ALEXION PHARMACEUTICALS INC
Form 10-K
February 08, 2018
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
x Annual report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2017
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.)

100 College Street, New Haven, Connecticut 06510
(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 x 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 x
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 x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x 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 x Accelerated filer ¨ Non-accelerated filer ¨ (Do not check if a smaller reporting company)
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 x

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 30, 2017, was $26,128,956,666.(1)

The number of shares of Common Stock outstanding as of February 5, 2018 was 221,681,437.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be used in connection with its Annual Meeting of Stockholders to be held on May 8, 2018, are incorporated by reference into Part III of this report.

(1) Excludes 8,789,185 shares of common stock held by directors and executive officers at June 30, 2017. 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.

Alexion Pharmaceuticals, Inc.
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PART I

Unless the context requires otherwise, references in this report to “Alexion”, the “Company”, “we”, “our” or “us” refer to Alexion Pharmaceuticals, Inc. and its subsidiaries.

Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Words such as “anticipates,” “expects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such statements. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management's beliefs, and certain assumptions made by our management, and may include, but are not limited to, statements regarding:

- the potential benefits and commercial potential of Soliris®, Strensiq® and Kanuma® for approved indications and any expanded uses, timing and effect of sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, level of future product sales and collections, timing regarding development and regulatory approvals for additional indications or in additional territories;
- the medical and commercial potential of additional indications for Soliris;
- costs, expenses and capital requirements, cash outflows, cash from operations, status of reimbursement, price approval and funding processes in various countries worldwide;
- progress in developing interest about our products and our product candidates in the patient, physician and payer communities;
- the safety and efficacy of our products and our product candidates;
- estimates of the potential markets and estimated commercialization dates for our products and our product candidates around the world;
- sales and marketing plans, any changes in the current or anticipated market demand or medical need for our products or our product candidates;
- status of our ongoing clinical trials for eculizumab, ALXN1210 and our other product candidates, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies, the adequacy of our pharmacovigilance and drug safety reporting processes, prospects for regulatory approval of our products and our product candidates, need for additional research and testing, the uncertainties involved in the drug development process and manufacturing;
- performance and reliance on third party service providers;
- our future research and development activities, plans for acquired programs, our ability to develop and commercialize products with our collaborators;
- assessment of competitors and potential competitors;
- periods of patent, regulatory and market exclusivity for our products;
- the scope of our intellectual property and the outcome of any challenges or opposition to our intellectual property;
- assertion or potential assertion by third parties that the manufacture, use or sale of our products infringes their intellectual property;
- estimates of the capacity of manufacturing and other service facilities to support our products and our product candidates; and
- potential costs resulting from product liability or other third party claims, the sufficiency of our existing capital resources and projected cash needs.

Such risks and uncertainties include, but are not limited to, the possibility that expected tax benefits will not be realized, assessment of impact of recent accounting pronouncements, potential declines in sovereign credit ratings or sovereign defaults in countries where we sell our products, delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to

reimbursement, uncertainties surrounding legal proceedings, company investigations and government investigations, including our Securities and Exchange Commission (SEC) and U.S. Department of Justice (DOJ) investigations, the securities class action litigation filed in December 2016, the inquiry by the U.S. Attorney's Office for the District of Massachusetts requesting documents relating generally to our support of patient assistance programs, the investigation of our Brazilian operations by Brazilian authorities, risks related to potential disruptions to our business as a result of the leadership changes and transition announced in December 2016 and March 2017, the anticipated effects of the company-wide restructuring initiated in the first quarter 2017 and operational plan initiated in the third quarter 2017, including relocation of our global headquarters, the short and long-term effects of other government healthcare measures, and the effect of shifting foreign exchange rates, as well as those risks and uncertainties discussed later in this report under the section entitled “Risk Factors.” Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in this and other reports or documents we file from time to time with the SEC.

Item 1. BUSINESS.
(dollars and shares in millions)

Overview

Alexion Pharmaceuticals, Inc. (Alexion, the Company, we, our or us) is a global biopharmaceutical company focused on serving patients and families affected by rare diseases through the innovation, development and commercialization of life-changing therapies.

We are the global leader in complement inhibition and have developed and commercialize the first and only approved complement inhibitor to treat patients with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG). In addition, Alexion has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D).

As the leader in complement biology for over 20 years, Alexion focuses its research efforts on novel molecules and targets in the complement cascade, and its development efforts on the core therapeutic areas of hematology, nephrology, neurology, and metabolic disorders. We were incorporated in 1992 under the laws of the State of Delaware.

Products and Development Programs

We focus our product development programs on life-transforming therapeutics for rare diseases for which current treatments are either non-existent or inadequate.

Marketed Products

Our marketed products include the following:

Product	Development Area	Indication
	Hematology	Paroxysmal Nocturnal Hemoglobinuria (PNH)
	Hematology/Nephrology	Atypical Hemolytic Uremic Syndrome (aHUS)
	Neurology	Generalized Myasthenia Gravis (gMG)
	Metabolic Disorders	Hypophosphatasia (HPP)
	Metabolic Disorders	Lysosomal Acid Lipase Deficiency (LAL-D)

Soliris (eculizumab)

Soliris is designed to inhibit a specific aspect of the complement component of the immune system and thereby treat inflammation associated with chronic disorders in several therapeutic areas, including hematology, nephrology and neurology. Soliris is a humanized monoclonal antibody that effectively blocks terminal complement activity at the doses currently prescribed. The initial indication for which we received approval for Soliris is PNH.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

PNH is a debilitating and life-threatening, ultra-rare genetic blood disorder defined by chronic uncontrolled complement activation leading to the destruction of red blood cells (hemolysis). The chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria). We continue to work with researchers to expand the base of knowledge in PNH and the utility of Soliris to treat patients with PNH. Soliris is approved for the treatment of PNH in the U.S., Europe, Japan and in several other countries. We are sponsoring a multinational registry to gather information regarding the natural history of patients with PNH and the longer term outcomes during Soliris treatment. In addition, Soliris has been granted orphan drug designation for the treatment of PNH in the U.S., Europe, Japan and several other countries.

Atypical Hemolytic Uremic Syndrome (aHUS)

aHUS is a severe and life-threatening, ultra-rare genetic disease characterized by chronic uncontrolled complement activation and thrombotic microangiopathy (TMA), the formation of blood clots in small blood vessels throughout the body, causing a reduction in platelet count (thrombocytopenia) and life-threatening damage to the kidney, brain, heart and other vital organs. Soliris is approved for the treatment of pediatric and adult patients with aHUS in the U.S., Europe, Japan and in several other countries. We are sponsoring a multinational registry to gather information regarding the natural history of patients with aHUS and the longer-term outcomes during Soliris treatment. In addition, the U.S. Food and Drug Administration (FDA) and European Commission (EC) have granted Soliris orphan drug designation for the treatment of patients with aHUS.

Generalized Myasthenia Gravis (gMG)

Myasthenia Gravis (MG), is a debilitating, complement-mediated neuromuscular disease in which patients suffer profound muscle weakness throughout the body, resulting in slurred speech, impaired swallowing and choking, double vision, upper and lower extremity weakness, disabling fatigue, shortness of breath due to respiratory muscle weakness and episodes of respiratory failure. Soliris has received orphan drug designation for the treatment of patients with MG in the U.S. and Europe, and for the treatment of patients with refractory gMG, a subset of MG, in Japan.

In August 2017, we announced that the EC approved the extension of the indication for Soliris to include the treatment of refractory gMG in adults who anti-acetylcholine receptor (AChR) antibody-positive. In October 2017, the FDA approved the Company's supplemental Biologics License Application to extend the indication for Soliris as a potential treatment for adult patients with gMG who are AChR antibody-positive. In December 2017, the Ministry of Health, Labour and Welfare (MHLW) in Japan approved Soliris as a treatment for patients with generalized myasthenia gravis (gMG) who are AChR antibody-positive and whose symptoms are difficult to control with high-dose intravenous immunoglobulin therapy or plasmapheresis (PLEX).

Strensiq (asfotase alfa)

Hypophosphatasia (HPP)

HPP is an ultra-rare genetic and progressive metabolic disease in which patients experience devastating effects on multiple systems of the body, leading to debilitating or life-threatening complications. HPP is characterized by defective bone mineralization that can lead to deformity of bones and other skeletal abnormalities, as well as systemic complications such as profound muscle weakness, seizures, pain, and respiratory failure leading to premature death in infants.

Strensiq, a targeted enzyme replacement therapy, is the first and only approved therapy for patients with HPP and is designed to directly address underlying causes of HPP by aiming to restore the genetically defective metabolic process, thereby preventing or reversing the severe and potentially life-threatening complications in patients with HPP. In 2015, the FDA approved Strensiq for patients with perinatal-, infantile- and juvenile-onset HPP, the EC granted marketing authorization for Strensiq for the treatment of patients with pediatric-onset HPP, and the MHLW

approved Strensiq for the treatment of patients with HPP. We are sponsoring a multinational registry to gather information regarding the natural history of patients with HPP and the longer-term outcomes during Strensiq treatment.

Kanuma (sebelipase alfa)
Lysosomal Acid Lipase Deficiency (LAL Deficiency or LAL-D)
LAL-D is a serious, life-threatening ultra-rare disease associated with premature mortality and significant morbidity. LAL-D is a chronic disease in which genetic mutations result in decreased activity of the LAL enzyme that leads to marked accumulation of lipids in vital organs, blood vessels, and other tissues, resulting in progressive and systemic organ damage including hepatic fibrosis, cirrhosis, liver failure, accelerated atherosclerosis, cardiovascular disease, and other devastating consequences.

Kanuma, a recombinant form of the human LAL enzyme, is the only enzyme-replacement therapy that is approved for the treatment for patients with LAL-D. In 2015, the FDA approved Kanuma for the treatment of patients with LAL-D and the EC granted marketing authorization of Kanuma for long-term enzyme replacement therapy in patients of all ages with LAL-D. In 2016, the MHLW approved Kanuma for the treatment of patients of all ages in Japan with LAL-D. We are sponsoring a multinational registry to gather information regarding the natural history of patients with LAL-D and the longer-term outcomes during Kanuma treatment.

Clinical Development Programs
Our clinical development programs include the following:

Product	Development Area	Phase I	Phase II	Phase III	Filed
ALXN1210 (IV)	Next Generation Complement Inhibitor	Paroxysmal Nocturnal Hemoglobinuria (PNH) Atypical Hemolytic Uremic Syndrome (aHUS)			
ALXN1210 (Subcutaneous)	Next Generation Complement Inhibitor	PNH aHUS			
Soliris (eculizumab)	Neurology	Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD)			

ALXN1210
ALXN1210 is an innovative, long-acting C5 inhibitor discovered and developed by Alexion that works by inhibiting the C5 protein in the terminal complement cascade. In early studies, ALXN1210 demonstrated rapid, complete, and sustained reduction of free C5 levels. Alexion has completed enrollment in four ongoing clinical studies of ALXN1210 in patients with PNH: 1) an open-label Phase I/II dose-escalating study to evaluate the safety, tolerability, efficacy, pharmaco-kinetics (PK) and pharmaco-dynamics (PD) of ALXN1210 administered by intravenous (IV) infusion; 2) a Phase II, open-label, study to evaluate the efficacy, safety, tolerability, immunogenicity, PK and PD of ALXN1210 administered by IV infusion investigating multiple dosing intervals from four to twelve weeks; 3) a Phase III open-label, randomized, active-controlled multicenter study to evaluate the safety and efficacy of ALXN1210 versus eculizumab administered by IV infusion to adult patients with PNH who have never received treatment of a complement inhibitor; and 4) a Phase III open-label, randomized, active-controlled, multicenter study to evaluate the safety and efficacy of ALXN1210 versus eculizumab administered by IV infusion to adult patients with PNH who have been treated with eculizumab for at least the past 6 months.

In addition, two clinical studies in patients with aHUS are ongoing and continuing to enroll: 1) a Phase III, single arm, multicenter study to evaluate the safety and efficacy of ALXN1210 administered by IV infusion to adolescent and adult patients with aHUS who have never been treated with a complement inhibitor; and 2) a Phase III, single arm, multicenter study to evaluate the safety, efficacy, PK, and PD of ALXN1210 administered by IV infusion in pediatric patients with aHUS who have never been treated with a complement inhibitor.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Chronic hemolysis in patients with PNH may be associated with life-threatening thromboses, recurrent pain, kidney disease, disabling fatigue, impaired quality of life, severe anemia, pulmonary hypertension, shortness of breath and intermittent episodes of dark-colored urine (hemoglobinuria). Two open-label studies were designed to provide dose ranging data to optimize the dosing regimen for the Phase III development of ALXN1210 as a treatment for patients with PNH based on exposure-response assessments.

In 2016, we announced interim data from a Phase I/II study in patients with PNH showing that once-monthly dosing of ALXN1210 achieved rapid and sustained reductions in hemolysis, as measured by mean levels of lactate dehydrogenase (LDH), in 100

percent of treated patients. At the time of analysis, 80 percent of patients who required at least 1 blood transfusion in the 12 months prior to treatment with ALXN1210 did not require transfusions while on treatment with ALXN1210. Patients also had improvements in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score from baseline, with patients in the higher-dose cohort achieving a two-fold greater improvement compared with the lower-dose cohort. In 2017, these studies showed continued treatment of PNH patients with ALXN1210 for up to eight months resulted in rapid and sustained reduction of plasma LDH levels, with reductions in mean LDH levels from Baseline (BL) ranging from 73% to 88%.

We have also initiated a Phase III open-label, randomized, active-controlled multicenter study to evaluate the safety and efficacy of ALXN1210 versus eculizumab administered by IV infusion to adult patients with PNH who have never been treated by a complement inhibitor. The study is evaluating ALXN1210 administered intravenously every eight weeks. Patient enrollment has been completed in this trial and we expect to receive data from this study in the second quarter 2018.

In addition, we have initiated a supportive Phase III open-label, randomized, active-controlled, multicenter study to evaluate the safety and efficacy of ALXN1210 versus eculizumab administered by IV infusion to adult patients with PNH who have been treated with eculizumab for at least the past six months. The study is evaluating ALXN1210 administered intravenously every eight weeks. Patient enrollment has been completed in this trial and we expect to receive data from this study in the second quarter 2018.

In June 2016 and January 2017, the EC and the FDA, respectively, granted orphan drug designation to ALXN1210, for the treatment of patients with PNH.

Atypical Hemolytic Uremic Syndrome (aHUS)

We have initiated a Phase III, single arm, multicenter study to evaluate the safety and efficacy of ALXN1210 administered by intravenous (IV) infusion to adolescent and adult patients with aHUS who have never been treated with a complement inhibitor. In patients with aHUS, complement-mediated TMA leads to life-threatening damage to the kidney, brain, heart and other vital organs. The study will evaluate ALXN1210 administered intravenously every eight weeks. Patient enrollment is ongoing in this trial.

In addition, we have initiated a supportive Phase III, single arm, multicenter study to evaluate the safety, efficacy, PK, and PD of ALXN1210 administered by intravenous (IV) infusion in pediatric patients with aHUS who have never been treated with a complement inhibitor. The study is evaluating

ALXN1210 administered intravenously every eight weeks. Patient enrollment is ongoing in this trial.

Subcutaneous (SC) Delivery

Initial data from a Phase I study in healthy volunteers to evaluate ALXN1210 delivered subcutaneously supports progressing the development of a subcutaneous formulation of ALXN1210. Based on discussions with regulators, Alexion plans to initiate a single, PK-based Phase III study of ALXN1210 delivered subcutaneously once per week in PNH and aHUS in late 2018.

Soliris (eculizumab)

Relapsing Neuromyelitis Optica Spectrum Disorder (NMOSD)

Relapsing NMOSD is a severe and ultra-rare autoimmune disease of the central nervous system (CNS) that primarily affects the optic nerves and spinal cord. The disease leads to severe weakness, paralysis, respiratory failure, loss of bowel and bladder function, blindness and premature death. Patient enrollment is complete and we expect to receive data from this study in mid-2018. Dosing is ongoing in a global, randomized, double-blind, placebo-controlled trial to evaluate eculizumab as a treatment for patients with relapsing NMOSD. The FDA, EC, and MHLW have each granted orphan designation for eculizumab as a treatment for patients with relapsing NMOSD.

Other Programs

cPMP (ALXN1101)

Molybdenum Cofactor Deficiency (MoCD) Disease Type A (MoCD Type A)

MoCD Type A is an ultra-rare metabolic disorder characterized by severe and rapidly progressive neurologic damage and death in newborns. MoCD Type A results from a genetic deficiency in cyclic Pyranopterin Monophosphate

(cPMP), a molecule that enables the function of certain enzymes and the absence of which allows neurotoxic sulfite to accumulate in the brain. To date, there is no approved therapy available for MoCD Type A. There has been some early clinical experience with the recombinant cPMP replacement therapy in a small number of children with MoCD Type A, and we have completed enrollment in a natural history study in patients with MoCD Type A. cPMP has received Breakthrough Therapy Designation from the FDA for the treatment of patients with MoCD Type A. Evaluation of our synthetic form of cPMP replacement therapy in a Phase I healthy volunteer study is complete. In addition, we completed enrollment in a multi-center, multinational open-label clinical trial of synthetic cPMP in patients with MoCD Type A switched from treatment with

recombinant cPMP. These trials will not be expanded and no new patients will be added to the trials. Patients currently enrolled in the trials will continue to receive therapy. No additional studies are planned. Out-licensing opportunities are being pursued for cPMP.

Samalizumab (ALXN6000)

Samalizumab is a first-in-class immunomodulatory humanized monoclonal antibody that blocks CD200, a key immune checkpoint protein expressed in both hematologic and solid malignancies. The safety and efficacy of samalizumab were being evaluated in patients with advanced solid tumors and in conjunction with the Leukemia and Lymphoma Society, in patients with acute myeloid leukemia (AML). The solid tumor Phase I trial has been terminated and no new patients will be added to the multi-arm AML study, referred to as the BEAT AML Master Trial. Out-licensing opportunities are being pursued for samalizumab.

Manufacturing

We currently rely on internal manufacturing facilities and third party contract manufacturers, including Lonza Group AG and its affiliates (Lonza), to supply clinical and commercial quantities of our commercial products and product candidates. Our internal manufacturing facilities include our Ireland manufacturing facilities, our Rhode Island manufacturing facility (ARIMF), and facilities in Massachusetts and Georgia. We also utilize third party contract manufacturers for other manufacturing services including purification, product filling, finishing, packaging, and labeling. In September 2017, we announced our intention to close ARIMF to align our manufacturing facilities with our ongoing multi-product network manufacturing strategy, which utilizes manufacturing operations in the U.S. and Ireland, and manufacturing capacity through manufacturing partners. During the fourth quarter 2017, we began to actively market the facility to potential buyers. We do not expect the closing of ARIMF to impact our clinical or commercial supply of inventory.

We have various agreements with Lonza through 2028, with remaining total non-cancellable commitments of approximately $1,098.9. If we terminate certain supply agreements with Lonza without cause, we will be required to pay for product scheduled for manufacture under our arrangements. Under an existing arrangement with Lonza, we also pay Lonza a royalty on sales of Soliris manufactured at ARIMF and a payment with respect to sales of Soliris manufactured at Lonza facilities. During 2015, we entered into a new supply agreement with Lonza whereby Lonza will construct a new manufacturing

facility dedicated to Alexion manufacturing at one of its existing facilities.

In addition, we have non-cancellable commitments of approximately $27.3 through 2019 with other third party manufacturers.

In March 2013, we received a Warning Letter (Warning Letter) from the FDA regarding compliance with current Good Manufacturing Practices (cGMP) at ARIMF. In October 2017, the FDA notified Alexion that the Warning Letter has been resolved.

In April 2014, we purchased a fill/finish facility in Athlone, Ireland, which has been refurbished to become our first company-owned fill/finish facility. In July 2016, we announced plans to construct a new biologics manufacturing facility at this site, which is expected to be completed and receive regulatory approval in 2019.

In May 2015, we announced plans to construct a new biologics manufacturing facility on our existing property in Dublin, Ireland, which is expected to be completed and receive regulatory approval in 2020.

Sales and Marketing

We have established a commercial organization to support current and future sales of our products in the U.S., Europe, Japan, Latin America, Asia Pacific countries, and other territories. Our sales force is small compared to that of other drugs with similar revenues; however, we believe that a relatively smaller sales force is appropriate to effectively market our products due to the incidence and prevalence of rare diseases. If we receive regulatory approval in new territories or for new products or indications, we may expand our own commercial organizations in such territories and market and sell our products through our own sales force in these territories. However, we evaluate each jurisdiction on a country-by-country basis, and, in certain territories, we promote our products in collaboration with marketing partners or rely on relationships with one or more companies with established distribution systems and direct sales forces in certain countries.

Customers

Our customers are primarily comprised of distributors, pharmacies, hospitals, hospital buying groups, and other healthcare providers. In some cases, we may also sell our products to governments and government agencies. During 2017, 2016, and 2015, sales to our largest customer accounted for 15.0%, 16.0%, and 17.5% r