ROCHE OPERATIONS LTD. – PUERTO RICO BRANCH

Financial Statements

December 31, 2018

(With Independent Auditors' Report Thereon)

ROCHE OPERATIONS LTD. – PUERTO RICO BRANCH

Balance Sheet

December 31, 2018

(In U.S. Dollars)

Assets		
Current assets:		
Cash and cash equivalents	$	31,113,035
Due from affiliate		19,448,436
Inventories		11,914,394
Prepaid tax		855,474
Prepaid expenses and other current assets		367,441
Total current assets		63,698,780
Property, plant, and equipment, net		41,973,783
Total assets	$	105,672,563
Liabilities and Home Office Account		
Liabilities:		
Accounts payable	$	13,179,971
Due to affiliates		695,388
Accrued liabilities		6,026,950
Total liabilities		19,902,309
Home Office account		85,770,254
Total liabilities and Home Office account	$	105,672,563

See accompanying notes to financial statements.

ROCHE OPERATIONS LTD. – PUERTO RICO BRANCH

Statement of Income

Year ended December 31, 2018

(In U.S. Dollars)

Revenue	$	154,200,199
Cost of sales		(98,292,773)
Gross profit		55,907,426
Expenses:		
Marketing and distribution		(5,293,562)
Research and development		(2,197,462)
General and administrative		(4,099,367)
Operating profit		44,317,035
Other income & expense		
Other income		205,473
Other expense		(128,439)
Interest income – affiliate		1,267,756
Interest expense – affiliate		(3)
Other income, net		1,344,787
Income before income taxes		45,661,822
Income tax expense		(407,735)
Net income	$	45,254,087

See accompanying notes to financial statements.

ROCHE OPERATIONS LTD. – PUERTO RICO BRANCH

Statement of Changes in Home Office Account

Year ended December 31, 2018

(In U.S. Dollars)

Balance at beginning of year	$	120,516,167
Net income		45,254,087
Remittances to Home Office		(80,000,000)
Balance at end of year	$	85,770,254

See accompanying notes to financial statements.

ROCHE OPERATIONS LTD. – PUERTO RICO BRANCH

Statement of Cash Flows

Year ended December 31, 2018

(In U.S. Dollars)

Cash flows from operating activities:	
Net income	$
Adjustments to reconcile net income to cash provided by operating activities:	
Depreciation	
Change in operating assets and liabilities:	
Decrease in due from affiliate	
Increase in inventories	
Decrease in prepaid income tax	
Increase in prepaid expenses and other current assets	
Decrease in accounts payable and accrued liabilities	
Increase in due to affiliates	
Cash provided by operating activities	
Cash flows from investing activities:	
Additions to construction in progress	
Net cash used in investing activities	
Cash flows from financing activities:	
Remittances to Home Office	
Net cash used in financing activities	
Net decrease in cash and cash equivalents	
Cash and cash equivalents at beginning of year	
Cash and cash equivalents at end of year	$
Supplemental disclosure of cash flow information:	
Income tax paid during the year	$
Interest paid	
Noncash transactions:	
Increase in construction in progress accrued at year-end	$

See accompanying notes to financial statements.

45,254,087
3,755,936
2,390,365
(3,421,730)
171,926
(20,914)
(1,294,620)
488,238
47,323,288
(1,681,851)
(1,681,851)
(80,000,000)
(80,000,000)
(34,358,563)
65,471,598
31,113,035
235,809
3
360,050

(1) Nature of Business

Roche Operations Ltd. – Puerto Rico Branch (hereinafter referred to as the Branch) is a branch of Roche Operations Ltd. (Home Office), a Bermuda corporation, duly qualified to do business in Puerto Rico, which is engaged in the manufacture of medical devices for blood glucose level analysis. Roche Operations Ltd. is a wholly owned subsidiary of F. HoffmanLa Roche, Ltd. (a Swiss corporation) (the Roche Group). Roche Operations Ltd. is a member of the Roche Group.

(2) Summary of Significant Accounting Policies

The following summarizes the most significant accounting policies followed by the Branch in the preparation of the accompanying financial statements:

(a) Basis of Presentation

The financial statements of Branch are prepared for the purpose of complying with statutory tax filing requirements of the Commonwealth Puerto Rico and its municipalities.

The financial statements of the Branch are intended to present the financial condition as of December 31, 2018 and the result of operations and cash flows for the year then ended of only that portion of Roche Operations Ltd. that is attributable to the transactions of the Branch in Puerto Rico.

(b) Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management of the Branch to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include the useful live of fixed assets, deferred tax assets, fixed assets, inventory, reserves for employee benefit obligations, income tax uncertainties, and other contingencies.

(c) Revenue Recognition and Due from Affiliate

Revenue from the sales of goods is recognized when the products are shipped to affiliates and the affiliates take ownership and assume risk of loss, collection of the relevant receivable is probable, and persuasive evidence of an arrangement exists and the sales price is fixed or determinable. The related receivable is recorded as a due from affiliate in the accompanying balance sheet. Collections of the amounts are included in net cash provided by operating activities in the accompanying statement of cash flows.

Revenue from accounting and managerial services to an affiliate, under a service contract, is recognized based on a monthly fee plus additional cost incurred for the period.

(d) Cost of Sales

Cost of sales includes the corresponding direct production costs and related production overhead of goods sold and services rendered. Startup costs between validation and the achievements of normal production capacity are expensed as incurred.

(e) ***Cash and cash equivalents***

The Branch considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents at December 31, 2018 include deposits with affiliate amounting to $31,113,035.

On October 1, 2007, the Branch signed a deposit facility agreement with Roche Pharm holding B.V. (RPH), an affiliate in the Netherlands. The agreement grants the Branch an unsecured and unrestricted deposit facility. The Branch has the right at any time to withdraw any amount, which has previously been deposited plus capitalized interest which is calculated using one month LIBOR plus a margin of 0.075%. Interest is credited in arrears to the account on the last day of a calendar quarter with value first day of the subsequent month.

(f) ***Inventories***

Inventories are stated at the lower of cost and net realizable value. The cost of inventories is based on the firstin, firstout principle, and includes expenditures incurred in acquiring the inventories, production or conversion costs, and other costs incurred in bringing them to their existing location and condition. In the case of manufactured inventories and work in progress, cost includes an appropriate share of production overheads based on normal operating capacity. Variances are capitalized on a monthly basis.

(g) ***Property, Plant, and Equipment***

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed on the straightline method, except for land, which is not depreciated. Estimated useful lives of major classes of depreciable assets are as follows:

Land improvements	40 years
Buildings and improvements	10 – 50 years
Machinery and equipment	3 – 15 years
Furniture and fixtures	10 years
Office equipment	3 – 6 years
Vehicles	5 – 8 years

Maintenance, repairs, and renewals are charged to expense as incurred. Costs and accumulated depreciation related to assets retired or otherwise disposed of are removed from the accounts at the time of retirement or sale, and any gain or loss is included in current income.

(h) ***LongLived Assets***

Longlived assets, such as property, plant, and equipment, and purchased intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a longlived asset or asset group be tested for possible impairment, the Branch first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the longlived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values, and thirdparty independent appraisals, as considered necessary.

(i) ***Research and Development***

The Branch is party in a costsharing agreement with Roche Diabetes Care, Inc. Research costs are charged against expense through a research and development expense allocation based on the costsharing agreement.

For the year ended December 31, 2018, research and development expenses amounted to $2,197,462 as reflected in the statement of income.

(j) ***Pension and Other Postretirement Plans***

The Branch participate with other affiliates in a noncontributory defined benefit pension plan covering substantially all of its employees upon their retirement. The benefits are based on age, years of service and average compensation in the year preceding retirement.

The Branch records annual amounts relating to its pension and postretirement plans based on calculations that incorporate various actuarial and other assumptions, including discount rates, mortality, assumed rates of return, compensation increases, turnover rates and healthcare cost trend rates. The Plan Sponsor reviews its assumptions on an annual basis and makes modifications to the assumptions based on current rates and trends when it is appropriate to do so.

(k) ***Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Branch recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Branch records interest related to unrecognized tax benefits in interest expense and penalties in selling, general, and administrative expenses.

(l) ***Fair Value Measurements***

The Branch utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Branch determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.
- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

(m) Financial Instruments

The Branch's financial instruments include cash and cash equivalents, which fair value is equal to its carrying value, due from affiliate, accounts payable, accrued liabilities, and due to affiliates, which are stated at their cost, which approximates fair value.

(n) Intercompany Charges

The Branch receives from an affiliate the transfer pricing adjustment based on a cost sharing agreement for research and development, marketing, and other costs incurred by the affiliate in the same products owned and manufactured by the Branch (note 3).

(o) Commitments and Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines and penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred.

(3) Transactions with Affiliated Companies

The Branch sells all its production to Roche Diabetes Care, Inc. (RDCI), an affiliate. The balance due from RDCI at December 31, 2018 amounted to $19,448,436. In addition, RDCI and the Branch participate in a cost sharing arrangement for research and development, marketing, and other costs incurred by RDCI in the same products owned and manufactured by the Branch. During 2018, transactions with RDCI were as follows:

Revenue from product sales	$	154,095,200
Marketing and distribution expenses		5,293,562
Research and development expenses		2,197,462
Code assignment charges*		677,848
Pension cost allocated*		912,362
Product support charges*		1,200,000
Start-up costs*		1,941,528
Other general and administrative expenses		860,657

* Amounts are included within cost of sales, except for $82,132 in pension cost included in general and administrative expenses, in the accompanying statement of income.

The Branch purchases some of its raw material from Roche Diagnostic GmbH, an affiliate. Purchases during 2018 amounted to $2,760,050, which are initially recorded as inventory and are expensed through cost of sales when the inventory is sold.

(4) Inventories

Inventories consisted of the following:

Raw materials		$	6,189,622
Work in process			5,634,467
Finished goods			90,305
	Total inventories	$	11,914,394

(5) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

Land and land improvements		$	3,844,315
Building and building improvements			47,121,632
Machinery and equipment			59,424,754
Furniture and fixtures			1,609,673
Office equipment			2,180,448
	Sub-total		114,180,823
Less accumulated depreciation			(74,192,030)
	Sub-total		39,988,793
Construction in progress			1,984,991
	Total	$	41,973,783

There were no impairment charges recognized during the year.

(6) Income taxes

On January 16, 2007, the Branch received a tax exemption grant effective and retroactive to January 1, 2007 for income tax on industrial development income, property tax, and municipal license tax. Under the tax grant, the Branch is entitled to an exemption period of 20 years. The grant provides for a flat income tax rate of 2% on its industrial development income subject to certain employment requirements. The percentages of exemption under the grant for municipal and property taxes are 60% and 90%, respectively.

The Branch is 100% exempt from tollgate tax related to the repatriation of undistributed earnings, accumulated under this grant.

Income tax expense for the year ended December 31, 2018 differs from the amounts computed by applying Puerto Rico income tax statutory rate of 39% to profit before income tax as a result of the following:

Computed expected tax expense	$	17,688,425
Effect of different taxation rate per tax grant		(16,781,327)
Income tax credits – products manufactured in Puerto Rico		(1,328,402)
Change in valuation allowance		810,736
Return to provision adjustment		18,301
	$	407,735

The income tax effects of temporary differences that led to deferred tax assets as of December 31, 2016 are as follows:

Deferred tax asset:		
Income tax credits –		
Products manufactured in Puerto Rico	$	8,291,604
Less valuation allowance		(8,291,604)
Net deferred tax asset	$	—

The Branch is entitled to a tax credit for the 25% of purchase of products manufactured in Puerto Rico provided by Act No. 73 of 2008, known as the Economic Incentives Act for the Development of Puerto Rico. According to Resolution 2017-05 of June 30, 2017 that establishes the rules for the use of tax credits granted, any granted credit available to be used in tax year 2017 and subsequent years may be claimed against the income tax liability subject to the provisions of the law under which the credit was granted up to a maximum of twenty five percent (25%) of said income tax liability. This limitation applies to tax year 2017 and each of the three (3) subsequent tax years, for a maximum of four (4) tax years.

The valuation allowance at December 31, 2018 is related to tax credits carryforwards that, in the judgment of management, are not more-likely than-not to be realized. In assessing the reliability of deferred tax assets, management considers whether it is more-likely than-not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible.

The New Code requires that entities exceeding a predefined volume of business file audited financial statements with local taxing authorities. This predefined volume of business is determined in a "controlled group" basis. Among the requirements imposed by the New Code, domestic entities that are part of a controlled group should file a consolidated audited financial statement, including a consolidating schedule presenting the financial condition and result of operations of each entity. The Department of the Treasury of the Commonwealth of Puerto Rico recently issued Administrative Determination No. 1113 and Administrative Determination No. 1407 to provide an alternative requirement in lieu of the consolidated audited financial statement. Entities required to file audited financial statements with income tax returns, may file a statutory audited financial statement and, in lieu of providing a consolidated audited financial statement, should disclose in the notes to the statutory audited financial statements the names of related entities engaged in active trade or business in Puerto Rico, as defined by the New Code. The following related entities are engaged in active trade or business within Puerto Rico:

- Genentech Puerto Rico, Inc.
- HoffmannLa Roche, Inc.
- Roche Pharma, Inc.
- Roche Products, Inc.
- Syntex Puerto Rico, Inc.
- Roche Diagnostics Corporation, and
- Ventana Medical Systems, Inc.
- Roche Diagnostic Operations

(7) Retirement Plans and Other Retiree Benefits

The Branch participates with other affiliates in the Roche Diagnostics Corporation Pension Equity Plan (Group Plan), a plan sponsored by Roche Diagnostics Corporation, an affiliate. The purpose of the plan is to provide eligible employees with income following their retirement, without requiring contributions from the employees. This plan provides for benefits based on the employee's age, years of service, and average compensation in the year preceding retirement. The Branch contributes actuarially determined amounts to provide the plan with sufficient assets to meet benefit payment requirements. Pension cost allocated to the Branch for this plan in 2018 amounted to $912,362 distributed as follows: $830,230 is included within cost of sales and $82,132 is included in the general and administrative expenses.

All eligible employees of the Branch may also elect to participate in a thrift plan. Each eligible employee may contribute, through payroll deductions, a basic pretax contribution no to exceed the lesser of: (i)10% of participant's compensation or (ii) $8,000 for the taxable years 2008, 9,000 for taxable year commencing after January 1, 2011 and 13,000 for taxable year commencing on or after January 1, 2013 regardless of the employee's annual compensation. The Branch matches the participant's pretax contribution up to a maximum of 4% of the participant's compensation for the plan year. During 2018, the Branch made contributions under this plan of $431,759. Each participant may also elect an after-tax contribution of 2% to 10% of their earnings subject to certain limitations.

(8) Subsequent Events

The Branch has evaluated subsequent events from the balance sheet date through October 11, 2019, the date at which the financial statements were available to be issued, and determined that there are no other items to disclose.

KPMG LLP
American International Plaza
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250 Munoz Rivera Avenue
San Juan, PR 00918-1819

Independent Auditors' Report

The Board of Directors
Roche Operations Ltd.:

Report on the Financial Statements

We have audited the accompanying balance sheet of Roche Operations Ltd. – Puerto Rico Branch (the Branch) as of December 31, 2018, and the related statements of income, changes in home office account, and cash flows for the year then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Roche Operations Ltd. – Puerto Rico Branch as of December 31, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

Emphasis of Matter

As discussed in note 2 (a) to the financial statements, the financial statements of the Branch are prepared for the purpose of complying with statutory tax filing requirements of the Commonwealth of Puerto Rico. The financial statements of the Branch are intended to present the financial condition as of December 31, 2018, and

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the results of operations and cash flows for the year then ended of only that portion of Roche Operations Ltd. that is attributable to the transactions of the Branch in Puerto Rico.

As further discussed in note 3 to the financial statements, the Branch has significant related party transactions with the Home Office and certain affiliates. Our opinion was not modified with respect to this matter.

KPMG LLP

San Juan, Puerto Rico
October 11, 2019

License No. 21
Expires December 1, 2019