SPECTRUM PHARMACEUTICALS INC
Form 10-K
February 28, 2019

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

Form 10-K

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x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-35006

SPECTRUM PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	93-0979187
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11500 South Eastern Avenue, Suite 240
Henderson, Nevada 89052
(Address of principal executive offices)
(702) 835-6300
(Registrant’s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.001 par value Rights to Purchase Series B Junior Participating Preferred Stock	The NASDAQ Global Select

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 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 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, 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.

Large accelerated filer	x	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 ý

As of June 29, 2018, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $1,786,580,557 (based upon the $20.96 per share closing sale price for shares of the registrant's Common Stock as reported by the NASDAQ Global Select Market on June 29, 2018, the last trading date of the registrant's most recently completed second fiscal quarter).

As of February 21, 2019, approximately 111,049,989 shares of the registrant's Common Stock, $0.001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2019 Annual Meeting of Stockholders, to be filed on or before April 30, 2019, are incorporated by reference into Part III, Items 10-14 of this Annual Report on Form 10-K.

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Cautionary Note Concerning Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934 as amended, or the Exchange Act, in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, statements regarding our future product development activities and costs, the revenue potential (licensing, royalty and sales) of our products and product candidates, the success, safety and efficacy of our drug products, revenues and revenue assumptions, clinical studies, including designs and implementation, development timelines, product acquisitions, litigation and regulatory actions, liquidity and capital resources and trends, and other statements containing forward-looking words, such as, “believes,” “may,” “could,” “will,” “expects,” “intends,” “estimates,” “anticipates,” “plans,” “seeks,” “continues,” or the negative thereof or variations thereon or similar terminology (although not all forward-looking statements contain these words). Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. All forward-looking statements included in this Form 10-K speak only as of the date of this Form 10-K and readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed elsewhere in this Annual Report on Form 10-K, and the following factors, among others:

- our ability to successfully develop, obtain regulatory approval for and market our products;
- our ability to continue to grow sales revenue of our marketed products;
- risks associated with doing business internationally;
- our ability to generate and maintain sufficient cash resources to fund our business;
- our history of net losses;
- our ability to enter into strategic alliances with partners for manufacturing, development and commercialization;
- efforts of our development partners;
- the ability of our manufacturing partners to meet our timelines;
- our ability to identify new product candidates and to successfully integrate those product candidates into our operations;
- the timing and/or results of pending or future clinical trials, and our reliance on contract research organizations;
- our ability to protect our intellectual property rights;
- competition in the marketplace for our drugs;
- delay in approval of our products or new indications for our products by the U.S. Food and Drug Administration, or the FDA;
- decreases in our revenue from the limited number of distributors that make up a significant portion of our revenue;
- actions by the FDA and other regulatory agencies, including international agencies;
- securing positive reimbursement for our products;
- the impact of any product liability, or other litigation to which we are, or may become a party;
- the impact of legislative or regulatory reform of the healthcare industry and the impact of recently enacted healthcare reform legislation;
- the availability and price of acceptable raw materials and components from third-party suppliers, and their ability to meet our demands;
- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards, and the application and interpretation of those laws, regulations and standards, that govern or affect the pharmaceutical and biotechnology industries, the non-compliance with which may delay or prevent the development, manufacturing, regulatory approvals and sale of our products;

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- defending against claims relating to improper handling, storage or disposal of hazardous chemical, radioactive or biological materials which could be time consuming and expensive;
- our ability to maintain the services of our key executives and technical and sales and marketing personnel;
- the difficulty in predicting the timing or outcome of product development efforts and regulatory approvals; and
- demand and market acceptance for our approved products.

All subsequent written and oral forward-looking statements attributable to us or by persons acting on our behalf are expressly qualified in their entirety by these cautionary statements.

In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we do not undertake to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this Annual Report on Form 10-K.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the “Company”, “we,” “us,” “our,” “Spectrum” and “Spectrum Pharmaceuticals” refer to Spectrum Pharmaceuticals, Inc. and its subsidiaries and other consolidated entities, as a consolidated entity. We primarily conduct our business activities as Spectrum Pharmaceuticals.

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PART I

ITEM 1. BUSINESS

Company Overview

Spectrum Pharmaceuticals, Inc. ("Spectrum", the "Company", "we", "our", or "us") is a biopharma company, with a primary strategy comprised of acquiring, developing, and commercializing a broad and diverse pipeline of clinical and commercial products. We have an in-house clinical development organization with regulatory and data management capabilities, in addition to commercial infrastructure and a field-based sales force for our marketed products.

Currently, we have seven approved oncology/hematology products (FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA) that target different types of cancer including: non-Hodgkin's lymphoma ("NHL"), advanced metastatic colorectal cancer ("mCRC"), acute lymphoblastic leukemia ("ALL"), and multiple myeloma ("MM").

We also have two drugs in late-stage development:

- Poziotinib, a novel pan-HER inhibitor under investigation for non-small cell lung cancer ("NSCLC") tumors with either EGFR or HER2 exon-20 insertion mutations; and
- ROLONTIS, a novel long-acting granulocyte colony-stimulating factor ("G-CSF"), analog for chemotherapy-induced neutropenia.

On January 17, 2019, we entered into a definitive asset purchase agreement for the sale of our FDA-approved product portfolio of FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA to Acrotech Biopharma L.L.C. ("Acrotech"), a New Jersey-based wholly-owned subsidiary of Aurobindo Pharma USA Inc. (the "Acrotech Transaction"). Upon the closing of the Acrotech Transaction, we are entitled to receive up to $160 million in an upfront cash payment (of which $4 million will be held in escrow for six months). In addition, we expect a purchase price adjustment for certain ongoing research and development activities of the commercialized product portfolio. We are also entitled to receive an aggregate $140 million upon Acrotech's achievement of certain regulatory and sales-based milestones relating to this product portfolio. We plan to reduce our staff by approximately 90 employees, the majority of which we expect to transition to

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Acrotech. The accounting recognition and financial reporting for the disposal of this commercial component of our business will be reflected in our financial statements in the period corresponding with its closing.

Cancer Background and Market Size

Cancer is a group of diseases characterized by the uncontrolled growth and spread of abnormal cells, which can result in death. The development of cancer is multi-factorial and includes both external factors (tobacco, infectious organisms, chemicals, and radiation) and internal factors (inherited mutations, hormones, immune conditions, and mutations that occur from exposure to environmental factors or errors in making DNA (deoxyribonucleic acid) during normal cell division). These causal factors may act together or in sequence to initiate or promote the development of cancer. Ten or more years often pass between exposure to these factors and the development of detectable cancer. Cancer is treated through surgery, radiation, chemotherapy, hormone therapy, immunotherapy, and/or targeted drug therapy.

According to the American Cancer Society's publication Cancer Facts & Figures 2018, cancer is the second leading cause of death in the U.S. (only behind heart disease). In the U.S., approximately 1.7 million new cancer cases were expected to be diagnosed in 2018 and approximately 610,000 persons were expected to die from the disease. Anyone can develop cancer. Since the risk of being diagnosed with cancer increases with age, most cases occur in adults who are middle aged or older. About 87% of all cancers are diagnosed in people 50 years of age and older. In the U.S., approximately 40 out of 100 men and 38 out of 100 women will develop cancer during their lifetime. These probabilities are estimated based on the overall experience of the general population. Individuals within the population may have higher or lower risk because of differences in exposures (e.g., smoking), and/or genetic susceptibility. In addition, currently available treatments are variably effective in the different cancers and individual patients. Together these patients' risks and the treatment limitations suggest a significant current and long-term demand for improved and novel cancer treatments.

Product Portfolio

We currently have a product portfolio consisting of both commercial stage and development stage products that address various cancer types (see the section titled Research and Development below for our pipeline of cancer therapeutics that are in various development stages). Our commercialized products and products in development may have serious adverse effects, or SAEs, that could result in a negative impact on sales and delays, or removal of regulatory approval. For further information on these SAEs, see the risk factor within accompanying Item 1A. Risk Factors – Risks Related to Our Business --Reports of adverse events or safety concerns involving each of our products or similar agents, sold by us or our development partners and/or licensees, could delay or prevent us from obtaining or maintaining regulatory approval or negatively impact sales.

Commercialized Products

FUSILEV

FUSILEV (levoleucovorin) is a novel folate analog and the pharmacologically active isomer (the levo-isomer) of the racemic compound, calcium leucovorin. Leucovorin is a mixture of equal parts of both isomers: the pharmacologically active levo-isomer and the inactive dextro-isomer. Preclinical studies have demonstrated that the inactive dextro-isomer may compete with the active levo-isomer for uptake at the cellular level. By removing the inactive dextro form, the dosage of FUSILEV is one-half that of leucovorin and patients are spared the administration of an inactive substance. FUSILEV is approved as a ready-to-use solution, and as freeze-dried powder. FUSILEV has the following indications for use:

- in combination chemotherapy with 5-fluorouracil in the palliative treatment of patients with advanced mCRC;
- for rescue after high-dose methotrexate, or MTX, therapy in osteosarcoma; and
- to diminish the toxicity and counteract the effects of impaired MTX elimination and of inadvertent over dosage of folic acid antagonists.

Effective December 2018, FUSILEV has been discontinued and we are no longer selling this product. We have since transitioned to marketing KHAPZORY (see below) for identical indications as FUSILEV.

KHAPZORY

On October 19, 2018, the FDA approved KHAPZORY (levoleucovorin), which is formulated as a freeze-dried powder. KHAPZORY is a novel folate analog and the pharmacologically active levo-isomer of d,1-leucovorin. Preclinical studies have

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demonstrated that the inactive dextro-isomer may compete with the active levo-isomer for uptake at the cellular level. By removing the inactive dextro form, the dosage of KHAPZORY is one-half that of leucovorin and patients are spared the administration of an inactive substance. While FUSILEV uses a calcium-based formulation, KHAPZORY uses a sodium-based formulation, though has the same indications for use as FUSILEV.

FOLOTYN

FOLOTYN (pralatrexate injection), a folate analogue metabolic inhibitor, was discovered by Memorial Sloan-Kettering Cancer Center, SRI International and Southern Research Institute, and was developed by Allos Therapeutics, Inc., or Allos. In September 2009, the FDA granted accelerated approval for FOLOTYN for use as a single agent for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma, or PTCL. FOLOTYN was the first chemotherapy approved by the FDA, under its accelerated approval program, for the treatment of relapsed or refractory PTCL and has been available to patients in the U.S. since October 2009.

According to the Lymphoma Research Foundation, lymphoma is the most common blood cancer. Hodgkin’s lymphoma and NHL are the two main forms of lymphoma. Lymphoma occurs when lymphocytes, a type of white blood cell, grow abnormally and accumulate in one or more lymph nodes or lymphoid tissues. The body has two main types of lymphocytes that can develop into lymphomas: B-lymphocytes, or B-cells, and T-lymphocytes, or T-cells. PTCL comprises a group of rare and aggressive NHLs that develop from mature T-cells and accounts for approximately 5 to 15% of all NHL cases in the U.S. and Europe.

Based on preclinical studies, we believe that FOLOTYN selectively enters cancer cells expressing reduced folate carrier, or RFC-1, a protein that is frequently over expressed on cancer cells compared to normal cells. Once inside cancer cells, FOLOTYN is efficiently polyglutamylated and retained inside the cells for a longer time. FOLOTYN and its polyglutamates inhibit dihydrofolate reductase, or DHFR, an enzyme critical in the folate pathway, thereby interfering with DNA and RNA synthesis and triggering cancer cell death.

The safety and efficacy of FOLOTYN was evaluated in an open-label, single-arm, multi-center, international trial that enrolled patients with relapsed or refractory PTCL. One hundred and eleven patients were treated with FOLOTYN at 30 mg/m² once weekly by IV push over three to five minutes for six weeks in seven-week cycles until disease progression or unacceptable toxicity. Of the 111 patients treated, 109 patients were evaluable for efficacy. The primary efficacy endpoint was overall response rate (complete response, complete response unconfirmed, and partial response) as assessed by International Workshop Criteria, or IWC. Of the 109 evaluable patients, 27% of patients achieved a response that met these criteria.

In addition to its approved indication, FOLOTYN is being investigated in a Phase 1 study in combination with the CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) chemotherapy regimen. Once the proper dose of FOLOTYN in combination with CHOP has been determined, a Phase 3 study of the combinations of FOLOTYN and CHOP, and BELEODAQ and CHOP, compared to CHOP alone for the treatment of first line PTCL may be initiated. The Phase 1 study and the Phase 3 study concept are also the current post-marketing requirements for the FDA’s accelerated approval of our currently marketed indication for FOLOTYN.

BELEODAQ

BELEODAQ (belinostat) is a histone deacytelase, or HDAC, inhibitor for the treatment of patients with relapsed or refractory PTCL. This indication was FDA approved in July 2014 under its accelerated approval program, based on tumor response rate and duration of response. BELEODAQ's anticancer effect is thought to be mediated through multiple mechanisms of action, including the inhibition of cell proliferation, induction of apoptosis (programmed cell death), inhibition of angiogenesis, induction of differentiation, and the activity in tumors that had become resistant to anticancer agents such as the platinums, taxanes, and topoisomerase II inhibitors.

The safety and effectiveness of BELEODAQ was evaluated in an open-label, single-arm, non-randomized international trial involving 129 participants with relapsed or refractory PTCL. Patients were treated with BELEODAQ 1,000 mg/m2 administered over 30 minutes via IV infusion once daily on days one to five of a 21-day cycle until disease progression or unacceptable toxicity. The primary efficacy endpoint was response rate (complete response and partial response) as assessed by an independent review committee, or IRC, using IWC. In all evaluable patients (N = 120) treated with BELEODAQ, the overall response rate per central review using IWC was 25.8%.

We market FOLOTYN and BELEODAQ for the treatment of relapsed or refractory PTCL. These drugs have different mechanisms of action, and as a result, the treating physician may prefer to start treatment with one drug over the other. In

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addition, physicians may prefer one drug over another based on specific patient factors such as the subtype of PTCL being treated, existing comorbidities, or the performance status of the patient. However, both drugs have similar response rates of approximately 25-30%. It is common for patients to cycle through multiple drugs, including both FOLOTYN and BELEODAQ, though these drugs are not FDA-approved for use in combination with one another.

In addition to its approved indication, BELEODAQ has been investigated in a Phase 1 study in combination with the CHOP chemotherapy regimen. Once the proper dose of FOLOTYN in combination with CHOP has been determined, a Phase 3 study may be assessed for the combination of BELEODAQ and CHOP and FOLOTYN and CHOP, compared to CHOP alone for the treatment of first line PTCL. The Phase 1 study and the Phase 3 study concept are also the current post-marketing requirements for the FDA's accelerated approval of our currently marketed indication for BELEODAQ.

ZEVALIN

ZEVALIN (ibritumomab tiuxetan) injection for intravenous use is a prescription medication that is part of a three step treatment regimen consisting of: two treatments of Rituximab and one treatment of Yttrium-90 (Y-90) ZEVALIN. The National Cancer Institute, or NCI, estimated 75,000 new cases of NHL in the U.S. in 2018. Rituximab is used to reduce the number of B-cells in the blood and Y-90 ZEVALIN is then given to treat NHL. It is currently approved in the U.S. and more than 40 countries outside the U.S. including countries in Europe, Latin America and Asia for (i) treatment of patients with recurring, low-grade or follicular B-cell NHL after other anticancer drugs are no longer working, and (ii) newly diagnosed follicular NHL following a response to initial anticancer therapy.

MARQIBO

MARQIBO (vincristine sulfate liposome injection) is a novel, sphingomyelin/cholesterol liposome-encapsulated formulation of the FDA-approved anticancer drug Vincristine. MARQIBO’s approved indication is for the treatment of adult patients with Philadelphia chromosome-negative - ALL, or Ph-ALL, in second or greater relapse or whose disease has progressed following two or more lines of anti-leukemia therapy. According to the NCI, in 2018 it is estimated that there will be approximately 6,000 patients diagnosed with ALL in the U.S., of which approximately 1,600 can be categorized as ALL in second or greater relapse.

MARQIBO was studied in an international, open-label, multi-center, single-arm trial. Eligible patients were 18 years of age or older with Ph-ALL in second or greater relapse or whose disease progressed after two or greater treatment lines of anti-leukemia therapy. Patients received intravenous MARQIBO monotherapy at 2.25 mg/m2 over 60 minutes every seven days. The treated population included 65 patients who received at least one dose of MARQIBO. Of the 65 evaluable patients, three (4.6%) achieved complete remission, or CR, seven (10.8%) achieved complete remission with incomplete blood count recovery, or CRi, for a total of 10 (15.4%) total patients who achieved a CR or CRi.

In addition to its approved indication, MARQIBO is being investigated in pediatric ALL in a Phase 1 investigator-initiated study in the U.S. Based on data from this study, Spectrum will determine whether to conduct a registration study for MARQIBO in this setting. We are in discussions with the FDA regarding the possibility of using this development plan to satisfy one of the post-marketing requirements for the accelerated approval of our currently marketed indication for MARQIBO.

MARQIBO is also being investigated in diffuse large B-cell lymphoma in a Phase 3 investigator-initiated study in Europe in combination with the standard CHOP chemotherapy regimen in Europe, CHOP-14. Based on interim data from this study, Spectrum will consider whether to conduct a study of the combination of MARQIBO with the standard CHOP regimen in the U.S., CHOP-21 may be initiated.

EVOMELA

EVOMELA is intended for use as a high-dose conditioning treatment prior to autologous stem cell transplant, or ASCT, for patients with MM. MM is a cancer of plasma cells, a type of white blood cell present mainly in the bone marrow that produces antibodies. In MM, a group of plasma cells (myeloma cells) become cancerous and multiply, raising the number of plasma cells to a higher-than-normal level, which can crowd out normal blood cells and lead to abnormally high proteins in the blood or urine. The NCI estimated 31,000 new cases of MM in the U.S. in 2018, with the incidence of new cases increasing by approximately 2% per year.

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The EVOMELA formulation avoids the use of propylene glycol, or PG, which is required as a co-solvent in the currently-available formulation of this product. The use of Betadex Sulfobutyl Ether Sodium technology to reformulate EVOMELA may allow for longer administration durations and slower infusion rates, potentially enabling clinicians to avoid reductions.

EVOMELA was approved by the FDA based on its bioequivalence to the standard melphalan formulation (Alkeran) via the new drug regulatory pathway provided by Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. The safety and effectiveness of EVOMELA in high-dose conditioning treatment was evaluated in an open-label, single-arm, non-randomized trial. The objective of the trial was to determine the overall safety and toxicity profile of 200 mg/m2 of EVOMELA in patients with MM undergoing ASCT. The overall response rate (partial response or better) improved from 79% prior to the ASCT procedure to 95% at 90 to 100 days post-transplant. There was also an increase in the number of patients with a stringent complete response from zero patients prior to the ASCT procedure to 16% at 90 to 100 days post-transplant. Myeloablation, neutrophil engraftment, and platelet engraftment were achieved by all 61 patients. Myeloablation occurred on day five of ASCT (range of ASCT days was one to six) with the median time to myeloablation from dosing of eight days. The median time to neutrophil engraftment was 12 days (range of ASCT days was 10 to 16). The median time to platelet engraftment was 13 days (range of ASCT days was 10 to 28).

New Product Pipeline

Poziotinib

Poziotinib is a novel, pan-HER inhibitor that irreversibly blocks signaling through the Epidermal Growth Factor Receptor (EGFR, HER) Family of tyrosine-kinase receptors, including HER1 (erbB1; EGFR), HER2 (erbB2), HER4 (erbB4), and HER receptor mutations. This, in turn, leads to the inhibition of the proliferation of tumor cells that over-express these receptors. Mutations or over-expression/amplification of EGFR family receptors have been associated with a number of different cancers, including NSCLC, breast cancer, and gastric cancer.

Our clinical development program for poziotinib is focused on four pillars, including previously treated NSCLC, first-line treatment of NSCLC, combination therapy and treatment of other solid tumors with EGFR or HER2 mutations. Specifically, we are investigating poziotinib for the treatment of NSCLC tumors with either EGFR or HER2 exon-20 insertion mutations. NSCLC tumors with EGFR or HER2 exon-20 insertion mutations are rare, and have generally not been responsive to other tyrosine kinase inhibitors. Patients with these mutations have a poor prognosis, and available treatment options are limited. Poziotinib, due to its unique chemical structure and characteristics, is believed to inhibit cell growth of EGFR or HER2 exon-20 insertions. In collaboration with The University of Texas MD Anderson Cancer Center ("MD Anderson"), an investigator-sponsored Phase 2 trial was initiated in NSCLC patients with EGFR or HER2 exon-20 mutations (the "MD Anderson Phase 2 Trial"). The EGFR cohort of 50 patients has completed enrollment; the enrollment of the HER2 cohort of 30 patients is ongoing. In addition to the MD Anderson study, we have ongoing pivotal Phase 2 global study with active sites in the U.S., Canada, and Europe ("ZENITH20").

In April 2018, poziotinib data were published in Nature Medicine from the ongoing study led by MD Anderson, which provided an update on the preliminary clinical data of poziotinib dosing on the 11 NSCLC patients previously reported at World Conference on Lung Cancer in October 2017. This publication summarized the current preclinical and clinical data with poziotinib for EGFR or HER2 exon-20 mutations. MD Anderson utilized in silico, in vitro, and in vivo testing to model structural alterations induced by exon-20 mutations and identify potentially effective inhibitors. 3-D modeling indicated alterations restricted the size of the drug binding pocket, limiting the binding of large, rigid inhibitors. It was found that poziotinib, due to its small size and flexibility, can circumvent these steric changes, and is a potent inhibitor of the most common EGFR and HER2 exon-20 mutants. Poziotinib demonstrated greater activity than approved EGFR tyrosine kinase inhibitors ("TKIs") in vitro and in EGFR or HER2 exon-20 mutant patient-derived xenograft models, and genetically engineered mouse models of NSCLC.

In September 2018 we announced preliminary poziotinib data from the MD Anderson Phase 2 NSCLC study which were released during an oral presentation at the IASLC 19th World Conference on Lung Cancer. The MD Anderson study is the single largest data set of patients with an exon 20 mutation in EGFR or HER2. This Phase 2 study demonstrated high anti-tumor activity for poziotinib in metastatic, heavily pretreated EGFR exon 20 mutant NSCLC, a group for which no targeted agents have proven to be effective to date. This data is summarized below:

- In 44 evaluable patients with EGFR exon-20 mutations, the confirmed overall response rate (ORR) was 43% and disease control rate was 90%. Median progression free survival (PFS) was 5.5 months (ITT).
- In evaluable patients with HER2 exon-20 mutations, the confirmed overall response rate (ORR) was 42% and disease control rate was 83%. Median progression free survival (PFS) was 5.1 months (ITT).

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- EGFR-related toxicities (including rash, diarrhea, and paronychia) were manageable and required dose reductions in 60% of patients. Discontinuation due to poor tolerance was rare (approximately 3% of patients).

On January 2, 2019 we announced full enrollment of cohort 1 (N=87) for previously treated NSCLC patients with EGFR exon 20 insertion mutations with sites across the U.S., Europe, and Canada. The EGFR previously treated cohort is part of the ZENITH20 trial - an open-label, multi-center, global Phase 2 trial evaluating NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Results from this cohort are expected by the second half of 2019. We have also been studying poziotinib in patients with HER2+ breast cancer, however we are no longer focusing on studying poziotinib in this group of patients as the unmet need is not as significant as it is for patients with EGFR or HER2 exon 20 insertion mutations. A Phase 2 study including patients with HER2+ metastatic breast cancer, who have failed at least two HER2 directed therapies, has been fully enrolled. A Phase 1b study testing the combination of poziotinib and ado-trastuzumab emtansine (T-DM1) in patients with metastatic breast cancer has now been closed to further enrollment.

ROLONTIS

ROLONTIS (eflapegrastim injection) is a novel long-acting G-CSF that employs a proprietary technology to enhance the duration of therapeutic effects and reduces the frequency of administration. ROLONTIS is being investigated for the treatment of chemotherapy-induced neutropenia. In January 2012, we entered into a co-development and commercialization agreement for ROLONTIS worldwide rights, except for Korea, China, and Japan, with Hanmi, based on their proprietary LAPSCOVERY™ technology.

Chemotherapy can cause myelosuppression and unacceptably low levels of white blood cells, making patients prone to infections, hospitalizations, and interruption of chemotherapy treatments.

Neutropenia, a common side effect of chemotherapy, is a condition where the number of neutrophils or white blood cells are too low, and can lead to infection, hospitalization, and even death. G-CSF stimulates the production of white blood cells by the bone marrow. A recombinant form of G-CSF is used in appropriate cancer patients to accelerate recovery from neutropenia after chemotherapy, allowing higher-intensity treatment regimens to be given at full-dose and on schedule. The worldwide annual market opportunity for long-acting G-CSF-related drugs is over $4 billion, based on a 2016 revenue and sales analysis performed by Evaluate Pharma.

In December 2015, we reached agreement with the FDA regarding our Phase 3 Special Protocol Assessment, or SPA, for ROLONTIS. This pivotal Phase 3 study (ADVANCE Study, or SPI-GCF-301) was initiated in the first quarter of 2016 to evaluate ROLONTIS as a treatment for chemotherapy-induced neutropenia. We announced in February 2018 that the top line results of this study met the non-inferiority of ROLONTIS to pegfilgrastim endpoint in the Duration of Severe Neutropenia, or DSN, across all four cycles (all $p<0.0001$). We initiated a second pivotal Phase 3 study (RECOVER Study, or SPI-GCF-302) and announced in June 2018, that it had also met its primary efficacy endpoint of non-inferiority in DSN between ROLONTIS and pegfilgrastim.

We submitted our Biologics License Application ("BLA") with the FDA in late December 2018. Due to the recent federal government shutdown, the BLA was officially received by the FDA on January 28, 2019. Once this BLA is accepted by the FDA, our Prescription Drug User Fee Act date is expected to be set for 10 months thereafter.

QAPZOLA

QAPZOLA is a potent tumor-activated drug that is being tested in non-muscle invasive bladder cancer ("NMIBC"). The NCI estimates that the 2018 incidence and prevalence of bladder cancer in the U.S. was approximately 79,000 cases. The global presence of bladder cancer is estimated at 2.7 million cases. According to Botteman et al., (PharmacoEconomics 2003), bladder cancer is the most expensive cancer to treat on a lifetime basis. The overall cost of bladder cancer treatment in the U.S. is approximately $3.4 billion annually, most of which is related to the direct treatment of this disease.

The initial treatment of bladder cancer is to attempt a complete surgical removal of the tumor. However, bladder cancer is a highly recurrent disease with approximately 80% of patients recurring within five years, and a majority of patients recurring within two years. This high recurrence rate is attributed to:

- the highly implantable nature of cancer cells that are dispersed during surgery;
- incomplete tumor resection; and

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- tumors present in multiple locations in the bladder which may be missed or too small to visualize at the time of resection.

Despite evidence in the published literature and guidance from the American and European Urology Associations, instillation of a chemotherapeutic agent immediately following surgery is not a standard clinical practice. Currently, there are no FDA approved drugs for this indication which may, in part, explain the difference between the literature and urology guidelines and actual clinical management of this disease. For more than 30 years, no new drugs have been introduced in the market for treatment of NMIBC. QAPZOLA represents much needed therapy for patients and may provide a meaningful opportunity to reduce overall medical costs.

Pharmacokinetic studies have verified that QAPZOLA is rarely detectable in the bloodstream of patients when it is administered either after surgical resection or as a part of a delayed multi-instillation protocol. QAPZOLA is inactivated in the systemic circulation by the red blood cell fraction. The proposed dose therefore carries a minimal risk of systemic toxicity that could arise from absorption of a drug through the bladder wall into the bloodstream. An immediate instillation of QAPZOLA may help by:

- reducing tumor recurrence by destroying dispersed cancer cells that would otherwise re-implant onto the inner lining of the bladder;
- destroying remaining cancer cells at the site of tumor resection (also known as chemo-resection); and
- destroying tumors not observed during resection (also known as chemo-ablation).

We submitted an NDA on December 11, 2015, which was accepted on February 9, 2016. In November 2016, we received a Complete Response Letter, or CRL, from the FDA. In February 2017, we received a SPA from the FDA for our redesigned Phase 3 study of QAPZOLA. The new Phase 3 study has been specifically designed to build on learnings from the previous studies as well as recommendations from the FDA. The Phase 3 study is currently enrolling up to 425 evaluable patients, using a single dose of 8 mg of QAPZOLA, and will evaluate time-to-recurrence as the primary endpoint.

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For information on operating revenue related to our principal products, as well as our net loss, see Item 8 of Part II to this Annual Report on Form 10-K. Additionally, for information regarding possible adverse events or safety concerns regarding our commercialized and development stage products, see Item 1A. Risk Factors - Risks Related to Our Business - Reports of adverse events or safety concerns involving each of our products or similar agents, sold by us or our development partners and/or licensees, could delay or prevent us from obtaining or maintaining regulatory approval or negatively impact sales.

Manufacturing

We currently do not have internal manufacturing capabilities; therefore, all of our products are manufactured on a contract basis. We expect to continue to contract with third-party providers for manufacturing and packaging services, including active pharmaceutical ingredients, or API, and finished-dosage products. We believe that our current agreements with third-party manufacturers provide for sufficient operating capacity to support the anticipated commercial demand and clinical requirements for our products. Where technically feasible, we maintain secondary supplier sources for our drug products to mitigate the risk of over-reliance on any one supplier. We attempt to prevent supply disruption through supply agreements, appropriate forecasting, and maintaining base stock levels.

Sales and Marketing

We presently market our pharmaceutical products through group purchasing organizations, or GPOs, wholesalers or directly to major hospitals and cancer centers in the U.S., except for our U.S. sales of ZEVALIN, in which case we sell directly to the end-user; and through distributors in Europe (and previously in Japan). Most of our revenues are derived from sales within the U.S. For information regarding the portion of our revenue attributable to sales outside the U.S., see Note 5, "Composition of Total Revenue," to our accompanying Consolidated Financial Statements. Our

U.S. sales team is divided between “corporate accounts” and “oncology accounts” that generally interact with different end-user types. The primary decision makers for our products are oncologists and hematologists. As of December 31, 2018, our U.S. sales force (sales management, sales representatives, and sales administrative support) numbered 61 employees.

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During fiscal years 2018, 2017, and 2016, each of FOLOTYN, EVOMELA and BELEODAQ accounted for 10% or more of our total revenue. The percentage of our total revenue contributed by such products in fiscal years 2018, 2017, and 2016 are as follows:

	Year Ended December 31,		
	2018	2017	2016
FOLOTYN	43.9 %	33.5 %	31.6 %
EVOMELA	25.9 %	27.4 %	11.1 %
BELEODAQ	11.3 %	9.6 %	9.1 %

Customers

Our product sales are concentrated to large pharmaceutical distributors (that ship and bill to hospitals and clinics). The customers that represented 10% or more of our total gross product sales in fiscal years 2018, 2017, and 2016 are as follows:

	Product Sales		
	2018	2017	2016
McKesson Corporation and its affiliates	36.3 %	31.1 %	31.0 %
AmerisourceBergen Corporation and its affiliates	29.1 %	32.3 %	38.4 %
Cardinal Health, Inc. and its affiliates	22.0 %	26.3 %	24.0 %

We are exposed to credit risk associated with trade receivables that result from these product sales. We do not require collateral or deposits from our customers due to our assessment of their creditworthiness and our long-standing relationship with them. We maintain reserves for potential bad debt, though credit losses have historically been nominal and within management's expectations. A summary of our customers that represented 10% or more of our "accounts receivable, net of allowance for doubtful accounts," as of December 31, 2018 and 2017 are as follows:

	Accounts Receivable, Net of Allowance for Doubtful Accounts December 31,	
	2018	2017
AmerisourceBergen Corporation, and its affiliates	35.0 %	22.2 %
Cardinal Health, Inc. and its affiliates	27.5 %	29.5 %
McKesson Corporation and its affiliates	25.5 %	34.7 %

See Note 5 to the accompanying Consolidated Financial Statements for additional summaries of revenue by geography and product/service source.

Competition

The pharmaceutical industry is characterized by rapidly-evolving technology and intense competition, which we expect will continue. Many companies are engaged in research and development of compounds that are similar to ours – both commercialized and in development, which fosters continuous innovation. In the event that one or more of our competitor's programs are successful, the market for some of our drug products could be reduced or eliminated. Any product for which we obtain FDA approval must also compete for market acceptance and market share.

Successful marketing of branded products depends primarily on the ability to communicate the effectiveness, safety, and value of the products to healthcare professionals in private practice, group practices, hospitals, academic institutions, and managed care organizations. Competition for branded drugs is less driven by price and is more focused on innovation in treatment of disease, advanced drug delivery, and specific clinical benefits over competitive drug therapies. Unless our products are shown to be differentiated, i.e., have a better safety profile, efficacy, and cost-effectiveness, compared to other alternatives, they may not gain acceptance by medical professionals and may therefore never be commercially successful.

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Companies that have products on the market or in research and development that target the same indications as our products include, among others, AstraZeneca plc, Bayer AG, Endo International plc, Eli Lilly and Company, Novartis International AG, Genentech, Inc. (Roche Holding AG), Bristol-Myers Squibb Company, Seattle Genetics, Inc., GlaxoSmithKline plc, Biogen Inc., OSI Pharmaceuticals, Inc. (Astellas Pharma Inc.), Cephalon, Inc. (Teva Pharmaceutical Industries Ltd.), Sanofi S.A., Pfizer, Inc., Merck & Co., Inc., Celgene Corporation, BiPar Sciences, Inc. (Sanofi S.A.), Sanofi Genzyme, Shire plc, AbbVie Inc., Poniard Pharmaceuticals, Inc., Johnson & Johnson, Amgen, Inc., Coherus BioSciences, and Takeda Pharmaceutical Company Ltd.

Each of the aforementioned companies may be more advanced in the development of competing drug products. Many of these competitors are large and well-capitalized companies focusing on a wide range of cancers and drug indications, and have substantially greater resources and expertise than we do.

We believe that the current competitive landscape for each of our commercialized products, and key in-development products, is as follows:

(a) KHAPZORY is the sodium levo-isomeric form of the racemic compound calcium, leucovorin, a product already approved for the same indication as FUSILEV. There are several generic companies approved by the FDA to sell the calcium leucovorin product, we are competing with lower-cost alternatives.

(b) ZEVALIN has two competitive products for its currently approved indications:

- Rituxan® (rituximab), marketed by Genentech Inc. and Biogen Inc., is indicated for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent; previously untreated follicular, CD20-positive, B-cell NHL in combination with CVP (cyclophosphamide, vincristine and prednisone combination) chemotherapy; and non-progressing (including stable disease), low-grade, CD20-positive B-cell NHL, as a single agent, after first-line CVP chemotherapy. Rituxan is administered as a part of various chemotherapy regimens and schedules, the vast majority of which, could be used in concert with other therapeutic agents, such as ZEVALIN, as part of a treatment plan.

- Bendeka® (bendamustine hydrochloride) for Injection, for Intravenous Infusion, marketed by Teva Pharmaceutical Industries Ltd., is indicated for the treatment of patients with indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

(c) FOLOTYN, was the first agent approved by the FDA for treatment of patients with relapsed or refractory PTCL. BELEODAQ is a HDAC inhibitor, also indicated for the treatment of patients with relapsed or refractory PTCL. Both drugs were approved under accelerated approval based on tumor response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

There are many existing approaches used in the treatment of relapsed or refractory PTCL, including combination chemotherapy and single agent regimens, which represent competition for FOLOTYN and BELEODAQ. Both drugs have two primary competitive products for their currently approved indications:

- Istodax® (Romidepsin), marketed by Celgene Corporation, was granted accelerated approval by the FDA in June 2011 for the treatment of patients with PTCL who have received at least one prior therapy.

- Adcetris® (Brentuximab vedotin), marketed by Seattle Genetics, Inc., was granted accelerated approval by the FDA in August 2011 for the treatment of patients with systemic anaplastic large cell lymphoma, or ALCL, after failure of at least one prior multi-agent chemotherapy regimen. ALCL is one of the subtypes of PTCL included in the labels of FOLOTYN, BELEODAQ and Istodax.

We are aware of multiple investigational agents that are currently being studied in clinical trials for PTCL which, if approved, may compete with FOLOTYN and BELEODAQ. Many patients with PTCL do not adequately respond to a single treatment agent, so many patients receive treatment with more than one agent (e.g., BELEODAQ and FOLOTYN).

(d) MARQIBO is a liposomal form of standard vincristine. In its current indication, MARQIBO is approved for adult patients with relapsed or refractory Ph-ALL who have not responded or relapsed after two prior treatments. This indication received the FDA's accelerated approval based on tumor response rate. Clinical benefit such as improvement

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in overall survival has not been verified. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Currently, standard vincristine is not approved for the same indication as MARQIBO. However, there are many existing approaches used in the treatment of relapsed or refractory Ph-ALL, including combination chemotherapy and single agent regimens, which represent competition for MARQIBO. There are a variety of investigational agents in clinical trials for ALL that if approved could represent future competition for MARQIBO.

(e) EVOMELA is a propylene glycol-free formulation. Given its unique formulation, there are no generic forms of EVOMELA on the market. However, there are currently several generic forms of melphalan used in the treatment of MM, which represent direct competition for EVOMELA. The current companies with forms of generic melphalan include Mylan, Teva Pharmaceutical Industries Ltd., Sagent Pharmaceuticals, PAR Pharmaceutical Dr. Reddy's Laboratories, and Fresenius Kabi Global.

(f) ROLONTIS is a novel long-acting granulocyte colony-stimulating factor that employs a proprietary technology that prolongs the duration of biologics, reducing the frequency of administration. There is currently one novel long-acting granulocyte colony stimulating factor (G-CSF) and two biosimilar G-CSFs marketed in the United States including, Neulasta® (pegfilgrastim), marketed by Amgen, Inc., UDENYCA™ (pegfilgrastim-cbqv), a biosimilar marketed by Coherus BioSciences, and Fulphila® (pegfilgrastim-jmdb), a biosimilar marketed by Mylan Pharmaceuticals, Inc.

(g) Poziotinib is a novel investigational, oral, quinazoline-based pan-HER inhibitor that irreversibly blocks signaling through the EGFR family of tyrosine-kinase receptors, including human epidermal growth factor receptor (HER1\ErbB1/EGFR), HER2 (ErbB2), and HER4 (ErbB4), as well as HER receptor mutations. Poziotinib’s development program is primarily focused on advanced NSCLC patients harboring exon 20 insertion mutations in both HER1/Erb1/EGFR and HER2(ErbB2). At present there are no FDA approved therapies for metastatic NSCLC patients with EGFR or HER2 exon 20 mutations expect for afatinib, which is FDA- approved for S768I point mutations.

There are a number of other targeted therapies focused on this subtype of NSCLC that are in early clinical investigation by our potential competitors, including: TAK788 - Millennium Pharmaceuticals, Inc., TAGRISSO (Osimertinib) - AstraZeneca, Tarloxotinib - Rain Therapeutics Inc., DS-8201a - Daiichi Sankyo, and JNJ-61186372- Janssen Research & Development.

Research and Development

New drug development is the process whereby drug product candidates are tested for the purpose of filing an NDA or a BLA, in the U.S. (or similar filing in other countries). Obtaining marketing approval from the FDA or similar regulatory authorities outside of the U.S. is an inherently uncertain, lengthy, and expensive process that requires several phases of clinical trials to demonstrate to the satisfaction of the appropriate regulatory authorities that the products are both safe and effective for their respective indications. Our development focus is primarily based on acquiring and developing late-stage development drugs as compared to new drug discovery, which is particularly uncertain and lengthy.

Our in-development products are summarized below:

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Our research and development expenses for drug development are comprised of our personnel expenses, contracted services with third parties, license fees and milestone payments to third parties, clinical trial costs, laboratory supplies, drug products, and certain allocations of corporate costs. The below table summarizes our research and development expenses by project in 2018, 2017, and 2016:

	Research and Development Expenses for the Year Ended December 31, (in thousands)		
	2018	2017	2016
ROLONTIS	$ 31,612	$ 20,254	$ 14,829 *
POZIOTINIB	18,272	6,761	976
MARQIBO	5,255	5,813	4,249
ZEVALIN	5,001	4,412	3,814
QAPZOLA	1,091	4,156	5,437
FOLOTYN	1,517	1,470	1,717
EVOMELA	1,880	1,050	4,964
BELEODAQ	704	718	772
FUSILEV	20	61	—
KHAPZORY	3,580	1,462	2,667
Other in-development indications/drugs	151	153	283
Total — Direct costs	69,083	46,310	39,708
Add: General research and development expenses (including personnel costs that correspond to more than one in-development project)	26,612	21,584	21,335
(Less): Reimbursements from development partners	(350)	(1,999)	(1,710)
(Less): Incurred FOLOTYN study costs that credit expense and reduce our drug development liability (see Note 16 to Consolidated Financial Statements)	(389)	—	(210)
Total research and development expenses	$ 94,956	$ 65,895	$ 59,123

* Inclusive of 2016 milestone payment of $2.7 million (see Note 17(b)(xiii) to the accompanying Consolidated Financial Statements).

Patents and Proprietary Rights

Overview

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We in-license from third parties certain patent and related intellectual property rights related to our proprietary drug products. Under most of these license arrangements, we are generally responsible for all development, patent filing and maintenance costs, sales, marketing and liability insurance costs related to the drug products.

In addition, these licenses and agreements may require us to make royalty and other payments and to reasonably utilize the underlying technology of applicable patents. If we fail to comply with these and other terms in these licenses and agreements, we could lose the underlying rights to one or more of our potential products, which would adversely affect our product development and harm our business. For more information regarding these arrangements see Note 17(b), "Financial Commitments & Contingencies and License Agreements," to our accompanying Consolidated Financial Statements.

The protection, preservation and infringement-free commercial utilization of these patents and related intellectual property rights are very important to the successful execution of our strategy. However, the issuance of a patent is neither conclusive as to its validity nor as to the enforceable scope of the claims of the patent. Accordingly, our patents and the patents we have licensed may not prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents. If our patent applications are not allowed or, even if allowed and issued as patents, if such patents or the patents we have in-licensed are circumvented or not upheld by the courts, our ability to competitively utilize our patented products and technologies may be significantly reduced. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by competitors, in which case our ability to commercially sell these products may be diminished.

From time-to-time, we may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially exploit such products may be inhibited or prevented.

Commercialized and In-Development Drug Products - Patents and Licenses Summary

We believe that our patents and licenses are critical to operating our business, as summarized below by commercialized and in-development drug products.

FUSILEV: FUSILEV had orphan drug exclusivity for two indications. Marketing of the product has been discontinued in the U.S. beginning in December 2018.

ZEVALIN: We have sublicensed U.S. patents that cover the processes and tools for making monoclonal anti-bodies or MABs, in general, licensed U.S. patents that cover the CD-20 MAB in ZEVALIN as well as the use of ZEVALIN to treat NHL, and acquired patents covering the ZEVALIN compounding process (i.e., process of linking the CD-20 MAB to a radioactive isotope to make the patient-ready dosage form of ZEVALIN). These patents expire over a wide range of dates, and the licensed patents covering the CD-20 MAB began to expire in 2015. Additionally, we have U.S. patents covering the compounding process expiring in 2019.

FOLOTYN: We have a composition of matter patent due to expire in November 2022, following a five-year patent term extension in the U.S., as well as through confidential settlement agreements executed in June 2016 with five parties resulting from Paragraph IV certifications in connection with four separate ANDAs to manufacture a generic version of FOLOTYN. The composition of matter patent expired in Europe in 2017.

We also have patents covering the use of FOLOTYN for PTCL that will not expire until 2025. We have filed for extension of this patent in Japan where FOLOTYN was approved in 2017. If the extension is granted, the patent will be extended by approximately 3 years and 11 months. The use patent is eligible for similar patent term extension in Europe following regulatory approval.

BELEODAQ: The composition of matter patents that cover BELEODAQ and related compounds do not begin to expire until 2021. We have applied for extension of the composition of matter patent in US. If an extension is granted, the patent will expire in 2026. In addition, there is a formulation patent which will not expire until 2027 in the U.S. Currently, there are multiple U.S. and foreign patent applications pending that cover BELEODAQ formulations, uses and manufacturing and synthesis processes.

We and Onxeo have filed a patent infringement lawsuit against Fresenius which triggered an automatic stay of this ANDA for 30 months, which will expire in April of 2021. The trial is currently scheduled to start in February of 2021.

In addition, BELOEDAQ is protected from competition in the U.S. by an Orphan Drug Exclusivity indication until July 3, 2021.

MARQIBO: We have U.S. and European patents covering the use of MARQIBO for leukemia, lymphoma and melanoma, and a U.S. patent covering the MARQIBO kit, all expiring in 2020. We have filed a patent cooperation treaty, or PCT, application claiming a method of encapsulating vincristine sulphate into liposomes. We are presently in the process of developing a "single vial" formulation of MARQIBO and filed patent applications covering the formulation worldwide. If we are successful, we believe our patent coverage could be extended to 2036.

EVOMELA: This drug is covered by issued patents claiming improved Captisol® technology that are due to expire between 2025 and 2034 in the U.S. Outside the U.S., we have issued patents that cover improved Captisol technology that are due to expire in 2025 and pending applications with anticipated expiry in 2029 (if issued). We also have filed patent applications covering the Captisol-based formulation of EVOMELA in the U.S. and a number of other countries.

EVOMELA has orphan drug exclusivity for use as a high-dose conditioning treatment prior to hematopietic progenitor (stem) cell transplantation in patients with MM, which expires on March 10, 2023.

We obtained global development and commercialization rights to EVOMELA from Ligand Pharmaceuticals Incorporated, or Ligand, in March 2013. We thereafter assumed responsibility for completing its clinical trials and were responsible for filing the NDA. Under our license agreement with Ligand, Ligand received a license fee and is eligible to receive milestone payments and royalties. On December 20, 2017, CyDex Pharmaceuticals, Inc., a Ligand company, filed an action against Teva Pharmaceuticals USA, Inc., TEVA Pharmaceuticals Industries Ltd., and Actavis, LLC, together Teva, in the U.S. District Court for the District of Delaware, alleging patent infringement with respect to a paragraph IV certification, or an ANDA, filed with the FDA seeking approval to market a generic version of EVOMELA. Ligand brought suit against Teva to protect its intellectual property rights.

KHAPZORY: The U.S. patent application is currently underway, and depending its outcome, it may provide intellectual property protections for this product.

Poziotinib: A composition of matter patent covering poziotinib is due to expire in 2028. The patent is eligible for patent term extension following regulatory approval. Poziotinib is also covered by additional patents and patent applications covering its formulations and synthetic processes which will expire between 2032 and 2034. We are also considering filing of additional patent applications covering new formulations and uses.

QAPZOLA: The U.S. formulation patent for QAPZOLA does not expire until 2022, and a patent for the method of treatment of bladder cancer using a stabilized formulation does not expire until 2024. Formulation patents outside the U.S. are due to expire in 2022. We have filed additional U.S. and foreign patent applications covering new formulations and/or uses for this product.

ROLONTIS: Composition of matter patents covering ROLONTIS are due to expire in 2025 in the U.S. and in 2024 outside the U.S. We also have a ROLONTIS formulation patent granted in the U.S., Europe, Japan and other countries. The formulation patent will not expire until 2031. One of these patents is eligible for patent term extension following regulatory approval of ROLONTIS. ROLONTIS is also covered by additional patents and pending applications claiming various aspects of the technology that are due to expire between 2024 and 2030.

Patent Protection and Value Maximization

We are constantly evaluating our patent portfolio and are currently assessing and filing patent applications for our drug products and considering new patent applications in order to maximize the life cycle of each of our products. While the U.S. and the European Union, or EU, are currently the largest potential markets for most of our products, we also have patents issued and patent applications pending outside of the U.S. and Europe. Limitations on patent protection in these countries, and the differences in what constitutes patentable subject matter in countries outside the U.S., may limit the protection we have on patents issued or licensed to us outside of the U.S. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws in the U.S.

To minimize our costs and expenses and to maintain effective protection, we usually focus our patent and licensing activities within the U.S., the EU, Canada, and Japan. In determining whether or not to seek a patent or to license any patent in a certain foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential and profitability, the scope of patent protection afforded by the law of the jurisdiction and its enforceability, and the nature of terms with any potential licensees. Failure to obtain adequate patent protection for our proprietary drugs and technology would impair our ability to be commercially competitive in these markets.

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In conducting our business, we rely upon trade secrets, know-how, and licensing arrangements. We use customary practices for the protection of our confidential and proprietary information such as confidentiality agreements and trade secret protection measures. It is possible that these agreements will be breached or will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. It is also possible that our trade secrets or know-how will otherwise become known or independently developed by competitors. The protection of know-how is particularly important because it is often necessary or useful information that allows us to practice the claims in the patents related to our proprietary drug products.

In addition to the specific intellectual property subjects discussed above, we have trademark registrations in the U.S. for Spectrum Pharmaceuticals, Inc.®, FUSILEV®, FOLOTYN®, ZEVALIN®, MARQIBO®, BELEODAQ®, EVOMELA®, and ROLONTIS®. We also have trademarks in KHAPZORY™, REDEFINING CANCER CARE™, and the Spectrum Pharmaceuticals' logos. Any other trademarks are the property of their respective owners.

The Patent Process

The U.S. Constitution provides Congress with the authority to provide inventors the exclusive right to their discoveries. Congress codified this right in U.S. Code Title 35, which gave the United States Patent and Trademark Office, or USPTO, the right to grant patents to inventors and defined the process for securing a U.S. patent. This process involves the filing of a patent application that instructs a person having ordinary skill in the respective art how to make and use the invention in clear and concise terms. The invention must be novel (i.e., not previously known) and non-obvious (i.e., not an obvious extension of what is already known). The patent application concludes with a series of claims that specifically describe the subject matter that the patent applicant considers his invention.

The USPTO undertakes an examination process that can take from one to seven years, or more, depending on the complexity of the patent and the problems encountered during examination.

In exchange for disclosing the invention to the public, for all U.S. patent applications filed after 1995, the successful patent applicant is currently provided a right to exclude others from making, using or selling the claimed invention for a period of 20 years from the effective filing date of the patent application.

Under certain circumstances, a patent term may be extended. Patent extensions are most frequently granted in the pharmaceutical and medical device industries under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, to recover some of the time lost during the FDA regulatory process, subject to a number of limitations and exceptions. The patent term may be extended up to a maximum of five years, but cannot be extended beyond a total of 14 years from the date of the product's approval; however, as a general rule, the average extension period granted for a new drug is approximately three years. Only one patent can be extended per FDA approved product, and a patent can only be extended once.

Product Exclusivity

Under the Hatch-Waxman Act, drug products are provided exclusivity whereby the FDA will not approve applications to market a generic form of an innovator reference listed drug product until the end of the prescribed period. A product is granted a five-year period of exclusivity if it contains a chemical entity never previously approved by the FDA either alone or in combination, although generic applications may be submitted after four years if they contain a certification of patent invalidity or non-infringement as further discussed below. A three-year period of exclusivity is granted to a previously approved product based on certain changes (e.g., in strength, dosage form, route of administration or conditions of use), where the application is supported by new clinical investigations that are essential to approval. In addition, in 1997, Congress amended the law to provide an additional six months of exclusivity as a reward for studying drugs in children. This pediatric exclusivity, which can be obtained during the approval process or after approval, effectively prevents the FDA from approving a generic application until six months after the expiration of any patent. In order to qualify for pediatric exclusivity, the FDA must make a written request for pediatric studies, the application holder must agree to the request and complete the studies within the required timeframe, and the studies must be accepted by the FDA based on a determination that the studies fairly respond to the request.

Generic Approval and Patent Certification

The Hatch-Waxman Act also created the ANDA approval process, which permits the approval of a generic version of a previously approved branded drug without the submission of a full NDA, and based in part on the FDA's finding of safety and effectiveness for the reference listed drug. Applicants submitting an NDA are required to list patents associated with the drug product, which are published in the FDA Orange Book, and the timing of an ANDA approval depends in part on patent protection for the branded drug. When an ANDA is filed, the applicant must file a certification for each of the listed patents for the branded drug, stating one of the following: (1) that there is no patent information listed; (2) that such patent has expired; (3) that the patent will expire on a particular date (indicating that the ANDA may be approved on that date); or (4) that the drug for which approval is sought either does not infringe the patent or the patent is unenforceable or invalid, otherwise known as paragraph IV certification. If an ANDA applicant files a paragraph IV certification, it is required to provide the patent holder with notice of that certification. If the patent holder brings suit against the ANDA applicant for patent infringement within 45 days of receiving notice, generally the FDA may not approve the ANDA until the earlier of (i) 30 months from the patent holder's receipt of the notice (the 30-month stay) or (ii) the issuance of a final, non-appealed, or non-appealable court decision finding the patent invalid, unenforceable or not infringed.

The Hatch-Waxman Act also provided an incentive for generic manufacturers to file paragraph IV certifications challenging patents that may be invalid, unenforceable, or not infringed, whereby the first company to successfully challenge a listed patent and receive ANDA approval is protected from competition from subsequent generic versions of the same drug product for up to 180 days after the earlier of (1) the date of the first commercial marketing of the first-filed ANDA applicant's generic drug or (2) the date of a decision of a court in an action holding the relevant patent invalid, unenforceable, or not infringed. These 180-day exclusivity provisions have been the subject of litigation and administrative review, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, amended the provisions in several ways, including by providing that an ANDA applicant entitled to 180-day exclusivity may lose such exclusivity if any of the following events occur: (1) failure to market; (2) withdrawal of the ANDA; (3) change in patent certification; (4) failure to obtain tentative approval; (5) illegal settlement agreement; or (6) patent expiration.

With respect to the illegal settlement prong, the MMA amendments require that certain types of settlement agreements entered into between branded and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs are required to be filed with the Federal Trade Commission and the Department of Justice for review of potential anti-competitive practices. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with branded pharmaceutical companies, and could result generally in an increase in private-party litigation against pharmaceutical companies. The impact of this requirement, and the potential governmental investigations and private-party lawsuits associated with arrangements between brand name and generic drug manufacturers, remains uncertain. In addition, Congress has considered enacting legislation that would prohibit such settlements between brand name and generic drug manufacturers. Such a provision was considered as part of the Patient Protection and Affordable Care Act, or PPACA, signed into law on March 23, 2010. However, Congress removed the provision prior to passage. It is possible that Congress will again consider a ban on such settlements between brand name and generic drug manufacturers in the future.

The PPACA provides exclusivity protections for certain innovator biological products and a framework for FDA review and approval of biosimilar and interchangeable versions of innovator biologic products. The PPACA provides that no application for a biosimilar product may be approved until 12 years after the date on which the innovator product was first licensed, and no application may be submitted until four years after the date of first licensure. Products deemed interchangeable (as opposed to biosimilar) are also eligible for certain exclusivity.

Orphan Drug Designation

Some jurisdictions, including Europe and the U.S., may designate drugs for relatively small patient populations as "orphan" drugs. The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S., and a drug may also be considered an orphan even if the drug treats a disease or condition affecting more than 200,000 individuals in the U.S. Orphan drug designation does not necessarily convey any advantage in, or shorten the duration of, the regulatory review and process for marketing approval. If a product with an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to seven years of orphan drug exclusivity, during which time the FDA will not approve any other application to market the same drug for the same indication except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Also, competitors are not prohibited from receiving approval to market the same drug or biologic for a different indication than that which received orphan approval.

Under EU medicines laws, the criteria for designating an “orphan medicinal product” are similar in principle to those in the U.S. Criteria for orphan designation are set out in Article 3 of Regulation (EC) 141/2000 on the basis of two alternative conditions. A medicinal product may be designated as orphan if it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU, when the application is made. This is commonly known as the “disease prevalence criterion,” Alternatively, a product may be so designated if it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the EU and if, without incentives, it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment. This is commonly known as the “insufficient return criterion.”

These two alternative criteria must cumulatively meet the second condition that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. “Significant benefit” is defined in Regulation (EC) 847/2000 as a clinically relevant advantage or a major contribution to patient care.

Upon grant of a marketing authorization, orphan medicinal products are entitled to ten years of market exclusivity in respect of the approved therapeutic indication. Within the period of market exclusivity, no competent authority in the EU is permitted to accept an application for marketing authorization, a variation or a line-extension for the same approved therapeutic indication in respect of a similar medicinal product pursuant to Article 8.1 of Regulation (EC) 141/2000 unless one of the derogations set out in Article 8.3 of the same Regulation applies. In order to determine whether two products are considered similar, Regulation (EC) 847/2000 requires an assessment of the principal molecular structure and the underlying mode of action. Any minor variation or modification of the principal molecular structure would not ordinarily render the second product dissimilar to the first authorized product.

In order for the second applicant to break the market exclusivity granted to the first authorized similar medicinal product in respect of the same therapeutic indication, the second applicant would principally rely upon data to demonstrate that its product is safer, more efficacious or clinically superior to the first product pursuant to Article 8.3(i) of Regulation (EC) 141/2000. Ordinarily, such an assessment will require a head-to-head comparative clinical trial for the purpose of demonstrating clinical superiority.

The 10-year market exclusivity may be reduced to six years if at the end of the fifth year it is established that the product no longer meets the criteria for orphan designation on the basis of available evidence. We have in the past received, and currently hold, orphan drug designations for some of our products.

Currently, BELEODAQ has orphan drug designation for use in PTCL, and EVOMELA has orphan drug designation as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with MM. In addition, MARQIBO has orphan drug designations for its use in the treatment of adult patients with ALL in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies, and ZEVALIN has orphan drug designations for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell NHL, including patients with Rituximab refractory follicular NHL.

Governmental Regulation

The development, production and marketing of our proprietary and biologic products are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the U.S. and other countries. In the U.S., drugs and biologics are subject to rigorous regulation. The Federal Food, Drug, and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder, as well as other federal and state statutes and regulations, govern, among other things, the development, approval, manufacture, safety, labeling, storage, record keeping, distribution, promotion, and advertising of our products. Product development and approval within this regulatory framework, including for drugs already at a clinical stage of development, can take many years and require the expenditure of substantial resources, and to obtain FDA approval, a product must satisfy mandatory quality, safety, and efficacy requirements. In addition, each drug-manufacturing establishment must be registered with the FDA. Domestic manufacturing establishments must comply with the FDA’s current Good Manufacturing Practices, or cGMP, regulations and are subject to inspections by the FDA. To supply drug ingredients or products for use in the U.S., foreign manufacturing establishments must also comply with cGMP and are subject to inspections by the FDA or by other regulatory authorities in certain countries under reciprocal agreements with the FDA.

General Information about the Drug Approval Process and Post-Marketing Requirements

The U.S. system of new drug and biologics approval is a rigorous process. Only a small percentage of compounds that enter the pre-clinical testing stage are ever approved for commercialization. Our strategy focuses on in-licensing clinical stage drug products that are already in or about to enter human clinical trials. A late-stage focus helps us to effectively manage the high cost of drug development by focusing on compounds that have already passed the many hurdles in the pre-clinical and early clinical process.

The following general comments about the drug approval process are relevant to the development activities we are undertaking with our proprietary products.

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Pre-clinical Testing: During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of a drug or biologic compound against the targeted disease. The compound is evaluated for safety. While some of our compounds are currently in clinical trials, it is possible that additional pre-clinical testing could be requested by a regulatory authority for any of our compounds.

Investigational New Drug Application: After certain pre-clinical studies are completed, an IND application is submitted to the FDA to request the ability to begin human testing of the drug or biologic. An IND becomes effective thirty days after the FDA receives the application (unless the FDA notifies the sponsor of a clinical hold), or upon prior notification by the FDA.

Phase 1 Clinical Trials: These trials typically involve small numbers of healthy volunteers or patients and usually define a drug candidate's safety profile, including the safe dosage range.

Phase 2 Clinical Trials: In Phase 2 clinical trials, controlled studies of human patients with the targeted disease are conducted to assess the drug's effectiveness. These studies are designed primarily to determine the appropriate dose levels, dose schedules and route(s) of administration, and to evaluate the effectiveness of the drug or biologic on humans, as well as to determine if there are any side effects on humans to expand the safety profile following Phase 1. These clinical trials, and Phase 3 trials discussed below, are designed to evaluate the product's overall benefit-risk profile, and to provide information for physician labeling.

Phase 3 Clinical Trials: This Phase usually involves a larger number of patients with the targeted disease. Investigators (typically physicians) monitor the patients to determine the drug candidate's efficacy and to observe and report any adverse reactions that may result from long-term use of the drug on a large, more widespread, patient population. During the Phase 3 clinical trials, typically the drug candidate is compared to either a placebo or a standard treatment for the target disease.

New Drug Application or Biologics License Application: After completion of all three clinical trial Phases, if the data indicates that the drug is safe and effective, an NDA or BLA is filed with the FDA requesting FDA approval to market the new drug as a treatment for the target disease.

Fast Track and Priority Review: The FDA has established procedures for accelerating the approval of drugs to be marketed for serious or life-threatening diseases for which the manufacturer can demonstrate the potential to address unmet medical needs. As discussed above, we have obtained accelerated approval to market FOLOTYN, BELEODAQ and MARQIBO.

Abbreviated New Drug Application: An ANDA is an abbreviated new drug application for generic drugs created by the Hatch-Waxman Act. When a company files an ANDA, it must make a patent certification regarding the patents covering the branded product listed in the FDA's Orange Book. The ANDA drug development process generally takes less time than the NDA drug development process since the ANDA process usually does not require new clinical trials establishing the safety and efficacy of the drug product.

Breakthrough Therapy Designation: A BTD is available from the FDA for drugs or drug combinations used to treat serious or life-threatening disease conditions based on preliminary clinical evidence that the drug may offer substantial improvement over existing therapies. FDA may grant priority approval to breakthrough drug indications. FDA may also grant accelerated approval and priority review for drugs that fill an unmet medical need. An advantage to this designation is that clinical trials may use surrogate endpoints to predict clinical benefit, requiring less time than other objective endpoints such as overall survival.

NDA/BLA and ANDA Approval: The FDA approves drugs and biologics that are subject to NDA and BLA review based on data in the application demonstrating the product is safe and effective in its proposed use(s) and that the product's benefits outweigh its risks. The FDA will also review the NDA or BLA applicant's manufacturing process and controls to ensure they are adequate to preserve the drug's identity, strength, quality, and purity. Finally, the FDA will review and approve the product's proposed labeling. As for the ANDA approval process, these "abbreviated" applications are generally not required to include pre-clinical or clinical data to establish safety and effectiveness. Rather, an ANDA must demonstrate both chemical equivalence and bio-equivalence (the rate and extent of absorption in the body) to the innovator drug — unless a bio-equivalence waiver is granted by the FDA.

Phase 4 Clinical Trials: After a drug has been approved by the FDA, Phase 4 studies may be conducted to explore additional patient populations, compare the drug to a competitor, or to further study the risks, benefits and optimal use of a drug. These studies may be a requirement as a condition of the initial approval of the NDA or BLA.

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Post-Approval Studies Requirements under FDAAA: The Food and Drug Administration Amendments Act of 2007, or FDAAA, significantly added to the FDA's authority to require post-approval studies. Under the FDAAA, if the FDA becomes aware of new safety information after approval of a product, they may require us to conduct further clinical trials to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk. If required to conduct a post-approval study, periodic status reports must be submitted to the FDA. Failure to conduct such post-approval studies in a timely manner may result in administrative action being taken by FDA, including substantial civil fines.

Risk Evaluation and Mitigation Strategy Authority under FDAAA: The FDAAA also gave the FDA authority to require the implementation of a Risk Evaluation and Mitigation Strategy, or REMS, for a product when necessary to minimize known and preventable safety risks associated with the product. The FDA may require the submission of a REMS before a product is approved, or after approval based on "new safety information," including new analysis of existing safety information. A REMS may include a medication guide, patient package insert, a plan for communication with healthcare providers, or other elements as the FDA deems are necessary to assure safe use of the product, which could include imposing certain restrictions on distribution or use of a product. A REMS must include a timetable for submission of assessments of the strategy at specified time intervals. Failure to comply with a REMS, including the submission of a required assessment, may result in substantial civil or criminal penalties.

Other Issues Related to Product Safety: Adverse events that are reported after marketing approval also can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market. In addition, under the FDAAA, the FDA has authority to mandate labeling changes to products at any point in a product's life cycle based on new safety information derived from clinical trials, post-approval studies, peer-reviewed medical literature, or post-market risk identification and analysis systems data.

FDA Enforcement

The development of drug and biologic products, as well as the marketing of approved drugs and biologics, is subject to substantial continuing regulation by the FDA, including regulation of adverse event reporting, manufacturing practices and the advertising and promotion of the product. Failure to comply with the FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, BLAs, ANDAs or other product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals.

With respect specifically to information submitted to the FDA in support of marketing applications, the FDA, under its Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Policy, can significantly delay the approval of a marketing application, or seek to withdraw an approved application where it identifies fraud or discrepancies in regulatory submissions. Such actions by the FDA may significantly delay or suspend substantive scientific review of a pending application during validity assessment or remove approved products from the market until the assessment is complete and questions regarding reliability of the data are resolved. In addition, the Generic Drug Enforcement Act of 1992 established penalties for wrongdoing in connection with the development or submission of an ANDA. Under this Act, the FDA has the authority to permanently or temporarily bar companies or individuals from submitting or assisting in the submission of an ANDA, and to temporarily deny approval and suspend applications to market generic drugs. The FDA may also suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct and/or withdraw approval of an ANDA and seek civil penalties.

Healthcare Reform

Continuing studies of the proper utilization, safety and efficacy of pharmaceuticals and other health care products are being conducted by industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products and in some cases have resulted, and may in the future result, in the discontinuance of their marketing.

The Patient Centered Outcomes Research Institute, or the Institute, a private, non-profit corporation created as a result of the PPACA, is tasked with assisting patients, clinicians, purchasers, and policy-makers in making informed health decisions. One of the Institute’s initiatives will be to conduct comparative clinical effectiveness research, which is defined as “research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of two or more medical treatments, services, and items.” It is important to note that the Institute would not be permitted to mandate coverage, reimbursement, or other policies for any public or private payer, however, the outcome of the Institute's initiatives could influence prescriber behavior.

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Foreign Regulation

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country/region to country/region, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also may vary, sometimes significantly, from country/region to country/region.

Under the EU regulatory systems, we may submit marketing authorization applications either under a centralized procedure or decentralized procedure or the mutual recognition procedure. The centralized procedure is mandatory for medicines produced by a biotechnological process. The procedure is also mandatory for new active substances which are indicated for treatment of several diseases or conditions, including cancer and orphan conditions. Companies may apply for centralized assessment if the product contains a new active substance or the product constitutes significant therapeutic, scientific or technical innovation or the granting of authorization under the centralized procedure is in the interests of the EU patients. A centralized marketing authorization is valid in all EU member states. This marketing authorization is issued in the form of a European Commission decision which is legally binding in its entirety to which it is addressed.

Directive 2004/27/EC introduced two parallel procedures to the centralized procedure to allow a product to be progressively authorized in each of the member states of the EU. They are the decentralized procedure and the mutual recognition procedure. The mutual recognition procedure applies where the product has already been authorized in a member state of the EU that will act as reference member state. The national marketing authorization granted by the reference member state forms the basis for mutual recognition in the member states chosen by the applicant. In the decentralized procedure, the product in question is not authorized in any one the EU member states. In such a situation, the applicant company will request a member state to act as the reference member state to lead the scientific assessment for the benefit/risk balance for agreement by the concerned member states. In both cases, the concerned member states have up to 90 days to accept or raise reasoned objections to the assessment made by the reference member state.

In addition, pricing and reimbursement is subject to negotiation and regulation in most countries outside the U.S. Increasingly, adoption of a new product for use in national health services is subject to health technology assessment under the national rules and regulations to establish the clinical effectiveness and cost-effectiveness of a new treatment. In some countries, in order to contain health care expenditures, reference price is introduced in order for the national healthcare providers to achieve a price comparable to the reference price in the same therapeutic category. We may therefore face the risk that the resulting prices would be insufficient to generate an acceptable return to us.

Third Party Reimbursement and Pricing Controls

In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. It is time-consuming and expensive for us to go through the process of seeking coverage from Medicare and private payers. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The PPACA enacted significant reforms, including revising the definition of “average manufacturer price” for reporting purposes, increasing Medicaid rebates, expanding the 340B drug discount program, and making changes to affect the Medicare Part D coverage gap, or “donut hole.” In the coming years, additional significant changes could be made to governmental healthcare programs, and to the U.S. healthcare system as a whole, that may result in significantly increased demand for rebates, decreased pricing flexibility, diminished negotiating flexibility, coverage and reimbursement limitations based upon comparative and cost-effectiveness reviews, and other measures that could significantly impact the success of our products.

In many foreign markets, including the countries in the EU, pricing of pharmaceutical products is subject to governmental control. In the U.S., there have been, and we expect that there will continue to be, a number of federal

and state proposals to implement similar governmental pricing controls or product coverage limitations.
Employees
As of December 31, 2018, we had 235 employees (as compared to 215 employees as of December 31, 2017), 8 of whom hold an M.D. degree, and 17 of whom hold a Ph.D. degree. We believe that the success of our business will depend, in part, on

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our ability to attract and retain uniquely qualified personnel. Our employees are not part of any collective bargaining agreements, and we believe that we have good relations with our employees.

Upon the closing of the Acrotech Transaction, we plan to reduce our staff by approximately 90 employees, the majority of which we expect to transition to Acrotech.

General Information

We are a Delaware corporation. We originally incorporated in Colorado in December 1987 as Americus Funding Corporation. We changed our corporate name in August 1996 to NeoTherapeutics, Inc., and reincorporated in Delaware in June 1997. We changed our corporate name in December 2002 to Spectrum Pharmaceuticals, Inc.

Our principal executive office is located at 11500 South Eastern Avenue, Suite 240, Henderson, Nevada 89052. Our telephone number is (702) 835-6300. Our website is located at www.sppirx.com. The information that can be accessed through our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part hereof.

We make our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K (and related amendments to these reports, as applicable) available on our website free of charge as soon as practicable after filing or furnishing with the Securities and Exchange Commission, or the SEC.

All such reports are also available free of charge via EDGAR through the SEC website at www.sec.gov. In addition, the public may read and copy materials filed by us with the SEC at the SEC's public reference room located at 100 F Street, NE, Washington, D.C., 20549. Information regarding operation of the SEC's public reference room can be obtained by calling the SEC at 1-800-732-0330.

ITEM 1A. RISK FACTORS

Before deciding to invest in our company, or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10-K and other reports we have filed with the SEC. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, may also affect our business operations. If any of these risks are realized, our business, financial condition, or results of operations could be seriously harmed and in that event, the market price for our common stock could decline, and you may lose all or part of your investment.

These risk factors should be considered in connection with evaluating the forward-looking statements contained in this Annual Report on Form 10-K. These factors could cause actual results and conditions to differ materially from those projected in our forward-looking statements.

Risks Related to Our Business

Our sales depend on coverage and reimbursement from third-party payers and a reduction in the coverage and/or reimbursement for our products could have a material adverse effect on our product sales, business and results of operations.

Sales of our products are dependent on the availability and extent of coverage and reimbursement, or level of reimbursement, from third-party payers, including government programs and private insurance plans. Governments and private payers may regulate prices, reimbursement levels and/or access to our products to contain costs or to affect levels of use. We rely in large part on the reimbursement of our products through government programs such as Medicare and Medicaid in the U.S., and a reduction in the coverage and/or reimbursement for our products could have a material adverse effect on our product sales, business and results of operations.

A substantial portion of our U.S. business relies on reimbursement from the U.S. federal government under Medicare Part B coverage. Most of our products furnished to Medicare beneficiaries in both a physician office setting and hospital outpatient setting are reimbursed under the Medicare Part B Average Sales Price, or ASP, payment methodology. ASP-based reimbursement of our products under Medicare may be below or could fall below the cost that some medical providers pay for such products, which could materially and adversely affect sales of our products. We also face risks relating to the reporting of pricing data that affect the U.S. reimbursement of and discounts for our products. ASP data are calculated by the manufacturer

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based on a formula defined by statute and regulation and are then submitted to the Centers for Medicare & Medicaid Services, or CMS, the agency responsible for administering the Medicare program, on a quarterly basis.
CMS uses those ASP data to determine the applicable reimbursement rates for our products under Medicare Part B. However, the statute, regulations and CMS guidance do not define specific methodologies for all aspects of the reporting of ASP data. For example, CMS has not provided specific guidance regarding administrative fees paid to GPOs in the ASP calculation. CMS directs that manufacturers make “reasonable assumptions” in their calculation of ASP data in the absence of specific CMS guidance on a topic. As a result, we are required to apply our reasonable judgment to certain aspects of calculating ASP data. If our submitted ASP data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse impact on our business and results of operations.

Clinical trials may fail to demonstrate the safety and efficacy of our drug products, which could prevent or significantly delay obtaining regulatory approval.

Prior to receiving approval to commercialize any of our drug products, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, and other regulatory authorities in the U.S. and other countries, that each of the products is both safe and effective. For each drug product, we will need to demonstrate its efficacy and monitor its safety throughout the process. If such development is unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

We are currently conducting multiple clinical trials for our products. Each of our clinical trials requires investment of substantial financial and personnel resources. The commencement and completion of these clinical trials may be delayed by various factors, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delays in accumulating the required number of clinical events for data analysis, delay or failure to obtain the required approval to conduct a clinical trial at a prospective site, and shortages of available drug supply.

All of our drug products are prone to the risks of failure inherent in drug development. Clinical trials of new drug products sufficient to obtain regulatory marketing approval are expensive, uncertain, and take years to complete. We may not be able to successfully complete clinical testing within the time frame we have planned, or at all. Moreover, the outcome of a clinical trial is often uncertain. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our drug products. In this regard, reports of adverse events or concerns involving any of our products could interrupt, delay or halt clinical trials of such products or could result in our inability to obtain regulatory approvals for such products. In addition, the results of pre-clinical studies and early-stage clinical trials of our drug products do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a drug product is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our drug products is promising, data are susceptible to varying interpretations, and such data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval.
Pre-clinical and clinical data can be interpreted in different ways.
Accordingly, FDA officials could interpret such data in different ways than we or our partners do which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, our institutional review boards, our contract research organizations, or we may suspend or terminate our clinical trials for our drug products. Any failure or significant delay in completing clinical trials for our drug products, or in receiving regulatory approval for the sale of any drugs resulting from our drug products, may severely harm our business and reputation. Even if we receive FDA and other regulatory approvals, our drug products may later exhibit adverse effects that may limit or prevent their widespread use, may cause the FDA to revoke, suspend or limit their approval, or may force us to withdraw products derived from those drug products from the market. Furthermore, there is the risk that additional post-marketing requirements may be imposed by the FDA in the future on our products.

Moreover, the commencement and completion of clinical trials may be delayed by many factors that are beyond our control, including:

- delays obtaining regulatory approval to commence a trial;
- delays in reaching agreement on acceptable terms with contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining institutional review board, or IRB, approval at each site;

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- slower than anticipated patient enrollment or our inability to recruit and enroll patients to participate in clinical trials for various reasons;
- our inability to retain patients who have initiated a clinical trial;
- scheduling conflicts with participating clinicians and clinical institutions;
- lack of funding to start or continue the clinical trial, including as a result of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with our CROs and other third parties;
- negative or inconclusive results;
- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements, GCP or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- patient noncompliance with the protocol;
- adverse medical events or side effects experienced by patients during the clinical trials as a result of or resulting from the clinical trial treatments;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- our ability to sustain the quality or stability of the applicable product candidate in compliance with acceptable standards;
- our inability to produce or obtain sufficient quantities of the applicable product candidate to complete the clinical trials;
- changes in governmental regulations or administrative actions that adversely affect our ability to continue to conduct or complete clinical trials;
- negative or problematic FDA inspections of our clinical operations or manufacturing operations; and
- real or perceived lack of effectiveness or safety.

We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the clinical trial sites in which such trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Any delays, interruptions or halts in our clinical trials involving any of our products or other adverse events negatively impacting our ability to obtain regulatory approvals for such products in a timely manner could adversely affect our overall profitability, results of operations and financial condition and prospects.

If we are unable to continue to successfully develop poziotinib, ROLONTIS, or any of our other pipeline products, our business, prospects, operating results, and financial condition will be materially harmed.

We are currently conducting clinical trials for poziotinib. This product will require significant further development, including financial resources and personnel to possibly obtain regulatory approval. In December 2018, we submitted our NDA to the FDA for ROLOTNIS. Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop these drugs or others, and thus it is possible that none of our pipeline compounds will ever become viable commercial products.

The announcement of any negative or unexpected data, any delay in our anticipated timelines for filing for regulatory approval, or a significant advancement of a competitor, may cause our stock price to decline significantly and may have an adverse impact on our business, financial condition and prospects. In addition, clinical trial results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. There is no assurance that data from our clinical trials will support filings for regulatory approval of any of our pipeline products, or even if approved, that these drugs will become commercially successful for all approved indications. In addition, we may experience significant setbacks in our advanced clinical trials, even after promising results in earlier trials, including unexpected adverse events. Any deficiencies in the our clinical trial operations or other unexpected adverse events impacting such trials could cause increased costs, program delays or both, which may harm our business.

If one of our pipeline products fails at any stage of development, or we otherwise determine to discontinue development of that product, we will not have the anticipated revenues from that product, and we may not receive any return of our investment on it. Consequently, our stock price could decline significantly and there could be an adverse impact on our business, financial condition, results of operations and prospects.

Pricing for pharmaceutical products has come under increasing scrutiny by governments, legislative bodies and enforcement agencies. Changes in laws and regulations that control drug pricing for government programs, allow for negotiated pricing, or limit product coverage and reimbursements may adversely impact our operating results and our business.

Many companies in our industry have received a governmental request for documents and information relating to drug pricing and patient assistance programs. We may become subject to similar requests, which would require us to incur significant expense and result in distraction for our management team. Additionally, to the extent there are findings, or even allegations, of improper conduct on the part of the company or its employees, such findings or allegations could result in negative publicity or other negative actions that could harm our reputation; cause changes in our product pricing and distribution strategies; reduce demand for our approved products and/or reduce reimbursement of approved products, including by federal health care programs such as Medicare and Medicaid and state health care programs.

In addition, President Trump’s administration has indicated an interest in taking measures pertaining to drug pricing, including potential proposals relating to Medicare price negotiations, and importation of drugs from other countries. There have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At this time, it is unclear whether any of these proposals will be pursued; however, if pursued they could adversely affect our products or our future product candidates.

Our supply of APIs, and drug products will be dependent upon the production capabilities of contract manufacturing organizations, or CMOs, component and packaging supply sources, other third-party suppliers, and other providers of logistical services. Some of these parties are based overseas and, if they are not able to meet our demands and FDA scrutiny, we may be limited in our ability to meet demand for our products, ensure regulatory compliance, or maximize profit on the sale of our products.

We have no internal manufacturing capacity for APIs or our drug products, and, therefore, we have entered into agreements with CMOs and other suppliers to supply us with APIs and our finished drug product. Success in the development and marketing of our drug products depends, in part, upon our ability to maintain, expand and enhance our existing relationships and establish new sources of supply. Some of the third-party manufacturing facilities used in the production of APIs and our drug products are located outside the U.S. The manufacture of APIs and finished drug products, including the acquisition of compounds used in the manufacture of the finished drug product, may require considerable lead times. We have little or no control over the production processes of third-party manufacturers, CMOs or other suppliers.

Our ability to source APIs and drug products is also dependent on providers of logistical services who may be subject to disruptions that we cannot predict or sufficiently plan around. Accordingly, while we do not currently anticipate shortages of supply, circumstances could arise in which we will not have adequate supplies to timely meet our requirements or market demand for a particular drug product could outstrip the ability of our supply source to timely manufacture and deliver the product, thereby causing us to lose sales. In addition, our ability to make a profit on the sale of our drug products depends on our ability to obtain price arrangements that ensure a supply of product at favorable prices.

If problems arise during the production of a batch of our drug products, that batch of product may have to be discarded. This could, among other things, lead to increased costs, lost revenue, damage to customer relations, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. To the extent that one of our suppliers experiences significant manufacturing problems, this could have a material adverse effect on our revenues and profitability.

Finally, reliance on CMOs entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and adherence to the cGMP, requirements, the possible breach

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of the manufacturing agreement by the CMO and the possibility of termination or non-renewal of the agreement by the CMO, based on its own business priorities, at a time that is costly or inconvenient for us. Before we can obtain marketing approval for our drug products, our CMO facilities must pass an FDA pre-approval inspection. In order to obtain approval, all of the facility's manufacturing methods, equipment and processes must comply with cGMP requirements.

The cGMP requirements govern all areas of record keeping, production processes and controls, personnel and quality control. In addition, our CMOs will be subject to on-going periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations, similar foreign regulations and other regulatory standards. We do not have control over our CMOs' compliance with these regulations and standards. Any failure of our third party manufacturers or us to comply with applicable regulations, including an FDA pre-approval inspection, periodic on-going inspection by the FDA and cGMP requirements, could result in sanctions being imposed on them or us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operation restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

Our efforts to acquire or in-license and develop additional drug products may fail, or acquired or in-licensed products may fail to perform as we anticipate, which might limit our ability to grow our business.

To remain competitive and grow our business, our long-term strategy includes the acquisition or in-license of additional drug products. We are actively seeking to acquire, or in-license, additional commercial drug products as well as drug products that have demonstrated positive pre-clinical and/or clinical data. We have certain criteria that we are looking for in any drug product acquisition and in-license and we may not be successful in locating and acquiring, or in-licensing, additional desirable drug products on acceptable terms.

To accomplish our acquisition and in-license strategy, we intend to commit efforts, funds and other resources to research and development and business development. Even with acquired and in-licensed drug products, a high rate of failure is inherent in the development of such products. We must make ongoing substantial expenditures without any assurance that our efforts will be commercially successful. Failure can occur at any point in the process, including after significant funds have been invested. For example, promising new drug product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, limited payer coverage or infringement of the intellectual property rights of others.

In addition, many other large and small companies within the pharmaceutical and biotechnology industry seek to establish collaborative arrangements for product research and development, or otherwise acquire products in late-stage clinical development, in competition with us. We face additional competition from public and private research organizations, academic institutions and governmental agencies in establishing collaborative arrangements for drug products in late-stage clinical development. Many of the companies and institutions that compete against us have substantially greater capital resources, research and development staffs and facilities than we have, and greater experience in conducting business development activities. These entities represent significant competition to us as we seek to expand our portfolio through the in-license or acquisition of compounds. Finally, while it is not feasible to predict the actual cost of acquiring and developing additional drug products, that cost could be substantial and we may need to obtain additional financing for such purpose, which may further dilute existing stockholders.

We are aware of several competitors attempting to develop and market products competitive to our products, which may reduce or eliminate our commercial opportunities.

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological changes, and a number of companies are pursuing the development of pharmaceuticals and products that target the same diseases and conditions that our products target, including products currently commercialized. We cannot predict with accuracy the timing or impact of the introduction of potentially competitive products or their possible effect on our sales. Certain potentially competitive products to our products are in various stages of development, some of which have pending applications for approval with the FDA or have been approved by regulatory authorities in other countries. Also, there are many ongoing studies with currently marketed products and other developmental products, which may yield new data that could adversely impact the use of our products in their current and potential future indications. The introduction of competitive products or the development of technological advances that compete with our products could significantly reduce our sales, which, in turn would adversely impact our financial and operating results.

Reports of adverse events or safety concerns involving each of our products or similar agents, sold by us or our development partners and/or licensees, could delay or prevent us from obtaining or maintaining regulatory approval or negatively impact sales.

Certain of our products may cause SAEs. In addition to the risk associated with known SAEs, discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, could interrupt, delay or halt clinical trials of such products, including the FDA-required post-approval studies, and could result in the FDA or other regulatory authorities denying or withdrawing approval of our products for any or all indications. The FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. We may also be required to update the package inserts based on reports of adverse events or safety concerns or implement a risk evaluation and mitigation strategy, or REMS, which could adversely affect such product's acceptance in the market. In addition, the public perception of our products might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company's product or product candidate. Our planned trials to demonstrate efficacy in a variety of indications and to better manage side effect profiles of certain of our products may not be successful and there are no assurances that patients receiving our products will not experience SAEs in the future.

Future reports of SAEs or safety concerns involving any of our products could adversely affect our business, results of operations and prospects.

The known SAEs related to our commercialized products are as follows:

FOLOTYN:

Forty-four percent of patients experienced a serious adverse event while on the study or within 30 days after their last dose. The most common serious adverse events (> 3%), regardless of causality, were fever, mucositis (redness and sores of the mucous membrane lining of the mouth, lips, throat, stomach, and genitals), sepsis (complication of infection), febrile neutropenia (fever associated with low white blood cell count), dehydration, dyspnea (shortness of breath), and thrombocytopenia (low platelet count). One death from cardiopulmonary arrest in a patient with mucositis and febrile neutropenia was reported in this trial. Deaths from mucositis, febrile neutropenia, sepsis, and pancytopenia (deficiency of all three cellular components of the blood) occurred in 1.2% of patients treated on all FOLOTYN trials at doses ranging from 30 to 325 mg/m2.

FOLOTYN may cause serious side effects, including bone marrow suppression, manifested by thrombocytopenia (low platelet counts), neutropenia (low white blood cell counts), and/or anemia (low red blood cell count); mucositis (redness and sores of the mucous membrane lining of the mouth, lips, throat, stomach, and genitals); dermatologic reactions (severe skin reactions); tumor lysis syndrome (tumor cells releasing contents into blood stream); hepatic toxicity (harm to liver); risk of increased toxicity in the presence of impaired renal function (increased harm to the patients with abnormal kidney function); and embryo-fetal toxicity (harm to an unborn baby).

ZEVALIN:

ZEVALIN is associated with the following serious adverse reactions: serious infusion reactions, prolonged and severe cytopenias (low blood cell count), cutaneous and mucocutaneous (skin and mucus membrane) reactions, and leukemia and myelodysplastic syndrome. The most serious adverse reactions of ZEVALIN are prolonged and severe cytopenias (low platelets, red blood cells, lymphocytes, white blood cells) and secondary malignancies.

MARQIBO:

Seventy-six percent of patients experienced serious adverse events during the studies. The most commonly reported serious adverse events (> 6%) included, febrile neutropenia (fever associated with low white blood cell count), fever, low-blood pressure, respiratory distress, and cardiac arrest.

MARQIBO may cause serious side effects, including extravasation tissue injury (leakage-induced tissue injury); neurologic toxicity (nerve problems, e.g., neuropathy); myelosuppression (low blood cell counts); tumor lysis syndrome (tumor cells releasing contents into blood stream); constipation and bowel obstruction (constipation and bowel blockage); fatigue (tiredness); hepatic toxicity (harm to liver); and embryo-fetal toxicity (harm to an unborn baby).

BELEODAQ:

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Forty-seven percent of patients experienced serious adverse reactions while taking BELEODAQ or within 30 days after their last dose of BELEODAQ. The most common serious adverse reactions (> 2%) were pneumonia, fever, infection, anemia (low red blood cell count), increased creatinine, thrombocytopenia (low platelet count), and multi-organ failure. One treatment-related death associated with hepatic failure was reported in the trial.

BELEODAQ may cause serious side effects, including hematologic toxicity (low blood cell counts); serious infections; hepatotoxicity (liver problems); tumor lysis syndrome (tumor cell releasing contents into blood stream); gastrointestinal toxicity, including nausea, vomiting, and diarrhea; and embryo-fetal toxicity (harm to an unborn baby).

EVOMELA:

Twenty percent of patients experienced a treatment emergent serious adverse reaction while on study. The most common serious adverse reactions (>1 patient, 1.6%) were fever, hematochezia (blood in stools), febrile neutropenia (fever associated with low white blood cell count), and kidney failure. Treatment-related serious adverse reactions reported in >1 patient were pyrexia, febrile neutropenia, and hematochezia.

EVOMELA may cause serious side effects, including bone marrow suppression (low blood cell counts); gastrointestinal toxicity, including nausea, vomiting, diarrhea and mucositis (redness and sores of the lining of the mouth, lips, throat, stomach, and genitals); hepatotoxicity (liver problems); hypersensitivity (allergic reactions); secondary malignancies (secondary cancers); embryo-fetal toxicity (harm to an unborn baby); and infertility (harm to reproductive system).

KHAPZORY:

The most common adverse reactions (>20%) in patients receiving high-dose methotrexate therapy with levoleucovorin rescue were stomatitis (38%) and vomiting (38%). The most common adverse reactions (>50%) in patients receiving levoleucovorin in combination with fluorouracil for metastic colorectal cancer were stomatitis (72%), diarrhea (70%), and nausea (62%).

Our dependence on key executives, scientists and sales and marketing personnel could impact the development and management of our business.

We are highly dependent upon our ability to attract and retain qualified scientific, technical sales and marketing and managerial personnel. There is intense competition for qualified personnel in the pharmaceutical and biotechnology industries, and we cannot be sure that we will be able to continue to attract and retain the qualified personnel necessary, particularly as business prospects change, for the development and management of our business. Although we do not believe the loss of one individual would materially harm our business, our business might be harmed by the loss of the services of multiple existing personnel, as well as the failure to recruit additional key scientific, technical and managerial personnel in a timely manner. Much of the know-how we have developed resides in our scientific and technical personnel and is not readily transferable to other personnel. We do not have employment agreements with most of our key scientific, technical, or managerial employees. However, we entered into new employment agreements with each of our named executive officers (chief executive officer, chief operating officer, chief financial officer, and chief legal officer) in April and June 2018, which supersede any prior Change in Control Severance Agreements with such individuals.

A significant portion of our revenue currently comes from a limited number of distributors, and any decrease in revenue from these distributors could harm our business

A significant portion of our revenue comes from a limited number of distributors. In the years ended December 31, 2018 and December 31, 2017, three distributors (and their affiliates) together represented approximately 88% and 90%, respectively, of our worldwide revenues. We expect that a significant portion of our future revenue will continue to depend on sales to a limited number of distributors in the foreseeable future. We do not have long-term commitments from our distributors to carry our products, and any of our distributors may from quarter to quarter comprise a significant concentration of our revenues. These distributors comprise a significant part of the distribution network for pharmaceutical products in the U.S. and a small number of large distributors and wholesalers control a significant share of the market, which can increase competitive and pricing pressures on pharmaceutical manufacturers, including us. In addition, wholesalers may apply pricing pressure through their fee-for-service arrangements. Any reduction in the prices we receive for our products could adversely impact our revenues and financial condition. In addition, any individual distributor could choose to stop selling some or all of our products at any time, and without notice. If we lose our relationship with any of our significant distributors, we would experience

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disruption and delays in marketing our products and could also experience declines in our revenues which in turn could materially adversely impact our financial condition.

If the distributors that we rely upon to sell our products fail to perform, our business may be adversely affected.

Our success depends on the continued customer support efforts of our network of distributors. In the U.S., we sell our products to a small number of distributors who in turn sell-through to patient health care providers. These distributors also provide multiple logistics services relating to the distribution of our products, including transportation, warehousing, cross-docking, inventory management, packaging and freight-forwarding. We do not promote products to these distributors and they do not set or determine demand for products. The use of distributors involves certain risks, including, but not limited to, risks that these distributors will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using our products or complaints about our products;
- not purchase sufficient inventory on hand to fulfill end user orders in a timely manner;
- be unable to satisfy financial obligations to us or others; and
- cease operations.

Any such actions may result in decreased sales of our products, which would harm our business.

Adverse economic conditions may have material adverse consequences on our business, results of operations and financial condition as well as our ability to raise additional capital.

Unpredictable and unstable changes in economic conditions, including recession, inflation, increased government intervention, or other changes, may adversely affect our general business strategy. In recent years, we have funded our operations through a combination of equity and debt offerings and sales of our pharmaceutical products. Based on our current plans and expectations, we believe that we will require additional funding to achieve our goals. We may need to raise these additional funds through public or private debt or equity financings, and any adverse economic conditions could adversely affect our ability to raise funds. If our business deteriorates, we may not be able to maintain compliance with any covenants or representations and warranties in any such financings which could result in reduced availability of such financings, an event of default under such financings, or could make other sources of financing unavailable to us. Any such event would have a material adverse impact on our business, results of operations and financial condition.

While we believe we have adequate capital resources to meet our current working capital and capital expenditure requirements, an economic downturn or an increase in our expenses could require us to seek additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans or plans to acquire additional technology.

Volatile economic conditions may not only limit our access to capital, but may also make it difficult for our customers and us to accurately forecast and plan future business activities, and they could cause businesses to slow spending on our products, which would delay and lengthen sales cycles. Furthermore, during challenging economic times, our customers may face issues gaining timely access to sufficient credit, which could result in an impairment of their ability to make timely payments to us. In addition, adverse economic conditions could also adversely impact our suppliers' ability to provide us with materials which would negatively impact on our business, financial condition, and results of operations.

We are a small company relative to our principal competitors, and our limited financial resources may limit our ability to develop and market our drug products.

Many companies, both public and private, including well-known pharmaceutical companies and smaller niche-focused companies, are developing products to treat many, if not all, of the diseases we are pursuing or are currently distributing drug products that directly compete with the drugs that we sell or that we intend to develop, market and distribute.

Competition for branded or proprietary drugs is less driven by price and is more focused on innovation in the treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies. We may not be successful in any or all of our current clinical studies; or if successful, and if one or more of our drug products is approved by the FDA, we may

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encounter direct competition from other companies who may be developing products for similar or the same indications as our drug products.

Companies that have products on the market or in research and development that target the same indications as our products include, among others, AstraZeneca plc, Bayer AG, Endo International plc, Eli Lilly and Company, Novartis International AG, Genentech, Inc. (Roche Holding AG), Bristol-Myers Squibb Company, Seattle Genetics, Inc., GlaxoSmithKline plc, Biogen Inc., OSI Pharmaceuticals, Inc. (Astellas Pharma Inc.), Cephalon, Inc. (Teva Pharmaceutical Industries Ltd.), Sanofi S.A., Pfizer, Inc., Merck & Co. Inc., Celgene Corporation, BiPar Sciences, Inc. (Sanofi S.A.), Sanofi Genzyme, Shire plc, AbbVie Inc., Poniard Pharmaceuticals, Inc., and Johnson & Johnson. These companies may be more advanced in the development of competing drug products or are more established in the market.

Many of our competitors are large and well-capitalized companies focusing on a wide range of diseases and drug indications, and have substantially greater financial, research and development, marketing, human and other resources than we do. Furthermore, large pharmaceutical companies have significantly more experience than we do in pre-clinical testing, human clinical trials and regulatory approval procedures, among other things. As a result, our competitors may be more successful than us in developing their products, obtaining regulatory approvals and marketing their products to consumers.

If actual future payments for allowances for discounts, returns, rebates and chargebacks exceed the estimates we made at the time of the sale of our products, including, without limitation, due to a change in the composition of our sales over time, our financial position, results of operations and cash flows may be materially and negatively impacted.

We recognize product revenue net of estimated allowances for discounts, returns, rebates and chargebacks. Such estimates require subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Based on industry practice, pharmaceutical companies, including us, have liberal return policies. Our FUSILEV, MARQIBO, and BELEODAQ customers are permitted to return purchased products beginning at its expiration date and within six months thereafter. Our EVOMELA customers are permitted to return purchased product beginning at six months prior to its expiration date, and within 12 months following its expiration date (as well as for overstock inventory, as determined by end-users). We authorize returns for damaged products and exchanges for expired products in accordance with our returned goods policy and procedures. Also, like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to hospitals, GPOs, pharmacies or other retail customers.

A chargeback is the difference between the price the wholesale customer (in our case, wholesalers/distributors) pays (wholesale acquisition cost) and the price that the wholesalers/distributor's customer pays for a product (contracted customer). Our products are subject to certain programs with federal government qualified entities whereby pricing on products is discounted to such entities and results in a chargeback claim to us. To the extent that our sales to discount purchasers, such as federal government qualified entities, increases, our chargebacks will also increase. There may be significant lag time between our original sale to the wholesaler and our receipt of the corresponding government chargeback claims from our wholesalers.

Our products are subject to state government-managed Medicaid programs, whereby rebates for purchases are issued to participating state governments. These rebates arise when the patient treated with our products is covered under Medicaid. Our calculations related to these Medicaid rebate accruals require us to estimate end-user and patient mix to determine which of our sales will likely be subject to these rebates. There is a significant time lag in us receiving these rebate notices (generally several months after our sale is made). Our estimates are based on our historical claims from participating state governments, as supplemented by management’s judgment.

Although we believe that we have sufficient allowances, actual results may differ significantly from our estimated allowances for discounts, returns, rebates and chargebacks. Changes in estimates and assumptions based upon actual results may have a material impact on our financial condition, results of operations and cash flows. Such changes to estimates will be made to the financial statements in the year in which the estimate is changed. In addition, our financial position, results of operations and cash flows may be materially and negatively impacted if actual future payments for allowances, discounts, returns, rebates and chargebacks exceed the estimates we made at the time of the sale of our products.

The marketing and sale of our products may be adversely affected by the marketing and sales efforts of third parties who sell our products or similar products outside of our territories.

We have only licensed the rights to develop and market our products in limited territories. Other companies market and sell the same products in other parts of the world. If, as a result of other companies' actions, negative publicity is associated with our products or similar products, our own efforts to successfully market and sell our products in our markets may be adversely impacted.

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We have engaged in, and may in the future engage in strategic transactions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.
We actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses. Any potential acquisitions or in-licensing transactions may entail numerous risks, including but not limited to:

- risks associated with satisfying the closing conditions relating to such transactions and realizing their anticipated benefits;
- increased operating expenses and cash requirements;
- difficulty in conforming standards, procedures and policies, business cultures and compensation structures;
- difficulty integrating acquired technologies, products and personnel with our existing business;
- difficulty conforming acquired operations, such as corporate and administrative functions, sales and marketing, or information technology and accounting systems with our existing business;
- diversion of management's attention in connection with both negotiating the acquisition or license and integrating the business, technology or product;
- retention of key employees
- uncertainties in our ability to maintain key business relationships of any acquired entities;
- strain on managerial and operational resources;
- exposure to regulatory, compliance and legal risks of the acquired entities;
- tax costs or inefficiencies associated with integrating operations;
- modifications to operating control standards to comply with the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder;
- difficulty coordinating geographically dispersed organizations;
- exposure to unforeseen liabilities of acquired companies or products or companies or products in which we invest; and
- potential costly and time-consuming litigation, including stockholder lawsuits.

As a result of these or other problems and risks, businesses, technologies or products we acquire or invest in or obtain licenses to may not produce the revenues, earnings or business synergies that we anticipated. In addition, acquired or licensed products may not perform as expected or we may not obtain necessary regulatory approvals on our anticipated timeline or at all.
As a result, we may incur higher costs and realize lower revenues than we had anticipated. We cannot assure you that any acquisitions or investments we have made or may make in the future will be completed or that, if completed, the acquired business, licenses, investments, products, or technologies will generate sufficient revenue to offset the negative costs or other negative effects on our business. Failure to effectively manage our growth through acquisition or in-licensing transactions could adversely affect our growth prospects, business, results of operations, financial condition, and cash flow.

In addition, in connection with acquisitions and in-licensing transactions, we may spend significant amounts of capital, issue dilutive securities, assume or incur significant debt obligations or contingent liabilities, and acquire intangible assets that could result in significant future amortization expense and write-offs. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Even if appropriate opportunities are available, we may not be able to successfully identify them or we may not have the financial resources necessary to pursue them, and if pursued, we may be unable to structure and execute transactions in on our anticipated timeframe, or at all. Other pharmaceutical companies, many of which may have substantially greater financial, marketing and sales resources than we do, compete with us for these opportunities.

Even if we are able to successfully identify and acquire complementary products, technologies or businesses, we cannot assure you that we will be able to successfully manage the risks associated with integrating acquired products, technologies or businesses or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing transaction. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions

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through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business. Additionally, actual costs and sales synergies, if achieved at all, may be lower than we expect and may take longer to achieve than we anticipate. Furthermore, the products of companies we acquire may overlap with our products or those of our customers, creating conflicts with existing relationships or with other commitments that are detrimental to the integrated businesses.

If we are unable to successfully integrate our acquisitions with our existing business, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock.

Our divestiture activities, including the Acrotech Transaction, may disrupt our ongoing business, may involve increased expenses and may present risks not contemplated at the time of the transactions.

As previously discussed, we have entered into an agreement with Acrotech to divest certain assets that no longer fit with our strategic direction. We may in the future engage in additional divestiture transactions. Divestitures generally involve significant risks and uncertainties, including, without limitation:

- our failure to effectively transfer contracts, facilities and employees to buyers;
- requirements that we indemnify buyers against certain liabilities and obligations;
- the possibility that we will become subject to third-party claims arising out of such divestitures;
- challenges in identifying and separating the intellectual property and data to be divested from the intellectual property and data that we wish to retain;
- our inability to reduce fixed costs previously associated with the divested assets;
- challenges in collecting the proceeds from any divestiture;
- disruption of our ongoing business and distraction of management; and
- loss of key employees who leave our Company as a result of a divestiture.

Because divestitures are inherently risky, our transactions, including the Acrotech Transaction, may not be successful and may, in some cases, harm our operating results or financial condition.

We may not be able to successfully or timely complete the Acrotech Transaction, which could materially impact the market price of our Company’s common stock, as well as our future business prospects and our financial condition, results of operations and cash flows.

On January 17, 2019, we entered into a definitive asset purchase agreement with Acrotech for the sale of our FDA-approved product portfolio. The Acrotech Transaction may not be completed, or may not be completed in the timeframe, on the terms or in the manner currently anticipated. The completion of the Acrotech Transaction is subject to the satisfaction or waiver of customary closing conditions, such as receipt of certain regulatory approvals. There can be no assurance that these conditions will be satisfied or waived, or that other events will not intervene to delay or result in the failure to close the Acrotech Transaction.

In addition, while we believe that we will receive all required approvals for the Acrotech Transaction and Acrotech and we have agreed to use reasonable best efforts, subject to certain limitations, to obtain such approvals, there can be no assurance as to the receipt or timing of receipt of these approvals. As a condition to approving the Acrotech Transaction, governmental authorities may impose conditions, terms, obligations or restrictions or require divestitures or place restrictions on the conduct of the business after consummation of the Acrotech Transaction, including those which Acrotech may not be required to accept pursuant to the terms of the executed asset purchase agreement. A substantial delay in obtaining any required authorizations or approvals or the imposition of unfavorable terms, conditions or restrictions contained in such authorizations or approvals, could prevent the completion of the Acrotech Transaction or have an adverse effect on the anticipated benefits of the Acrotech Transaction. If the Acrotech Transaction is not consummated in a timely manner or at all, our ongoing business may be materially adversely affected, including without limitation, as follows:

- we may experience negative reactions from financial markets and our stock price could decline;
- we may experience negative reactions from employees, customers, suppliers or other third parties;

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- our management's focus would have been diverted from pursuing other valuable opportunities; and
- the costs of completing the Acrotech Transaction may be higher than anticipated and, in any event, would be borne entirely by us.

Our collaborations with outside scientists may be subject to change, which could limit our access to their expertise.
We work with scientific advisors and collaborators at research institutions. These scientists are not our employees and may have other commitments that would limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services, which could negatively impact our research and development activities.

We may rely on CROs and other third parties to conduct clinical trials and, in such cases, we are unable to directly control the timing, conduct and expense of our clinical trials.
We may rely, in full or in part, on third parties to conduct our clinical trials. In such situations, we have less control over the conduct of our clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be challenging or impossible to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

Because we have obtained accelerated approval to market FOLOTYN, BELEODAQ and MARQIBO, we are subject to
ongoing regulatory obligations and review, including completion of the post-approval requirements.

FOLOTYN and BELEODAQ were approved for the treatment of patients with relapsed or refractory PTCL, and MARQIBO was approved for the treatment of adult patients with Ph-ALL in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies, under the FDA's accelerated approval regulations. These provisions allow the FDA to approve products for cancer or other serious or life threatening diseases based on initial positive data from clinical trials. Under these provisions, we are subject to certain post-approval requirements. Specifically, we are required to conduct Phase 1 dose escalating studies and a Phase 3 randomized study for FOLOTYN and BELEODAQ in patients with PTCL. The FDA also required that we conduct two Phase 1 trials to assess whether FOLOTYN poses a serious risk of altered drug levels resulting from organ impairment as well as additional post-marketing studies with BELEODAQ. For MARQIBO, we are required to conduct a randomized Phase 3 study in patients over 60 years of age with newly diagnosed ALL. Negative or inconclusive results in these additional trials could negatively impact, or preclude altogether, our ability to continue commercializing FOLOTYN, BELEODAQ OR MARQIBO. Failure to complete the studies or adhere to the timelines established by the FDA could result in penalties, including fines or withdrawal of FOLOTYN, BELEODAQ, and/or MARQIBO from the market, which could materially adversely affect our business.

The FDA may also initiate proceedings to withdraw approval or request that we voluntarily withdraw these drugs from the market if our Phase 3 studies fail to confirm clinical benefit. Further, the FDA may require us to amend the package inserts for these drugs, including by strengthening the warnings and precautions section or institute a REMS based on the results of these studies or clinical experience. Later discovery of previously unknown problems with our proposed products, including unanticipated clinical trial results or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties, which could materially adversely affect our business. We are also subject to additional, continuing post-approval regulatory obligations, including the possibility of additional clinical studies required by the FDA, safety reporting requirements and regulatory oversight of the promotion and marketing of these drugs.

We may have conflicts with our third-party development partners that could delay or prevent the development or commercialization of our drug products.

We may have conflicts with our third-party development partners, such as conflicts concerning the interpretation of pre-clinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our third-party development partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our drug product, and in turn prevent us from generating revenues from such drug product:

- unwillingness on the part of a third-party development partner to pay us milestone payments or royalties that we believe are due to us under a collaboration;
- uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;
- unwillingness to cooperate in the manufacture of the product, including providing us with product data or materials;
- unwillingness to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;
- initiation of litigation or alternative dispute resolution options by either party to resolve the dispute;
- attempts by either party to terminate the collaboration;
- our ability to maintain or defend our intellectual property rights may be compromised by our partner’s acts or omissions;
- a third-party development partner may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- a third-party development partner may change the focus of its development and commercialization efforts due to internal reorganizations, mergers, consolidations or otherwise;
- unwillingness to fully fund or commit sufficient resources to the testing, marketing, distribution or development of our products;
- unwillingness or inability to fulfill their obligations to us due to the pursuit of alternative products, conflicts of interest that arise or changes in business strategy or other business issues; and/or
- we may not be able to guarantee supplies of development or marketed products.

Given these risks, it is possible that any collaborative arrangements which we have or could enter into may not be successful.

From time to time we may need to in-license patents and proprietary technologies from third parties, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our drug products. As an example, it may be necessary to use a third party’s proprietary technology to reformulate one of our drug products in order to improve upon the capabilities of the drug product. If we are unable to timely obtain these licenses on reasonable terms, or at all, our ability to commercially exploit our drug products may be inhibited or prevented.

The potential size of the market for our drug products is uncertain.

We often provide estimates of the number of people who suffer from the diseases that our drugs are targeting. However, there is limited information available regarding the actual size of these patient populations. In addition, it is uncertain whether the results from previous or future clinical trials of drug products will be observed in broader patient populations, and the number of patients who may benefit from our drug products may be significantly smaller than the estimated patient populations.

Our collaboration partner, Mundipharma International Corporation Limited, or Mundipharma, may not be successful in obtaining regulatory approval for FOLOTYN in a number of countries and FOLOTYN is subject to numerous complex regulatory requirements.

Our collaboration partner, Mundipharma, may not be successful in obtaining regulatory approval for FOLOTYN in a number of countries and FOLOTYN is subject to numerous complex regulatory requirements. Failure to comply with, or

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changes to, the regulatory requirements that are applicable to FOLOTYN outside the U.S. may result in a variety of consequences, including the following:

- restrictions on FOLOTYN or our manufacturing processes;
- warning letters;
- withdrawal of FOLOTYN from the market;
- voluntary or mandatory recall of FOLOTYN;
- fines against us;
- suspension or withdrawal of regulatory approvals for FOLOTYN;
- suspension or termination of any of our ongoing clinical trials of FOLOTYN;
- refusal to permit import or export of FOLOTYN;
- refusal to approve pending applications or supplements to approved applications that we submit;
- denial of permission to file an application or supplement in a jurisdiction;
- product seizure; and/or
- injunctions, consent decrees, or the imposition of civil or criminal penalties against us.

The occurrence of one or more of the above-mentioned actions could have a material and adverse impact on our business, financial condition, results of operations and cash flows.

Changes in our effective income tax rate could adversely affect our profitability.

We are subject to federal and state income taxes in the U.S. and our tax liabilities are dependent upon the distribution of income among these different jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to:

- interpretations of existing tax laws;
- the accounting for stock options and other share-based compensation;
- changes in tax laws and rates;
- future levels of research and development spending;
- changes in accounting standards;
- changes in the mix of earnings in the various tax jurisdictions in which we operate;
- the outcome of examinations by the Internal Revenue Service and tax regulators in other jurisdictions;
- the accuracy of our estimates for unrecognized tax benefits;
- realization of deferred tax assets; and
- changes in overall levels of pre-tax earnings.

The impact on our income taxes resulting from the above-mentioned factors may be significant and could have an impact on our profitability.

Our sales and operations are subject to the risks of doing business internationally.

We have a presence in international markets subjecting us to many risks that could adversely affect our business and revenues, such as:

- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- collectability of accounts receivable;
- fluctuations in foreign currency exchange rates, in particular the recent strength of the U.S. dollar versus foreign currencies that has adversely impacted our revenues and net income;

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- difficulties in staffing and managing international operations;
- the imposition of governmental controls;
- less favorable intellectual property or other applicable laws;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the far-reaching anti-bribery and anti-corruption legislation in the U.K., including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- compliance with complex import and export control laws;
- restrictions on direct investments by foreign entities and trade restrictions;
- greater political or economic instability; and
- changes in tax laws and tariffs.

Failure to comply with domestic or foreign laws applicable to our international operations could result in various adverse consequences, including: possible delay in approval or refusal to approve a product; recalls, seizures or withdrawal of an approved product from the market; disruption in the supply or availability of our products or suspension of export or import privileges; the imposition of civil or criminal sanctions; the prosecution of executives overseeing our international operations; and damage to our reputation. Any significant impairment of our ability to sell products outside of the U.S. could adversely impact our business and financial results.

If our employees, representatives or agents fail to comply with regulatory standards and requirements, we could be exposed to financial, reputational or other harm.

Our business and financial condition could be adversely affected to the extent that our employees, representatives or agents fail to:

- comply with FDA regulations or similar regulations of similar regulatory authorities in other countries;
- provide accurate information to the FDA or similar regulatory authorities in other countries;
- comply with manufacturing standards we, the FDA or similar authorities in other countries have established;
- comply with federal and state healthcare fraud and abuse laws and regulations or similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- comply with the provisions of the Foreign Corrupt Practices Act, or the FCPA; or
- report financial information or clinical or preclinical data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by our employees, representatives or agents could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, even if we are ultimately exonerated, we could incur substantial costs and expenses in an effort to defend ourselves or to assert our rights and any such actions could result in reputational harm to us or have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Earthquakes or other natural or man-made disasters and business interruptions could adversely affect our business.

Our operations are vulnerable to interruption by fire, power loss, floods, telecommunications failure and other events beyond our control. In addition, our operations are susceptible to disruption as a result of natural disasters such as earthquakes. So far we have never experienced any significant disruption of our operations as a result of earthquakes or other natural or

man-made disasters. Although we have a contingency recovery plan, any significant business interruption could cause delays in our drug development and future sales and harm our business.

A breakdown or breach of our information technology systems and cybersecurity efforts could subject us to liability, reputational damage or interrupt the operation of our business.

We rely upon our sophisticated information technology systems and infrastructure to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property), and we deploy and operate an array of technical and procedural controls to maintain the confidentiality and integrity of such confidential information. Data privacy breaches by those who access our systems, whether by employees or others, may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, employees, customers or other business partners, may be exposed to unauthorized persons or to the public or otherwise used for unauthorized purposes.We could also experience a business interruption, noncompliance with data privacy laws, theft of confidential information, or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Such attacks are of ever-increasing levels of sophistication, frequency and intensity, and have become increasingly difficult to detect. There can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems (or that of our third-party providers). Any such interruption or breach of our systems or improper use of confidential data could adversely affect our business operations, financial condition, and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us.

We have a history of net losses. We expect to continue to incur net losses and may not achieve profitability for some time, if at all.

We have incurred net losses in each of the years ended December 31, 2018, 2017, and 2016, respectively. We have incurred these losses principally from costs incurred in our research and development programs and from our selling, general and administrative expenses. We expect that in the foreseeable future we will continue to spend substantial amounts on research and development to further develop and potentially commercialize poziotinib and ROLONTIS. Accordingly, we expect to continue to incur net losses in the foreseeable future and may not achieve profitability for some time, if at all. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

Risks Related to Our Industry

If we are unable to adequately protect our technology or enforce our patent rights, our business could suffer.

Our success with the drug products that we develop will depend, in part, on our ability and the ability of our licensors to obtain and maintain patent protection for these products. We currently have a number of U.S. and foreign patents issued and pending, however, we primarily rely on patent rights licensed from others. Our license agreements generally give us the right and/or obligation to maintain and enforce the subject patents. We may not receive patents for any of our pending patent applications or any patent applications we may file in the future. If our pending and future patent applications are not allowed or, if allowed and issued into patents, if such patents and the patents we have licensed are not upheld in a court of law, our ability to competitively exploit our drug products would be substantially harmed. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by our competitors, in which case our ability to commercially exploit these products may be diminished.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical and biotechnology patents has emerged to date in the U.S. The laws of many countries may not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Filing, prosecuting and defending patents on all our products or product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions not covered by any of our patent claims or other intellectual property rights.

Changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. We do not know whether any of our patent applications will result in the issuance of any patents, and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we license from others.

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The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- in certain jurisdictions, we or our licensors might not have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative product candidates or duplicate any of our or our licensors' product candidates;
- our or our licensors' pending patent applications may not result in issued patents;
- our or our licensors' issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
- others may design around our or our licensors' patent claims to produce competitive products that fall outside the scope of our or our licensors' patents;
- we may not develop or in-license additional patentable proprietary technologies related to our product candidates; or
- the patents of others may prevent us from marketing one or more of our product candidates for one or more indications that may be valuable to our business strategy.

An issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Patents issued to us and our licensors and those that may be issued in the future to us and our licensors may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing related product candidates or could limit the length of the term of patent protection of our product candidates. Our competitors may independently develop similar technologies. In addition, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We also rely on trade secret protection and contractual protections for our unpatented and proprietary drug compounds. Trade secrets are difficult to protect. While we enter into confidentiality agreements with our employees, consultants and others, these agreements may not successfully protect our trade secrets or other confidential and proprietary information. It is possible that these agreements will be breached, or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Likewise, although we conduct periodic trade secret audits of certain partners, vendors and contract manufacturers, these trade secret audits may not protect our trade secrets or other confidential and proprietary information. It is possible that despite having certain trade secret audit security measures in place, trade secrets or other confidential and proprietary information may still be leaked or disclosed to a third party. It is also possible that our trade secrets will become known or independently developed by our competitors.

We also rely on trademarks to protect the names of our products. These trademarks may be challenged by others. If we enforce our trademarks against third parties, such enforcement proceedings may be expensive. Some of our trademarks, including ZEVALIN are owned by, or assignable to, our licensors and, upon expiration or termination of the applicable license agreements, we may no longer be able to use these trademarks. If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our patents and trademarks, our business, financial condition and prospects could suffer.

Intellectual property rights are complex and uncertain and therefore may subject us to infringement claims.

The patent positions related to our drug products are inherently uncertain and involve complex legal and factual issues. We believe that there is significant litigation in the pharmaceutical and biotechnology industry regarding patent and other intellectual property rights. A patent does not provide the patent holder with freedom to operate in a way that infringes the patent rights of others. We may be accused of patent infringement at any time. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the U.S.

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Although we are not aware of any infringement by any of our drug products on the rights of any third party, there may be third party patents or other intellectual property rights, including trademarks and copyrights, relevant to our drug products of which we are not aware. Third parties may assert patent or other intellectual property infringement claims against us, or our licensors and collaborators, with products. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and result in the loss of our use of the intellectual property that is critical to our business strategy.

In the event that we or our partners are found to infringe any valid claim of a patent held by a third party, we may, among other things, be required to:

- pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;
- cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;
- expend significant resources to redesign our products so they do not infringe others' patent rights, which may not be possible;
- discontinue manufacturing or other processes incorporating infringing technology; or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

Rapid bio-technological advancement may render our drug products obsolete before we are able to recover expenses incurred in connection with their development. As a result, some of our drug products may never become profitable.

The pharmaceutical industry is characterized by rapidly evolving biotechnology. Biotechnologies under development by other pharmaceutical companies could result in treatments for diseases and disorders for which we are developing our own treatments. Several other companies are engaged in the research and development of compounds that are similar to our efforts. A competitor could develop a new biotechnology, product or therapy that has better efficacy, a more favorable side-effect profile or is more cost-effective than one or more of our drug products and thereby cause our drug products to become commercially obsolete. Some of our drug products may become obsolete before we recover the expenses incurred in their development. As a result, such products may never become profitable.

Failure to obtain regulatory approval outside the U.S. will prevent us from marketing our product candidates abroad.

We intend to market certain of our existing and future product candidates in and outside of the U.S. In order to market our existing and future product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals according to the applicable domestic laws and regulations. We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval as well as other risks specific to the jurisdictions in which we may seek approval. Approval by the FDA does not guarantee approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not necessarily ensure approval by regulatory authorities in other countries.

A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for foreign regulatory approvals and may not receive necessary approvals to commercialize our existing and future product candidates in any market.

Competition for patients in conducting clinical trials may prevent or delay product development and strain our limited financial resources.

Many pharmaceutical companies are conducting clinical trials involving patients with the disease indications that our drug products target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment

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may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

Even after we receive regulatory approval to market our drug products, the market may not be receptive to our drug products upon their commercial introduction, which would negatively impact our ability to achieve profitability.

Our drug products may not gain market acceptance among physicians, patients, healthcare payers and the medical community. The degree of market acceptance of any approved drug products will depend on a number of factors, including:

- the effectiveness of the drug product;
- the prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the price of the drug product, both in absolute terms and relative to alternative treatments; and
- sufficient third-party coverage and reimbursement.

If our drug products receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payers and patients, we may not generate drug product revenues sufficient to attain profitability.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies, such as the CMS, promulgate regulations, and issue guidelines, directly applicable to us and to our products. In addition, third parties such as professional societies, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations may relate to such matters as utilization, dosage, route of administration and use of related therapies and coverage and reimbursement of our products by government and private payers. Third-party organizations like the above have in the past made recommendations about our products. Recommendations or guidelines that are followed by patients and healthcare providers could result in decreased utilization and/or dosage of our products, any of which could adversely affect our product sales and operating results materially.

The sale of our products is subject to regulatory approvals, and our business is subject to extensive regulatory requirements, and if we are unable to obtain regulatory approval for our product candidates, or if we fail to comply with governmental regulations, we will be limited in our ability to commercialize our products and product candidates and/or subject us to penalties.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Obtaining regulatory approval of a new drug is an uncertain, lengthy and expensive process, and success is never guaranteed. Despite the time, resources and effort expended, failure can occur at any stage. During each stage, there is a substantial risk that we will encounter serious obstacles that will further delay us and add substantial expense, that we will develop a product with limited potential for commercial success, or that we will be forced to abandon a product in which we have invested substantial amounts of time and money. These risks may include failure of the product candidate in preclinical studies, difficulty enrolling patients in clinical trials, clinical trial holds or other delays in completing clinical trials, delays in completing formulation and other testing and work necessary to support an application for regulatory approval, adverse reactions to the product candidate or other safety concerns, insufficient clinical trial data to support the safety or efficacy of the product candidate or to differentiate our product candidate from competitors, an inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-effective manner, and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured. In order to receive approval from the FDA for each product candidate, we must demonstrate that the new drug product is safe and effective for its intended use and that the manufacturing processes for the product candidate comply with the FDA’s cGMPs, which include requirements related to production processes, quality control and assurance, and recordkeeping. The FDA has substantial discretion in the approval process for human medicines.

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The FDA and comparable agencies in foreign countries impose many requirements related to the drug development process through lengthy and rigorous clinical testing and data collection procedures, and other costly and time consuming compliance procedures. While we believe that we are currently in compliance with applicable FDA regulations, if we or our partners, the CROs or CMOs with which we have relationships, fail to comply with the regulations applicable to our clinical testing, the FDA may delay, suspend or cancel our clinical trials, or the FDA might not accept the test results. The FDA, an institutional review board, third party investigators, any comparable regulatory agency in another country, or we, may suspend clinical trials at any time if the trials expose subjects participating in such trials to unacceptable health risks. Further, human clinical testing may not show any current or future drug product to be safe and effective to the satisfaction of the FDA or comparable regulatory agencies, or the data derived from the clinical tests may be unsuitable for submission to the FDA or other regulatory agencies. Once we submit an application seeking approval to market a drug product, the FDA or other regulatory agencies may not issue their approvals on a timely basis, if at all. If we are delayed or fail to obtain these approvals, our business and prospects may be significantly damaged. In addition, any regulatory approvals that we receive for our future product candidates may also be subject to limitations on the indicated uses for which they may be marketed or contain requirements for potentially cost prohibitive post-marketing follow-up studies and surveillance to monitor the safety and efficacy of the product.
If we obtain regulatory approval for our drug products, we, our partners, our manufacturers, and other contract entities will continue to be subject to extensive requirements by a number international, federal, state and local agencies. These regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, effectiveness, labeling, storage, quality control, adverse event reporting, record keeping, approval, advertising and promotion of our future products. The FDA and foreign regulatory authorities strictly regulate the promotional claims that may be made about prescription products and our product labeling, advertising and promotion is subject to continuing regulatory review. Physicians may nevertheless prescribe our product to their patients in a manner that is inconsistent with the approved label, or that is off-label. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and if we are found to have improperly promoted off-label uses we may be subject to significant sanctions, civil and criminal fines and injunctions prohibiting us from engaging in specified promotional conduct.

In addition, the Company is subject to the federal False Claims Act, or the FCA, as well as the false claims laws of several states. The FCA prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Suits filed under the FCA, known as "qui tam" actions, can be brought by any private individual on behalf of the government and such private individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The filing of qui tam actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend a FCA action. When an entity is determined to have violated the FCA, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states also have enacted laws modeled after the federal FCA.

In order to comply with these laws, we have implemented a compliance program designed to identify, prevent and mitigate risk through the implementation of compliance policies and training systems. We cannot guarantee that our compliance program will be sufficient or effective, that our employees will comply with our policies, that our employees will notify us of any violation of our policies, that we will have the ability to take appropriate and timely corrective action in response to any such violation, or that we will make decisions and take actions that will necessarily limit or avoid liability for whistleblower claims that individuals, such as employees or former employees, may bring against us or that governmental authorities may prosecute against us based on information provided by individuals. If we are found to be in violation of any of the laws and regulations described above or other applicable state and federal healthcare laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, imprisonment, diminished profits and future earnings, exclusion from government healthcare reimbursement programs such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and/or the curtailment or restructuring of our operations, any of which could have a material adverse effect on our business, results of operations and growth prospects. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal, state and foreign healthcare laws is costly and time-consuming for our management.

The discovery of previously unknown safety risks with drug products approved to go to market or on the market may raise costs, prevent us from marketing such products, or require us to change the labeling of our products or take other potentially limiting or costly actions.

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The later discovery of previously unknown safety risks with our commercial products may result in the imposition of restrictions on distribution or use of the drug product, including withdrawal from the market. The FDA may revisit and change its prior determinations with regard to the safety and efficacy of our products. If the FDA's position changes, we may be required to change our labeling or to cease manufacture and marketing of the products at issue. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale or recall any of our products if concerns about their safety or effectiveness develop.

The FDA has significant authority to take regulatory actions in the event previously unknown safety risks are identified or if data suggest that our products may present a risk to safety. For example, the FDA may:

- require sponsors of marketed products to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk;
- mandate labeling changes to products, at any point in a product's lifecycle, based on new safety information; and
- require sponsors to implement a REMS for a product which could include a medication guide, patient package insert, a communication plan to healthcare providers, or other elements the FDA deems necessary to assure safe use of the drug (either prior to approval or post-approval as necessary).

Failure to comply with a REMS could result in significant civil monetary penalties or other administrative actions by the FDA. Further, regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain or maintain approval of our existing or future products or require significant additional costs to obtain or maintain such approvals.

Legislative or regulatory reform of the healthcare system and pharmaceutical industry related to pricing, coverage or reimbursement may hurt our ability to sell our products profitably or at all.

Our ability to commercialize any products successfully will depend in part on the availability of coverage and reimbursement from third-party payers such as government authorities, private health insurers, health maintenance organizations including pharmacy benefit managers and other health care-related organizations, in both the U.S. and foreign markets. Even if we succeed in bringing one or more products to market, the amount reimbursed for our products may be insufficient to allow us to compete effectively and could adversely affect our profitability. Coverage and reimbursement by governmental and other third-party payers may depend upon a number of factors, including a governmental or other third-party payer's determination that use of a product includes but is not limited to:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from each third-party and governmental payer is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payer. We may not be able to provide data sufficient to obtain coverage and adequate reimbursement.

In both the U.S. and certain foreign jurisdictions, there have been and may continue to be a number of legislative and regulatory proposals related to coverage and reimbursement that could impact our ability to sell our products profitably. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the Healthcare Reform Law, was signed into law on March 30, 2010. The Healthcare Reform Law substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacted the pharmaceutical industry. The Healthcare Reform Law included, among other things, an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, revisions to the definition of "average manufacturer price" for reporting purposes, increases in the amount of rebates owed by drug manufacturers under the Medicaid Drug Rebate Program, expansion of the

340B drug discount program that mandates discounts to certain hospitals, community centers and other qualifying providers, and changes to affect the Medicare Part D coverage gap, or “donut hole.” The full effects of these provisions will become apparent as these laws are implemented and the CMS and other agencies issue

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applicable regulations or guidance as required by the Healthcare Reform Law. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

The high cost of pharmaceuticals continues to generate substantial government interest. It is possible that proposals will be adopted, or existing regulations that affect the coverage and reimbursement of pharmaceutical and other medical products may change, that may impact our products currently on the market and any of our products approved for marketing in the future. Cost control initiatives could decrease the price that we receive for any of our products or product candidates. In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the coverage and reimbursement status of newly-approved pharmaceutical products. Future developments may require us to decrease the price that we charge for our products, thereby negatively affecting our financial results.

In some foreign countries, particularly in the EU, prescription drug pricing is subject to governmental control. Drug pricing may be made against a reference price set by the healthcare providers as a measure for healthcare cost containment. Pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. If coverage and reimbursement of our products are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels for the purpose of adoption of these products in the national health services in these jurisdictions, our profitability will likely be negatively affected.

If we market products in a manner that violates federal or state health care fraud and abuse laws, we may be subject to civil or criminal penalties, including exclusion from participation in government health care programs.

As a pharmaceutical company, even though we do not provide healthcare services or receive payments directly from or bill directly to Medicare, Medicaid or other third-party payers for our products, we are subject to certain federal and state healthcare laws and regulations pertaining to fraud and abuse applicable to our business. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. government.

The laws that may affect our ability to operate include the federal health care program Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally-financed health care programs. This statute applies to arrangements between pharmaceutical manufacturers and prescribers, purchasers and formulary managers. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Drug Rebate Program. Federal enforcement agencies have also recently scrutinized product and patient assistance programs, including manufacturer reimbursement support services as well as relationships with specialty pharmacies. If our past or present operations are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal health care programs and/or the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

The Health Insurance Portability and Accountability Act of 1996 also created prohibitions against health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians. The federal "Sunshine" requirements pursuant to the Healthcare Reform Law imposed new requirements on (i) manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors and teaching hospitals), and (ii) applicable manufacturers and GPOs to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members. Manufacturers were required to begin data collection on August 1, 2013 and to report such data to the government by March 31, 2014 and by the 90th calendar day of each year thereafter. Failure to submit the required information may result in civil monetary penalties of up an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations.

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals, as amended. Certain states also mandate the tracking and reporting of gifts, compensation, and other remuneration paid by us to physicians and other health care providers. We have adopted and implemented a compliance program designed to comply with applicable federal, state and local requirements wherever we operate, including but not limited to the laws of the states of California and Nevada.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Compliance with these laws and regulations is costly and materially affects our business. Among other effects, health care regulations substantially increase the time, difficulty and costs incurred in obtaining and maintaining approval to market newly developed and existing products. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We expect compliance with these regulations to require significant technical expertise and capital investment to ensure the reasonable design and operation of an effective compliance program.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The Healthcare Reform Law also made several important changes to the federal Anti-Kickback Statute, false claims laws, and health care fraud statute by weakening the intent requirement under the anti-kickback and health care fraud statutes that may make it easier for the government, or whistleblowers to charge such fraud and abuse violations. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. In addition, the Healthcare Reform Law increases penalties for fraud and abuse violations. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may incur significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and negatively impact our financial results.

We may be involved in additional lawsuits to defend or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe upon our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S. or in Europe.

Furthermore, because of the substantial amount of discovery that could be required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our stock price.

We may be subject to product liability claims, and may not have sufficient product liability insurance to cover any such claims, which may expose us to substantial liabilities.

We may be held liable if any product we or our partners develop causes injury or is found otherwise unsuitable during product testing, manufacturing, clinical trials, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our product candidates, injury to our reputation, withdrawal of patients from our clinical trials, substantial monetary awards to trial participants and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health care providers, competing pharmaceutical companies or others selling or testing our products. Although we currently carry product liability insurance that we believe is adequate, it is possible that this coverage will be insufficient to protect us from future claims. Additionally, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. Failure to maintain sufficient insurance coverage could have a material adverse effect on our business, prospects and results of operations if claims are made that exceed our coverage.

On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and financial condition.

We could be adversely affected by violations of the FCPA, and other worldwide anti-bribery laws.

The FCPA prohibits U.S. companies and their respective representatives from offering, promising, authorizing, or making improper payments to foreign officials for the purpose of obtaining or retaining business abroad. In many countries, the health care professionals we regularly interact with meet the definition of a foreign government official for purposes of the FCPA. We have policies and procedures in place to ensure that we comply with the FCPA and similar laws; however, there is no assurance that such policies and procedures will protect us against liability under the FCPA or related laws for actions taken by our employees and intermediaries with respect to our business. Failure to comply with the FCPA and related laws could disrupt our business and lead to criminal and civil penalties including fines, suspension of our ability to do business with the federal government and denial of government reimbursement of our products, which could result in a material adverse impact on our business, financial condition, results of operations and cash flows. We could also be adversely affected by any allegation that we violated such laws.

The use of hazardous materials, including radioactive and biological materials, in our research and development and commercial efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.

Our research and development, manufacturing (including a radio labeling step for ZEVALIN) and administration of our drugs involves the controlled use of hazardous materials, including chemicals, radioactive and biological materials, such as radioactive isotopes. We are subject to federal, state, local and foreign environmental laws and regulations governing, among other matters, the handling, storage, use and disposal of these materials and some waste byproducts. We cannot completely eliminate the risk of contamination or injury from these materials and we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for environmental cleanup and removal. Currently the costs of complying with such federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts.

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Risks Related to Our Common Stock

Future issuances of our common stock or instruments convertible or exercisable into our common stock, may materially and adversely affect the price of our common stock and cause dilution to our existing stockholders.

We may obtain additional funds through public or private debt or equity financings in the near future. If we issue additional shares of common stock or instruments convertible into common stock, it may materially and adversely affect the price of our common stock. In the past, we have issued shares of common stock pursuant to at-the-market-issuance sales agreements and we may do so in the future. Certain issuances by us of equity securities may be at or below the prevailing market price of our common stock and may have a dilutive impact on our existing stockholders. In addition, future exercises of some or all of our outstanding options, warrants, or other rights may likewise dilute the ownership interests of our stockholders, and any sales in the public market of any shares of our common stock issuable upon such conversion or exercise, or the perception that such sales may occur, could adversely affect the prevailing market price of our common stock. These issuances or other dilutive issuances would also cause our per share net income, if any, to decrease in future periods.

Further, as of December 31, 2018, an aggregate 5.0 million shares of common stock were issuable pursuant to the exercise of outstanding options and the vesting of restricted stock awards and units. Further, 17.6 million shares of common stock were reserved for future issuance under our equity compensation plans.

We are subject to the risks of securities and related litigation, which may expose us to substantial liabilities and could seriously harm our business.

We may be subject to the risk of securities litigation and derivative actions from time to time as a result of being publicly traded, including the remaining unresolved actions set forth in “Item 3. Legal Proceedings.” There can be no assurance that any settlement or liabilities in such actions or any future lawsuits or claims against us would be covered or partially covered by our insurance policies, which could have a material adverse effect on our earnings in one or more periods. While we and our Board of Directors deny the allegations of wrongdoing against us in the unresolved actions initiated against us, there can be no assurance as to the ultimate outcome or timing of their resolutions. In addition to the potential costs and liabilities, securities litigation could divert management’s attention and resources, which could seriously harm our business.

The market price and trading volume of our common stock fluctuate significantly and could result in substantial losses for individual investors.

The stock market from time to time experiences significant price and trading volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price and trading volume of our common stock to decrease. In addition, the market price and trading volume of our common stock is often highly volatile.

Factors that may cause the market price and volume of our common stock to decrease include, among other things:

- recognition on up-front licensing or other fees or revenues;
- payments of non-refundable up-front or license fees, or payment for cost-sharing expenses, to third parties;
- adverse results or delays in our clinical trials;
- fluctuations in our results of operations;
- timing and announcements of our technological innovations or new products or those of our competitors;
- developments concerning any strategic alliances or acquisitions we may enter into;
- announcements of FDA non-approval of our products, or delays in the FDA or other foreign regulatory review processes or actions;
- changes in recommendations or guidelines of government agencies or other third parties regarding the use of our products;
- adverse actions taken by regulatory agencies with respect to our drug products, clinical trials, manufacturing processes or sales and marketing activities;

- concerns about our products being reimbursed;

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- any lawsuit involving us or our products;
- developments with respect to our patents and proprietary rights;
- public concern as to the safety of products developed by us or others;
- regulatory developments in the U.S. and in foreign countries;
- changes in stock market analyst recommendations regarding our common stock or lack of analyst coverage;
- the pharmaceutical industry generally and general market conditions;
- failure of our results of operations to meet the expectations of stock market analysts and investors;
- sales of our common stock by our executive officers, directors and significant stockholders or sales of substantial amounts of our common stock generally;
- changes in accounting principles; and
- loss of any of our key scientific or management personnel.

Also, certain dilutive securities such as warrants can be used as hedging tools which may increase volatility in our stock and cause a price decline. While a decrease in market price could result in direct economic loss for an individual investor, low trading volume could limit an individual investor's ability to sell our common stock, which could result in substantial economic loss as well. From January 2, 2018 through February 21, 2019, the closing price of our common stock ranged between $6.39 and $24.82, and the daily trading volume was as high as 12.4 million shares and as low as 0.5 million shares.

Following periods of volatility in the market price of a company's securities, a securities class action litigation may be instituted against that company. Regardless of their merit, these types of lawsuits generally result in substantial legal fees and management's attention and resources being diverted from the operations of a business.

Provisions of our charter, and bylaws may make it more difficult for someone to acquire control of us or replace current management even if doing so would benefit our stockholders, which may lower the price an acquirer or investor would pay for our stock.

Provisions of our certificate of incorporation and bylaws, both as amended, may make it more difficult for someone to acquire control of us or replace our current management. These provisions include:

- the ability of our Board of Directors to amend our bylaws without stockholder approval;
- the inability of stockholders to call special meetings;
- the ability of members of the Board of Directors to fill vacancies on the Board of Directors;
- the inability of stockholders to act by written consent, unless such consent is unanimous; and
- the establishment of advance notice requirements for the nomination of candidates for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions may make it more difficult for stockholders to take certain corporate actions and could delay, discourage or prevent someone from acquiring our business or replacing our current management, even if doing so would benefit our stockholders. These provisions could limit the price that certain investors might be willing to pay for shares of our common stock.

Our failure to establish and maintain effective internal control over financial reporting could result in material misstatements in our financial statements, our failure to meet our reporting obligations and cause investors to lose confidence in our reported financial information, which in turn could cause the trading price of our common stock to decline.

The results of our periodic management evaluations and annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting are required by the Sarbanes-Oxley Act of 2002. Any failure to maintain enhanced monitoring controls and improved detection and communication of financial misstatements across all levels of the organization could result in (i) material weaknesses, (ii) material misstatements in our financial statements, requiring restatements of our previously-filed financial statements, and (iii) cause us to fail to meet our timely reporting and debt compliance obligations.

These outcomes could cause us to lose public confidence, and could cause the trading price of our common stock to decline. For further information regarding our controls and procedures, see Item 9A. Controls and Procedures.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease 12,000 square feet for our principal executive office in Henderson, Nevada under a non-cancelable operating lease expiring October 31, 2021, and we lease 56,000 square feet for our administrative and research and development facility in Irvine, California under a non-cancelable operating lease expiring July 31, 2022. We also lease administrative space in Westlake Village, California; Westminster, Colorado; and Mumbai, India. We believe that these leased facilities are adequate to meet our current and planned business needs.

ITEM 3. LEGAL PROCEEDINGS

From time-to-time, we are involved with various legal matters arising from the ordinary course of operating our publicly-traded pharmaceutical business. These legal matters may include product liability claims, intellectual property claims, employment practices claims, shareholder claims, among other general claims. We record liability provisions to our financial statements for such matters when it is both: (1) probable that a payment will be made to the claimant, and (2) we can reasonably estimate the payment amount, given all available information.

Our legal accrual assessments are performed at least quarterly, and are adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to each particular case. Although litigation is inherently unpredictable, we do not believe that individually or in the aggregate, these claims will have a material adverse effect on our consolidated results of operations, cash flows, or financial condition.

Certain of our legal proceedings are discussed in Note 17(g), "Financial Commitments & Contingencies and License Agreements," to our accompanying Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is traded on the NASDAQ Global Select Market under the symbol “SPPI.”

On February 21, 2019, the closing price of our common stock on the NASDAQ Global Select Market was $11.57 per share, and there were 156 holders of record of our common stock.

During the year ended December 31, 2018, we purchased and retired an aggregate of 3,463,873 shares of common stock that were surrendered by our employees and members of our Board of Directors (at a weighted average price of $18.05 per share) to (i) satisfy the tax withholdings at the time of vesting for restricted stock awards, and at the time of stock option exercises, or (ii) satisfy the exercise price on stock option exercises. The table below presents our purchases of Spectrum's common stock during the year ended December 31, 2018.

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Period	Total Number of Shares Purchased	Average Price Paid Per Share
First Quarter	3,463,873	$ 18.05
Second Quarter	—	—
Third Quarter	—	—
Fourth Quarter	—	—
Year Ended December 31, 2018	3,463,873	$ 18.05

Stock Performance Graph (1)

The graph below compares the cumulative total stockholder return on $100 invested, assuming the reinvestment of all dividends, on December 31, 2013, the last trading day before our 2014 fiscal year, through the end of fiscal 2018 with the cumulative total return on $100 invested for the same period in the Russell 2000 index and our Peer Group.

During the first quarter of 2017, we re-engaged an independent executive compensation firm, Exequity, who performed an evaluation of our peer group companies. Exequity identified and selected a comparably sized, industry-affiliated peer group of companies operating within the biotechnology or pharmaceutical industries.

As of December 31, 2018, our Peer Group consists of the following publicly-traded companies:

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- AMAG Pharmaceuticals, Inc.
- Amphastar Pharmaceuticals, Inc.
- Eagle Pharmaceuticals, Inc.
- Enanta Pharmaceuticals, Inc.
- Fluidigm Corporation
- Genomic Health, Inc.
- Halozyme Therapeutics, Inc.
- Harvard Bioscience, Inc.
- Infinity Pharmaceuticals, Inc.
- Luminex Corporation
- Merrimack Pharmaceuticals, Inc.
- MiMedx Group, Inc.
- NewLink Genetics Corporation
- Pernix Therapeutics Holdings, Inc.
- Supernus Pharmaceuticals, Inc.
- Vanda Pharmaceuticals Inc.
- VIVUS, Inc.

	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
Spectrum Pharmaceuticals, Inc.	$ 78	$ 68	$ 50	$ 214	$ 99
Russell 2000	$ 105	$ 100	$ 122	$ 139	$ 124
Peer Group	$ 114	$ 109	$ 93	$ 105	$ 99

(1) The information in this section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Dividend Policy

We have not paid dividends on our common stock during the most two recent fiscal years. We currently intend to retain all earnings, if any, for use in the expansion of our business and do not anticipate paying any dividends in the foreseeable future. However, the payment of dividends, if any, will be at the discretion of the Board of Directors and subject to compliance at such time with any applicable restrictions contained in our various agreements and applicable law.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data has been derived from our audited Consolidated Financial Statements. The audited Consolidated Financial Statements for the fiscal years ended December 31, 2018, 2017, and 2016 are included elsewhere in this Annual Report on Form 10-K.

The information set forth below should be read in conjunction with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and the Consolidated Financial Statements and Notes thereto in Item 8. Financial Statements and Supplementary Data. The information set forth below is not necessarily indicative of our future financial condition or future results of operations.

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Selected Statement of Operations Data:	Year ended December 31, 2018	2017	2016	2015	2014
	(In thousands, except per share data)				
Total revenues*	$109,333	$128,367	$146,444	$162,556	$186,830
Operating costs and expenses:					
Cost of sales (excludes amortization of intangible assets)	26,756	42,859	27,953	27,689	27,037
Cost of service revenue	—	4,359	7,890	—	—
Selling, general and administrative	90,700	84,267	88,418	88,064	98,339
Research and development	94,956	65,895	59,123	51,073	70,116
Amortization of intangible assets	28,098	27,647	25,946	38,319	24,288
Loss from operations	(131,177)	(96,660)	(62,886)	(42,589)	(32,950)
Change in fair value of contingent consideration related to acquisitions	1,927	(4,957)	(649)	676	987
Other income (expense), net	9,240	(6,409)	(8,548)	(10,323)	(12,951)
Loss before income taxes	(120,010)	(108,026)	(72,083)	(52,236)	(44,914)
Benefit (provision) for income taxes	(1)	16,778	2,313	(406)	(2,186)
Net loss	$(120,011)	$(91,248)	$(69,770)	$(52,642)	$(47,100)
Net loss per share—basic	$(1.16)	$(1.07)	$(0.96)	$(0.81)	$(0.73)
Net loss per share—diluted	$(1.16)	$(1.07)	$(0.96)	$(0.81)	$(0.73)

* See Note 2(i) for a discussion of our adoption of ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), effective beginning on January 1, 2018.

Selected Balance Sheet Data:	As of December 31, 2018	2017	2016	2015	2014
	(In thousands)				
Cash, cash equivalents and marketable securities	$203,988	$227,571	$158,469	$139,986	$133,248
Working capital surplus (current assets minus current liabilities)	$164,214	$167,997	$151,137	$114,282	$113,030
Total assets	$390,886	$487,439	$428,768	$419,049	$490,033
Long term obligations, less current portion	$21,150	$26,351	$127,229	$129,849	$126,040
Total stockholders' equity	$283,262	$351,339	$236,026	$212,857	$254,554

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our consolidated financial statements and the related notes included in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of various factors including the risks we discuss in Item 1A. Risk Factors and elsewhere in this Annual Report on Form 10-K.

OVERVIEW

Our Business

We are a biopharma company, with a primary strategy comprised of acquiring, developing, and commercializing a broad and diverse pipeline of clinical and commercial products. We have an in-house clinical development organization with regulatory and data management capabilities, in addition to commercial infrastructure and a field-based sales force for our marketed products. Currently, we have seven approved oncology/hematology products (FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA) that target different types of cancer including: NHL, mCRC, ALL, and MM.

We also have two drugs in late-stage development:

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- Poziotinib, a novel pan-HER inhibitor under investigation for NSCLC tumors with either EGFR or HER2 exon-20 insertion mutations; and
- ROLONTIS, a novel long-acting GCSF analog for chemotherapy-induced neutropenia.

See Item 1. Business, for our discussion of:

- Company Overview
- Cancer Background and Market Size
- Product Portfolio
- Manufacturing
- Sales and Marketing
- Customers
- Competition
- Research and Development

Recent Highlights of Our Business, Product Development Initiatives, and Regulatory Approvals

During the year ended December 31, 2018 and through the filing date of this Annual Report on Form 10-K, we made a strategic shift in our business through executing an agreement to sell the distribution rights to our legacy commercialized drug portfolio. We also continued to make meaningful progress in the advancement of our product pipeline, as summarized below:

Execution of Asset Purchase Agreement for our Commercialized Drug Portfolio:

On January 17, 2019, we entered into a definitive asset purchase agreement for the sale of our FDA-approved product portfolio of FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA to Acrotech. Upon the closing of the Acrotech Transaction, we are entitled to receive up to $160 million in an upfront cash payment (of which $4 million will be held in escrow for six months). In addition, we expect a purchase price adjustment for certain ongoing research and development activities of the commercialized product portfolio. We are also entitled to receive an aggregate $140 million upon Acrotech's achievement of certain regulatory and sales-based milestones relating to this product portfolio. We plan to reduce our staff by approximately 90 employees, the majority of which we expect to transition to Acrotech.

Poziotinib, an irreversible tyrosine kinase inhibitor:

In September 2018, we announced preliminary poziotinib data from the University of Texas, MD Anderson Cancer Center ("MD Anderson") Phase 2 non-small cell lung cancer ("NSCLC") study which were released during an oral presentation at the IASLC 19th World Conference on Lung Cancer. The MD Anderson study is the single largest data set of patients with an exon 20 mutation in EGFR or HER2. This Phase 2 study demonstrated high anti-tumor activity for poziotinib in metastatic, heavily pretreated EGFR exon 20 mutant NSCLC, a group for which no targeted agents have proved to be effective to date. This data is summarized below:

- In 44 evaluable patients with EGFR exon-20 mutations, the confirmed overall response rate (ORR) was 43% and disease control rate was 90%. Median progression free survival (PFS) was 5.5 months (ITT).
- In evaluable patients with HER2 exon-20 mutations, the confirmed overall response rate (ORR) was 42% and disease control rate was 83%. Median progression free survival (PFS) was 5.1 months (ITT).
- EGFR-related toxicities (including rash, diarrhea, and paronychia) were manageable and required dose reductions in 60% of patients. Discontinuation due to poor tolerance was rare (approximately 3% of patients).

On January 2, 2019 we announced full enrollment of cohort 1 (N=87) for previously treated NSCLC patients with EGFR exon 20 insertion mutations with sites across the U.S., Europe, and Canada. The EGFR previously treated cohort is part of the ZENITH20 trial - an open-label, multi-center, global Phase 2 trial evaluating NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Results from this cohort are expected to be released during the second half of 2019.

ROLONTIS, a novel long-acting G-CSF:

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Top-Line Results of our ADVANCE and RECOVER Studies

In February 2018 and June 2018, we announced that the top line results of our pivotal Phase 3 studies (ADVANCE and RECOVER) demonstrated that it was non-inferior to the current standard of care, and had a similar safety profile.

BLA Submission

We submitted our Biologics License Application ("BLA") with the FDA in late December 2018. Due to the recent federal government shutdown, the BLA was officially received by the FDA on January 28, 2019. Once this BLA is accepted by the FDA, our Prescription Drug User Fee Act date is expected to be set for 10 months thereafter.

CHARACTERISTICS OF OUR REVENUE AND EXPENSES

The below summarizes the nature of our revenue and operating expense line items within our Consolidated Statements of Operations:

Revenue

The majority of our revenue is derived from sales of our drug products to large pharmaceutical wholesalers and distributors, which we recognize upon title transfer (which is typically at time of delivery), provided our other revenue recognition criteria have been met.

To a lesser extent we also derive revenue from (i) upfront license fees, milestone receipts from our licensees' sales or regulatory achievements, and royalties from out-licensing our licensees' sales in applicable territories, and (ii) service revenue from third-parties under certain arrangements for our research and development activities, sales and marketing activities, clinical trial management, and supply chain services conducted for the benefit of third parties.

We are subject to normal inflationary trends and anticipate that any increased costs would be passed on to our customers. However, inflation has not, and is not expected to, have a material effect on our business.

Our revenue recognition criteria are described in greater detail below and in Note 2(i) to the accompanying Consolidated Financial Statements.

Cost of Sales (excluding amortization of intangible assets)

Cost of sales includes production and packaging materials, contract manufacturer fees, allocated personnel costs (including stock-based compensation expense), shipping expenses, and royalty fees.

Cost of Service Revenue

Cost of service revenue includes: (i) allocation of compensation of our sales personnel, and other reimbursable costs, for the marketing of certain products at the direction of its beneficial owner, and (ii) reimbursable costs and services provided to our licensees in connection with their clinical, regulatory, and commercial activities within their territories.

Selling, General and Administrative

Selling, general and administrative expenses primarily consist of compensation (including stock-based compensation) and benefits for our sales force and personnel that support our sales and marketing operations, and our general operations such as information technology, executive management, financial accounting, and human resources. It also includes costs attributable to marketing our products to our customers and prospective customers, patent and legal fees, financial statement audit fees, insurance coverage fees, bad debt expense, personnel recruiting fees, and other professional services.

Research and Development

Our research and development activities primarily relate to the clinical development and testing of new drugs, and conducting studies in order to gain regulatory approval for the commercialization of our drug products. These expenses consist of compensation (including stock-based compensation) and benefits for research and development and clinical and regulatory personnel, materials and supplies, consultants, and regulatory and clinical payments related to studies. In addition, we include within research and development expense, technology transfer costs and manufacture qualification costs– prior to FDA approval of the product, its formulation, and/or its manufacturing sites.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES
The preparation and presentation of financial statements in conformity with generally accepted accounting principles in the United States of America, or GAAP, requires management to establish policies and make estimates and assumptions that affect (i) the amounts of assets and liabilities as of the date presented on the accompanying Consolidated Balance Sheets and (ii) the amounts of revenue and expenses for each year presented in the accompanying Consolidated Statements of Operations.

Our management believes its estimates and assumptions are supportable, reasonable, and consistently applied. Nonetheless, estimates are inherently uncertain. As a result, our financial position and operating results could materially differ from the amounts reported within the accompanying Consolidated Financial Statements if management's estimates require prospective adjustment. Our critical accounting policies and estimates arise in conjunction with the following accounts:

- Revenue recognition
- Inventories – lower of cost or net realizable value
- Fair value of acquired assets and assumed liabilities
- Goodwill and intangible assets – impairment evaluations
- Income taxes
- Stock-based compensation
- Litigation accruals

Revenue Recognition
Impact of the Adoption of the New Revenue Recognition Standard: ASU No. 2014-09, Revenue from Contracts with Customers ("Topic 606"), became effective for us on January 1, 2018. Our disclosure within the below sections reflects our updated accounting policies that are affected by this new standard. We applied the "modified retrospective" transition method for open contracts for the implementation of Topic 606; this resulted in the recognition of an aggregate $4.7 million, net of tax, decrease to our January 1, 2018 "accumulated deficit" on our accompanying Consolidated Balance Sheets for the cumulative impact of applying this new standard. We made no adjustments to our previously-reported total revenues, as those periods continue to be presented in accordance with our historical accounting practices under Topic 605, Revenue Recognition ("Topic 605"). See Notes 4, 5, and 20 to the accompanying Consolidated Financial Statements, for additional disclosures in accordance with Topic 606.
Required Elements of Our Revenue Recognition: Revenue from our (a) product sales, (b) out-license arrangements, and (c) service arrangements is recognized under Topic 606 in a manner that reasonably reflects the delivery of our goods and/or services to customers in return for expected consideration and includes the following elements:
(1) we ensure that we have an executed contract(s) with our customer that we believe is legally enforceable;
(2) we identify the "performance obligations" in the respective contract;
(3) we determine the "transaction price" for each performance obligation in the respective contract;
(4) we allocate the transaction price to each performance obligation; and
(5) we recognize revenue only when we satisfy each performance obligation.

These five elements, as applied to each of our revenue categories, are summarized below:
(a) Product Sales: We sell our products to pharmaceutical wholesalers/distributors (i.e., our customers), except for our U.S. sales of ZEVALIN, and limited sales of EVOMELA, in which case the end-user (i.e., clinic or hospital) is our customer. Our wholesalers/distributors in turn sell our products directly to clinics, hospitals, and private oncology-based practices. Revenue from our product sales is recognized as physical delivery of product occurs (when our customer obtains control of the product), in return for agreed-upon consideration.
Our gross product sales (i.e., delivered units multiplied by the contractual price per unit) are reduced by our corresponding gross-to-net ("GTN") estimates using the "expected value" method, resulting in our reported "product sales, net" in the accompanying Consolidated Statements of Operations, reflecting the amount we ultimately expect to realize in net cash proceeds, taking into account our current period gross sales and related cash receipts, and the subsequent

cash disbursements on these sales that we estimate for the various GTN categories discussed below. These estimates are based upon information received from external sources (such as written or oral information obtained from our customers with respect to their period-

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end inventory levels and sales to end-users during the period), in combination with management’s informed judgments. Due to the inherent uncertainty of these estimates, the actual amount incurred (of some, or all) of product returns, government chargebacks, prompt pay discounts, commercial rebates, Medicaid rebates, and distribution, data, and GPO administrative fees may be materially above or below the amount estimated, then requiring prospective adjustments to our reported net product sales.

These GTN estimate categories are each discussed below:

Product Returns Allowances: Our FUSILEV, MARQIBO, and BELEODAQ customers are contractually permitted to return purchased products beginning at its expiration date and within six months thereafter. Our EVOMELA customers are permitted to return purchased product beginning at six months prior to its expiration date, and within 12 months thereafter (as well as for overstock inventory, as determined by end-users). ZEVALIN and FOLOTYN returns for expiry are not contractually permitted. Returns outside of this aforementioned criteria are not customarily allowed. We estimate expected product returns for our allowance based on our historical return rates. Returned product is typically destroyed, since substantially all returns are due to expiry and cannot be resold.

Government Chargebacks: Our products are subject to pricing limits under certain federal government programs (e.g., Medicare and 340B Drug Pricing Program). Qualifying entities (i.e., end-users) purchase products from our customers at their qualifying discounted price. The chargeback amount we incur represents the difference between our contractual sales price to our customer, and the end-user’s applicable discounted purchase price under the government program. There may be significant lag time between our reported net product sales and our receipt of the corresponding government chargeback claims from our customers.

Prompt Pay Discounts: Discounts for prompt payment are estimated at the time of sale, based on our eligible customers’ prompt payment history and the contractual discount percentage.

Commercial Rebates: Commercial rebates are based on (i) our estimates of end-user purchases through a group purchasing organization (“GPO”), (ii) the corresponding contractual rebate percentage tier we expect each GPO to achieve, and (iii) our estimates of the impact of any prospective rebate program changes made by us.

Medicaid Rebates: Our products are subject to state government-managed Medicaid programs, whereby rebates are issued to participating state governments. These rebates arise when a patient treated with our product is covered under Medicaid, resulting in a discounted price for our product under the applicable Medicaid program. Our Medicaid rebate accrual calculations require us to project the magnitude of our sales, by state, that will be subject to these rebates. There is a significant time lag in us receiving rebate notices from each state (generally several months or longer after our sale is recognized). Our estimates are based on our historical claim levels by state, as supplemented by management’s judgment.

Distribution, Data, and GPO Administrative Fees: Distribution, data, and GPO administrative fees are paid to authorized wholesalers/distributors of our products (except for U.S. sales of ZEVALIN) for various commercial services including: contract administration, inventory management, delivery of end-user sales data, and product returns processing. These fees are based on a contractually-determined percentage of our applicable sales.

(b) License Fees: Our out-license arrangements allow licensees to market our product(s) in certain territories for a specific term (representing the out-license of “functional intellectual property”). These arrangements may include one or more of the following forms of consideration: (i) upfront license fees, (ii) sales royalties, (iii) sales milestone-achievement fees, and (iv) regulatory milestone-achievement fees. We recognize revenue for each based on the contractual terms that establish our right to collect payment once the performance obligation is achieved, as follows:

(1) Upfront License Fees: We determine whether upfront license fees are earned at the time of contract execution (i.e., when rights transfer to the customer) or over the actual (or implied) contractual period of the out-license. As part of this determination, we evaluate whether we have any other requirements to provide substantive services that are inseparable from the performance obligation of the license transfer. Our customers’ “distinct” rights to licensed “functional intellectual property” at the time of contract execution results in concurrent revenue recognition of all upfront license fees (assuming that there are no other performance obligations at contract execution that are inseparable from this license transfer).

(2) Royalties: Under the “sales-or-usage-based royalty exception” we recognize revenue in the same period that our licensees complete product sales in their territory for which we are contractually entitled to a percentage-based royalty receipt.

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(3) Sales Milestones: Under the “sales-or-usage-based royalty exception” we recognize revenue in full within the period that our licensees achieve annual or aggregate product sales levels in their territories for which we are contractually entitled to a specified lump-sum receipt.

(4) Regulatory Milestones: Under the terms of the respective out-license, regulatory achievements may either be our responsibility, or that of our licensee.

- When our licensee is responsible for the achievement of the regulatory milestone, we recognize revenue in full (for the contractual amount due from our licensee) in the period that the approval occurs (i.e., when the “performance obligation” is satisfied by our customer) under the “most likely amount” method. This revenue recognition remains “constrained” (i.e., not recognized) until regulatory approval occurs, given its inherent uncertainty and the requirement of a significant revenue reversal not being probable if achievement does not occur. At each reporting period, we re-evaluate the probability of milestone achievement and the associated revenue constraint; any resulting adjustments would be recorded on a cumulative catch-up basis, thus reflected in our financial statements in the period of adjustment.

- When we are responsible for the achievement of a regulatory milestone, the “relative selling price method” is applied for purposes of allocating the transaction price to our performance obligations. In such case, we consider (i) the extent of our effort to achieve the milestone and/or the enhancement of the value of the delivered item(s) as a result of milestone achievement and (ii) if the milestone payment is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. We have historically assessed the contractual value of these milestones upon their achievement to be identical to the allocation of value of our performance obligations and thus representing the “transaction price” for each milestone at contract inception. We recognize this revenue in the period that the regulatory approval occurs (i.e., when we complete the “performance obligation”) under the “most likely amount” method, and revenue recognition is otherwise “constrained” until regulatory approval occurs, given its inherent uncertainty and the requirement of a significant revenue reversal not being probable if achievement does not occur. At each reporting period, we re-evaluate the probability of milestone achievement and the associated revenue constraint; any resulting adjustments would be recorded on a cumulative catch-up basis, thus reflected in our financial statements in the period of adjustment.

(c) Service Revenue: We receive fees under certain arrangements for (i) sales and marketing services, (ii) supply chain services, (iii) research and development services, and (iv) clinical trial management services.

Our rights to receive payment for these services may be established by (1) a fixed-fee schedule that covers the term of the arrangement, so long as we meet ongoing performance obligations, (2) our completion of product delivery in our capacity as a procurement agent, (3) the successful completion of a phase of drug development, (4) favorable results from a clinical trial, and/or (5) regulatory approval events.

We consider whether revenue associated with these service arrangements is reportable each period, based on our completed services or deliverables (i.e., satisfied “performance obligations”) during the reporting period, and the terms of the arrangement that contractually result in fixed payments due to us. The promised service(s) within these arrangements are distinct and explicitly stated within each contract, and our customer benefits from the separable service(s) delivery/completion. Further, the nature of the promise to our customer as stated within the respective contract is to deliver each named service individually (not a transfer of combined items to which the promised goods or services are inputs), and thus are separable for revenue recognition.

Inventories – Lower of Cost or Net Realizable Value

We value our inventory at the lower of (i) the actual cost of its purchase or manufacture, or (ii) its net realizable value. Inventory cost is determined on the first-in, first-out method. We regularly review our inventory quantities in process of manufacture and on hand. When appropriate, we record a provision for obsolete and excess inventory to derive its new cost basis, which takes into account our sales forecast by product and corresponding expiry dates of each product lot.

Manufacturing costs of drug products that are pending FDA approval are fully expensed through “research and development,” on the accompanying Consolidated Statements of Operations.

Fair Value of Acquired Assets and Assumed Liabilities

The accounting for business combinations and asset acquisitions requires extensive use of estimates and judgments to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed. Additionally, we must determine whether the acquisition meets the criteria for business combination accounting (rather than asset acquisition accounting), because in a business combination, the excess of the purchase price over the fair value of net assets acquired can only be recognized as “goodwill.”

The fair value of acquired tangible and identifiable intangible assets and liabilities assumed, are based on their estimated fair values at the acquisition date and requires extensive use of accounting estimates, judgments, and assumptions, including but not limited to the following: (i) the likelihood, timing, and costs to complete the in-process projects; (ii) the probability of achieving regulatory approvals; (iii) the cash flows to be derived from the acquired assets, and (iv) the application of appropriate discount rates.

For each acquisition, we engage an independent third-party valuation specialist to assist management in determining the fair value of in-process research and development, identifiable intangible assets, and any contingent consideration.

In connection with certain of our acquisitions, we must record a contingent consideration liability for cash or stock payments upon the completion of certain future performance milestones. In these cases, a liability is recorded on the acquisition date for an estimate of the acquisition date fair value of the contingent consideration by applying the income approach utilizing variable inputs such as probability of achievement and risk-free adjusted discount rates. Any change in the fair value of the contingent consideration subsequent to the acquisition date is recognized in earnings.

Goodwill and Intangible Assets – Impairment Evaluations

Our goodwill represents the excess of our business acquisition cost over the estimated fair value of the net assets acquired in the corresponding transaction. Goodwill has an indefinite accounting life and is therefore not amortized. Instead, goodwill is evaluated for impairment on an annual basis (as of each October 1st), unless we identify impairment indicators that would require earlier testing.

We evaluate the recoverability of indefinite-lived intangible assets at least annually, or whenever events or changes in our business indicate that an intangible asset’s (whether indefinite or definite-lived) carrying amount may not be recoverable. Such circumstances could include, but are not limited to the following:

(a) a significant decrease in the market value of an asset;

(b) a significant adverse change in the extent or manner in which an asset is used; or

(c) an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset.

Intangible assets with finite useful lives are amortized over their estimated useful lives on a straight-line basis. We review these assets for potential impairment if/when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

Income Taxes

Deferred tax assets and liabilities are recorded based on the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the financial statements, as well as operating losses and tax credit carry forwards using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain.

We have recorded a valuation allowance to reduce our deferred tax assets, because we believe that, based upon a weighting of positive and negative factors, it is more likely than not that these deferred tax assets will not be realized. If/when we were to determine that our deferred tax assets are realizable, an adjustment to the corresponding valuation allowance would increase our net income in the period that such determination was made.

In the event that we are assessed interest and/or penalties from taxing authorities that have not been previously accrued, such amounts would be included in “(provision) benefit for income taxes” within the Consolidated Statements of Operations in the period the notice was received.

Stock-Based Compensation

Stock-based compensation expense for equity awards granted to our employees and members of our Board of Directors is recognized on a straight-line basis over each award's vesting period. Recognized compensation expense is net of an estimated forfeiture rate, representing the percentage of awards that are expected to be forfeited prior to vesting, though is ultimately

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adjusted for actual forfeitures. We use the Black-Scholes option pricing model to determine the fair value of stock options (as of the date of grant) that have service conditions for vesting. We use the Monte Carlo valuation model to value equity awards (as of the date of grant) that have combined market conditions and service conditions for vesting. The recognition of stock-based compensation expense and the initial calculation of stock option fair value requires uncertain assumptions, including (a) the pre-vesting forfeiture rate of the award, (b) the expected term that the stock option will remain outstanding, (c) our stock price volatility over the expected term (and that of our designated peer group with respect to certain market-based awards), and (d) the prevailing risk-free interest rate for the period matching the expected term.

With regard to (a)-(d): We estimate forfeiture rates based on our employees' overall forfeiture history, which we believe will be representative of future results. We estimate the expected term of stock options granted based on our employees' historical exercise patterns, which we believe will be representative of their future behavior. We estimate the volatility of our common stock on the date of grant based on the historical volatility of our common stock for a look-back period that corresponds with the expected term. We estimate the risk-free interest rate based upon the U.S. Department of the Treasury yields in effect at award grant, for a period equaling the expected term of the stock option.

Litigation Accruals

From time-to-time, we are involved with various legal matters arising from the ordinary course of operating our publicly-traded pharmaceutical business. These legal matters may include product liability claims, intellectual property claims, employment practices claims, shareholder claims, among other general claims. We accrue for these contingent liabilities when it is both: (1) probable that a payment will be made to the claimant, and (2) we can reasonably estimate the payment amount, given all available information.

RESULTS OF OPERATIONS

Operations Overview – 2018, 2017, and 2016

	Year Ended December 31,					
	2018		2017		2016	
	($ in thousands)					
Total revenues	$109,333	100.0 %	$128,367	100.0 %	$146,444	100.0 %
Operating costs and expenses:						
Cost of sales (excludes amortization of intangible assets)	26,756	24.5 %	42,859	33.4 %	27,953	19.1 %
Cost of service revenue	—	— %	4,359	3.4 %	7,890	5.4 %
Selling, general and administrative	90,700	83.0 %	84,267	65.6 %	88,418	60.4 %
Research and development	94,956	86.9 %	65,895	51.3 %	59,123	40.4 %
Amortization of intangible assets	28,098	25.7 %	27,647	21.5 %	25,946	17.7 %
Total operating costs and expenses	240,510	220.0 %	225,027	175.3 %	209,330	142.9 %
Loss from operations	(131,177)	(120.0)%	(96,660)	(75.3)%	(62,886)	(42.9)%
Interest expense, net	(340)	(0.3)%	(6,798)	(5.3)%	(9,435)	(6.4)%
Change in fair value of contingent consideration related to acquisitions	1,927	1.8 %	(4,957)	(3.9)%	(649)	(0.4)%
Other income, net	9,580	8.8 %	389	0.3 %	887	0.6 %
Loss before income taxes	(120,010)	(109.8)%	(108,026)	(84.2)%	(72,083)	(49.2)%
(Provision) benefit for income taxes	(1)	— %	16,778	13.1 %	2,313	1.6 %
Net loss	$(120,011)	(109.8)%	$(91,248)	(71.1)%	$(69,770)	(47.6)%

YEAR ENDED DECEMBER 31, 2018 VERSUS DECEMBER 31, 2017

Total Revenues

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	Year Ended December 31,			
	2018	2017	$ Change	% Change
	($ in millions)			
Product sales, net:				
FOLOTYN	$ 48.0	$ 43.0	$ 5.0	11.6 %
EVOMELA	28.3	35.2	(6.9)	(19.6)%
BELEODAQ	12.3	12.4	(0.1)	(0.8)%
ZEVALIN	7.0	11.8	(4.8)	(40.7)%
MARQIBO	5.5	6.6	(1.1)	(16.7)%
FUSILEV**	2.4	7.3	(4.9)	(67.1)%
KHAPZORY	0.9	—	0.9	— %
	104.5	116.2	*(11.7)	(10.1)%
License fees and service revenue	4.9	12.2	(7.3)	(59.8)%
Total revenues	$ 109.4 *	$ 128.4	$ (19.0)	(14.8)%

* Does not agree to the face of the accompanying Consolidated Statements of Operations for the year ended December 31, 2018 by an immaterial amount due to rounding.

** Effective December 2018, FUSILEV has been discontinued and we are no longer selling this product. We have since transitioned to marketing KHAPZORY for identical indications as FUSILEV.

Product sales, net. To derive net product sales, gross product revenues in each period are reduced by management's latest estimated provisions for (i) product returns, (ii) government chargebacks, (iii) prompt pay discounts, (iv) commercial rebates, (v) Medicaid rebates, and (vi) distribution, data, and GPO administrative fees. Management considers various factors in the determination of these provisions, which are described in more detail within “Critical Accounting Policies and Estimates” above.

FOLOTYN revenue increased $5.0 million due to an increase in our average net sales price per unit, partially offset by a decrease in units sold in the current year.

EVOMELA revenue decreased $6.9 million due to a decrease in our average net sales price per unit in the current year, partially offset by an increase in unit sales.

BELEODAQ revenue decreased $0.1 million due to a decrease in units sold, partially offset by an increase in our average net sales price per unit in the current year.

ZEVALIN revenue decreased $4.8 million due to a decrease in both units sold, and our average net sales price per unit.

MARQIBO revenue decreased $1.1 million due to a decrease in units sold during the period, partially offset by an increase in our average net sales price per unit.

FUSILEV revenue decreased $4.9 million as a result of both the decrease in the number of units sold and our average net sales price per unit, due to the competitive generic levo-leucovorin products, beginning in 2015 (see Note 3(f)) to our accompanying Consolidated Financial Statements). As noted above, effective December 2018, FUSILEV has been discontinued and we are no longer selling this product. We have since transitioned to marketing KHAPZORY for identical indications as FUSILEV.

KHAPZORY revenue of $0.9 million in the current year is due to its commercial launch during the fourth quarter of 2018.

License fees and service revenue. Our license fees and service revenue in 2018 decreased by $7.3 million primarily due to the following: (i) $4.7 million of non-recurring service revenue from our expired co-promotion arrangement with Eagle Pharmaceuticals, Inc. ("Eagle") in 2017 (see Note 14 to our accompanying Consolidated Financial Statements); and (ii) $4 million decrease in FOLOTYN royalties, primarily related to the non-recurrence of $5 million of regulatory and commercial milestone achievements of our licensee within Japan in 2017 (see Note 17(b)(vii) to our accompanying Consolidated Financial Statements). This decrease was partially offset by (i) $1 million milestone associated with our licensee's November 2018 Canadian approval of FOLOTYN (see Note 17(b)(xv)), and (ii) $0.8 million increase of ZEVALIN license fees within the Asia

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territory. See Note 5 to our accompanying Consolidated Financial Statements for a tabular comparative summary, by source, of these license fees and service revenue amounts.

Operating Expenses

	Year Ended December 31,			
	2018	2017	$ Change	% Change
	($ in millions)			
Operating expenses:				
Cost of sales (excludes amortization intangible assets)	$ 26.8	$ 42.9	$ (16.1)	(37.5)%
Cost of service revenue	—	4.4	(4.4)	— %
Selling, general and administrative	90.7	84.3	6.4	7.6 %
Research and development	95.0	65.9	29.1	44.2 %
Amortization of intangible assets	28.1	27.6	0.5	1.8 %
Total operating costs and expenses	$ 240.5	$ 225.0	$ 15.5	6.9 %

Cost of Sales. Cost of sales decreased $16.1 million in 2018, primarily due to our product sales decrease, as well as the sales mix in each year.

Cost of Service Revenue. Cost of service revenue substantially relates to our allocated commercial and marketing expenses (from “selling, general, and administrative” expenses) for our 2017 promotion and sale of Eagle’s products by our sales force. We ceased marketing these products beginning July 1, 2017 (see Note 14 to the accompanying Consolidated Financial Statements).

Selling, General and Administrative. Selling, general and administrative expenses increased $6.4 million in 2018, primarily due to (i) the non-recurrence of certain marketing cost allocations out of this account; in the prior year, an aggregate $4.2 million was reclassified from this account and presented within “cost of service revenue” (see above for Eagle); (ii) $3.3 million increase in legal expenses primarily associated with the termination of our former chief executive officer in December 2017, and our corporate development initiatives; (iii) $2.2 million increase in various marketing activities, including the forthcoming commercial launch of ROLONTIS upon FDA approval; (iv) $2.1 million increase in payroll tax expenses primarily related to stock option exercises during the year by our former chief executive officer; and (v) $1.7 million increase in various other expenses to further support our current operations and planned business growth. These increases were partially offset by a $7 million decrease in personnel and benefit-related costs as compared to prior year, largely attributable to the contractual amounts due to our former chief executive officer upon his termination in December 2017.

Research and Development. Research and development expenses increased $29.1 million in 2018 due to several factors, including: (i) $19.1 million increase in product manufacturing costs related to the planned commercial launch of ROLONTIS; (ii) $0.9 million increase in clinical activities; (iii) $2.9 million increase in pre-FDA approval manufacturing costs associated with the launch of KHAPZORY in the fourth quarter of 2018; (iv) $0.9 million increase in product development costs for BELEODAQ; (v) $0.8 million in technical transfer costs associated with ZEVALIN production at a new site; (vi) $0.8 million increase in manufacture validation costs for EVOMELA production at a new site; and (vii) $5.2 million increase in personnel-related costs to drive these various clinical, manufacture validation, and product development initiatives. These increases were partially offset by a $2.7 million decrease in product manufacturing costs associated with QAPZOLA, as we refine our product development priorities.

Amortization and Impairment Charges of Intangible Assets. Amortization expense, recorded on a straight-line basis, increased in 2018 due to the capitalization of KHAPZORY distribution rights and its incremental amortization in the current year (see Note 3(g)).

Total Other Income (Expense)

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	Year Ended December 31,			
	2018	2017	$ Change	% Change
	($ in millions)			
Total other income (expense)	$ 11.2	$ (11.4)	$ 22.6	198.2 %

Total other income (expense) increased by $22.6 million due to multiple offsetting components including: (i) $10.5 million increase in unrealized gain on our CASI Pharmaceuticals, Inc. equity securities, which are now recorded within “other income (expense), net” rather than “other comprehensive (loss) income” due to our adoption of ASU 2016-01 (see Note 3(a) to our accompanying Consolidated Financial Statements); (ii) $7.3 million aggregate decrease of interest and principal retirement expense related to our 2018 Convertible Notes (see Note 15 to our accompanying Consolidated Financial Statements); and (iii) $6.9 million decrease in the fair value of contingent consideration related to our MARQIBO product (see Note 10(a) to our accompanying Consolidated Financial Statements). These net increases to other income was partially offset by $2 million increase in executive deferred compensation expense (see Note 17(f) to our accompanying Consolidated Financial Statements).

(Provision) benefit for Income Taxes

	Year Ended December 31,			
	2018	2017	$ Change	% Change
	($ in millions)			
(Provision) benefit for income taxes	$ —	$ 16.8	$ (16.8)	(100.0)%

Our provision for income taxes was a nominal $1 thousand for 2018. Our $16.8 million benefit for income taxes in 2017 principally relates to tax benefits allocated to continuing operations as a result of unrealized gains in "other comprehensive income (loss)". During 2017, we had unrealized gains from the change in value of our available-for-sale securities that are reported within "other comprehensive income (loss)" of $25.8 million, while we also reported a pretax "loss from continuing operations" of $108 million. These gains in "other comprehensive income (loss)" resulted in our recording a tax benefit of $9.7 million to continuing operations and an offsetting tax charge to "other comprehensive income (loss)" of $9.7 million (this did not recur in the current year with our January 1, 2018 adoption of ASU 2016-01, Recognition and Measurement of Financial Assets and Liabilities). The other portion of our 2017 benefit for income taxes relates to the re-measurement of deferred taxes and our updated assessment of the realizability of deferred tax assets, as part of the enactment of the Tax Jobs and Cuts Act.

YEAR ENDED DECEMBER 31, 2017 VERSUS DECEMBER 31, 2016

Total Revenues

	Year Ended December 31,			
	2017	2016	$ Change	% Change
	($ in millions)			
Product sales, net:				
FOLOTYN	43.0	46.2	(3.2)	(6.9)%
EVOMELA	35.2	16.2	19.0	117.3 %
BELEODAQ	12.4	13.4	(1.0)	(7.5)%
ZEVALIN	11.8	10.7	1.1	10.3 %
MARQIBO	6.6	7.2	(0.6)	(8.3)%
FUSILEV	7.3	34.8	(27.5)	(79.0)%
	116.2 *	128.6 *	(12.4)	(9.6)%
License fees and service revenue	12.2	17.8	(5.6)	(31.5)%
Total revenues	$ 128.4	$ 146.4	$ (18.0)	(12.3)%

* Does not agree to the face of the accompanying Consolidated Statements of Operations for the years ended December 31, 2017 and 2016, respectively, by an immaterial amount due to rounding.
Product sales, net. To derive net product sales, gross product revenues in each period are reduced by management's latest estimated provisions for (i) product returns, (ii) government chargebacks, (iii) prompt pay discounts, (iv) commercial

rebates, (v) Medicaid rebates, and (vi) distribution, data, and GPO administrative fees. Management considers various factors in the determination of these provisions, which are described in more detail within “Critical Accounting Policies and Estimates” above.

FOLOTYN revenue decreased $3.2 million in 2017 compared to 2016 as a result of a decrease in the numbers of units sold in the year, partially offset by an increase in our net average sales price per unit.

EVOMELA revenue increased significantly by $19.0 million during 2017 compared to 2016 as a result of an increase in the number of units sold, partially offset by a decrease in our average net sales price per unit. The commercial launch of this product commenced in April 2016.

BELEODAQ revenue decreased $1.0 million in 2017 compared to 2016 primarily as a result of a decrease in the number of units sold in the current year, and also as a result of a decrease in our average net sales price per unit.

ZEVALIN revenue increased $1.1 million in 2017 compared to 2016 primarily as a result of an overall increase in units sold and an increase in the net average price per unit in our ex-U.S territories.

MARQIBO revenue decreased $0.6 million in 2017 compared to 2016 as a result of a decline in the number of units sold in the year, partially offset by an increase in our net average sales price per unit.

FUSILEV revenue decreased $27.5 million in 2017 compared to 2016 as a result of the continued significant decline in both our net average sales price and unit sales due to the competitive launch of generic levo-leucovorin products beginning in April 2015 (see Note 3(g) to the accompanying Consolidated Financial Statements).

License fees and service revenue. Our license fees and service revenue in 2017 decreased by $5.6 million primarily due to the following: (i) an upfront receipt of $6 million in 2016 for the out-license of ZEVALIN, FOLOTYN, BELEODAQ, and MARQIBO (see Note 13 to the accompanying Consolidated Financial Statements) which did not reoccur in 2017, (ii) $4.3 million decrease in fees from our co-promotion with Eagle (see Note 14 to the accompanying Consolidated Financial Statements) as our sales force is no longer marketing Eagle's products as of July 1, 2017, and (iii) $0.5 million decrease in our sales of ZEVALIN to Asia and certain other territories, excluding China (see Note 12 to the accompanying Consolidated Financial Statements). These decreases were partially offset by the recognition in 2017 of (i) $3.0 million contractual milestone for FOLOTYN approval in Japan, (ii) $2.0 million contractual milestone receipt for the first commercial sale of FOLOTYN in Japan (see Note 17(b)(vii) to the accompanying Consolidated Financial Statements), and (iii) $0.3 million of regulatory service revenue that was provided for the benefit of our licensee.

Operating Expenses

	Year Ended December 31,			
	2017	2016	$ Change	% Change
	($ in millions)			
Operating expenses:				
Cost of sales (excludes amortization and impairment of intangible assets)	$ 42.9	$ 28.0	$ 14.9	53.2 %
Cost of service revenue	4.4	7.9	(3.5)	(44.3)%
Selling, general and administrative	84.3	88.4	(4.1)	(4.6)%
Research and development	65.9	59.1	6.8	11.5 %
Amortization and impairment charges of intangible assets	27.6	25.9	1.7	6.6 %
Total operating costs and expenses	$ 225.0	$ 209.3	$ 15.7	7.5 %

Cost of Sales. Despite our decreased product revenue in 2017, cost of sales increased $14.9 million in 2017 compared to 2016, resulting in a gross margin decrease. This increase in cost of sales was primarily due to (i) changes to our product sales mix and (ii) royalty expense for FOLOTYN regulatory and commercial milestone achievements (see Note 17(b)(vii) to the accompanying Consolidated Financial Statements), partially offset by our FUSILEV royalty settlement also recognized in 2017 (see Note 17(b)(v) to the accompanying Consolidated Financial Statements).

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Cost of Service Revenue. Cost of service revenue substantially relates to our allocated commercial and marketing expenses (from "selling, general, and administrative" expenses) for promotion and sale of Eagle's products by our sales force. Our cost of service revenue decreased $3.5 million in 2017 compared to 2016 because we ceased marketing these products beginning July 1, 2017 (see Note 14 to the accompanying Consolidated Financial Statements).

Selling, General and Administrative. Selling, general and administrative expenses decreased $4.1 million largely driven by a $12.3 million decrease in non-recurring legal expenses and settlements related to shareholder litigation and FOLOTYN patent matters in 2016, and $2.4 million of non-recurring contract termination fees in 2016. These overall reductions were partially offset by (i) one-time severance and legal expenses of $7.1 million associated with the termination of our former chief executive officer in December 2017, and (ii) $3.7 million increase related to reimbursable expenses from Eagle as the agreement expired under its terms on June 30, 2017 (see Note 14).

Research and Development. Research and development expenses increased in 2017 by $6.8 million compared to the prior year due to various items primarily including (i) $7.1 million increase in clinical initiatives and activities primarily related to ROLONTIS and POZIOTINIB, and (ii) $1.2 million FDA filing fee associated with the NDA for KHAPZORY, and a corresponding $0.3 million milestone payment to a licensor. These increases were partially offset by decreased expense associated with ROLONTIS, attributable to a non-recurring $2.7 million clinical milestone fee in 2016 (see Note 17(b)(xiii) to the accompanying Consolidated Financial Statements).

Amortization and Impairment Charges of Intangible Assets. Amortization expense increased $1.7 million in 2017 compared to 2016 due to a prospectively-applied adjustment in June 2016 of the amortization period of our FOLOTYN distribution rights (to November 2022 from March 2025), representing the period through which we expect to have patent protection from generic competition (see Note 3(g) to the accompanying Consolidated Financial Statements). As a result, in 2017 we incurred a full-year of increased amortization expense related to this adjustment. Amortization expense otherwise remained consistent with the prior year period as we continue to recognize expense on a straight-line basis for the distribution rights to our commercialized products.

Total Other Expenses

	Year Ended December 31,			
	2017	2016	$ Change	% Change
	($ in millions)			
Total other expenses	$ (11.4)	$ (9.2)	$ (2.2)	(23.9)%

Total other expenses increased $2.2 million in 2017 compared to 2016 due to multiple offsetting components, including (i) $0.8 million loss on our 2018 Convertible Notes repurchase of $69.5 million (see Note 15 to the accompanying Consolidated Financial Statements), (ii) $0.6 million increase in foreign currency exchange rate translation adjustment (i.e. unrealized loss), and (iii) $5.0 million increase in the fair value of contingent consideration related to our MARQIBO product (see Note 10(a) to the accompanying Consolidated Financial Statements), offset by a $0.8 million decrease in the fair value of contingent consideration related to our EVOMELA product (see Note 10(b) to the accompanying Consolidated Financial Statements) that is recognized through "other (expense) income" for its quarterly re-measurement. In 2017, we increased our revenue projections for in development indications of MARQIBO, and this led to an overall increase in the contingent consideration liability and corresponding expense. These expense increases were partially offset by (i) $2.6 million decrease in interest expense on our 2018 Convertible Notes as a result of our December 2016 and October 2017 repurchases of $10 million and $69.5 million principal of these notes, respectively (see Note 15 to the accompanying Consolidated Financial Statements), and (ii) a $0.9 million decrease in executive deferred compensation expense as a result of increases in the fair value of plan assets (see Note 17(f)) to the accompanying Consolidated Financial Statements).

Benefit for Income Taxes

Year Ended December 31,

	2017	2016	$ Change	% Change
	($ in millions)			
Benefit for income taxes	$ 16.8	$ 2.3	$ 14.5	>100.0 %

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Our $16.8 million benefit for income taxes in 2017 principally relates to tax benefits allocated to continuing operations as a result of unrealized gains in "other comprehensive income (loss)". During 2017, we had unrealized gains from the change in value of our available-for-sale securities that are reported within "other comprehensive income (loss)" of $25.8 million, while we also reported a pretax "loss from continuing operations" of $108 million. The gains in "other comprehensive income (loss)" resulted in our recording a tax benefit of $9.7 million to continuing operations and an offsetting tax charge to "other comprehensive income (loss)" of $9.7 million. The remaining benefit for 2017 income taxes relates to the re-measurement of deferred taxes and changes in judgment regarding the realizability of deferred tax assets, resulting from tax changes enacted as part of the Tax Jobs and Cuts Act.

Our 2016 benefit for income taxes of $2.3 million is primarily due to unrealized gains from the change in value of our available-for-sale securities while we also reported a pretax operating loss in the same period.

LIQUIDITY AND CAPITAL RESOURCES

	December 31,		
	2018	2017	2016
	(in thousands, except financial metrics data)		
Cash, cash equivalents and marketable securities	$203,988	$227,571	$158,469
Accounts receivable, net	$29,873	$32,260	$39,782
Total current assets	$250,688	$277,746	$216,650
Total current liabilities	$86,474	$109,749	$65,513
Working capital surplus (a)	$164,214	$167,997	$151,137
Current ratio (b)	2.9	2.5	3.3

(a) Total current assets at period end minus total current liabilities at period end.

(b) Total current assets at period end divided by total current liabilities at period end.

Net Cash Used In Operating Activities

Cash used in operating activities was $62.4 million in 2018, as compared to $38.9 million and $40.5 million in 2017 and 2016, respectively.

For the years ended December 31, 2018, 2017, and 2016, our cash collections from customers totaled $126.3 million, $161.5 million, and $159.5 million respectively, representing 115%, 126%, and 109% of reported net revenue for the same years.

For the years ended December 31, 2018, 2017, and 2016, cash payments to our employees and vendors for products, services, and rebates totaled $209.7 million, $210.2 million, and $206.9 million respectively.

Net Cash Provided By (Used In) Investing Activities

Net cash provided by investing activities was $1.4 million for the year ended December 31, 2018, as compared to $1.1 million and $0.7 million of cash used in investing activities for the years ended December 31, 2017 and 2016, respectively. Our cash provided by investing activities in 2018 primarily related to $4.1 million receipt of cash for corporate-owned life insurance premiums. This amount was partially offset by (i) cash paid for KHAPZORY distribution rights of $2.7 million (see Note 3(g)), and (ii) $0.1 million of computer hardware and software purchases.

Net Cash (Used In) Provided By Financing Activities

Net cash used in financing activities was $8.5 million for the year ended December 31, 2018, as compared to $108.7 million and $59.6 million of cash provided by financing activities for the years ended December 31, 2017 and 2016, respectively. Our cash used in financing activities during the year ended December 31, 2018 related to: (i) $13.5 million of proceeds from the issuance of common stock as a result of the exercise of employee stock options, (ii) $1.1 million of proceeds from employee stock purchases under our employee stock purchase plan, and (iii) $4.6 million of proceeds received from employees related to remittances to federal and state tax authorities for taxes due at vesting/exercise of equity awards. These amounts were offset by (i) $27.7 million of aggregate payments to federal and state tax authorities related to our employees’ tax

liabilities at the time of stock vestings and exercises, and (ii) $20 thousand payment upon the maturity of our 2018 Convertible Notes on December 15, 2018 (see Note 15).

2013 Convertible Senior Notes - Maturity on December 15, 2018

On December 17, 2013, we entered into an agreement for the sale of $120 million aggregate principal amount of 2.75% Convertible Senior Notes (equaling 120,000 notes, denominated in $1,000 principal units) the "2013 Convertible Notes." As of December 31, 2017, $38.2 million of debt principal was outstanding. Maturity of the 2013 Convertible Notes occurred on December 15, 2018, and substantially all of these notes were converted into our common stock at a rate of 95 shares per $1,000 principal units, with an in-the-money conversion price of $10.53 per common share. As a result, there were no amounts outstanding as of December 31, 2018.

Sale of Common Stock Under ATM Agreements

In December 2015 and August 2017, we entered into collective at-market-issuance sales agreements with FBR Capital Markets & Co., MLV & Co. LLC, and H.C. Wainwright & Co., LLC. These agreements allowed us to raise aggregate gross proceeds through these brokers of up to $250 million from the sale of our common stock on the public market. Through December 31, 2018, we had raised aggregate gross net proceeds of $202.1 million through these at-market sales, of which $128.3 million was raised during the year ended December 31, 2017. We had no sales under the ATM during the year ended December 31, 2018. We are using these proceeds to continue to develop our product pipeline and to provide additional capital structure flexibility.

Sale of Our Commercialized Drug Portfolio and Future Proceeds

On January 17, 2019, we entered into a definitive asset purchase agreement for the sale of our FDA-approved product portfolio of FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA to Acrotech. Upon the closing of the Acrotech Transaction, we are entitled to receive up to $160 million in an upfront cash payment (of which $4 million will be held in escrow for six months). In addition, we expect a purchase price adjustment for certain ongoing research and development activities of the commercialized product portfolio. We are also entitled to receive an aggregate $140 million upon Acrotech's achievement of certain regulatory and sales-based milestones relating to this product portfolio. We plan to reduce our staff by approximately 90 employees, the majority of which we expect to transition to Acrotech.

We plan to use the anticipated proceeds from the Acrotech Transaction to advance our in-development drug pipeline, as well as providing for our general working capital requirements.

Future Capital Requirements

We believe that the future growth of our business will depend on our ability to successfully develop and acquire new drugs for the treatment of cancer and successfully bring these drugs to market.

The timing and amount of our future capital requirements will depend on many factors, including:

- the need for additional capital to fund future development programs;
- the need for additional capital to fund strategic acquisitions;
- the need for additional capital to fund licensing arrangements;
- our requirement for additional information technology infrastructure and systems; and
- adverse outcomes from potential litigation and the cost to defend such litigation.

We believe that our $204 million in aggregate cash and cash equivalents, and marketable securities as of December 31, 2018, in addition to the pending proceeds from the Acrotech Transaction, will be sufficient to fund operations for at least the next three years.

We may, however, require additional liquidity as we continue to execute our business strategy, and in connection with opportunistic acquisitions or licensing arrangements. We anticipate that to the extent that we require additional liquidity, it will be funded through additional equity or debt financings (see Note 7 to the accompanying Consolidated Financial Statements). We cannot assure you that we will be able to obtain this additional liquidity on terms favorable to us or our current stockholders, or at all. Additionally, our liquidity and our ability to fund our capital requirements are also dependent on our

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future financial performance, which is subject to general economic, financial and other factors that are beyond our control, including those described in Item 1A Risk Factors.

Contractual Obligations

The following table summarizes our contractual financial commitments as of December 31, 2018:

	Total	Less than 1 Year	1-3 Years	3-5 Years	After 5 Years
	(in thousands)				
Operating lease obligations (1)	$5,308	$ 1,486	$ 2,907	$ 915	$—
Purchase obligations (2)	82,865	67,888	7,859	1,087	6,031
Contingent milestone obligations (3)	1,195,812	10,000	22,000	6,000	1,157,812
Drug development liability (4)	11,997	2,311	8,430	1,256	—
Total	$1,295,982	$ 81,685	$ 41,196	$ 9,258	$1,163,843

(1) The operating lease obligations are primarily related to the facility lease for our corporate headquarters in Henderson, Nevada, expiring October 31, 2021; and our research and development and administrative facility in Irvine, California, expiring July 31, 2022.

(2) Purchase obligations represent the amount of open purchase orders and contractual commitments to vendors for products and services that have not been delivered, or rendered, as of December 31, 2018.

(3) Milestone obligations are payable contingent upon successfully reaching certain development and regulatory milestones. Given the unpredictability of the drug development process, and the impossibility of predicting the success of current and future clinical trials, these values assume that all development and regulatory milestones under all of our license agreements are successfully met, and represent our best estimate of each achievement date. In the event that the milestones are met, we believe it is likely that the increase in the potential value of the related drug product will exceed the amount of the milestone obligation.

(4) Research and development services under the Mundipharma Collaboration Agreement (see Note 16 to the accompanying Consolidated Financial Statements) over the period required to complete the jointly agreed-upon clinical development activities.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements (except for operating leases) that provide financing, liquidity, market or credit risk support, or involve derivatives. In addition, we have no arrangements that may expose us to liability that are not expressly reflected in the accompanying Consolidated Financial Statements and/or notes thereto.

As of December 31, 2018, we did not have any relationships with unconsolidated entities or financial partnerships, often referred to as “structured finance” or “special purpose entities,” established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not subject to any material financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the normal course of business, our operations are exposed to risks associated with fluctuations in interest rates and foreign currency exchange rates.

The primary objective of our investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. We do not utilize hedging contracts or similar instruments as part of our investing activities. Because of our ability to generally redeem these investments at par on short notice and without penalty, changes in interest rates would have an immaterial effect on the fair value of these investments. If a 10% change in interest rates were to have occurred on December 31, 2018, any decline in the fair value of our investments would not be material in the context of our accompanying Consolidated Financial Statements. In addition, we are exposed to certain market risks associated with credit ratings of corporations whose corporate bonds we may purchase from time to time. If these companies were to experience a significant detrimental change in their credit ratings, the fair market value of such corporate bonds may significantly decrease.

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If these companies were to default on these corporate bonds, we may lose part or all of our principal. We believe that we effectively manage this market risk by diversifying our investments, and investing in highly rated securities.

We are exposed to foreign currency exchange rate fluctuations relating to payments we make to vendors, suppliers and license partners in Euros (and other currencies to a lesser extent). We mitigate this risk by maintaining a limited portion of our cash in Euros for our vendor payments in Euros.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Spectrum Pharmaceuticals, Inc.

By: /s/ JOSEPH W. TURGEON
Joseph W. Turgeon
President and Chief Executive Officer

Date: February 28, 2019

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Joseph W. Turgeon and Kurt A. Gustafson as his attorney-in-fact, with full power of substitution, for him in any and all capacities, to sign any amendments to this Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each attorney-in-fact, or his substitute, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

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Signature	Title	Dates
/s/ JOSEPH W. TURGEON Joseph W. Turgeon	President and Chief Executive Officer	February 28, 2019
/s/ KURT A. GUSTAFSON Kurt A. Gustafson	Executive Vice President and Chief Financial Officer	February 28, 2019
/s/ STUART M. KRASSNER, SC.D., PSY.D Stuart M. Krassner, Sc.D., Psy.D.	Chairman of the Board	February 28, 2019
/s/ DOLATRAI M. VYAS, PH.D. Dolatrai M. Vyas, Ph.D.	Director	February 28, 2019
/s/ BERNICE R. WELLES, M.D., M.B.A. Bernice R. Welles, M.D., M.B.A.	Director	February 28, 2019
/s/ ANTHONY E. MAIDA, III, M.A., M.B.A., PH.D. Anthony E. Maida, III, M.A., M.B.A., Ph.D.	Director	February 28, 2019
/s/ RAYMOND W. COHEN Raymond W. Cohen	Director	February 28, 2019
/s/ GILLES R. GAGNON, M.Sc., M.B.A, ICD.D Gilles R. Gagnon, M.Sc., M.B.A	Director	February 28, 2019
/s/ JEFFREY L. VACIRCA, M.D., F.A.C.P. Jeffrey L. Vacirca, M.D., F.A.C.P.	Director	February 28, 2019
/s/ WILLIAM L. ASHTON William L. Ashton	Director	February 28, 2019

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
SPECTRUM PHARMACEUTICALS, INC.
FORM 10-K ANNUAL REPORT
For the Fiscal Years Ended December 31, 2018, 2017, and 2016
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and Board of Directors of Spectrum Pharmaceuticals, Inc.

Opinion of the Financial Statements

We have audited the accompanying consolidated balance sheets of Spectrum Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018, and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on the criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

Changes in Accounting Principles

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for revenue from contracts with customers in 2018 due to adoption of Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606).

As discussed in Note 3 to the financial statements, the Company has changed its method of accounting for unrealized gains and losses on equity securities in 2018 due to adoption of ASU No. 2016-01, Recognition and Measurement of Financial Assets and Liabilities.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP
Costa Mesa, California
February 28, 2019

We have served as the Company's auditor since 2014.

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SPECTRUM PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and par value amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$157,480	$227,323
Marketable securities	46,508	248
Accounts receivable, net of allowance for doubtful accounts of $67 and $71, respectively	29,873	32,260
Other receivables	3,698	2,133
Inventories	3,550	5,715
Prepaid expenses and other assets	9,579	10,067
Total current assets	250,688	277,746
Property and equipment, net of accumulated depreciation	385	589
Intangible assets, net of accumulated amortization	111,594	137,159
Goodwill	18,061	18,162
Other assets	10,158	53,783
Total assets	$390,886	$487,439
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$69,460	$58,117
Accrued payroll and benefits	9,853	9,261
Contract liabilities	4,850	—
Deferred revenue	—	3,872
FOLOTYN development liability	2,311	275
Convertible senior notes	—	38,224
Total current liabilities	86,474	109,749
FOLOTYN development liability, less current portion	9,686	12,111
Deferred revenue, less current portion	—	315
Acquisition-related contingent obligations	4,345	6,272
Deferred tax liabilities	1,469	1,438
Other long-term liabilities	5,650	6,215
Total liabilities	107,624	136,100
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 110,525,141 and 100,742,735 issued and outstanding at December 31, 2018 and 2017, respectively	110	100
Additional paid-in capital	886,740	837,347
Accumulated other comprehensive (loss) income	(3,702)	15,999
Accumulated deficit	(599,886)	(502,107)
Total stockholders' equity	283,262	351,339
Total liabilities and stockholders' equity	$390,886	$487,439

See accompanying notes to these consolidated financial statements.

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SPECTRUM PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Product sales, net	$104,466	$116,178	$128,596
License fees and service revenue	4,867	12,189	17,848
Total revenues	109,333	128,367	146,444
Operating costs and expenses:			
Cost of sales (excludes amortization of intangible assets)	26,756	42,859	27,953
Cost of service revenue	—	4,359	7,890
Selling, general and administrative	90,700	84,267	88,418
Research and development	94,956	65,895	59,123
Amortization of intangible assets	28,098	27,647	25,946
Total operating costs and expenses	240,510	225,027	209,330
Loss from operations	(131,177)	(96,660)	(62,886)
Other income (expense):			
Interest expense, net	(340)	(6,798)	(9,435)
Change in fair value of contingent consideration related to acquisitions	1,927	(4,957)	(649)
Other income, net	9,580	389	887
Total other income (expenses)	11,167	(11,366)	(9,197)
Loss before income taxes	(120,010)	(108,026)	(72,083)
(Provision) benefit for income taxes	(1)	16,778	2,313
Net loss	$(120,011)	$(91,248)	$(69,770)
Net loss per share:			
Basic	$(1.16)	$(1.07)	$(0.96)
Diluted	$(1.16)	$(1.07)	$(0.96)
Weighted average shares outstanding:			
Basic	103,305,911	85,115,592	72,824,070
Diluted	103,305,911	85,115,592	72,824,070

See accompanying notes to these consolidated financial statements.

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SPECTRUM PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	$(120,011)	$(91,248)	$(69,770)
Other comprehensive (loss) income :			
Unrealized gain on available-for-sale securities, net of income tax expense of $0, $9.7 million and $2.2 for the years ended December 31, 2018, 2017, and 2016, respectively (see Note 3(a))	—	16,039	4,185
Foreign currency translation adjustments	(2,490)	1,539	(445)
Other comprehensive (loss) income	(2,490)	17,578	3,740
Total comprehensive loss	$(122,501)	$(73,670)	$(66,030)

See accompanying notes to these consolidated financial statements.

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SPECTRUM PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)

	Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
Balance as of January 1, 2016	20	$ 123	68,228,935	$ 68	$ 559,068	$ (5,319)	$ (341,083)	$ 212,857
Net loss	—	—	—	—	—	—	(69,770)	(69,770)
Other comprehensive income, net	—	—	—	—	—	3,740	—	3,740
Issuance of common stock to 401(k) plan	—	—	172,650	—	953	—	—	953
Issuance of common stock for ESPP	—	—	150,303	—	668	—	—	668
Issuance of common stock upon exercise of stock options	—	—	39,010	—	202	—	—	202
RSA and stock option issuances and forfeitures for terminations, net	—	—	868,032	1	12,717	—	—	12,718
Repurchase/retirement of RSAs to satisfy employee tax withholding	—	—	(266,860)	—	(1,397)	—	—	(1,397)
Common stock issued under an at-the-market sales agreement (Note 7)	—	—	10,890,915	11	73,858	—	—	73,869
Issuance of common stock for ROLONTIS milestone achievement (Note 17(b)(xiii))	—	—	318,750	—	2,308	—	—	2,308
Issuance of common stock for QAPZOLA milestone achievement (Note 17(b)(x))	—	—	25,000	—	111	—	—	111
Conversion hedge unwind in connection with open market purchases of 2018 Convertible Notes (Note 15)	—	—	—	—	(227)	—	—	(227)
Conversion of preferred shares into common stock (Note 7)	(20)	(123)	40,000	—	123	—	—	—
Dividend paid on preferred shares (Note 7)	—	—	—	—	—	—	(6)	(6)
Balance as of December 31, 2016	—	$ —	80,466,735	$ 80	$ 648,384	$ (1,579)	$ (410,859)	$ 236,026
Net loss	—	—	—	—	—	—	(91,248)	(91,248)
	—	—	—	—	—	17,578	—	17,578

Other comprehensive income, net								
Issuance of common stock to 401(k) plan	—	—	102,874	—	912	—	—	912
Issuance of common stock for ESPP	—	—	203,229	—	1,010	—	—	1,010
Issuance of common stock upon exercise of stock options, net	—	—	864,897	1	5,477	—	—	5,478
RSA and stock option issuances and forfeitures for terminations, net	—	—	548,394	—	13,197	—	—	13,197
Repurchase/retirement of RSAs to satisfy employee tax withholding	—	—	(373,822)	—	(4,331)	—	—	(4,331)
Issuance of common stock upon vesting of RSUs	—	—	—	—	1,030	—	—	1,030
Common stock issued under an at-the-market sales agreement (Note 7)	—	—	13,558,132	14	128,258	—	—	128,272
Conversion hedge unwind in connection with open market purchases of 2018 Convertible Notes (Note 15)	—	—	5,372,296	5	43,410	—	—	43,415
Balance as of December 31, 2017	—	$—	100,742,735	$ 100	$ 837,347	$ 15,999	$ (502,107)	$ 351,339
Net loss	—	—	—	—	—	—	(120,011)	(120,011)
Cumulative-effect adjustment of ASU 2016-01 adoption (Note 3(a))	—	—	—	—	—	(17,211)	17,211	—
Cumulative-effect adjustment of Topic 606 adoption (Note 3(j))	—	—	—	—	—	—	4,678	4,678
Foreign currency adjustment related to new adoptions	—	—	—	—	—	—	343	343
Other comprehensive income, net	—	—	—	—	—	(2,490)	—	(2,490)
Issuance of common stock to 401(k) plan	—	—	70,379	—	1,175	—	—	1,175
Issuance of common stock for ESPP	—	—	97,804	—	1,122	—	—	1,122
Issuance of common stock upon exercise of stock options	—	—	7,858,141	8	52,977	—	—	52,985
RSA and stock option issuances and forfeitures for terminations, net	—	—	874,532	1	14,113	—	—	14,114
Issuance of common stock upon vesting of RSUs	—	—	200,652	—	2,196	—	—	2,196
Issuance of common stock upon exercise of warrants			292,575	—	—	—	—	—

Repurchase/retirement of RSAs and option exercises to satisfy employee tax withholdings and exercise price	—	—	(3,463,873)	(3)	(62,541)	—	—	(62,544)
Common stock redeemed on 2018 Convertible Notes (Note 15)	—	—	3,852,196	4	40,351	—	—	40,355
Balance as of December 31, 2018	—	$ —	110,525,141	$ 110	$ 886,740	$ (3,702)	$ (599,886)	$ 283,262

See accompanying notes to these consolidated financial statements.

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SPECTRUM PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash Flows From Operating Activities:			
Net loss	(120,011)	(91,248)	(69,770)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	28,409	27,972	26,492
Stock-based compensation	17,483	15,139	13,670
Accretion of debt discount on 2018 Convertible Notes, recorded to interest expense (Note 15)	1,931	4,890	5,710
Amortization of deferred financing costs on 2018 Convertible Notes, recorded to interest expense (Note 15)	220	567	696
Bad debt expense (recovery)	12	(17)	57
Unrealized loss (gains) from transactions denominated in foreign currency	10	(23)	(153)
Loss on 2018 Convertible Note purchase (Note 15)	—	845	25
Change in cash surrender value of corporate-owned life insurance policy	(5)	(418)	(137)
Deferred tax liabilities	31	(5,237)	(104)
Income tax recognition on unrealized gain for available-for-sale securities	—	(9,651)	(2,217)
Unrealized gains on marketable securities (Note 3(a))	(10,458)	—	—
Change in fair value of contingent consideration related to the Talon and EVOMELA acquisitions (Note 10)	(1,927)	4,957	649
Research and development expense recognized for the value of common stock issued in connection with QAPZOLA (Note 17(b)(x)) and ROLONTIS (Note 17(b)(xiii)) milestone achievements	—	—	2,419
Changes in operating assets and liabilities:			
Accounts receivable, net	2,844	7,694	(9,494)
Other receivables	(1,571)	3,663	6,895
Inventories	3,390	4,318	(5,800)
Prepaid expenses	(3,642)	(6,137)	(423)
Other assets	5,010	1,573	(2,043)
Accounts payable and other accrued obligations	11,382	5,518	(4,033)
Accrued payroll and benefits	592	280	790
FOLOTYN development liability	(389)	(744)	(1,556)
Acquisition-related contingent obligations	—	—	(1,300)
Contract liabilities	4,850	—	—
Deferred revenue	—	593	(2,985)
Other long-term liabilities	(564)	(3,389)	2,153
Net cash used in operating activities	(62,403)	(38,855)	(40,459)
Cash Flows From Investing Activities:			
Proceeds from redemption of corporate-owned life insurance policy	4,130	—	—
Payment for corporate-owned life insurance premiums	—	(601)	(601)
Purchases of property and equipment	(107)	(465)	(78)
Cash paid for KHAPZORY distribution rights (Note 3(g))	(2,650)	—	—
Purchase of equity securities (Note 11)	—	(15)	—
Net cash provided by (used in) investing activities	1,373	(1,081)	(679)

Cash Flows From Financing Activities:			
Proceeds from employees for exercises of stock options, net	13,475	5,477	203
Proceeds from sale of stock under our employee stock purchase plan	1,122	1,010	668
Proceeds from employees, for our remittance to tax authorities, upon vesting of restricted stock	4,645	—	—
Payments to tax authorities upon employees' surrender of restricted stock at vesting and exercises of stock options	(27,679)	(4,331)	(1,397)
Payment of principal upon the maturity of the 2018 Convertible Notes (Note 15)	(20)	—	—
Payment of contingent consideration related to EVOMELA acquisition (Note 10(b))	—	—	(4,700)
Purchase of 2018 Convertible Notes (Note 15)	—	(27,500)	(9,014)
Purchase of warrants related to the conversion hedge of 2018 Convertible Notes (Note 15)	—	(27,189)	(330)
Proceeds from sale of call options related to the conversion hedge of 2018 Convertible Notes (Note 15)	—	32,982	351
Proceeds from sale of common stock under an at-the-market sales agreement (Note 7)	—	128,272	73,869
Dividends paid upon conversion of Series E Convertible Voting Preferred Stock (Note 7)	—	—	(6)
Net cash (used in) provided by financing activities	(8,457)	108,721	59,644
Effect of exchange rates on cash and equivalents	(356)	316	(25)
Net (decrease) increase in cash and cash equivalents	(69,843)	69,101	18,481
Cash and cash equivalents — beginning of year	227,323	158,222	139,741
Cash and cash equivalents — end of year	$157,480	$227,323	$158,222
Supplemental Disclosure of Cash Flow Information:			
Cash paid for income taxes	$45	$17	$11
Cash paid for interest	$1,031	$2,692	$3,300

See accompanying notes to these consolidated financial statements.

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

1. DESCRIPTION OF BUSINESS, BASIS OF PRESENTATION, AND OPERATING SEGMENT

(a) Description of Business

Spectrum Pharmaceuticals, Inc. (“Spectrum,” the “Company,” “we,” “our,” or “us”) is a biopharma company, with a primary strategy comprised of acquiring, developing, and commercializing a broad and diverse pipeline of clinical and commercial products. We have an in-house clinical development organization with regulatory and data management capabilities, in addition to commercial infrastructure and a field-based sales force for our marketed products.

Currently, we have seven approved oncology/hematology products (FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA) that target different types of non-Hodgkin's lymphoma ("NHL"), advanced metastatic colorectal cancer ("mCRC"), acute lymphoblastic leukemia ("ALL"), and multiple myeloma ("MM").

We also have two drugs in late-stage development:

- Poziotinib, a novel pan-HER inhibitor under investigation for non-small cell lung cancer ("NSCLC") tumors with either EGFR or HER2 exon-20 insertion mutations; and
- ROLONTIS, a novel long-acting granulocyte colony-stimulating factor ("G-CSF"), analog for chemotherapy-induced neutropenia.

On January 17, 2019, we entered into a definitive asset purchase agreement for the sale of our FDA-approved product portfolio of FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA to Acrotech Biopharma L.L.C. ("Acrotech"), a New Jersey-based wholly-owned subsidiary of Aurobindo Pharma USA Inc. (the "Acrotech Transaction"). Upon the closing of the Acrotech Transaction, we are entitled to receive up to $160 million in an upfront cash payment (of which $4 million will be held in escrow for six months). In addition, we expect a purchase price adjustment for certain ongoing research and development activities of the commercialized product portfolio. We are also entitled to receive an aggregate $140 million upon Acrotech's achievement of certain regulatory and sales-based milestones relating to this product portfolio. We plan to reduce our staff by approximately 90 employees, the majority of which we expect to transition to Acrotech. The accounting recognition and financial reporting for the disposal of this commercial component of our business will be reflected in our financial statements in the period corresponding with its closing.

(b) Basis of Presentation

Principles of Consolidation

The accompanying Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and with the rules and regulations of the Securities and Exchange Commission ("SEC"). These financial statements include the financial position, results of operations, and cash flows of Spectrum and its subsidiaries, all of which are wholly-owned (except for Spectrum Pharma Canada ("SPC")), as discussed below. All inter-company accounts and transactions among these legal entities have been eliminated in consolidation.

Variable Interest Entity

We own fifty-percent of SPC, a legal entity organized in Quebec, Canada in January 2008. Some of our clinical studies are conducted through this “variable interest entity” (as defined under applicable GAAP). We fund all of SPC’s operating costs, and since we assume all risks and rewards for this entity, we meet the criteria as being its “primary beneficiary” (as defined under applicable GAAP). Accordingly, SPC’s balance sheets and statements of operations are included in our Consolidated Financial Statements as if it were a wholly-owned subsidiary for all periods presented.

(c) Operating Segment

We operate in one reportable operating segment that is focused exclusively on developing and marketing oncology and hematology drug products. For the years ended December 31, 2018, 2017, and 2016, all of our revenue and related expenses were solely attributable to these activities. Substantially all of our assets (excluding our cash held in certain foreign bank accounts and our ZEVALIN distribution rights for the ex-U.S. territories - see Note 3(g)) are held in the U.S.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND USE OF ESTIMATES

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Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

The preparation of financial statements in conformity with GAAP requires our management to make informed estimates and assumptions that affect our reported amounts of assets, liabilities, revenues, and expenses. These amounts may materially differ from the amounts ultimately realized and reported due to the inherent uncertainty of any estimate or assumption. On an on-going basis, our management evaluates its most critical estimates and assumptions, including those related to: (i) gross-to-net revenue adjustments; (ii) the timing of revenue recognition; (iii) the collectability of customer accounts; (iv) whether the cost of our inventories can be recovered; (v) the recoverability of our reported goodwill and intangible assets; (vi) the realization of our tax assets and estimates of our tax liabilities; (vii) the likelihood of payment and value of contingent liabilities; (viii) the fair value of our investments; (ix) the valuation of our stock options and the periodic expense recognition of stock-based compensation; and (x) the potential outcome of our ongoing or threatened litigation.

Our accounting policies and estimates that most significantly impact the presented amounts within these Consolidated Financial Statements are further described below:

(i) Revenue Recognition

Impact of the Adoption of the New Revenue Recognition Standard: ASU No. 2014-09, Revenue from Contracts with Customers ("Topic 606"), became effective for us on January 1, 2018. Our disclosure within the below sections to this footnote reflects our updated accounting policies that are affected by this new standard. We applied the "modified retrospective" transition method for open contracts for the implementation of Topic 606; this resulted in the recognition of an aggregate $4.7 million, net of tax, decrease to our January 1, 2018 "accumulated deficit" on our accompanying Consolidated Balance Sheets for the cumulative impact of applying this new standard. We made no adjustments to our previously-reported total revenues, as those periods continue to be presented in accordance with our historical accounting practices under Topic 605, Revenue Recognition ("Topic 605"). See Notes 4, 5, and 20 for additional quantitative and qualitative revenue disclosures in accordance with Topic 606.

Required Elements of Our Revenue Recognition: Revenue from our (a) product sales, (b) out-license arrangements, and (c) service arrangements is recognized under Topic 606 in a manner that reasonably reflects the delivery of our goods and/or services to customers in return for expected consideration and includes the following elements:

(1) we ensure that we have an executed contract(s) with our customer that we believe is legally enforceable;
(2) we identify the "performance obligations" in the respective contract;
(3) we determine the "transaction price" for each performance obligation in the respective contract;
(4) we allocate the transaction price to each performance obligation; and
(5) we recognize revenue only when we satisfy each performance obligation.

These five elements, as applied to each of our revenue categories, are summarized below:

(a) Product Sales: We sell our products to pharmaceutical wholesalers/distributors (i.e., our customers), except for our U.S. sales of ZEVALIN, and limited sales of EVOMELA, in which case the end-user (i.e., clinic or hospital) is our customer. Our wholesalers/distributors in turn sell our products directly to clinics, hospitals, and private oncology-based practices. Revenue from our product sales is recognized as physical delivery of product occurs (when our customer obtains control of the product), in return for agreed-upon consideration.

Our gross product sales (i.e., delivered units multiplied by the contractual price per unit) are reduced by our corresponding gross-to-net ("GTN") estimates using the "expected value" method, resulting in our reported "product sales, net" in the accompanying Consolidated Statements of Operations, reflecting the amount we ultimately expect to realize in net cash proceeds, taking into account our current period gross sales and related cash receipts, and the subsequent cash disbursements on these sales that we estimate for the various GTN categories discussed below. These estimates are based upon information received from external sources (such as written or oral information obtained from our customers with respect to their period-end inventory levels and sales to end-users during the period), in combination with management's informed judgments. Due to the inherent uncertainty of these estimates, the actual amount incurred (of some, or all) of product returns, government chargebacks, prompt pay discounts, commercial rebates, Medicaid

rebates, and distribution, data, and GPO administrative fees may be materially above or below the amount estimated, then requiring prospective adjustments to our reported net product sales.
These GTN estimate categories are each discussed below:

Product Returns Allowances: Our FUSILEV, MARQIBO, and BELEODAQ customers are contractually permitted to return purchased products beginning at its expiration date and within six months thereafter. Our EVOMELA customers are permitted to return purchased product beginning at six months prior to its expiration date, and within 12 months thereafter (as well as for overstock inventory, as determined by end-users). ZEVALIN and FOLOTYN returns for expiry are not contractually permitted. Returns outside of this aforementioned criteria are not customarily allowed. We estimate expected product returns for our allowance based on our historical return rates. Returned product is typically destroyed, since substantially all returns are due to expiry and cannot be resold.

Government Chargebacks: Our products are subject to pricing limits under certain federal government programs (e.g., Medicare and 340B Drug Pricing Program). Qualifying entities (i.e., end-users) purchase products from our customers at their qualifying discounted price. The chargeback amount we incur represents the difference between our contractual sales price to our customer, and the end-user's applicable discounted purchase price under the government program. There may be significant lag time between our reported net product sales and our receipt of the corresponding government chargeback claims from our customers.

Prompt Pay Discounts: Discounts for prompt payment are estimated at the time of sale, based on our eligible customers' prompt payment history and the contractual discount percentage.

Commercial Rebates: Commercial rebates are based on (i) our estimates of end-user purchases through a group purchasing organization ("GPO"), (ii) the corresponding contractual rebate percentage tier we expect each GPO to achieve, and (iii) our estimates of the impact of any prospective rebate program changes made by us.

Medicaid Rebates: Our products are subject to state government-managed Medicaid programs, whereby rebates are issued to participating state governments. These rebates arise when a patient treated with our product is covered under Medicaid, resulting in a discounted price for our product under the applicable Medicaid program. Our Medicaid rebate accrual calculations require us to project the magnitude of our sales, by state, that will be subject to these rebates. There is a significant time lag in us receiving rebate notices from each state (generally several months or longer after our sale is recognized). Our estimates are based on our historical claim levels by state, as supplemented by management's judgment.

Distribution, Data, and GPO Administrative Fees: Distribution, data, and GPO administrative fees are paid to authorized wholesalers/distributors of our products (except for U.S. sales of ZEVALIN) for various commercial services including: contract administration, inventory management, delivery of end-user sales data, and product returns processing. These fees are based on a contractually-determined percentage of our applicable sales.

(b) License Fees: Our out-license arrangements allow licensees to market our product(s) in certain territories for a specific term (representing the out-license of "functional intellectual property"). These arrangements may include one or more of the following forms of consideration: (i) upfront license fees, (ii) sales royalties, (iii) sales milestone-achievement fees, and (iv) regulatory milestone-achievement fees. We recognize revenue for each based on the contractual terms that establish our right to collect payment once the performance obligation is achieved, as follows:

(1) Upfront License Fees: We determine whether upfront license fees are earned at the time of contract execution (i.e., when rights transfer to the customer) or over the actual (or implied) contractual period of the out-license. As part of this determination, we evaluate whether we have any other requirements to provide substantive services that are inseparable from the performance obligation of the license transfer. Our customers' "distinct" rights to licensed "functional intellectual property" at the time of contract execution results in concurrent revenue recognition of all upfront license fees (assuming that there are no other performance obligations at contract execution that are inseparable from this license transfer).

(2) Royalties: Under the "sales-or-usage-based royalty exception" we recognize revenue in the same period that our

licensees complete product sales in their territory for which we are contractually entitled to a percentage-based royalty receipt.

(3) Sales Milestones: Under the "sales-or-usage-based royalty exception" we recognize revenue in full within the period that our licensees achieve annual or aggregate product sales levels in their territories for which we are contractually entitled to a specified lump-sum receipt.

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

(4) Regulatory Milestones: Under the terms of the respective out-license, regulatory achievements may either be our responsibility, or that of our licensee.

- When our licensee is responsible for the achievement of the regulatory milestone, we recognize revenue in full (for the contractual amount due from our licensee) in the period that the approval occurs (i.e., when the "performance obligation" is satisfied by our customer) under the "most likely amount" method. This revenue recognition remains "constrained" (i.e., not recognized) until regulatory approval occurs, given its inherent uncertainty and the requirement of a significant revenue reversal not being probable if achievement does not occur. At each reporting period, we re-evaluate the probability of milestone achievement and the associated revenue constraint; any resulting adjustments would be recorded on a cumulative catch-up basis, thus reflected in our financial statements in the period of adjustment.

- When we are responsible for the achievement of a regulatory milestone, the "relative selling price method" is applied for purposes of allocating the transaction price to our performance obligations. In such case, we consider (i) the extent of our effort to achieve the milestone and/or the enhancement of the value of the delivered item(s) as a result of milestone achievement and (ii) if the milestone payment is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. We have historically assessed the contractual value of these milestones upon their achievement to be identical to the allocation of value of our performance obligations and thus representing the "transaction price" for each milestone at contract inception. We recognize this revenue in the period that the regulatory approval occurs (i.e., when we complete the "performance obligation") under the "most likely amount" method, and revenue recognition is otherwise "constrained" until regulatory approval occurs, given its inherent uncertainty and the requirement of a significant revenue reversal not being probable if achievement does not occur. At each reporting period, we re-evaluate the probability of milestone achievement and the associated revenue constraint; any resulting adjustments would be recorded on a cumulative catch-up basis, thus reflected in our financial statements in the period of adjustment.

(c) Service Revenue: We receive fees under certain arrangements for (i) sales and marketing services, (ii) supply chain services, (iii) research and development services, and (iv) clinical trial management services.

Our rights to receive payment for these services may be established by (1) a fixed-fee schedule that covers the term of the arrangement, so long as we meet ongoing performance obligations, (2) our completion of product delivery in our capacity as a procurement agent, (3) the successful completion of a phase of drug development, (4) favorable results from a clinical trial, and/or (5) regulatory approval events.

We consider whether revenue associated with these service arrangements is reportable each period, based on our completed services or deliverables (i.e., satisfied "performance obligations") during the reporting period, and the terms of the arrangement that contractually result in fixed payments due to us. The promised service(s) within these arrangements are distinct and explicitly stated within each contract, and our customer benefits from the separable service(s) delivery/completion. Further, the nature of the promise to our customer as stated within the respective contract is to deliver each named service individually (not a transfer of combined items to which the promised goods or services are inputs), and thus are separable for revenue recognition.

(ii) Cash and Cash Equivalents

Cash and cash equivalents consist of bank deposits and highly liquid investments with maturities of three months or less from the purchase date.

(iii) Marketable Securities

Our marketable securities consist of our holdings in equity securities (beginning January 1, 2018 - see Note 3(a)), mutual funds, and bank certificates of deposit ("Bank CDs"). Beginning January 1, 2018, our realized and unrealized (loss) gains on marketable securities are included in "other income, net" on the accompanying Consolidated Statements of Operations. Prior to January 1, 2018, our unrealized (loss) gains were included in “other comprehensive (loss) income” on our accompanying Consolidated Statements of Comprehensive Loss.

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

(iv) Accounts Receivable

Our accounts receivable are derived from our product sales and license fees, and do not bear interest. The allowance for doubtful accounts is management’s best estimate of the amount of probable credit losses in our existing accounts receivable. Account balances are charged off against the allowance after appropriate collection efforts are exhausted.

(v) Inventories

We value our inventory at the lower of (i) the actual cost of its purchase or manufacture, or (ii) its net realizable value. Inventory cost is determined on the first-in, first-out method. We regularly review our inventory quantities in process of manufacture and on hand. When appropriate, we record a provision for obsolete and excess inventory to derive its new cost basis, which takes into account our sales forecast by product and corresponding expiry dates of each product lot.

Manufacturing costs of drug products that are pending U.S. Food and Drug Administration ("FDA") approval are fully expensed through “research and development,” on the accompanying Consolidated Statements of Operations.

(vi) Property and Equipment

Our property and equipment is stated at historical cost, and is depreciated on a straight-line basis over an estimated useful life that corresponds with its designated asset category. We evaluate the recoverability of “long-lived assets” (which includes property and equipment) whenever events or changes in circumstances in our business indicate that the asset’s carrying amount may not be recoverable through our on-going operations.

(vii) Goodwill and Intangible Assets

Our goodwill represents the excess of our business acquisition cost over the estimated fair value of the net assets acquired in the corresponding transaction. Goodwill has an indefinite accounting life and is therefore not amortized. Instead, goodwill is evaluated for impairment on an annual basis (as of each October 1st), unless we identify impairment indicators that would require earlier testing.

We evaluate the recoverability of indefinite-lived intangible assets at least annually, or whenever events or changes in our business indicate that an intangible asset’s (whether indefinite or definite-lived) carrying amount may not be recoverable. Such circumstances could include, but are not limited to the following:

(a) a significant decrease in the market value of an asset;

(b) a significant adverse change in the extent or manner in which an asset is used; or

(c) an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset.

Intangible assets with finite useful lives are amortized over their estimated useful lives on a straight-line basis. We review these assets for potential impairment if/when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

(viii) Stock-Based Compensation

Stock-based compensation expense for equity awards granted to our employees and members of our Board of Directors is recognized on a straight-line basis over each award’s vesting period. Recognized compensation expense is net of an estimated forfeiture rate, representing the percentage of awards that are expected to be forfeited prior to vesting, though is ultimately adjusted for actual forfeitures. We use the Black-Scholes option pricing model to determine the fair value of stock options (as of the date of grant) that have service conditions for vesting. We use the Monte Carlo valuation model to value equity awards (as of the date of grant) that have combined market conditions and service conditions for vesting.

The recognition of stock-based compensation expense and the initial calculation of stock option fair value requires uncertain assumptions, including (a) the pre-vesting forfeiture rate of the award, (b) the expected term that the stock option will remain outstanding, (c) our stock price volatility over the expected term (and that of our designated peer group with respect to certain market-based awards), and (d) the prevailing risk-free interest rate for the period matching the expected term.

With regard to (a)-(d): We estimate forfeiture rates based on our employees' overall forfeiture history, which we believe will be representative of future results. We estimate the expected term of stock options granted based on our employees' historical exercise patterns, which we believe will be representative of their future behavior. We estimate the volatility of our

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(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

common stock on the date of grant based on the historical volatility of our common stock for a look-back period that corresponds with the expected term. We estimate the risk-free interest rate based upon the U.S. Department of the Treasury yields in effect at award grant, for a period equaling the expected term of the stock option.

(ix) Foreign Currency Translation

Our foreign subsidiaries' separate financial statements are stated in their functional currencies (i.e., local operating currencies). To create the accompanying Consolidated Financial Statements, we translate the assets and liabilities of our subsidiaries to U.S. dollars at the rates of exchange in effect at the reported balance sheet date; revenues and expenses are translated using the monthly average exchange rates during the reported period. Unrealized gains and losses from these translations are included in "accumulated other comprehensive (loss) income" in the accompanying Consolidated Balance Sheets.

We record foreign currency-based transactions (i.e., when not denominated in the functional currency of our transacting legal entity) at the prevailing exchange rate on the date of the transaction. Resulting unrealized foreign exchange gains and losses from these unsettled transactions are included in "accumulated other comprehensive (loss) income" in the accompanying Consolidated Balance Sheets.

All unrealized foreign exchange gains and losses associated with our intercompany loans are included in "accumulated other comprehensive (loss) income" in the accompanying Consolidated Balance Sheets, as these loans with our foreign subsidiaries are not expected to be settled in the "foreseeable future."

(x) Basic and Diluted Net Loss per Share

We calculate basic and diluted net loss per share using the weighted average number of common shares outstanding during the periods presented. In periods of a net loss, basic and diluted loss per share are the same. For the diluted earnings per share calculation, we adjust the weighted average number of common shares outstanding to include only dilutive stock options, warrants, and other common stock equivalents outstanding during the period.

(xi) Income Taxes

Deferred tax assets and liabilities are recorded based on the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the financial statements, as well as operating losses and tax credit carry forwards using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain.

We have recorded a valuation allowance to reduce our deferred tax assets, because we believe that, based upon a weighting of positive and negative factors, it is more likely than not that these deferred tax assets will not be realized. If/when we were to determine that our deferred tax assets are realizable, an adjustment to the corresponding valuation allowance would increase our net income in the period that such determination was made.

In the event that we are assessed interest and/or penalties from taxing authorities that have not been previously accrued, such amounts would be included in "(provision) benefit for income taxes" within the Consolidated Statements of Operations in the period the notice was received.

(xii) Research and Development Costs

Our research and development costs are expensed as incurred (see Note 17(c)), or as certain milestone payments become contractually due to our licensors, as triggered by the achievement of clinical or regulatory events.

(xiii) Fair Value Measurements

We determine measurement-date fair value based on the proceeds that would be received through the sale of the asset, or that we would pay to settle or transfer the liability, in an orderly transaction between market participants. We utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include the following:

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that are publicly accessible at the measurement date.
Level 2: Observable prices that are based on inputs not quoted on active markets, but that are corroborated by market data. These inputs may include quoted prices for similar assets or liabilities or quoted market prices in markets that are not active to the general public.
Level 3: Unobservable inputs are used when little or no market data is available.

3. BALANCE SHEET ACCOUNT DETAIL

The composition of selected financial statement captions that comprise the accompanying Consolidated Balance Sheets are summarized below:

(a) Cash and Cash Equivalents and Marketable Securities

As of December 31, 2018 and December 31, 2017, our "cash and cash equivalents" were held with major financial institutions. Our "marketable securities" primarily relate to our equity holdings in CASI Pharmaceuticals, Inc. ("CASI"), as defined below.

We maintain cash balances in excess of federally insured limits with reputable financial institutions. To a limited degree, the Federal Deposit Insurance Corporation and other third parties insure these investments. However, these investments are not insured against the possibility of a complete loss of earnings or principal and are inherently subject to the credit risk related to the continued credit worthiness of the underlying issuer and general credit market risks. We manage such risks in our portfolio by investing in highly liquid, highly-rated instruments, and limit investing in long-term maturity instruments.

Our investment policy requires that purchased investments in marketable securities may only be in highly-rated instruments, which are primarily U.S. treasury bills or treasury-backed securities, and also limits our investments in securities of any single issuer (excluding any debt or equity securities received from our strategic partners in connection with an out-license arrangement, as discussed in Note 11).

The carrying amount of our equity securities, money market funds, and Bank CDs approximates their fair value (utilizing "Level 1" or "Level 2" inputs - see Note 2(xiii)) because of our ability to immediately convert these instruments into cash with minimal expected change in value.

The following is a summary of our presented "cash and cash equivalents" and "marketable securities":

	Cost	Foreign Currency Translation	Gross Unrealized Gains	Estimated fair Value	Cash and equivalents	Marketable Securities Current
December 31, 2018						
Equity securities* (see Note 3(h) and Note 10)	$8,710	$(2,168)	$39,880	$46,422	$—	$ 46,422
Bank deposits	14,735	—	—	14,735	14,735	—
Money market funds	142,745	—	—	142,745	142,745	—
Bank certificates of deposits	86	—	—	86	—	86
Total cash and cash equivalents and marketable securities	$166,276	$(2,168)	$39,880	$203,988	$157,480	$ 46,508
December 31, 2017						
Bank deposits	$10,965	$—	$—	$10,965	$10,965	$ —
Money market funds	216,358	—	—	216,358	216,358	—
Bank certificates of deposits	248	—	—	248	—	248
Total cash and cash equivalents and marketable securities	$227,571	$—	$—	$227,571	$227,323	$ 248

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

* Beginning January 1, 2018, under the new requirements of ASU 2016-01, Recognition and Measurement of Financial Assets and Liabilities, the unrealized (loss) gains on our CASI Pharmaceuticals, Inc. (NASDAQ: CASI) ("CASI") equity securities are recognized as a (decrease) increase to "other income, net" on the Consolidated Statements of Operations (rather than through "other comprehensive (loss) income" on the Consolidated Statements of Comprehensive Loss). Our adoption of ASU 2016-01 on January 1, 2018, resulted in a $17.2 million cumulative-effect adjustment, net of income tax, recorded as a decrease to "accumulated other comprehensive (loss) income" and a decrease to "accumulated deficit" on the accompanying Consolidated Balance Sheets. Our recognized unrealized gain on these equity securities for the year ended December 31, 2018 was $10.5 million, as reported in "other income, net" on the accompanying Consolidated Statements of Operations.
As of December 31, 2018, none of these securities had been in a continuous unrealized loss position longer than one year.

(b) Property and Equipment, net of Accumulated Depreciation
"Property and equipment, net of accumulated depreciation" consists of the following:

	December 31,	
	2018	2017
Computers hardware and software	$3,079	$2,994
Laboratory equipment	635	630
Office furniture	212	218
Leasehold improvements	2,957	2,938
Property and equipment, at cost	6,883	6,780
(Less): Accumulated depreciation	(6,498)	(6,191)
Property and equipment, net of accumulated depreciation	$385	$589

Depreciation expense (included within "total operating costs and expenses" in the accompanying Consolidated Statements of Operations) for the years ended December 31, 2018, 2017, and 2016 was $0.3 million, $0.3 million, and $0.5 million, respectively.
(c) Inventories
"Inventories" consists of the following:

	December 31,	
	2018	2017
Raw materials	$2,024	$1,077
Work-in-process	2,209	2,551
Finished goods	1,193	5,187
(Less:) Non-current portion of inventories included within "other assets" *	(1,876)	(3,100)
Inventories	$3,550	$5,715

* The "non-current" portion of inventories is presented within "other assets" in the accompanying Consolidated Balance Sheets at December 31, 2018 and 2017, respectively. This value of $1.9 million at December 31, 2018 represents product that we expect to sell beyond December 31, 2019, and the value at December 31, 2017 represented product that we expected to sell beyond December 31, 2018.
(d) Accounts receivable, net of Allowance for Doubtful Accounts
"Accounts receivable, net of allowance for doubtful accounts" consists of trade receivables from our customers. We are exposed to credit risk associated with trade receivables that result from these product sales. We do not require collateral or deposits from our customers due to our assessment of their creditworthiness and our long-standing relationship with them. We maintain reserves for potential bad debt, though credit losses have historically been

nominal and within management's expectations. A summary of our customers that represent 10% or more of our accounts receivables as of December 31, 2018 and 2017, are as follows:

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

	December 31,					
	2018			2017		
AmerisourceBergen Corporation, and its affiliates	$10,448	35.0	%	$7,175	22.2	%
Cardinal Health, Inc. and its affiliates	8,228	27.5	%	9,514	29.5	%
McKesson Corporation and its affiliates	7,615	25.5	%	11,186	34.7	%
All other customers	3,582	12.0	%	4,385	13.6	%
Accounts receivable, net	$29,873	100.0	%	$32,260	100.0	%

(e) Prepaid Expenses and Other Assets

“Prepaid expenses and other assets” consists of the following:

	December 31,	
	2018	2017
Other miscellaneous prepaid operating expenses	$8,186	$3,389
Prepaid insurance	782	645
Research and development supplies	611	1,883
Key employee life insurance – cash surrender value	—	4,150
Prepaid expenses and other assets	$9,579	$10,067

(f) Other Receivables

“Other receivables” consists of the following:

	December 31,			
	2018		2017	
CASI note - short term (Note 11)	$	1,525	$	—
Other miscellaneous receivables (including Medicaid rebate credits and royalty receivables)	1,189		1,152	
Insurance receivable	206		53	
Income tax receivable	643		665	
Reimbursements due from development partners for incurred research and development expenses	135		263	
Other receivables	$	3,698	$	2,133

(g) Intangible Assets and Goodwill

“Intangible assets, net of accumulated amortization” consists of the following:

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

	December 31, 2018						
	Historical Cost	Accumulated Amortization	Foreign Currency Translation	Impairment	Net Amount	Full Amortization Period (months)	Remaining Amortization Period (months)
MARQIBO IPR&D (NHL and other novel indications)	$17,600	$—	$—	$—	$ 17,600	n/a	n/a
EVOMELA distribution rights	7,700	(1,629)	—	—	6,071	156	123
KHAPZORY distribution rights (1)	2,650	(379)	—	—	2,271	14	12
BELEODAQ distribution rights	25,000	(8,438)	—	—	16,562	160	106
MARQIBO distribution rights	26,900	(21,501)	—	—	5,399	81	18
FOLOTYN distribution rights	118,400	(67,187)	—	—	51,213	152	47
ZEVALIN distribution rights – U.S.	41,900	(41,031)	—	—	869	123	3
ZEVALIN distribution rights – Ex-U.S.	23,490	(18,071)	(3,409)	—	2,010	96	15
FUSILEV distribution rights (2)	16,778	(9,618)	—	(7,160)	—	56	0
FOLOTYN out-license (3)	27,900	(17,278)	—	(1,023)	9,599	110	43
Total intangible assets (4)	$308,318	$(185,132)	$(3,409)	$(8,183)	$ 111,594		

	December 31, 2017				
	Historical Cost	Accumulated Amortization	Foreign Currency Translation	Impairment	Net Amount
MARQIBO IPR&D (NHL and other novel indications)	$17,600	$—	$—	$—	$ 17,600
EVOMELA distribution rights	7,700	(1,037)	—	—	6,663
BELEODAQ distribution rights	25,000	(6,563)	—	—	18,437
MARQIBO distribution rights	26,900	(17,182)	—	—	9,718
FOLOTYN distribution rights	118,400	(54,111)	—	—	64,289
ZEVALIN distribution rights – U.S.	41,900	(37,557)	—	—	4,343
ZEVALIN distribution rights – Ex-U.S.	23,490	(17,232)	(2,471)	—	3,787
FUSILEV distribution rights (2)	16,778	(9,618)	—	(7,160)	—
FOLOTYN out-license (3)	27,900	(14,555)	—	(1,023)	12,322
Total intangible assets (4)	$305,668	$(157,855)	$(2,471)	$(8,183)	$ 137,159

(1) In November 2018, we made a $2.7 million payment to Medac related to the FDA approval of KHAPZORY for its commercial sale. This amount was capitalized to "KHAPZORY distribution rights" during the fourth quarter of 2018 and will be amortized through December 31, 2019 (see Note 17(b)(xvi)).

(2) On February 20, 2015, the U.S. District Court for the District of Nevada found the patent covering FUSILEV to be invalid, which was upheld on appeal. On April 24, 2015, Sandoz began to commercialize a generic version of

FUSILEV. This represented a “triggering event” under applicable GAAP in evaluating the value of our FUSILEV distribution rights as of March 31, 2015, resulting in a $7.2 million impairment charge (non-cash) in the first quarter of 2015. We accelerated amortization expense recognition for the remaining net book value of FUSILEV distribution rights. Effective December 2018, FUSILEV has been discontinued and we are no longer selling this product. We have since transitioned to marketing KHAPZORY for the same indications as FUSILEV.

(3) On May 29, 2013, we amended our FOLOTYN collaboration agreement with Mundipharma. As a result of the amendment, Europe and Turkey were excluded from Mundipharma’s commercialization territory, and their royalty rates and milestone payments to us were modified. This constituted a change under which we originally valued the FOLOTYN out-license as part of business combination accounting, resulting in an impairment charge (non-cash) of $1.0 million resulted from this amendment.

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

(4) See Note 1(a) for a discussion of the Acrotech Transaction, relating to our pending sale of these intangible assets.

Our annual impairment evaluation (as of October 1st) of our indefinite-lived intangible assets was completed by our management, with no resulting impairment.

Intangible asset amortization expense recognized in 2018, 2017, and 2016, was $28.1 million, $27.6 million, and $25.9 million, respectively. Estimated intangible asset amortization expense for the five succeeding years and thereafter is as follows (without consideration of the completion of the Acrotech Transaction - see Note 1(a)):

Years Ending December 31,	
2019	$27,333
2020	19,748
2021	18,266
2022	15,882
2023	2,467
2024 and thereafter	10,298
	$93,994

“Goodwill” consists of the following:

	December 31,	
	2018	2017
Acquisition of Talon (MARQIBO rights)	$10,526	$10,526
Acquisition of ZEVALIN Ex-U.S. distribution rights	2,525	2,525
Acquisition of Allos (FOLOTYN rights)	5,346	5,346
Foreign currency exchange translation effects	(336)	(235)
Goodwill	$18,061	$18,162

(h) Other Assets

“Other assets” consists of the following:

	December 31,	
	2018	2017
Key employee life insurance – cash surrender value	$6,274	$10,737
Inventories - non-current portion	1,876	3,100
Research & development supplies and other	1,340	231
Income tax receivable*	668	668
Equity securities (see Note 11)**	—	37,530
CASI note - long term (see Note 11)	—	1,517
Other assets	$10,158	$53,783

* This value represents the non-current portion of the refundable alternative minimum tax credit that is expected to be received over the next few years (see Note 18).

** As of March 31, 2018, we reclassified our presentation of these equity securities from this account caption to “marketable securities” on our accompanying Consolidated Balance Sheets - (see Note 3(a)).

(i) Accounts Payable and Other Accrued Liabilities

"Accounts payable and other accrued liabilities" consists of the following:

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

	December 31,	
	2018	2017
Trade accounts payable and other accrued liabilities	$44,919	$33,648
Accrued rebates	8,371	7,990
Accrued product royalty	4,337	4,339
Allowance for returns	5,171	4,045
Accrued data and distribution fees	3,248	4,305
Accrued GPO administrative fees	296	296
Accrued inventory management fee	388	1,126
Allowance for chargebacks	2,730	2,368
Accounts payable and other accrued liabilities	$69,460	$58,117

Amounts presented within "accounts payable and other accrued liabilities" in the accompanying Consolidated Balance Sheets for GTN estimates (see Note 2(i)) were as follows:

Description	Rebates and Chargebacks	Data and Distribution, GPO Fees, and Inventory Management Fees	Returns
Balance as of December 31, 2016	$ 9,817	$ 5,146	$2,309
Add: provisions	106,647	20,104	2,807
(Less): credits or actual allowances	(106,106)	(19,523)	(1,071)
Balance as of December 31, 2017	10,358	5,727	4,045
Add: provisions	65,751	13,962	1,700
(Less): credits or actual allowances	(65,008)	(15,757)	(574)
Balance as of December 31, 2018	$ 11,101	$ 3,932	$5,171

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(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

(j) Contract Liabilities

"Contract liabilities" consists of the following:

	December 31, 2018	December 31, 2017
Deposit made by licensee for EVOMELA supply in China territory	$4,850	$ —
Contract liabilities	$4,850	$ —

(k) Deferred revenue

Deferred revenue (current and non-current) consists of the following:

	December 31, 2018	December 31, 2017
EVOMELA deferred revenue	$ —	$3,819
ZEVALIN out-license in India territory (see Note 17(b)(iii))	—	368
Deferred revenue*	$ —	$4,187

* On January 1, 2018, we reclassified the deferred revenue related to our EVOMELA product sales and our ZEVALIN out-license in the India territory of $3.8 million and $0.4 million, respectively. These amounts were included in the $4.7 million aggregate decrease to “accumulated deficit” on January 1, 2018, in accordance with the adoption of Topic 606 (see Note 2(i)).

(l) Other Long-Term Liabilities

"Other long-term liabilities" consists of the following:

	December 31, 2018	December 31, 2017
Accrued executive deferred compensation	$5,474	$5,928
Deferred rent (non-current portion)	—	52
Clinical study holdback costs, non-current	—	59
Other tax liabilities	176	176
Other long-term liabilities	$5,650	$6,215

4. GROSS-TO-NET PRODUCT SALES AND SIGNIFICANT CUSTOMERS

The below table presents a GTN revenue (see Note 2(i)) product sales reconciliation for the accompanying Consolidated Statement of Operations:

	Year Ended December 31, 2018		Year Ended December 31, 2017		Year Ended December 31, 2016	
Gross product sales	$190,825		$245,797		$244,770	
Commercial rebates and government chargebacks	(68,976)	(36.1)%	(105,148)	(42.8)%	(98,317)	(40.2)%
Data and distribution fees, GPO fees, and inventory management fees	(14,048)	(7.4)%	(20,083)	(8.2)%	(14,979)	(6.1)%
Prompt pay discounts	(1,553)	(0.8)%	(1,610)	(0.7)%	(755)	(0.3)%
Product returns	(1,782)	(0.9)%	(2,778)	(1.1)%	(2,123)	(0.9)%
Product sales, net	$104,466	54.7 %	$116,178	47.3 %	$128,596	52.5 %

The below table presents the customers that represent 10% or more of our gross product sales in 2018, 2017, and 2016:

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	Year Ended December 31,					
	2018		2017		2016	
McKesson Corporation and its affiliates	69,320	36.3 %	76,363	31.1 %	75,952	31.0 %
AmerisourceBergen Corporation, and its affiliates	$55,576	29.1 %	$79,362	32.3 %	$93,951	38.4 %
Cardinal Health, Inc. and its affiliates	42,074	22.0 %	64,634	26.3 %	58,780	24.0 %
All other customers	23,855	12.5 %	25,438	10.3 %	16,087	6.6 %
Gross product sales	$190,825	100.0%	$245,797	100.0%	$244,770	100.0%

5. COMPOSITION OF TOTAL REVENUE

The below table presents our net product sales by geography for the years ended December 31, 2018, 2017, and 2016:

	Year Ended December 31,					
	2018		2017		2016	
United States	$91,822	87.9 %	$107,135	92.2 %	$125,074	97.3 %
International:						
Europe/Canada	11,220	10.7 %	7,727	6.7 %	3,522	2.7 %
Asia Pacific	1,424	1.4 %	1,316	1.1 %	—	— %
Total International	12,644	12.1 %	9,043	7.8 %	3,522	2.7 %
Product sales, net	$104,466	100.0%	$116,178	100.0%	$128,596	100.0%

The below table presents our net sales by product for the years ended December 31, 2018, 2017, and 2016:

	Year Ended December 31,					
	2018		2017		2016	
FOLOTYN	$47,981	45.9 %	$43,015	37.0 %	$46,245	36.0 %
EVOMELA	28,292	27.1 %	35,178	30.3 %	16,169	12.6 %
BELEODAQ	12,328	11.8 %	12,353	10.6 %	13,368	10.4 %
ZEVALIN	7,044	6.7 %	11,759	10.1 %	10,730	8.3 %
MARQIBO	5,502	5.3 %	6,573	5.7 %	7,245	5.6 %
FUSILEV*	2,437	2.3 %	7,300	6.3 %	34,839	27.1 %
KHAPZORY	882	0.8 %	—	— %	—	— %
Product sales, net**	$104,466	100.0%	$116,178	100.0%	$128,596	100.0%

* Effective December 2018, FUSILEV has been discontinued and we are no longer selling this product. We have since transitioned to marketing KHAPZORY for identical indications as FUSILEV.

** See Note 2(i) for a discussion of our adoption of Topic 606 effective beginning on January 1, 2018.

The below table presents our license fees and service revenue by source for the years ended December 31, 2018, 2017, and 2016:

Notes to Consolidated Financial Statements
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

	Year Ended December 31,								
	2018			2017			2016		
Out-license of ZEVALIN: recognition of milestone achievement, upfront cash receipt and subsequent royalties for Asia and certain other territories, excluding China (Note 12)	$2,001	41.1	%	$1,245	10.2	%	$1,756	9.8	%
Out-license of FOLOTYN in all countries except the United States, Canada, Europe, and Turkey: royalties (Note 16)	1,860	38.2	%	5,848	48.0	%	927	5.2	%
Out-license of ZEVALIN, FOLOTYN, BELEODAQ, MARQIBO: upfront cash receipt and subsequent royalties for the Canada territory (Note 17(b)(xv))	1,006	20.7	%	5	—	%	6,000	33.6	%
Out-license of ZEVALIN: amortization of upfront cash receipt related to India territory (Note17(b)(iii)) and other	—	—	%	50	0.4	%	69	0.4	%
Sales and marketing contracted services (Note 14)	—	—	%	4,747	38.9	%	9,096	51.0	%
Regulatory services provided to licensee	—	—	%	294	2.4	%	—	—	%
License fees and service revenues	$4,867	100.0	%	$12,189	100.0	%	$17,848	100.0	%

6. STOCK-BASED COMPENSATION

2018 Long-Term Incentive Plan Overview

We have one active stockholder-approved stock-based compensation plan, the 2018 Long- Term Incentive Plan (the “2018 Plan”), which replaced our former 2009 Incentive Award Plan (the "2009 Plan") in June 2018. Under the 2018 Plan we may grant incentive stock options, non-qualified stock options, restricted stock awards, restricted stock units, performance awards, stock appreciation rights and other stock-based awards.

The maximum number of shares of our common stock available for issuance under the 2018 Plan at inception was 9.5 million shares. The number of shares of common stock that may be issued under the 2018 Plan may not exceed 9.5 million shares, plus any shares that become eligible for issuance under the 2018 Plan because of awards under the 2009 Plan that are terminated, forfeited, cancelled or expire unexercised. As of December 31, 2018, 17.6 million shares were available for grant, inclusive of aforementioned rollovers from our 2009 Plan. It is our policy that before stock is issued through the exercise of stock options, we must first receive all required cash payment for such shares (whether through an upfront cash exercise or net-settlement exercise).

Stock-based awards are governed by agreements between us and the recipients. Incentive stock options and nonqualified stock options may be granted under the 2018 Plan at an exercise price of not less than 100% of the fair market value of our common stock on the respective date of grant, and in some cases may not be less than 110% of such fair market value with respect to Incentive Stock Options ("ISOs"). The grant date is generally the date the terms of the award are approved by the Compensation Committee of the Board of Directors.

Stock-based awards generally vest at 25% to 33% on the first anniversary following the date of grant, or for new hires, the first anniversary of their initial date of employment. Awards generally vest annually thereafter on a straight-line basis over three to four years. Stock options must generally be exercised, if at all, no later than 10 years from the date of grant. Upon termination of employment, vested stock options may generally be exercised based on the option termination rules including the following: six months after the date of termination upon retirement; twelve months after the date of termination upon disability or death; ninety days after the date of termination for all other terminations (though whether vested or unvested, stock options of the employee recipient are immediately forfeited upon termination for "Cause", as defined in the 2018 Plan).

Employee Stock Purchase Plan

Under the terms of our 2009 Employee Stock Purchase Plan (the “ESPP”), eligible employees can purchase common stock through payroll deductions. The purchase price is equal to the closing price of our common stock on the first or last day of the offering period (whichever is less), minus a 15% discount. We use the Black-Scholes option-pricing model, in

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combination with the discounted employee price, in determining the value of ESPP expense to be recognized during each offering period. A participant may purchase a maximum of 50,000 shares of common stock during a six-month offering period, not to exceed $25,000 worth of stock on the offering date during each plan year.

As of December 31, 2018, a total of 8.9 million shares of common stock are authorized and remain available for issuance under the ESPP. Beginning on January 1, 2010, and each January 1st thereafter, the number of shares of common stock available for issuance under the ESPP shall automatically increase by an amount equal to the lesser of (i) one million shares or (ii) an amount determined by the ESPP administrator. However, in no event shall the number of shares of common stock available for future sale under the ESPP exceed 10 million shares, subject to capitalization adjustments occurring due to dividends, splits, dissolution, liquidation, mergers, or changes in control.

Stock-Based Compensation Expense Summary

We report our stock-based compensation expense (inclusive of our incentive stock plan, employee stock purchase plan, and 401(k) contribution matching program) in the accompanying Consolidated Statements of Operations, based on the assigned department of the recipient. Stock-based compensation expense included within “total operating costs and expenses” for the years ended December 31, 2018, 2017, and 2016, was as follows:

	Year Ended December 31,		
	2018	2017	2016
Cost of sales	$298	$203	$135
Selling, general and administrative	14,010	12,904	11,480
Research and development	3,175	2,032	2,055
Total stock-based compensation	$17,483	$15,139	$13,670

Employee stock-based compensation expense for the years ended December 31, 2018, 2017, and 2016 was recognized (reduced for estimated forfeitures) on a straight-line basis over the vesting period. Forfeitures are estimated at the time of grant and prospectively revised if actual forfeitures differ from those estimates. We estimate forfeitures of stock options using the historical exercise behavior of our employees. For purposes of this estimate, we have applied an estimated forfeiture rate of 15%, 14%, and 11% for the years ended December 31, 2018, 2017, and 2016, respectively.

Valuation Assumptions – Restricted Stock and Stock Options

The grant-date fair value per share for restricted stock awards was based upon the closing market price of our common stock on the award grant-date.

The fair value of stock options granted was estimated at the date of grant using the Black-Scholes option-pricing model. The following assumptions were used to determine fair value for the stock awards granted in the applicable year:

	Year Ended December 31,		
	2018	2017	2016
Expected option life (in years) (a)	4.73	4.84	5.02
Risk-free interest rate (b)	1.81% - 2.75%	0.82% - 1.90%	1.07% - 1.90%
Volatility (c)	50.0% - 56.2%	49.3% - 61.4%	48.9% - 50.6%
Dividend yield (d)	—%	—%	—%
Weighted-average grant-date fair value per stock option	$8.64	$2.89	$2.80

(a) Determined by the historical stock option exercise behavior of our employees (maximum term is 10 years).
(b) Based upon the U.S. Treasury yields in effect during the period which the options were granted (for a period equaling the stock options’ expected term).
(c) Measured using our historical stock price for a period equal to stock options’ expected term.
(d) We do not expect to declare any cash dividends in the foreseeable future.

Stock Option Activity

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(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

Stock option activity during the years ended December 31, 2018, 2017, and 2016 was as follows:

	Number of Shares	Weighted-Average Exercise Price/Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value	
Outstanding — December 31, 2015	3,836,851	$ 6.97			
Granted	1,435,550	5.94			
Exercised	(39,010)	5.18		$ 50	(1)
Forfeited	(379,268)	7.21			