugai will receive profit-sharing income from Roche so that the profits of both companies will be allocated as specified in the agreement.

Profit-sharing income is reported as “Other revenue,” and the costs associated with marketing activities are reported as “Selling, general and administration” in the income statement.

Example calculation of profit-sharing income

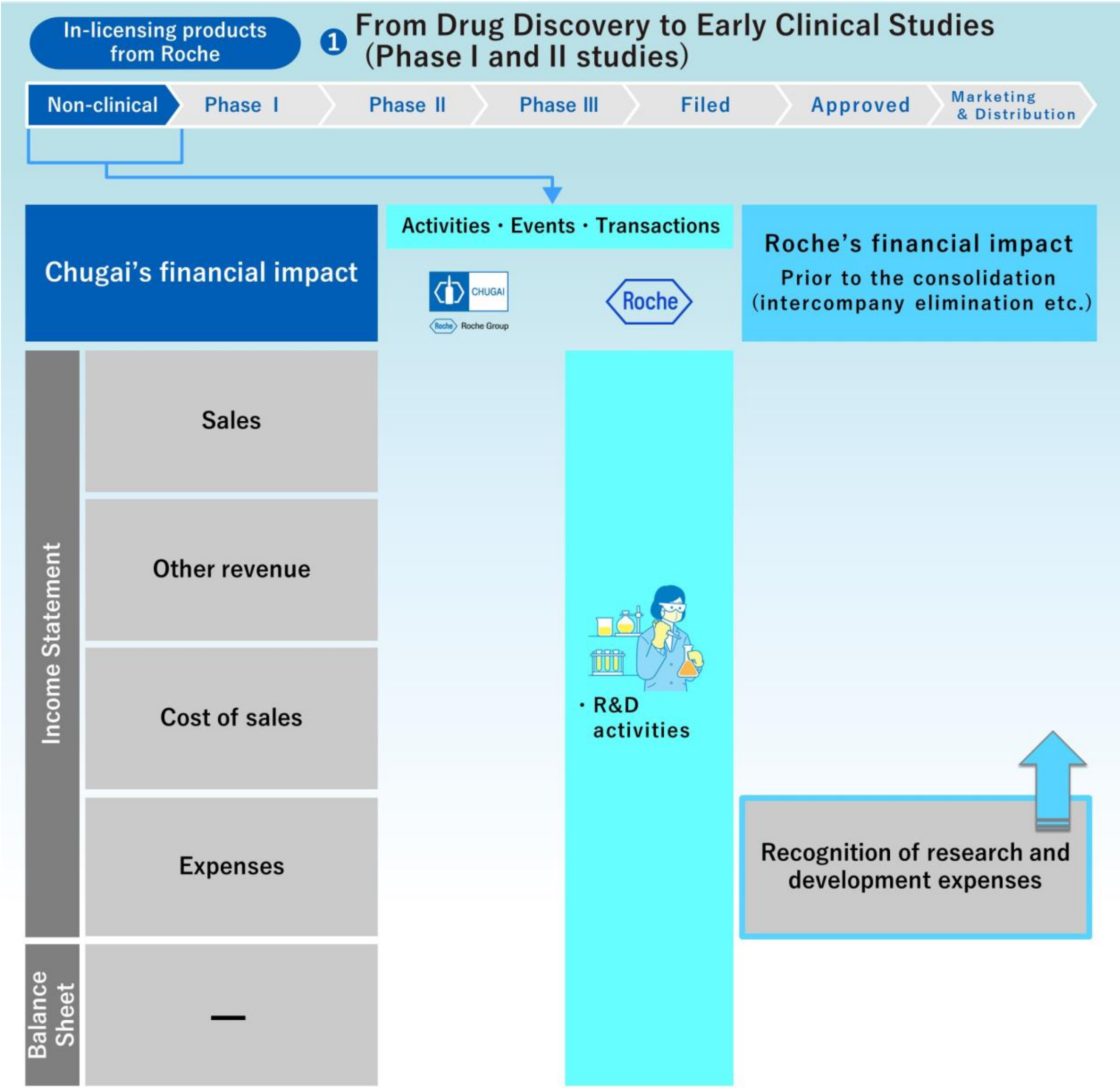
The following amounts are incurred.

・Sales by Roche	・・・ 100
・Cost of sales incurred by Roche	・・・ 40
・Selling, general and administration expenses paid by Roche	・・・ 10
・Selling, general and administration expenses paid by Chugai	・・・ 10

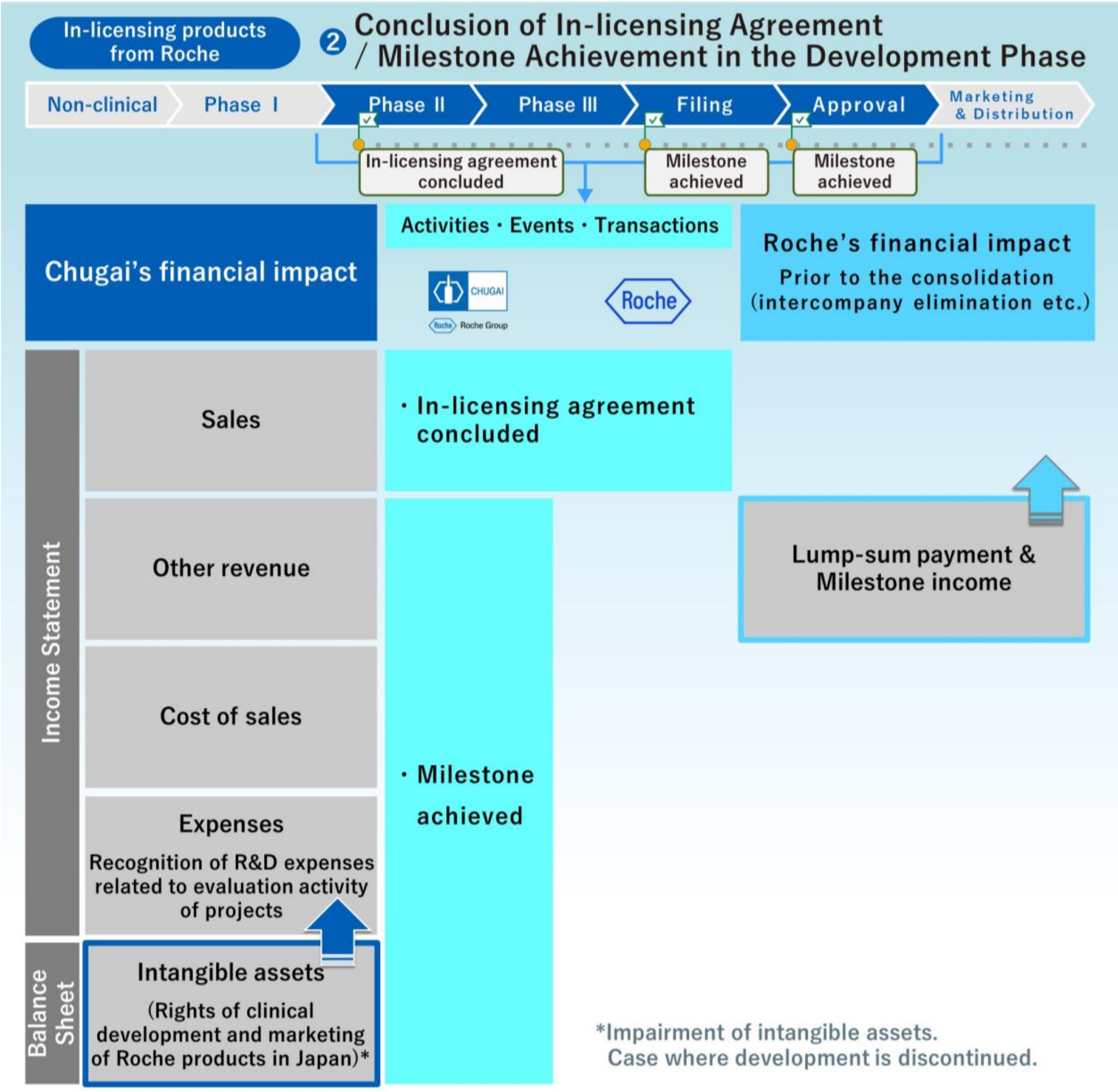
If the profit-sharing ratio is 50%, Chugai will receive 30, equivalent to 50% of Roche's gross profit of 60 (= 100 - 40), as profit-sharing income.

Since selling, general and administration expenses are equal, no settlement will be made. However, if either of them exceeds the profit share rate, settlement will be made.

In-Licensing of Products from Roche

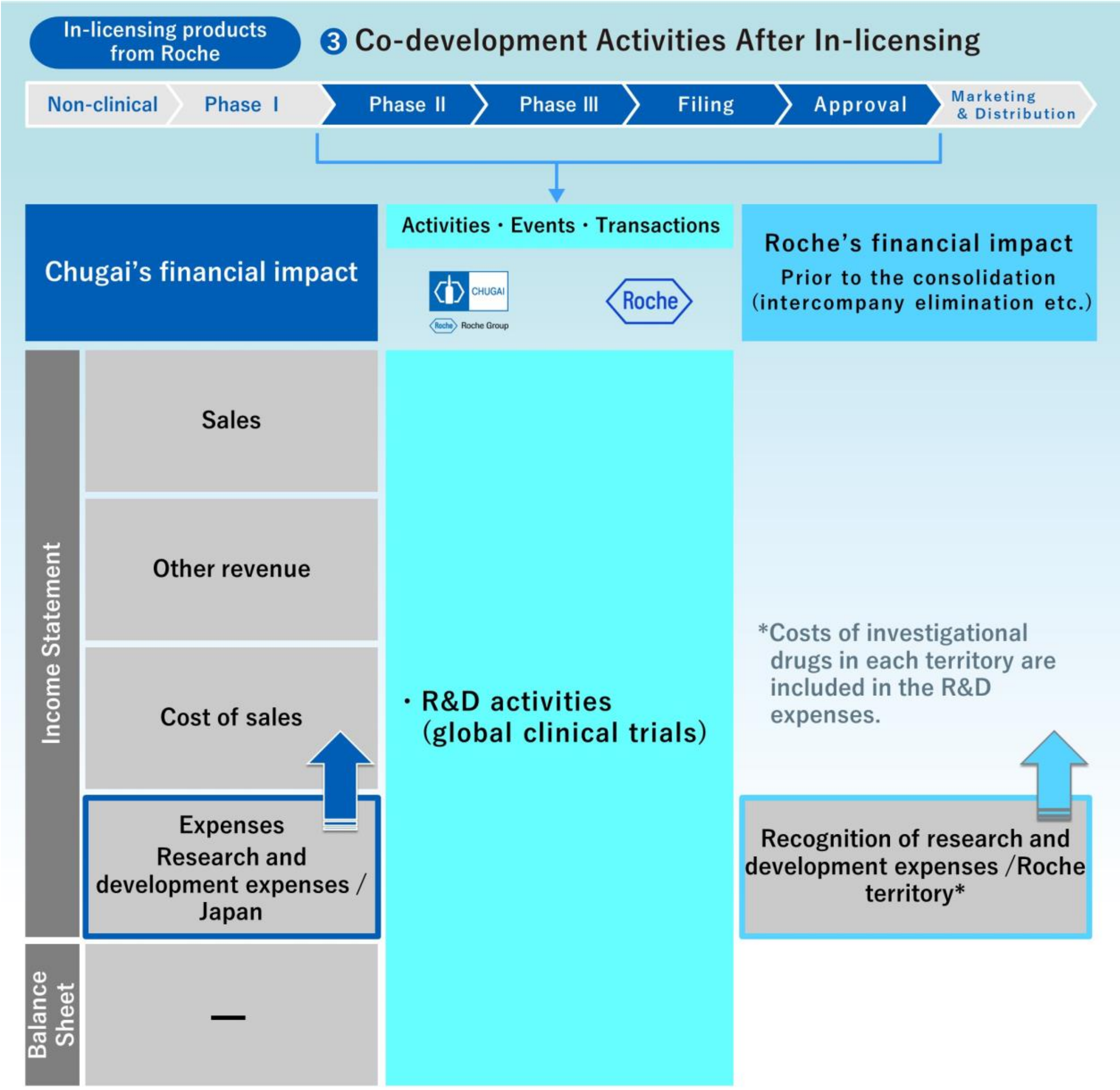


Research and development activities for drug discovery/non-clinical and early clinical studies (Phase I and II) are conducted by Roche or Roche partners (in the case where Roche introduced a product from a 3rd party). Therefore, the costs of R&D are not included in the Chugai income statement.



Based on early development data of the Roche product and its potential synergies with the Japanese market, if Chugai exercises first refusal rights regarding development and marketing in Japan, Chugai will enter into an in-licensing agreement with Roche. In consideration of this obligation, Chugai will make one-time payment to Roche at the timing of agreement, or upon achievement of a certain milestone predetermined in the contract.

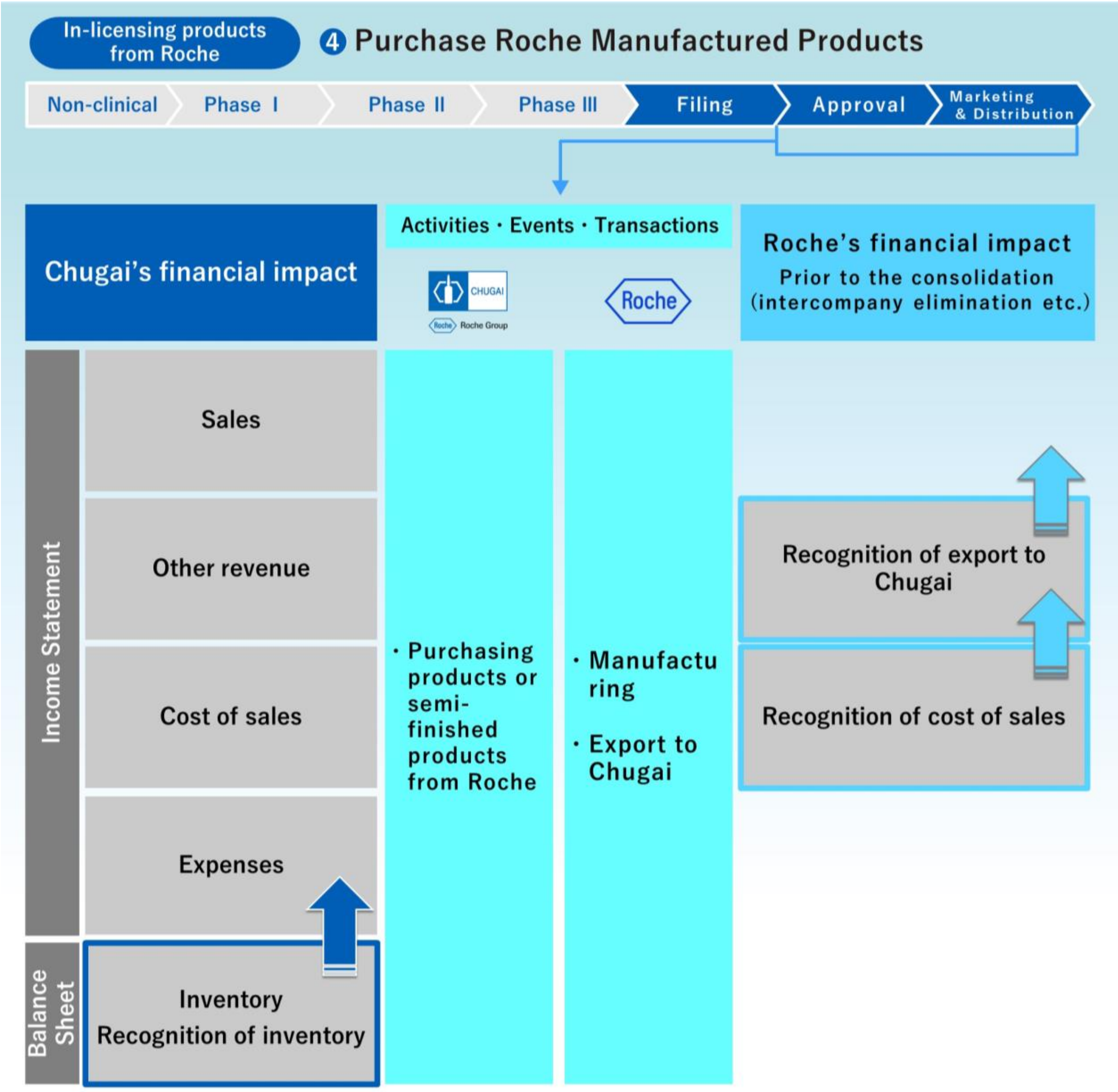
If it meets accounting requirements, the one-time payment is recorded as "Intangible assets" on the balance sheet.



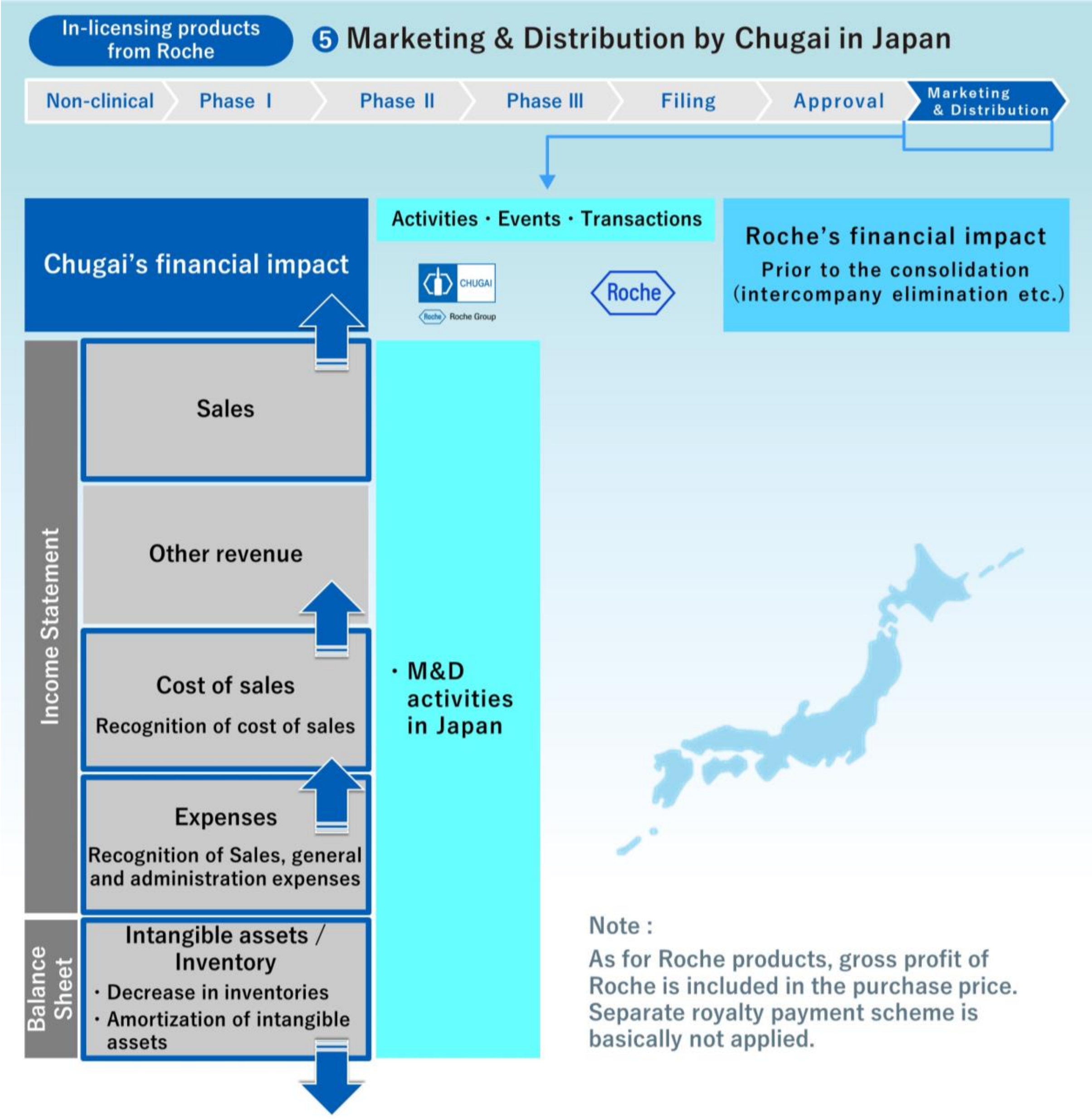
After the in-licensing of Roche products, Chugai joins multinational studies led by Roche from Japan, and Chugai mainly incurs the costs of studies in Japan. If a Japanese local Phase I clinical study is necessary, Chugai will lead the study. Also, depending on the product, Chugai may independently conduct clinical studies in Japan instead of taking part in multinational studies sponsored by Roche.

Costs associated with research and development activities are reported in the income statement as "Research and development expenses." Research and development expenses to be borne by Chugai include the cost of investigational products used for clinical studies in Japan.

If development is discontinued, impairment of intangible assets is conducted.



In the case where products for sale are manufactured by Roche, Chugai purchases the products from Roche in preparation for approval and distribution in Japan. Purchases are recognized as "Inventories" on the balance sheet.



Once the product is listed on the NHI reimbursement price list and launched in Japan, “Sales” are recognized with its corresponding "Cost of sales," as well as "Selling, general and administration" related to marketing activities in the income statement.

At the same time, “Inventories” on the balance sheet decreases as inventory decreases with sales. In addition, amortization of “Intangible assets” is initiated.