UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2018
or

☐ Transition report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the transition period from to
Commission file number: 0-27756

ALEXION PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	13-3648318
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

121 Seaport Boulevard, Boston Massachusetts 02210

(Address of Principal Executive Offices) (Zip Code)
475-230-2596
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value $0.0001

Name of each exchange on which registered: The Nasdaq Stock Market LLC
Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. Check One:

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐
Smaller reporting company ☐ Emerging growth company ☐
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on The Nasdaq Stock Market LLC on June 29, 2018, was $26,514,235,288.(1)

The number of shares of Common Stock outstanding as of January 31, 2019 was 223,469,381.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be used in connection with its 2019 Annual Meeting of Stockholders currently anticipated to be held on May 14, 2019, are incorporated by reference into Part III of this report.

(1) Excludes 9,186,789 shares of common stock held by directors, executive officers and their respective affiliates at June 29, 2018. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

Critical Accounting Policies and the Use of Estimates

The significant accounting policies and basis of preparation of our consolidated financial statements are described in Note 1, "Business Overview and Summary of Significant Accounting Policies" of the Consolidated Financial Statements included in this Annual Report on Form 10-K. Under accounting principles generally accepted in the U.S., we are required to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosure of contingent assets and liabilities in our financial statements. Actual results could differ from those estimates and such differences may be material.

We believe the judgments, estimates and assumptions associated with the following critical accounting policies have the greatest potential impact on our consolidated financial statements:

- Revenue recognition;
- Contingent liabilities;
- Inventories;
- Share-based compensation;
- Valuation of goodwill, acquired intangible assets and in-process research and development (IPR&D);
- Valuation of contingent consideration; and
- Income taxes.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard which amends revenue recognition principles. We adopted the new standard on January 1, 2018 by applying the modified retrospective method to all contracts that were not completed as of that date. Under the new guidance, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration expected to be received in exchange for those goods or services. Revenue is recognized through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract, and determines those that are performance obligations. Revenue is recognized for the applicable performance element when each distinct performance obligation is satisfied.

While results for reporting periods beginning after January 1, 2018 are presented under the new guidance, prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The accounting policy for revenue recognition for periods prior to January 1, 2018 is described in Note 1 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Nature of Products

Our principal source of revenue is product sales. Our contracts with customers generally contain a single performance obligation and we recognize revenue from product sales when we have satisfied our performance obligation by transferring control of the product to our customers. Control of the product generally transfers to the customer upon delivery. In certain countries, we sell to distributors on a consignment basis and record revenue when control of the product transfers to the customer upon sale to the end user.

Our customers are primarily comprised of distributors, pharmacies, hospitals, hospital buying groups, and other healthcare providers. In some cases, we may also sell to governments and government agencies. In addition to sales in countries where our products are commercially available, we have also recorded revenue on sales for patients receiving treatment through named-patient programs. The relevant authorities or institutions in those countries have agreed to reimburse for product sold on a named-patient basis where our products have not received final approval for commercial sale.

Revenue is recognized at the amount to which we expect to be entitled in exchange for the sale of our products. This amount includes both fixed and variable consideration and excludes amounts that are collected from customers and remitted to governmental authorities, such as value-added taxes in foreign jurisdictions. Shipping and handling costs associated with outbound freight after control of a product has transferred to our customers are accounted for as a fulfillment cost and are included in operating expenses. The cost for any shipping and handling activities (including customs clearance activities) associated with transactions for which revenue has been recognized are accrued if not completed before the respective period end.

The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Our standard credit terms, which vary based on the country of sale, generally range from 30 to 120 days and all arrangements generally are payable within one year of the transfer of the product. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between the transfer of the promised good to the customer and receipt of payment will be one year or less.

We evaluate the creditworthiness of customers on a regular basis. The length of time from sale to receipt of payment in certain countries exceeds our credit terms. In countries in which collections from customers extend beyond normal payment terms, we seek to collect interest. We record interest on customer receivables as interest income when collected. Subsequent adjustments for further declines in credit rating are recorded as bad debt expense as a component of selling, general and administrative expense. We also use judgments as to our ability to collect outstanding receivables and provide allowances for the portion of receivables if and when collection becomes doubtful, and we also assess on an ongoing basis whether collectibility is probable at the time of sale. As of December 31, 2018 and December 31, 2017, allowances on receivables were not material.

Variable Consideration

We pay distribution fees to our distributors and offer rebates and/or discounts, or enter into volume-based reimbursement arrangements with certain customers. We reduce the transaction price on our sales for these amounts. For variable amounts, we estimate the amount of consideration to which we expect to be entitled based on all available historic, current and forecast information. We primarily use the expected value method to estimate variable payments and, in limited circumstances, will apply the most likely method based on the type of variable consideration and what method better predicts the amount of consideration we expect to be entitled to. Consideration that is received from a customer that we expect will need to be refunded in the future is recorded as a refund liability to the customer within accrued expenses. Actual amounts of consideration ultimately received or refunded may differ from our estimates, and such difference may be material. If actual results in the future vary from our estimates, we adjust these estimates, which would affect net product sales and earnings in the period such variances become known, and such variances may be material.

Variability in the transaction price for our products pursuant to our contracts with customers primarily arises from the following:

Discounts and Rebates: We offer discounts and rebates to certain distributors and customers under our arrangements. In many cases, these amounts are fixed at the time of sale and the transaction price is reduced accordingly. We also provide for rebates under certain governmental programs, including Medicaid in the U.S. and other programs outside the U.S., which are payable based on actual claim data. We estimate these rebates based on an analysis of historical claim patterns and estimates of customer mix to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each period and record any necessary adjustments, which may have an impact on revenue in the period in which the adjustment is made (and such impact may be material). Generally, the length of time between product sale and the processing and reporting of the rebates is three to six months.

Volume-Based Arrangements: We have entered into volume-based arrangements with governments in certain countries and other customers in which reimbursement is limited to a contractual amount. Under this type of arrangement, amounts billed in excess of the contractual limitation are repaid to the customer as a rebate. We estimate incremental discounts resulting from these contractual limitations, based on forecasted sales during the limitation period, and we apply the discount percentage to product shipments as a reduction of revenue. Our calculations related to these arrangements require estimation of sales during the limitation period, and adjustments in these estimates may have a material impact in the period in which these estimates change.

We have provided balances and activity in the rebates payable account for the years ended December 31, 2018, 2017 and 2016 as follows:

	Rebates Payable
Balances, December 31, 2015	**$ 55.6**
Current provisions relating to sales in current year	114.6
Adjustments relating to prior years	(1.7)
Payments/credits relating to sales in current year	(50.3)
Payments/credits relating to sales in prior years	(48.7)
Balances, December 31, 2016	**$ 69.5**
Current provisions relating to sales in current year	193.8
Adjustments relating to prior years	(4.5)
Payments/credits relating to sales in current year	(97.4)
Payments/credits relating to sales in prior years	(62.3)
Balances, December 31, 2017	**$ 99.1**
Current provisions relating to sales in current year	235.4
Adjustments relating to prior years	(2.4)
Payments/credits relating to sales in current year	(119.3)
Payments/credits relating to sales in prior years	(90.0)
Balances, December 31, 2018	**$ 122.8**

Current provisions relating to sales in the current year increased by $41.6 in 2018 compared to 2017 and $79.2 in 2017 compared to 2016. The increase in 2018 was primarily due to increased unit volumes in the U.S. which were subject to rebates as well as increases in rebate rates in the U.S. on certain product sales. The increase in 2017 was attributable to increased unit volumes in the U.S. and Europe, which were subject to rebates, as well as to increases in rebate rates in certain geographical regions and on certain product sales as compared to the prior year.

Distribution & Other Fees: We pay distribution and other fees to certain customers in connection with the sales of our products. We record distribution and other

fees paid to our customers as a reduction of revenue, unless the payment is for a distinct good or service from the customer and we can reasonably estimate the fair value of the goods or services received. If both conditions are met, we record the consideration paid to the customer as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

Product Returns: Our contracts with customers generally provide for returns only if the product is damaged or defective upon delivery. We assess our sales transactions and arrangements with customers and monitor inventory within our sales channels to determine whether a provision for returns is warranted and a resulting adjustment to the transaction price is necessary. This assessment is based on historical experience and assumptions as of the date of sale and changes in these estimates could have an impact in the period in which the change occurs (and such impact may be material). Because of factors such as the price of our products, the limited number of patients, the short period from product sale to patient infusion and limited contractual return rights, our customers often carry limited inventory.

The amount of variable consideration included in the transaction price is constrained by the amount that is probable will not result in a significant reversal of revenue. We consider our experience with similar transactions and expectations regarding the contract in estimating the amount of variable consideration to which we expect to be entitled, and determining whether the estimated variable consideration should be constrained. We do not have any material constraints on the variable consideration included within the transaction price of our current revenue arrangements.

We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. For additional information related to our concentration of credit risk associated with certain international accounts receivable balances, refer to the *"Financial Condition, Liquidity and Capital Resources" and "Quantitative and Qualitative Disclosures About Market Risk"* sections below.

Contingent liabilities

We are currently involved in various claims and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on our best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims (and our offers of settlement), we may reassess the potential liability related to these matters and may revise these estimates, which could result in a material adjustment to our operating results and liquidity.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined in a manner that approximates average costs.

We capitalize inventory produced for commercial sale, which may include costs incurred for certain products awaiting regulatory approval. We capitalize inventory produced in preparation of product launches sufficient to support estimated initial market demand. Capitalization of such inventory begins when we have (i) obtained positive results in clinical trials that we believe are necessary to support regulatory approval, (ii) concluded that uncertainties regarding regulatory approval have been sufficiently reduced, and (iii) determined that the inventory has probable future economic benefit. In evaluating whether these conditions have been met, we consider clinical trial results for the underlying product candidate, results from meetings with regulatory authorities, and the compilation of the regulatory application. If we are aware of any material risks or contingencies outside of the standard regulatory review and approval process, or if there are any specific negative issues identified relating to the safety, efficacy, manufacturing, marketing or labeling of the product that would have a significant negative impact on its future economic benefits, the related inventory would not be capitalized.

Products that have been approved by the FDA or other regulatory authorities are also used in clinical programs to assess the safety and efficacy of the products for usage in diseases that have not been approved by the FDA or other regulatory authorities. The form of product utilized for both commercial and clinical programs is identical and, as a result, the inventory has an "alternative future use" as defined in authoritative guidance. Raw materials and purchased drug product associated with clinical development programs are included in inventory and charged to research and development expense when the product enters the

research and development process and no longer can be used for commercial purposes and, therefore, does not have an "alternative future use".

For products which are under development and have not yet been approved by regulatory authorities, purchased drug product is charged to research and development expense upon delivery. Delivery occurs when the inventory passes quality inspection and ownership transfers to us. Nonrefundable advance payments for research and development activities, including production of purchased drug product, are deferred and capitalized until the goods are delivered. We also recognize expense for raw materials purchased for developmental purposes when the raw materials pass quality inspection, and we have an obligation to pay for the materials.

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our product is subject to strict quality control, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to our inventory values. We also apply judgment related to the results of quality tests that we perform throughout the production process, as well as our understanding of regulatory guidelines, to determine if it is probable that inventory will be saleable. These quality tests are performed throughout the pre- and post-production process, and we continually gather information regarding product quality for periods after the manufacturing date. Our products currently have a maximum estimated life range of 36 to 48 months and, based on our sales forecasts, we expect to realize the carrying value of the product inventory. In the future, reduced demand, quality issues or excess supply beyond those anticipated by management may result in a material adjustment to inventory levels, which would be recorded as an increase to cost of sales.

The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical input in this determination is future expected inventory requirements based on internal sales forecasts. We then compare these requirements to the expiry dates of inventory on hand. For inventories that are capitalized in preparation of product launch, we also consider the expected approval date in assessing realizability. To the extent that inventory is expected to expire prior to being sold, we will write down the value of inventory. If actual results differ from those estimates, additional inventory write-offs may be required, and such write-offs may be material.

Share-Based Compensation

We have two share-based compensation plans pursuant to which awards are currently being made: (i) the 2017 Incentive Plan (2017 Plan) and (ii) the 2015 Employee Stock Purchase Plan (ESPP). The 2017 Plan replaced the Amended & Restated 2004 Incentive Plan, effective May 10, 2017. Under the 2017 Plan, restricted stock, restricted stock units, stock options and other stock-related awards may be granted to our directors, officers, employees and consultants or advisors of the Company or any subsidiary. Under the ESPP, eligible employees can purchase shares of common stock at a discount semi-annually through payroll deductions. To date, share-based compensation issued under the plans consists of incentive and non-qualified stock options, restricted stock and restricted stock units, including restricted stock units with market and non-market performance conditions, and shares issued under our ESPP.

Compensation expense for our share-based awards is recognized based on the estimated fair value of the awards on the grant date. Compensation expense reflects an estimate of the number of awards expected to vest and is primarily recognized on a straight-line basis over the requisite service period of the individual grants, which typically equals the vesting period. Compensation expense for awards with performance conditions is recognized using the graded-vesting method.

Our estimates of employee stock option values rely on estimates of factors we input into the Black-Scholes model. The key factors involve an estimate of future uncertain events. Significant assumptions include the use of historical volatility to determine the expected stock price volatility. We also estimate expected term until exercise and the reduction in the expense from expected forfeitures. We currently use historical exercise and cancellation patterns as our best estimate of future estimated life. Actual volatility and lives of options may be significantly different from our estimates.

For our non-market performance-based awards, we estimate the anticipated achievement of the performance targets, including forecasting the achievement of future financial targets. These estimates are revised periodically based on the probability of achieving the performance targets and adjustments are made throughout the performance period as necessary. We use payout simulation models to estimate the grant date fair value of market performance-based awards. The payout simulation models assume volatility of our common stock and the common stock of a comparator group of companies, as well as correlations of returns of the price of our common stock and the common stock prices of the comparator group.

The purchase price of common stock under our ESPP is equal to 85% of the lower of (i) the market value per share of the common stock on the first business day of an offering period or (ii) the market value per share

of the common stock on the purchase date. The fair value of the discounted purchases made under our ESPP is calculated using the Black-Scholes model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over the 6 month purchase period.

If factors change or we employ different assumptions to value our stock-based awards, the share-based compensation expense that we record in future periods may differ materially from our prior recorded amounts.

Valuation of Goodwill, Acquired Intangible Assets and In-Process Research and Development (IPR&D)

We have recorded goodwill, acquired intangible assets and IPR&D related to our business combinations. When identifiable intangible assets, including IPR&D, are acquired, we determine the fair values of the assets as of the acquisition date. Discounted cash flow models are typically used in these valuations if quoted market prices are not available, and the models require the use of significant estimates and assumptions including but not limited to:

- timing and costs to complete the in-process projects;
- timing and probability of success of clinical events or regulatory approvals;
- estimated future cash flows from product sales resulting from completed products and in-process projects; and
- discount rates.

We may also utilize a cost approach, which estimates the costs that would be incurred to replace the assets being purchased. Significant inputs into the cost approach include estimated rates of return on historical costs that a market participant would expect to pay for these assets.

Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events occur.

Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment. Impairment testing is performed at least annually or when a triggering event occurs that could indicate a potential impairment. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized over a period that best reflects the economic benefits provided by these assets.

If projects are not successfully developed, our sales and profitability may be adversely affected in future periods. Additionally, the value of the acquired intangible assets, including IPR&D, may become impaired if the underlying projects do not progress as we initially estimated. We believe that the assumptions used in developing our estimates of intangible asset values were reasonable at the time of the respective acquisitions. However, the underlying assumptions used to estimate expected project sales, development costs, profitability, or the events associated with such projects, such as clinical results, may not occur as we estimated at the acquisition date.

Goodwill represents the excess of purchase price over fair value of net assets acquired in a business combination and is not amortized. Goodwill is subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. We are organized and operate as a single reporting unit and therefore the goodwill impairment test is performed using our overall market value, as determined by our traded share price, compared to our book value of net assets.

Valuation of Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. We determine the fair value of the contingent consideration based primarily on the following factors:

- timing and probability of success of clinical events or regulatory approvals;
- timing and probability of success of meeting commercial milestones, such as estimated future sales levels of a specific compound; and
- discount rates.

Our contingent consideration liabilities arose in connection with our business combinations. On a quarterly basis, we revalue these obligations and record increases or decreases in their fair value as an adjustment to operating earnings. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in our estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval.

The assumptions related to determining the value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration expense recorded in any given period.

Income Taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse.

On December 22, 2017, the Tax Cuts and Jobs Act (Tax Act) was enacted into law. The Tax Act decreased the U.S. statutory corporate tax rate for years beginning after December 31, 2017, and included other domestic and international tax provisions that affect the measurement of our deferred tax assets and liabilities. As a result, we revalued our deferred tax assets and liabilities as of December 31, 2017 and recorded a deferred tax benefit of $292.4. We recorded other impacts of the Tax Act on a provisional basis in 2017. As of December 22, 2018, our accounting for the impact of the Tax Act was complete. See Note 12, "*Income Taxes*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

If our estimate of the tax effect of reversing temporary differences is not reflective of actual outcomes, is modified to reflect new developments or interpretations of the tax law, revised to incorporate new accounting principles, or changes in the expected timing or manner of the reversal our results of operations could be materially impacted.

We follow the authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. These unrecognized tax benefits relate primarily to issues common among multinational corporations in our industry. We apply a variety of methodologies in making these estimates which include studies performed by independent economists, advice from industry and subject experts, evaluation of public actions taken by the IRS and other taxing authorities, as well as our own industry experience. We provide estimates for unrecognized tax benefits which may be subject to material adjustments until matters are resolved with taxing authorities or statutes expire. If our estimates are not representative of actual outcomes, our results of operations could be materially impacted.

We continue to maintain a valuation allowance against certain deferred tax assets where realization is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. We consider many factors when assessing the likelihood of future realization of deferred tax assets, including our recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. Significant judgment is required in making this assessment and, to the extent future expectations change, we would assess the recoverability of our deferred tax assets at that time. If we determine that the deferred tax assets are not realizable in a future period, we would record adjustments to income tax expense in that period, and such adjustments may be material.

New Accounting Pronouncements

In February 2016, the FASB issued a new standard that requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The standard is effective on January 1, 2019, with early adoption permitted. We adopted the new standard on January 1, 2019 and use the effective date as our date of initial application. In July 2018, the FASB issued an update that provided an additional transition option that allows companies to continue applying the guidance under the lease standard in effect at that time in the comparative periods presented in the consolidated financial statements. Companies that elect this option would record a cumulative-effect adjustment to the opening balance of retained earnings on the date of adoption. We elected this optional transition method. We also elected the "package of practical expedients", which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. We continue to evaluate other practical expedients available under the standard.

We have substantially completed our assessment of the standard as well as implementation of our leasing software, including data upload and test procedures. We continue to finalize our calculations, including our discount rate assumptions, related to the new standard. We are also continuing to establish new processes and internal controls that may be required to comply with the new lease accounting and disclosure requirements set by the new standard. We expect the impact of the standard adoption to decrease our assets, liabilities and retained earnings within our consolidated balance sheet. These decreases will result from the derecognition of our existing assets and financing obligations related to our build to suit leases offset by the recognition of new ROU assets and liabilities as a result of the leasing standard.

In June 2016, the FASB issued a new standard intended to improve reporting requirements specific to loans, receivables and other financial instruments. The new standard requires that credit losses be reported based on expected losses compared to the current incurred loss model. The new standard also requires enhanced disclosure of credit risk associated with respective assets. The standard is effective for interim and annual periods beginning after December 15, 2019 with early adoption permitted. We are currently assessing the impact of this standard on our financial condition and results of operations.

In February 2018, the FASB issued a new standard that would permit entities to make a one time reclassification from accumulated other comprehensive income (AOCI) to retained earnings for the stranded tax effects resulting from the newly enacted corporate tax rates under the Tax Act, that was effective for the year ended December 31, 2017. The amount of the reclassification is calculated on the basis of the difference between the historical tax rate and newly enacted tax rate. The standard is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. We are currently assessing the impact of this standard on our financial condition.

In August 2018, the FASB issued a new standard on a customer's accounting for implementation, set-up, and other upfront costs incurred in a cloud computing arrangement (CCA). Under the new guidance, customers will assess if a CCA includes a software license and if a CCA does include a software license, implementation and set-up costs will be accounted for consistent with existing internal-use software implementation guidance. Implementation costs associated with a CCA that does not include a software license would be expensed to operating expenses. The standard also provides classification guidance on these implementation costs as well as additional quantitative and qualitative disclosures. The standard is effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in any interim periods. Entities can choose to adopt the new guidance prospectively or retrospectively. We are currently assessing the impact this standard will have on our statement of financial condition and results of operations.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five-step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted the new standard on January 1, 2018.

In January 2017, the FASB issued a new standard that clarifies the definition of a business and determines when an integrated set of assets and activities is not a business. This framework requires that if substantially all of the fair value of gross assets acquired or disposed of is concentrated in a single asset or group of similar identifiable assets, the assets would not represent a business. We adopted the new standard on January 1, 2018 and applied the new guidance prospectively to transactions occurring after adoption. We anticipate that the adoption of this new standard will likely result in more transactions, to the extent that such transactions are undertaken by the Company, being accounted for as asset acquisitions.

In January 2016, the FASB issued a new standard that changes accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in net income. Companies have the option to either measure equity investments without readily determinable fair values at fair value, or at cost adjusted for changes in observable prices minus impairment. We adopted the new standard on January 1, 2018, and elected to measure our existing equity investments without readily determinable fair values at cost adjusted for changes in observable prices minus impairment. In connection with the adoption of the new standard, we reclassified an immaterial amount of unrealized gains on equity securities from accumulated other comprehensive income to retained earnings. The guidance related to equity investments without readily determinable fair values was applied prospectively to equity investments that existed as of the date of adoption. We will assess equity investments without readily determinable fair values for observable price changes and impairment on a quarterly basis. See Note 7, "*Other Investments*," to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further details.

In March 2017, the FASB issued a new standard that improves the presentation of net periodic pension cost and net periodic post retirement benefit cost by requiring the bifurcation of net benefit cost. Under the new standard, the service cost component of net benefit cost will be presented with other employee costs in operating expenses, while other components will be reported separately in other income and expense. We adopted the new standard on January 1, 2018. The

adoption of this standard did not have a material impact on our consolidated statements of operations.

In November 2016, the FASB issued a new standard that clarifies how entities should present restricted cash in the statement of cash flows. Under the new standard, changes in total cash, inclusive of restricted cash, should be reflected in the statement of cash flows. As a result, transfers between cash and restricted cash will no longer be reflected as activity within the statement of cash flows. We adopted the new standard on January 1, 2018. The adoption of this standard did not have a material impact on our consolidated statements of cash flows.

In August 2017, the FASB issued a new standard intended to improve and simplify certain aspects of the accounting for hedges. The new standard is intended to more closely align hedge accounting with companies' risk management strategies, simplify the application of hedge accounting, and increase transparency as to the scope and results of hedging programs. It also amends the presentation and disclosure requirements and changes how companies assess effectiveness. The standard is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. We early adopted the new standard in the second quarter 2018 using the modified retrospective method. The adoption of this standard did not have a material impact on our consolidated financial statements.

Results of Operations

The following table sets forth consolidated statements of operations data for the periods indicated. This information has been derived from the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,		
	2018	2017	2016
Net product sales	$ 4,130.1	$ 3,549.5	$ 3,081.7
Other revenue	1.1	1.6	2.4
Total revenues	4,131.2	3,551.1	3,084.1
Cost of sales	374.3	454.2	258.3
Operating expenses:			
Research and development	730.4	878.4	757.2
Selling, general and administrative	1,111.8	1,094.4	953.0
Acquired in-process research and development	1,183.0	—	—
Amortization of purchased intangible assets	320.1	320.1	322.2
Change in fair value of contingent consideration	116.5	41.0	35.7
Acquisition-related costs	—	—	2.3
Restructuring expenses	25.5	104.6	3.0
Impairment of intangible assets	—	31.0	85.0
Total operating expenses	3,487.3	2,469.5	2,158.4
Operating income	269.6	627.4	667.4
Other expense	(27.4)	(79.6)	(91.2)
Income before income taxes	242.2	547.8	576.2
Income tax expense	164.6	104.5	176.8
Net income	$ 77.6	$ 443.3	$ 399.4
Earnings per common share:			
Basic	$ 0.35	$ 1.98	$ 1.78
Diluted	$ 0.35	$ 1.97	$ 1.76

Comparison of the Years Ended December 31, 2018, 2017, and 2016

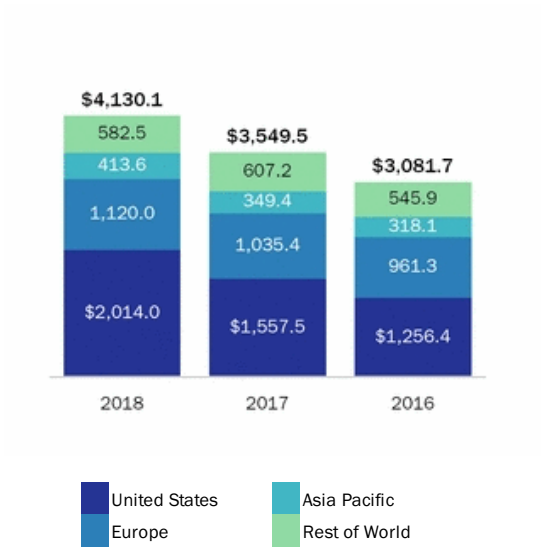
Net Product Sales

Net product sales by product and significant geographic region are as follows:

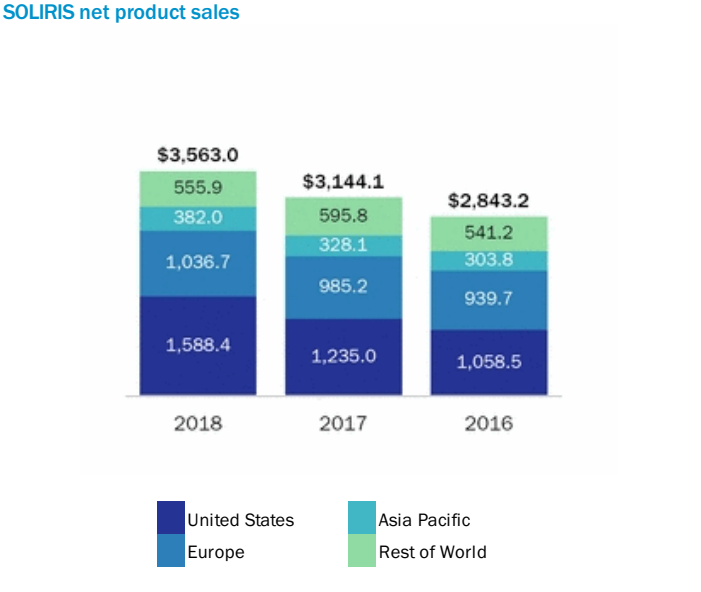
	Year Ended December 31,			% Change	
	2018	2017	2016	2018 compared to 2017	2017 compared to 2016
SOLIRIS					
United States	$ 1,588.4	$ 1,235.0	$ 1,058.5	28.6 %	16.7%
Europe	1,036.7	985.2	939.7	5.2 %	4.8%
Asia Pacific	382.0	328.1	303.8	16.4 %	8.0%
Rest of World	555.9	595.8	541.2	(6.7)%	10.1%
	$ 3,563.0	$ 3,144.1	$ 2,843.2	13.3 %	10.6%
STRENSIQ					
United States	$ 374.3	$ 280.1	$ 177.5	33.6 %	57.8%
Europe	61.7	35.6	15.3	73.3 %	132.7%
Asia Pacific	27.9	18.6	13.0	50.0 %	43.1%
Rest of World	11.2	5.5	3.6	103.6 %	52.8%
	$ 475.1	$ 339.8	$ 209.4	39.8 %	62.3%
KANUMA					
United States	$ 51.3	$ 42.4	$ 20.4	21.0 %	107.8%
Europe	21.6	14.6	6.3	47.9 %	131.7%
Asia Pacific	3.7	2.7	1.3	37.0 %	107.7%
Rest of World	15.4	5.9	1.1	**	**
	$ 92.0	$ 65.6	$ 29.1	40.2 %	125.4%
Total Net Product Sales	$ 4,130.1	$ 3,549.5	$ 3,081.7	16.4 %	15.2%

** Percentages not meaningful

Net Product Sales (consolidated)

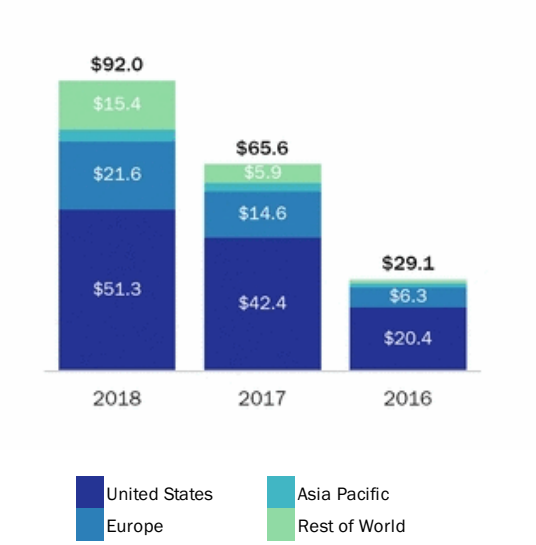


SOLIRIS net product sales



STRENSIQ net product sales

KANUMA net product sales



The components of the increase in net product sales for December 31, 2018 as compared to 2017 are as follows:

The increase in net product sales for fiscal year 2018, as compared to fiscal year 2017, was primarily due to an increase in unit volumes of 20.1%. This increase in unit volumes is primarily due to increased global demand for SOLIRIS therapy, including sales to patients with gMG, which received regulatory approval in the second half of 2017. Additional unit volume increases were due to increased sales of STRENSIQ and KANUMA during 2018 as a result of our continuing efforts to identify and reach more patients with HPP and LAL-D globally.

The increase in net product sales for fiscal year 2018, as compared to fiscal year 2017, was partially offset by price decreases of 3.9% due, in part, to a price change in Turkey resulting from a formalized reimbursement agreement, subsequent to marketing authorization, in the third quarter of 2018. In addition, rebates in the U.S. and reimbursement agreements outside the U.S. for our metabolic products also contributed to this decrease in net product sales.

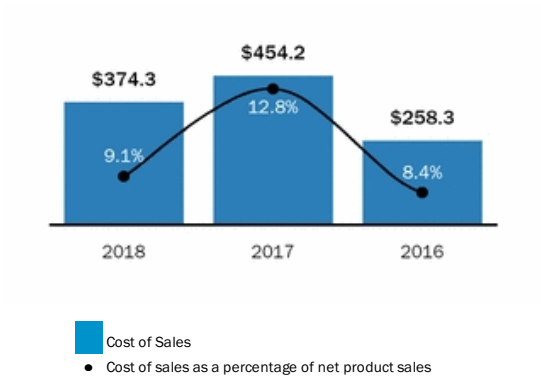
The components of the increase in revenues for the year ended December 31, 2017 as compared to the same period in 2016 are as follows:

The increase in net product sales for fiscal year 2017 as compared to fiscal year 2016 was primarily due to an increase in unit volumes of 16.8% due to increased demand globally for SOLIRIS therapy for patients with PNH and aHUS and increased sales of STRENSIQ and KANUMA during 2017.

Cost of Sales

Cost of sales includes manufacturing costs, actual and estimated royalty expenses associated with sales of our products, and amortization of licensing rights.

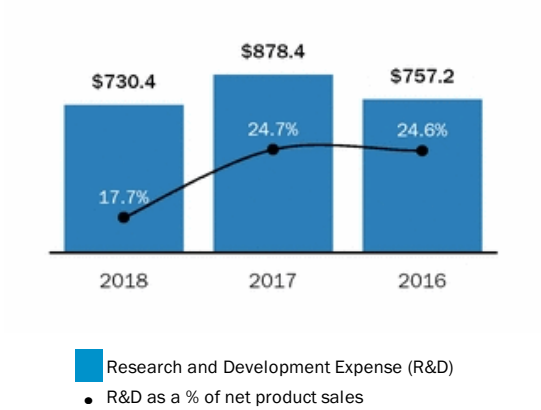
The following table summarizes cost of sales for the years ended December 31, 2018, 2017 and 2016:



Cost of sales for the year ended December 31, 2018 and December 31, 2017 included asset related charges of $5.8 and $152.1, respectively, associated with the closure of the ARIMF facility announced in the third quarter of 2017 (this facility was sold in 2018). These charges primarily relate to accelerated depreciation and the impairment of manufacturing assets.

Exclusive of the items mentioned above, cost of sales as a percentage of net product sales were 8.9%, 8.5% and 8.4% for the years ended December 31, 2018, 2017 and 2016, respectively.

Research and Development Expense

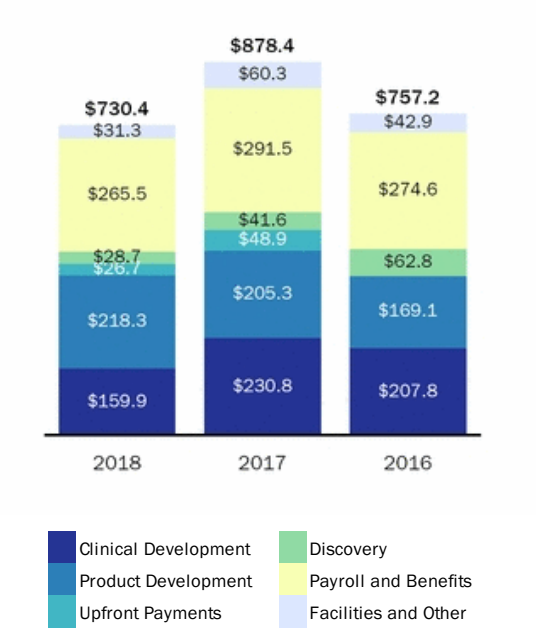


Our research and development expense includes personnel, facility and direct costs associated with the research and development (R&D) of our product candidates, as well as product development costs. For additional information on our development programs, please refer to *Product and Development Programs* in *Item I Business* of this Annual Report on Form 10-K.

R&D expenses are comprised of costs paid for clinical development, product development and discovery research, as well as costs associated with certain strategic licensing agreements we have entered into with third parties. Clinical development costs are comprised of costs to conduct and manage clinical trials related to eculizumab, ALXN1210 and other product candidates. Product development costs are those incurred in performing duties related to manufacturing development and regulatory functions, including manufacturing of material for clinical and research activities, milestone expenses related to our licensing agreements and collaborations and other administrative costs incurred during product development. Discovery research costs are incurred in conducting laboratory studies and performing preclinical research for other uses of our products and other product candidates and milestone expenses related to our licensing agreements and collaborations in the discovery stage. Upfront payments include upfront payments related to licenses and collaborations. Clinical development costs have been accumulated and allocated to each of our programs, while product development and discovery research costs have not been allocated.

Facilities and other R&D expenses consist of costs to compensate personnel, to maintain our facilities and equipment, and other occupancy costs associated with our research and development efforts. These costs relate to efforts on our clinical and preclinical products, our product development and our discovery research efforts. These costs have not been allocated directly to each program.

The following graph provides information regarding research and development expenses:



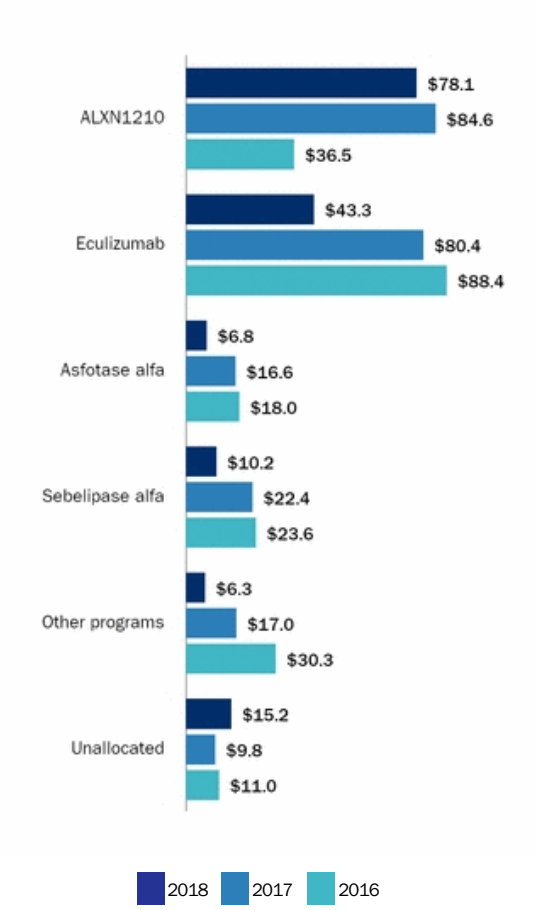
During the year ended December 31, 2018, we incurred R&D expenses of $730.4, a decrease of $148.0, or 16.8%, versus the $878.4 incurred during the year ended December 31, 2017. The decrease was primarily related to the following:

- Decrease of $70.9 in direct clinical development expenses related primarily to decreases in various eculizamab clinical studies, offset by expansion of studies for ALXN1210.
- Increase of $13.0 in direct product development expenses related primarily to an increase in costs associated with the manufacturing of material for ALXN1210 offset by a decrease in ALXN6000 clinical research activities (the ALXN6000 program has been discontinued).
- Decrease of $22.2 in upfront payments due to the nature and timing of licensing and collaborations agreements executed in 2018 compared to 2017.
- Decrease of $12.9 in discovery primarily related to de-prioritized preclinical arrangements with Moderna Therapeutics and Blueprint Medicines. We no longer conduct development efforts with these entities.
- Decrease of $26.0 in payroll and benefits primarily related to headcount reductions resulting from restructuring activities initiated in 2017.
- Decrease of $29.0 in facilities and other related expenses primarily related to decreased facilities expenses primarily resulting from the impact of the 2017 restructuring.

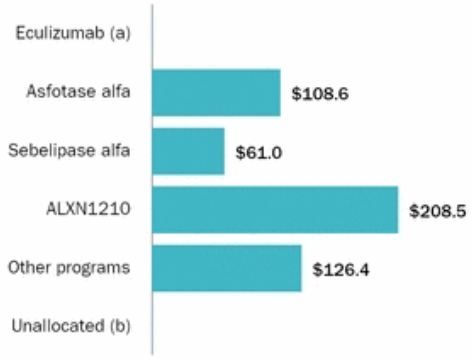
During the year ended December 31, 2017, we incurred research and development expenses of $878.4, an increase of $121.2, or 16.0%, versus the $757.2 incurred during the year ended December 31, 2016. The increase was primarily related to the following:

- Increase of $23.0 in direct clinical development expenses related primarily to an expansion of ALXN 1210 studies.
- Increase of $36.2 in direct product development expenses related primarily to an increase in costs associated with the manufacturing of material for ALXN1210 and ALXN6000 clinical research activities.
- Increase of $48.9 in upfront payments made in the fourth quarter of 2017 related to a collaboration and license agreement with Halozyme Therapeutics, Inc.
- Increase of $16.9 in payroll and benefits related primarily to increased bonus performance and stock compensation expense.
- Increase of $17.4 in facilities and other expenses related primarily to accelerated depreciation on assets that support R&D activities associated with the 2017 restructuring activities.

The following graph summarizes expenses related to our clinical development programs:



The following graph summarizes accumulated direct expenses related to our clinical development programs from January 1, 2006 to December 31, 2018:



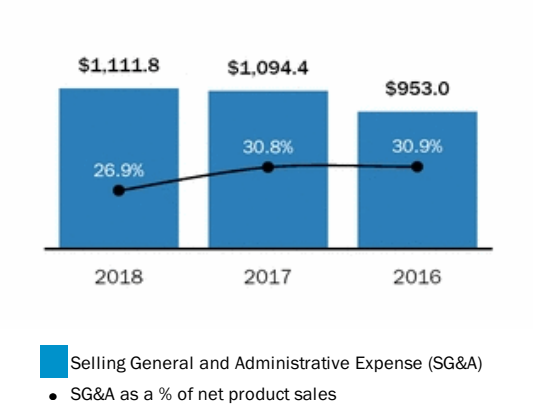
(a) From 1992 through 2006, substantially all research and development expenses were related to two products, eculizumab and pexelizumab. We obtained approval in the U.S. for eculizumab for PNH in 2007 and for aHUS in 2010, and we ceased development of pexelizumab in 2006.

(b) Unallocated costs shared across various development programs.

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support regulatory approvals for any of our product development programs. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our development programs, please refer to Item 1A “Risk Factors” in this Annual Report on Form 10-K.

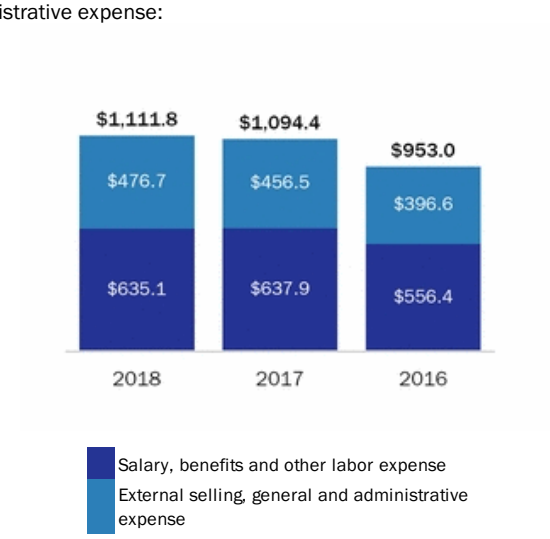
We expect our research and development expenses to remain consistent as a percentage of sales in 2019 as compared to 2018.

Selling, General and Administrative Expense



Our selling, general and administrative expense includes commercial and administrative personnel, corporate facility and external costs required to support the marketing and sales of our commercialized products. These selling, general and administrative costs include: corporate facility operating expenses and depreciation; marketing and sales operations in support of our products; human resources; finance, legal, information technology and support personnel expenses; and other corporate costs such as telecommunications, insurance, audit, government affairs and our global corporate compliance program.

The table below provides information regarding selling, general and administrative expense:



During the year ended December 31, 2018, we incurred selling, general and administrative expenses of $1,111.8, an increase of $17.4, or 1.6%, versus the $1,094.4 incurred during the year ended December 31, 2017. The increase was primarily related to the following:

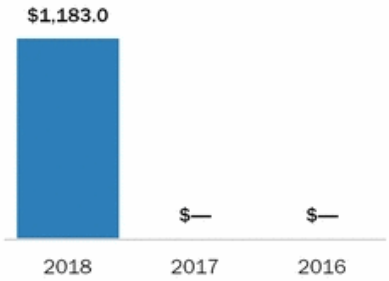
- Increase in external selling, general and administrative expenses of $20.2. The increase was primarily due to an increase in professional services and asset related charges associated with previously announced restructuring programs. These increases were partially offset by decreased distribution expenses as compared to the same period in 2017.

During the year ended December 31, 2017, we incurred selling, general and administrative expenses of $1,094.4, an increase of $141.4, or 14.8%, versus the $953.0 incurred during the year ended December 31, 2016. The increase was primarily related to the following:

- Increase in salary, benefits and other labor expenses of $81.5, primarily related to increase of commercial activities to support the continued global launches of STRENSIQ and KANUMA and the launch of SOLIRIS for gMG. Employee related costs associated with executive leadership changes and incentive compensation also increased.
- Increase in external selling, general and administrative expenses of $59.9. The increase was primarily due to an increase in charitable contributions and additional professional services, offset in part by decreases in advertising and promotional cost as compared to 2016. The increase was also due to asset impairment charges that were recorded in 2017 related to restructuring activities.

We expect our selling, general and administrative expenses to decrease as a percentage of sales in 2019 as compared to 2018.

Acquired In-Process Research and Development



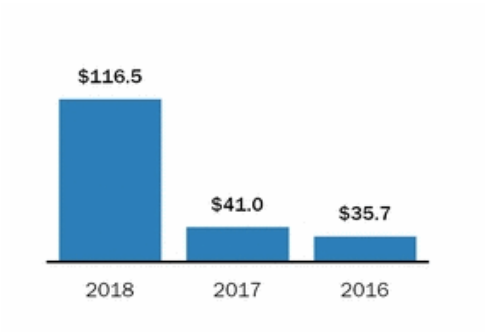
For the year ended December 31, 2018 we recorded acquired in-process research and development (IPR&D) expense of $1,183.0. The increase in acquired IPR&D for the year ended December 31, 2018, as compared to 2017 and 2016, is due to the Wilson Therapeutics acquisition completed in the second quarter of 2018 and the Syntimmune acquisition

completed in the fourth quarter of 2018. The IPR&D assets associated with each of these acquisitions, which were the principal assets acquired in each transaction, had not reached technological feasibility and had no alternative future use as of the acquisition date and were therefore expensed in 2018.

Amortization of Purchased Intangible Assets

Amortization expense associated with purchased intangible assets was $320.1, $320.1 and $322.2 for the years ended December 31, 2018, 2017 and 2016, respectively. Amortization expense is primarily associated with intangible assets related to STRENSIQ and KANUMA.

Change in Fair Value of Contingent Consideration

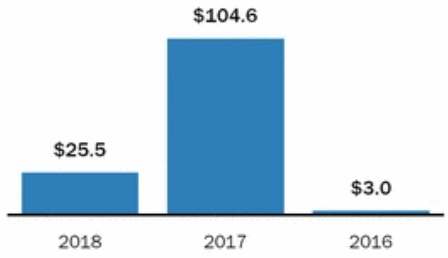


For the years ended December 31, 2018, 2017 and 2016, the change in fair value of contingent consideration expense associated with our prior business combinations was $116.5, $41.0 and $35.7, respectively. The change in the fair value of contingent consideration will fluctuate based on the timing of recognition of changes in the probability of achieving and the expected timing of milestone payments in connection with previous acquisitions.

In September 2018, we amended the terms of certain contingent milestone payments due under our prior merger agreement with Enobia Pharma Corp. (Enobia), dated December 28, 2011. The agreement removed our obligations with respect to a regulatory milestone and redistributed the contingent payment associated with this milestone to various sales milestones. As a result of this agreement and the probability of achieving the various sales milestones, our contingent consideration liability increased by $48.7 in the third quarter 2018.

For the year ended December 31, 2018, changes in the fair value of contingent consideration expense primarily reflect the impact of the agreement with Enobia to amend milestones and changes in the expected timing of payments of contingent consideration, as well as the interest component of contingent consideration related to the passage of time.

Restructuring Expenses



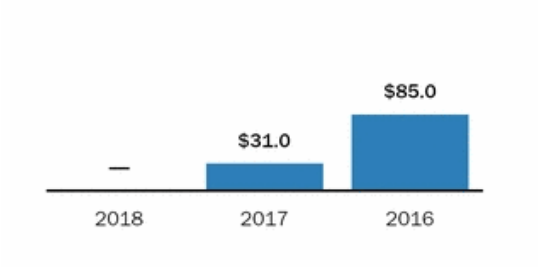
For the years ended December 31, 2018 and 2017, we recorded $25.5 and $104.6, respectively, in restructuring expenses. The charges for the year ended 2018 were mainly attributable to the relocation of our corporate headquarters from New Haven, Connecticut to Boston, Massachusetts and other related costs and the charges for the year ended 2017 were mainly attributable to employee separation costs in connection with the 2017 restructuring (as described below).

In the first quarter of 2017, we initiated a company-wide restructuring designed to help position the Company for sustainable, long-term growth that we believe will further allow us to fulfill our mission of serving patients and families with rare diseases. The initial restructuring activities primarily focused on a reduction of the Company's global workforce. In September 2017, we committed to an operational plan to re-align the global organization with its refocused corporate strategy. The re-alignment focused investments in priority growth areas to maximize leadership in complement and grow the rare disease business. The re-alignment also included the relocation of the Company's headquarters to Boston, Massachusetts in 2018. Our New Haven, Connecticut site continues to support employees working in the research and process development laboratories, the clinical supply and quality teams, nurse case management and a number of important enterprise business services. The 2017 restructuring plan reduced the Company's global workforce by approximately 20.0%. The restructuring achieved cost savings by focusing the development portfolio, simplifying

business structures and processes across the Company's global operations, and closing of multiple Alexion sites, including ARIMF and certain regional and country-based offices.

In the first quarter 2019, we have undertaken corporate restructuring activities to re-align our global organization with our re-focused strategy, reduce costs, and realize operational efficiencies. We expect to incur estimated expenses up to $25.0 associated with this recent restructuring by the end of 2019. For additional information on this 2019 corporate restructuring activity, see Item 1. "*Business - Sales and Marketing*" elsewhere in this Annual Report on Form 10-K.

Impairment of Intangible Assets



During the fourth quarter of 2016, we reviewed SBC-103, an early stage clinical indefinite-lived intangible asset related to the Synageva acquisition as part of our annual impairment testing. The estimated fair value that can be obtained for this asset from a market participant in an arm's length transaction was determined to be $31.0, which was lower than the carrying amount of the asset. As a result, in the fourth quarter 2016, we recognized an impairment charge of $85.0 to write-down this asset to fair value. In the second quarter 2017, due to clinical results, we recognized an impairment charge of $31.0 related to our SBC-103 acquired in-process research and development asset to write-down the asset to fair value, which was determined to be de minimis.

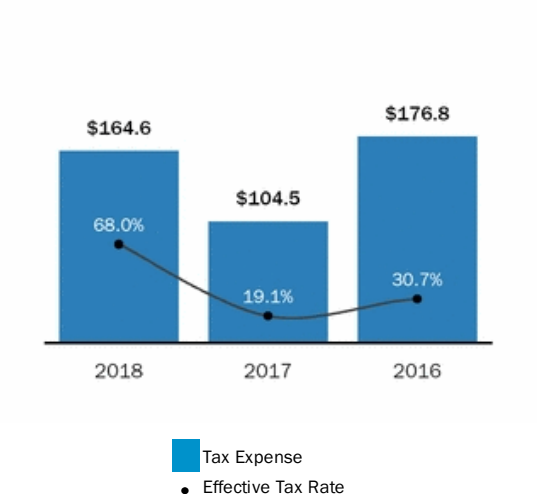
As of December 31, 2018, we reviewed the KANUMA asset for impairment and determined that there were no indicators of impairment. We will continue to review the related valuation and accounting of this asset in future quarters as new information becomes available to us. Changes to assumptions used in our net cash flow projections may result in impairment charges in subsequent periods. The net book value of the KANUMA intangible asset as of December 31, 2018 is $3,252.6.

Other Income and (Expense)

The following table provides information regarding other income and expense:

For the year ended December 31, 2018, we experienced an increase in investment income primarily due to the recognition of unrealized gains of $44.4 on our Moderna Therapeutics equity investment.

Income Taxes



The income tax expense for the years ended December 31, 2018, 2017 and 2016 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. During the year ended December 31, 2018, we recorded an income tax expense of $164.6 and an effective tax rate of 68.0%, compared to an income tax expense of $104.5 and $176.8 and an effective tax rate of 19.1% and 30.7% for the years ended December 31, 2017 and 2016, respectively. The increase in the effective tax rate during 2018, from 19.1% for the year ended December 31, 2017 to 68.0% for the year ended December 31, 2018 was primarily attributable to the acquisitions of Syntimmune and Wilson Therapeutics. Absent successful clinical results and regulatory approval, there is no alternative future use for the in-process research assets we acquired in these acquisitions. Accordingly, the value of the assets acquired of $1,183.0 were expensed as acquired in-process research and development, for which no tax benefit has been recognized. The Syntimmune and Wilson Therapeutics acquisitions resulted in an increase in the effective tax rate of approximately 102.6%. This increase was partially offset by the decrease to the U.S. statutory rate and other related adjustments as a result of the Tax Act. These items resulted in a decrease of approximately 45.7%.

In December 2017, the Tax Act was enacted into law. The Tax Act decreased the U.S. federal corporate tax rate to 21.0%, imposed a minimum tax on foreign earnings and incorporated a one-time transition tax on previously unremitted foreign earnings. We incorporated the impact of the Tax Act in our results of operations or calculated provisional amounts for the tax effects of the Tax Act that could be reasonably estimated for the year ended December 31, 2017. We recorded adjustments to this provisional accounting during 2018, which resulted in a decrease to tax expense of $56.5. We completed our accounting for the Tax Act in the fourth quarter 2018.

The Tax Act resulted in an increase to tax expense for the year ended December 31, 2017 of $45.8. This increase included a transition tax expense of $177.9 and deferred tax expense related to the new GILTI minimum tax of $165.4, partially offset by the $297.5 benefit of re-measuring balance sheet taxes to the new 21.0% US federal tax rate. The re-measurement benefit included $292.4 related to decreases to our net deferred tax liability and $5.1 related to decreases to income taxes payable. The deferred tax expense related to the GILTI minimum tax included incremental deferred tax of $236.9, net of a related $71.5 decrease for uncertain tax positions.

The decrease in the effective tax rate during 2017, from 30.7% for the year ended December 31, 2016 to 19.1% for the year ended December 31, 2017 was primarily attributable to the net increase to tax expense in 2017 of $45.8 attributable to the Tax Act, offset by decreases attributable to the deferred tax cost of $119.3 associated with the distribution of earnings from our captive foreign partnership in 2016 and the conclusion of the IRS examination of our 2013 and 2014 tax years in 2017. The impact of the enactment of the Tax Act increased our effective tax rate in 2017 by 8.4%. The 2016 distribution of earnings increased our 2016 effective tax rate by 20.7%. Conclusion of the IRS examination resulted in a decrease to our 2017 effective tax rate of approximately 3.6% for the year ended December 31, 2017.

We continue to maintain a valuation allowance against certain other deferred tax assets where realization is not certain. We periodically evaluate the likelihood of realizing deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized.

Financial Condition, Liquidity and Capital Resources

The following table summarizes the components of our financial condition as of December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 1,365.5	$ 584.4
Marketable securities	198.3	889.7
Long-term debt (includes current portion & revolving credit facility)	2,862.5	2,906.3
Current assets	$ 3,385.0	$ 2,953.9
Current liabilities	1,174.0	952.5
Working capital	$ 2,211.0	$ 2,001.4

The aggregate increase in cash and cash equivalents and marketable securities of $89.7 at December 31, 2018 as compared to December 31, 2017 was primarily attributable to cash generated from operations and net proceeds from the issuance of common stock under share-based compensation arrangements. Partially offsetting these increases was cash utilized to repurchase shares of common stock, principal payments on our term loan (in connection with entering into our Amended and Restated Credit Agreement in June 2018), and purchases of property, plant, and equipment.

Excluding the impact of any future asset acquisitions, we expect our annual operating expenses to decrease as a percentage of sales in 2019 as compared to 2018. We also expect reduced capital investment in 2019 as compared to 2018. We anticipate that cash generated from operations and our existing available cash, cash equivalents and marketable securities should provide us adequate resources to fund our operations as currently planned for at least the next twelve months.

We have financed our operations and capital expenditures primarily through positive cash flows from operations. We expect to continue to be able to fund our operations, including principal and interest payments on our Amended and Restated Credit Agreement and contingent payments from our acquisitions principally through our cash flows from operations. We may, from time to time, also seek additional funding through a combination of equity or debt financings or from other sources, if necessary for future acquisitions or other strategic purposes. New sources of financing through equity and/or debt financing(s) may not always be available on acceptable terms, or at all, and we may be required to obtain certain consents in connection with completing such financings.

Financial Instruments

Until required for use in the business, we may invest our cash reserves in money market funds, bank deposits, reverse repurchase agreements, and high-quality marketable debt securities in accordance with our investment policy. The stated objectives of our investment policy are to preserve capital, provide liquidity consistent with forecasted cash flow requirements, maintain appropriate diversification and generate returns relative to these investment objectives and prevailing market conditions.

Financial instruments that potentially expose us to concentrations of credit risk are cash equivalents, marketable securities, accounts receivable and our derivative contracts. At December 31, 2018, three customers accounted for 48.7% of the accounts receivable balance, with these individual customers accounting for 14.0% to 19.1% of the accounts receivable balance. At December 31, 2017, four customers accounted for 57.7% of the accounts receivable balance, with these individual customers accounting for 10.2% to 18.9% of the accounts receivable balance.

For the year ended December 31, 2018, four customers accounted for 50.3% of our product sales, with these individual customers ranging from 10.0% to 16.4% of product sales. For the year ended December 31, 2017, three customers accounted for 37.0% of our product sales, with these individual customers ranging from 10.8% to 15.0% of product sales. For the year ended December 31, 2016, three customers accounted for 36.7% of our product sales, with these individual customers ranging from 10.0% to 16.0% of product sales.

We continue to monitor economic conditions, including volatility associated with international economies and the associated impacts on the financial markets and our business. Substantially all of our accounts receivable are due from wholesale distributors, public hospitals and other government entities. We monitor the financial performance of our customers so that we can appropriately respond to changes in their credit worthiness. We operate in certain jurisdictions where weakness in economic conditions can result in extended collection periods. We continue to monitor these conditions and assess their possible impact on our business. To date, we have not experienced any significant losses with respect to collection of our accounts receivable.

We manage our foreign currency transaction risk and interest rate risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of December 31, 2018, we had foreign exchange forward contracts with notional amounts totaling $2,523.0. These outstanding foreign exchange forward contracts had a net fair value liability of $18.9, of which $40.8 is included in other current assets and noncurrent assets and $21.9 is included in other current liabilities and noncurrent liabilities. As of December 31, 2018, we had interest rate swap contracts with notional amounts totaling $3,881.3. These outstanding interest rate swap contracts had a net fair value of $2.0, of which $20.1 is included in other current assets and $18.1 is included in other current liabilities and noncurrent liabilities. The counterparties to these contracts are large domestic and multinational commercial banks, and we believe the risk of nonperformance is not material.

At December 31, 2018, our financial assets and liabilities were recorded at fair value. We have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of mutual

fund investments and equity securities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Our Level 2 assets consist primarily of money market funds, commercial paper, municipal bonds, reverse repurchase agreements, U.S. and foreign government-related debt, corporate debt securities, certificates of deposit, equity securities subject to holding period restrictions and derivative contracts. Our Level 2 liabilities consist also of derivative contracts. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. Our Level 3 liabilities consist of contingent consideration related to acquisitions.

Business Combinations and Contingent Consideration Obligations

At December 31, 2018, the purchase agreements for our business combinations include contingent payments totaling up to $702.0 that will become payable if and when certain development and commercial milestones are achieved. Of these milestone amounts, $367.0 and $335.0 of the contingent payments relate to development and commercial milestones, respectively. We do not expect these amounts to have an impact on our liquidity in the near-term, and, during the next 12 months, we expect to make milestone payments of approximately $100.0 associated with our prior business combinations. As additional future payments become probable, we will evaluate methods of funding payments, which could be made from available cash and marketable securities, cash generated from operations or proceeds from the sale of equity securities or debt.

Asset Acquisitions and License Agreements

In the fourth quarter 2018, Alexion acquired Syntimmune, a clinical-stage biotechnology company developing an antibody therapy targeting the neonatal Fc receptor (FcRn), for an upfront payment of $400.0. Under the terms of the agreement, we could also be required to pay up to $800.0 upon the achievement of specified research, development, regulatory and commercial milestones.

In October 2018, we entered into a collaboration agreement with Dicerna Pharmaceuticals, Inc. (Dicerna) that provides us with exclusive worldwide licenses and development and commercial rights for two preclinical RNA interference (RNAi) subcutaneously delivered molecules for complement-mediated diseases, as well as an exclusive option for other preclinical RNAi molecules for two additional targets within the complement pathway. In addition to the collaboration agreement, we made an equity investment in Dicerna. Under the terms of the agreements, we made an upfront payment of $37.0 for the exclusive licenses and the equity investment. The market value of the equity investment was $10.3 as of the date of acquisition, which we recorded in other assets in our consolidated balance sheets. Due to the early stage of the assets we are licensing, we recorded expense for the upfront license payment of $26.7 during the fourth quarter 2018. In addition, as of December 31, 2018, we could also be required to pay up to approximately $625.0 for option exercise fees and amounts due upon the achievement of specified research, development, regulatory and commercial milestones, as well as royalties on commercial sales.

In December 2017, we entered into a collaboration and license agreement with Halozyme Therapeutics, Inc. that allows us to use drug-delivery technology in the development of subcutaneous formulations for our portfolio of products for up to four targets. Due to the early stage of the assets we are licensing, we recorded expense for the upfront payment of $40.0 during the fourth quarter 2017. In addition, as of December 31, 2018, we could be required to pay an additional $160.0 for each target developed, subject to achievement of specified development, regulatory and sales-based milestones, as well as royalties on commercial sales.

In addition, we have entered into other license agreements under which we may be required to pay up to an additional $137.2 if certain development, regulatory and commercial milestones are met.

We do not expect the payments associated with milestones under our asset acquisitions and licensing agreements to have a significant impact on our liquidity in the near-term. During the next 12 months, we may make milestone payments related to these arrangements of approximately $255.0.

Financing Lease Obligations

In November 2012, we entered into a lease agreement for office and laboratory space to be constructed in New Haven, Connecticut. The term of the lease commenced in 2015 and will expire in 2030, with a renewal option of ten years. Although we do not legally own the premises, we are deemed to be the owner of the building due to the substantial improvements directly funded during the construction period based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord's costs of constructing the facility during the construction period are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet. Construction of the new facility was completed and the building was placed into service in the first quarter 2016. Associated with this arrangement we recognized interest expense of $13.3, $14.2, and $14.0 for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018 and 2017, our total facility lease

obligation was $133.5 and $134.6, respectively, recorded within other current liabilities and facility lease obligation in our consolidated balance sheets.

During the third quarter 2015, we entered into an agreement with Lonza Group AG and its affiliates (Lonza) whereby Lonza will construct a new manufacturing facility dedicated to Alexion at one of its existing facilities. As a result of our contractual right to full capacity of the new manufacturing facility, a portion of the payments under the agreement are considered to be lease payments and a portion as payment for the supply of inventory. Although we will not legally own the premises, we are deemed to be the owner of the manufacturing facility during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord's costs of constructing the facility during the construction period are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet. We expect the completion of the facility, including obtaining regulatory approval, to be in 2019. As of December 31, 2018 and 2017, we recorded a construction-in-process asset of $203.9 and $180.6, respectively, and an offsetting facility lease obligation of $155.1 and $159.1, respectively, within other current liabilities and facility lease obligation in our consolidated balance sheets.

In September 2017, we entered into a lease agreement for approximately 150,000 square feet of office space to be constructed in Boston, Massachusetts. Construction of the facility was completed and the building was placed into service in the second quarter 2018. The term of the lease commenced upon the landlord's substantial completion of the facility during the second quarter of 2018 and will expire on the thirteenth anniversary of commencement, with an option to renew for up to an additional 10 years. Although we do not legally own the premises, due to our involvement during the construction period, we are deemed to be the owner of the portion of the building that we will lease based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord's costs of constructing the facility during the construction period are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet. Interest expense recognized during 2018 was not material. As of December 31, 2018 and 2017, our total facility lease obligation was $83.6 and $59.6, respectively, recorded within facility lease obligation in our consolidated balance sheets.

Our facility lease obligations will be derecognized in 2019 upon adoption of the new lease accounting standard and will be replaced by ROU liabilities going forward. See Note 1 *Business Overview and Summary of Significant Accounting Policies* to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for more information.

Long-term Debt

On June 7, 2018, Alexion entered into an Amended and Restated Credit Agreement (the Credit Agreement) with Bank of America N.A. as administrative agent. The Credit Agreement amends and restates our credit agreement dated as of June 22, 2015 (the Prior Credit Agreement). The Credit Agreement provides for a $2,612.5 term loan facility and a $1,000.0 revolving facility. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes. Beginning with the quarter ending June 30, 2019, we are required to make amortization payments of 5.00% of the aggregate principal amount of the term loan facility annually, payable in equal quarterly installments.

As of December 31, 2018, we had $2,612.5 outstanding on the term loan and $250.0 of borrowings outstanding under the revolving credit facility. The $250.0 of proceeds on the revolving credit facility was used to refinance amounts outstanding under the Prior Credit Agreement. As of December 31, 2018, we had open letters of credit of $1.7 that offset our borrowing availability on the revolving facility. In January 2019 we paid the outstanding revolving credit facility of $250.0 in full.

Manufacturing Obligations

We have supply agreements with Lonza relating to the manufacture of SOLIRIS and STRENSIQ, which requires payments to Lonza at the inception of contract and upon the initiation and completion of product manufactured. On an ongoing basis, we evaluate our plans for future levels of manufacturing by Lonza, which depends upon our commercial requirements and the progress of our clinical development programs.

We have various agreements with Lonza, with remaining total non-cancellable commitments of approximately $1,084.6 through 2029. Certain commitments may be canceled only in limited circumstances. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangement. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of SOLIRIS that was manufactured at ARIMF prior to its sale and a payment with respect to sales of SOLIRIS manufactured at Lonza facilities.

In addition to Lonza, we have non-cancellable commitments of approximately $104.1 through 2020 with other third party manufacturers.

Taxes

We have recorded tax on the undistributed earnings of our controlled foreign corporation (CFC) subsidiaries. To the extent CFC earnings may not be repatriated to the U.S. as a dividend distribution due to limitations imposed by law, we have not recorded the related potential withholding, foreign local, and U.S. state income taxes.

Common Stock Repurchase Program

In November 2012, our Board of Directors authorized a share repurchase program. The repurchase program does not have an expiration date, and we are not obligated to acquire a particular number of shares. The repurchase program may be discontinued at any time at the Company's discretion. In February 2017, our Board of Directors increased the amount that we are authorized to expend on future repurchases to $1,000 under the repurchase program, which superseded all prior repurchase programs. Under the program, we repurchased 0.7 and 4.0 shares of our common stock at a cost of $85.0 and $463.6 during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, there is a total of $451.5 remaining for repurchases under the program.

Cash Flows

The following summarizes our net change in cash and cash equivalents:

	Year Ended December 31,		
	2018	2017	$ Change
Net cash provided by operating activities	$ 426.0	$ 1,115.6	$ (689.6)
Net cash provided by (used in) investing activities	470.5	(918.3)	1,388.8
Net cash used in financing activities	(102.4)	(596.6)	494.2
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(11.2)	17.7	(28.9)
Net change in cash and cash equivalents	$ 782.9	$ (381.6)	$ 1,164.5

Operating Activities

Cash flows provided by operations in 2018 were $426.0 compared to $1,115.6 in 2017. The decrease in cash provided by operating activities was primarily due to the acquisition of Wilson Therapeutics and Syntimmune and higher cash payments for restructuring and incentive compensation, as well as the impact of the timing of cash receipts and other payments for the year ended 2018 as compared to the same period in the prior year. This decrease was partially offset by an increase in operating income, excluding the impact of the IPR&D charge associated with the Wilson Therapeutics and Syntimmune acquisitions.

Investing Activities

Cash provided by (used in) investing activities in 2018 was $470.5 compared to $(918.3) in 2017. The increase in cash provided by investing activities was primarily attributable to proceeds and maturities of available-for-sale marketable securities, which resulted in a net cash inflows of $690.8 in 2018 compared to a net cash outflows of $(558.9) in 2017.

During 2018, we also had lower cash outlays associated with the purchase of property, plant and equipment of $213.0 as compared to $357.3 in 2017. The significant spending on property, plant and equipment in 2017 related primarily to the construction of our new biologics manufacturing facilities in Ireland.

Financing Activities

Cash flows used in financing activities in 2018 were $102.4 compared to $596.6 in 2017. The decrease in cash used for financing activities was primarily due to repurchasing $378.6 less of our common stock in 2018 than 2017. Additionally, cash used for financing activities decreased as a result of reduced net payments on our outstanding credit facility of $43.8 in 2018,compared to $175.0 in 2017.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2018 and the effect such obligations and commercial commitments are expected to have on our liquidity and cash flow in future fiscal years. These do not include potential milestone payments and assume non-termination of agreements.

These obligations, commitments and supporting arrangements represent payments based on current operating forecasts at December 31, 2018, which are subject to change:

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Contractual obligations:					
Long-term debt (1)	$ 2,862.5	$ 348.0	$ 261.2	$ 2,253.3	$ —
Interest expense (2)	407.2	81.8	194.7	130.7	—
Facility lease obligations (3)	197.6	13.7	31.1	32.2	120.6
Operating leases	48.0	14.1	14.9	7.4	11.6
Total contractual obligations	$ 3,515.3	$ 457.6	$ 501.9	$ 2,423.6	$ 132.2
Commercial commitments:					
Clinical and manufacturing development (4)	$ 1,188.7	$ 271.8	$ 317.5	$ 227.4	$ 372.0
Total commercial commitments	$ 1,188.7	$ 271.8	$ 317.5	$ 227.4	$ 372.0

(1) Includes our term loan and the $250.0 revolving credit facility balance. Our revolving credit facility is classified as a current liability and has been included in payments to be made within one year. In January 2019, we paid the revolving credit facility of $250.0 in full.

(2) Interest on variable rate debt is calculated based on interest rates at December 31, 2018. Interest that is fixed, associated to our interest rate swaps, is calculated based on the fixed interest swap rate at December 31, 2018.

(3) Facility lease obligations include the lease agreement signed in November 2012, for office and laboratory space in New Haven, Connecticut and the lease agreement signed in September 2017 for office space in Boston, Massachusetts. In the fourth quarter of 2018 we amended the New Haven lease agreement significantly reducing our leased square footage in the building beginning in 2019 through the expiration of the lease (in connection with this amendment, in the fourth quarter of 2018, we made a payment of $53.0 to a third party as in incentive to lease the released square footage). Although we do not legally own these premises, we were deemed to be the owner of the buildings during the construction period based on applicable accounting guidance for build-to-suit leases due to our involvement during the construction period. Accordingly, the landlord's costs of constructing the facility are required to be capitalized, as a non-cash transaction, offset by a corresponding facility lease obligation in our consolidated balance sheet.

(4) Clinical and manufacturing development commitments include only non-cancellable commitments, including all Lonza agreements, at December 31, 2018.

The contractual obligations table above does not include contingent royalties and other contingent contractual payments we may owe to third parties in the future because such payments are contingent on future sales of our products and the existence and scope of third party intellectual property rights and other factors described in Item 1A "*Risk Factors*" and Note 11 "*Commitments and Contingencies*" to the Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

The liability for unrecognized tax benefits related to various federal, state and foreign income tax matters of $92.7 at December 31, 2018 was not included within the table above. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2018. We do not expect payment of amounts related to the unrecognized tax benefits within the next twelve months.

Contingent payments related to business acquisitions, asset acquisitions or license agreements are not included within the table above, as the satisfaction of the contingent consideration obligations is uncertain at December 31, 2018 and, if satisfied, the timing of payment for these amounts was not reasonably estimable at December 31, 2018. Contingent payments associated with these business combinations total up to $702.0 which will become payable if and when certain development and commercial milestones are achieved. During the next 12 months, we expect to make milestone payments of approximately $100.0 associated with our prior business combinations. Commitments related to asset acquisitions and license agreements include contingent payments that will become payable if and when certain development, regulatory and commercial milestones are achieved. During the next 12 months, we may make milestone payments related to our asset acquisitions and license agreements of approximately $255.0.

Future obligations related to our defined benefit plans are not included within the table above, as the timing and amounts of these payments was not reasonably estimable as of December 31, 2018. The total unfunded obligation on our defined benefit plans as of December 31, 2018 was $17.6. Our unfunded obligation can be impacted by changes in the laws and regulations, interest rates, investment returns, and other variables.

Credit Facilities

On June 7, 2018, we entered into an Amended and Restated Credit Agreement (the Credit Agreement), with Bank of America N.A. as administrative agent. The Credit Agreement amends and restates our agreement dated as of June 22, 2015 (the Prior Agreement).

The Credit Agreement provides for a $1,000.0 revolving credit facility and a $2,612.5 term loan facility. The revolving credit facility and term loan facility mature on June 7, 2023. Beginning with the quarter ending June 30, 2019, we are required to make amortization payments of 5.00% of the aggregate principal amount of the term loan facility annually, payable in equal quarterly installments.

Loans under the Credit Agreement bear interest, at our option, at either the base rate or a Eurodollar rate, in each case plus an applicable margin. Under the Credit Agreement, the applicable margins on base rate loans range from 0.25% to 1.00% and the applicable margins on Eurodollar loans range from 1.25% to 2.00% in each case based on our consolidated net leverage ratio (as calculated in accordance with the Credit Agreement). Our obligations under the Credit Agreement are guaranteed by certain of our foreign and domestic subsidiaries and secured by liens on certain of our subsidiaries' equity interests, subject to certain exceptions. Under the terms of the Credit Agreement, we must maintain a ratio of total net debt to EBITDA of 3.50 to 1.00 (subject to certain limited adjustments) and EBITDA to cash interest expense ratio of at least 3.50 to 1.00, in each case as calculated in accordance with the Credit Agreement.

The Credit Agreement contains certain representations and warranties, affirmative and negative covenants and events of default. The negative covenants in the Credit Agreement restrict Alexion's and its subsidiaries' ability, subject to certain baskets and exceptions, to (among other things) incur liens or indebtedness, make investments, enter into mergers and other fundamental changes, make dispositions or pay dividends. The restriction on dividend payments includes an exception that permits us to pay dividends and make other restricted payments regardless of dollar amount so long as, after giving pro forma effect thereto, we have consolidated net leverage ratio, as defined in the Credit Agreement, within predefined ranges, subject to certain increases following designated material acquisitions.

Operating Leases

Our operating leases are principally for facilities and equipment. We currently lease office space in the U.S. and foreign countries to support our operations as a global organization.

We believe that our administrative office space is adequate to meet our needs for the foreseeable future. We also believe that our research and development facilities and our manufacturing facilities, together with third party manufacturing facilities, will be adequate for our on-going activities.

In addition to the minimum rental commitments on our operating leases we may also be required to pay amounts for taxes, insurance, maintenance and other operating expenses.

Commercial Commitments

Our commercial commitments consist of research and development, license, operational, clinical development, and manufacturing cost commitments, along with anticipated supporting arrangements, subject to certain limitations and cancellation clauses. The timing and level of our commercial scale manufacturing costs, which may or may not be realized, are contingent upon the progress of our clinical development programs and our commercialization plans. Our commercial commitments are represented principally by our supply agreements with Lonza described above. Our commitments with Lonza do not include amounts for estimated consumer price index, or CPI, adjustments which we are obligated to pay to Lonza.