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

Form 10-K

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

For the fiscal year ended December 31, 2019

☐ **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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	**SPPI**	**The NASDAQ Global Select Market**

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

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

Indicate by check mark 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 ☒	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 ☒

As of June 28, 2019, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $600,699,845 (based upon the $8.61 per share closing sale price for shares of the registrant's Common Stock as reported by the NASDAQ Global Select Market on June 28, 2019, the last trading date of the registrant's most recently completed second fiscal quarter).

As of February 21, 2020, approximately 113,689,862 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 2020 Annual Meeting of Stockholders, to be filed on or before April 29, 2020, 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 variation 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, and market our products;
- the approval, or timing of approval, of our products or new indications for our products by the U.S. Food and Drug Administration (the "FDA") and other international regulatory agencies;
- actions by the FDA and other regulatory agencies, including international agencies;
- the timing and/or results of pending or future clinical trials, and our reliance on contract research organizations;
- our ability to maintain sufficient cash resources to fund our business operations;
- our history of net losses;
- our ability to enter into strategic alliances with partners for manufacturing, development and commercialization;
- our competitors' progress with their drug development programs, which could adversely impact the perceived or actual value of our in-development drugs;
- the ability of our manufacturing partners to meet our product demands and timelines;
- our ability to identify and acquire new product candidates and to successfully integrate those product candidates into our operations;
- our ability to protect our intellectual property rights;
- the impact of legislative or regulatory reform on the pricing for pharmaceutical products;
- the impact of any litigation to which we are, or may become a party;
- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; and
- our ability to maintain the services of our key executives and other personnel.

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. We expressly disclaim any intent or obligation to update information contained in any forward-looking statement after the date thereof to conform such information to actual results or to changes in our opinions or expectations.

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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SPECTRUM PHARMACEUTICALS, INC.®, and ROLONTIS® are registered trademarks of Spectrum Pharmaceuticals, Inc. and its affiliates. REDEFINING CANCER CARE™ and the Spectrum Pharmaceuticals' logos are trademarks owned by Spectrum Pharmaceuticals, Inc. Any other trademarks are the property of their respective owners.

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 novel and targeted oncology therapies. Our in-house development organization includes clinical development, regulatory, quality and data management. We plan to build out our commercial and marketing capabilities in the second half of 2020 to prepare for the launch of ROLONTIS.

We have three drugs in development:

- ROLONTIS, a novel long-acting granulocyte colony-stimulating ("G-CSF") for chemotherapy-induced neutropenia which has been filed with the FDA and has a Prescription Drug User Fee Act ("PDUFA") date of October 24, 2020;
- Poziotinib, a novel irreversible tyrosine kinase inhibitor under investigation for non-small cell lung cancer ("NSCLC") tumors with various mutations; and
- Anti-CD20-IFNá, an antibody-interferon fusion molecule directed against CD20 that is in Phase 1 development for treating relapsed or refractory non-Hodgkin's lymphoma ("NHL") patients (including diffuse large B-cell lymphoma).

Our business strategy is the development of our late-stage assets through commercialization and the sourcing of additional assets that are synergistic with our existing portfolio (through purchase acquisitions, in-licensing transactions, or co-development and marketing arrangements).

On March 1, 2019, we completed the sale of our seven then-commercialized drugs, including FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA (the "Commercial Product Portfolio") to Acrotech Biopharma LLC ("Acrotech") (the "Commercial Product Portfolio Transaction"). Upon closing we received $158.8 million in an upfront cash payment of which $4 million was held in escrow until November 5, 2019. We are also entitled to receive up to an aggregate of $140 million upon Acrotech's future achievement of certain regulatory milestones (totaling $40 million) and sales-based milestones (totaling $100 million) relating to the Commercial Product Portfolio.

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 2019*, 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 2019 and approximately 607,000 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 80% of all cancers are diagnosed in people 55 years of age or older. In the U.S., approximately 39 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

Our product portfolio consists of in-development drug products for the treatment of cancer patients. Serious adverse effects ("SAEs") in patients from these products could result in the refusal/removal of regulatory approval and have a negative impact on future sales. See our specific SAE risk factor within *Item 1A. Risk Factors — Risks Related to Our Business — Reports of adverse events or safety concerns involving our in-development products or similar agents, could delay or prevent us from obtaining or maintaining regulatory approval or negatively impact sales.*

Product Pipeline

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 October 2019, integrated results from our pivotal Phase 3 studies (ADVANCE Study, or SPI-GCF-301and RECOVER Study, or SPI-GCF-302) were presented during a poster session at the 2019 Meeting of the American Society of Clinical Oncology (ASCO) Symposium in San Francisco. The integrated efficacy and safety data from both trials were consistent with results from the individual trials, demonstrating that ROLONTIS was non-inferior to pegfilgrastim in the reduction of duration of severe neutropenia in all four cycles of treatment. The integrated data also demonstrated that eflapegrastim provided an absolute risk reduction of severe neutropenia of 6.5% compared to pegfilgrastim in Cycle 1.

We submitted our updated Biologics License Application ("BLA") for ROLONTIS with the FDA on October 24, 2019. As previously announced, the BLA was accepted for review by the FDA on December 20, 2019. Our Prescription Drug User Fee Act date for the FDA's potential approval of ROLONTIS has been set for October 24, 2020.

Poziotinib

Poziotinib is a novel, pan-HER inhibitor that irreversibly blocks signaling through the Epidermal Growth Factor Receptor (EGFR) 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 previously treated NSCLC, first-line treatment of NSCLC and treatment of other solid tumors with EGFR or HER2 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 tumors with EGFR or HER2 exon-20 insertion mutations.

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") in March 2017. In September 2018 we announced preliminary poziotinib data from the MD Anderson Phase 2 Trial which were released during an oral presentation at the IASLC 19th World Conference on Lung Cancer. This Phase 2 trial demonstrated anti-tumor activity for poziotinib in metastatic, heavily pretreated EGFR exon 20 mutant NSCLC. This data is summarized below:

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

In October 2017, we announced the start of a pivotal Phase 2 global study with active sites in the U.S., Canada and Europe ("ZENITH20"). The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) have completed enrollment of previously treated NSCLC patients with exon 20 mutations. Cohort 3 (EGFR) and 4 (HER2) are currently enrolling first-line NSCLC patients with exon 20 mutations. Cohorts 1- 4 are each independently powered for a pre-specified statistical hypothesis and the primary endpoint is objective response rate (ORR). Cohort 5 includes previously treated or treatment-naïe NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Cohort 6 includes NSCLC patients with classical EGFR mutations who progressed while on treatment with first-line osimertinib and developed an additional EGFR mutation. Cohort 7 includes NSCLC patients with a variety of less common mutations in EGFR or HER2 exons 18-21 or the extracellular or transmembrane domains.

On December 26, 2019, we announced that the pre-specified primary endpoint in its Phase 2 clinical trial evaluating poziotinib in previously treated NSCLC patients with EGFR exon 20 insertion mutations was not met in Cohort 1 of the ZENITH20 trial. Cohort 1 enrolled a total of 115 patients who received 16 mg/day of poziotinib. The intent-to-treat analysis showed that 17 patients had a response (by RECIST) and 62 patients had stable disease for a 68.7% disease control rate (DCR). The confirmed objective response rate (ORR) was 14.8% (95% Confidence Interval (CI) 8.9%-22.6%). The median duration of response was 7.4 months and progression free survival was 4.2 months. The safety profile was in-line with other second-generation EGFR tyrosine kinase inhibitors. The results for this cohort have been accepted for a podium presentation at the 11th Annual Congress on Pulmonary and Respiratory Medicine in Amsterdam in March 2020. We expect to announce topline results for Cohort 2 in mid-2020 and for Cohort 3 by the end of 2020.

In addition, a basket study has been initiated to investigate poziotinib in patients with EGFR or HER2 mutation-positive malignant solid tumors in an investigator-led study, with the first patient enrolled by MD Anderson in late 2019.

Anti-CD20-IFNá

On April 15, 2019, we executed a license agreement with ImmunGene, Inc. ("ImmunGene") for an antibody-interferon fusion molecule directed against CD20 (Anti-CD20-IFNá) and is in Phase 1 development for treating relapsed or refractory NHL, including diffuse large B-cell lymphoma patients (representing a considerable unmet medical need). Under the terms of this agreement, we received the exclusive rights to commercialize this drug for any indication, and are financially responsible for the clinical and regulatory development programs.

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For information on 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 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. All of our products are/were manufactured by third parties that specialize in these services. We expect to continue to contract with third-parties for our manufacturing and packaging requirements, including active pharmaceutical ingredients (API) and finished-dosage products. We believe that our current agreements provide sufficient capacity to support our clinical requirements and anticipated commercial demand

for our products. Where feasible, we maintain secondary supplier sources for our drug products to mitigate the risk of over-reliance on any single supplier. We attempt to prevent supply disruption through our executed supply agreements, appropriate forecasting, and maintaining base stock levels.

Competition

The pharmaceutical industry is characterized by rapidly-evolving technology and intense competition, which we expect to persist. 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.

Our successful marketing of branded products, upon FDA approval, 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.

Companies that have products on the market or in research and development that target the same indications as our in-development products or new compounds sought include, among others: Amgen, Inc., Coherus BioSciences, Mylan Pharmaceuticals, Inc., Sandoz, AstraZeneca plc, Takeda Pharmaceutical Company Ltd, Rain Therapeutics Inc., Janssen Research & Development, Taiho Pharmaceutical Co., Ltd., Cullinan Oncology, LLC, Genetech, Inc., Gilead Sciences, Inc., and Novartis International AG.

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 cancer types and have substantially greater resources and expertise than we do.

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

(a) **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 G-CSF and three biosimilar G-CSFs marketed in the United States including, Neulasta® (pegfilgrastim), marketed by Amgen, Inc., UDENYCA™ (pegfilgrastim-cbqv), a biosimilar marketed by Coherus BioSciences, Fulphila® (pegfilgrastim-jmdb), a biosimilar marketed by Mylan Pharmaceuticals, Inc., and Ziextenzo® (pegfilgrastim-bmez), a biosimilar marketed by Sandoz, which recently received FDA approval during the fourth quarter of 2019.

(b) **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 insertion mutations.

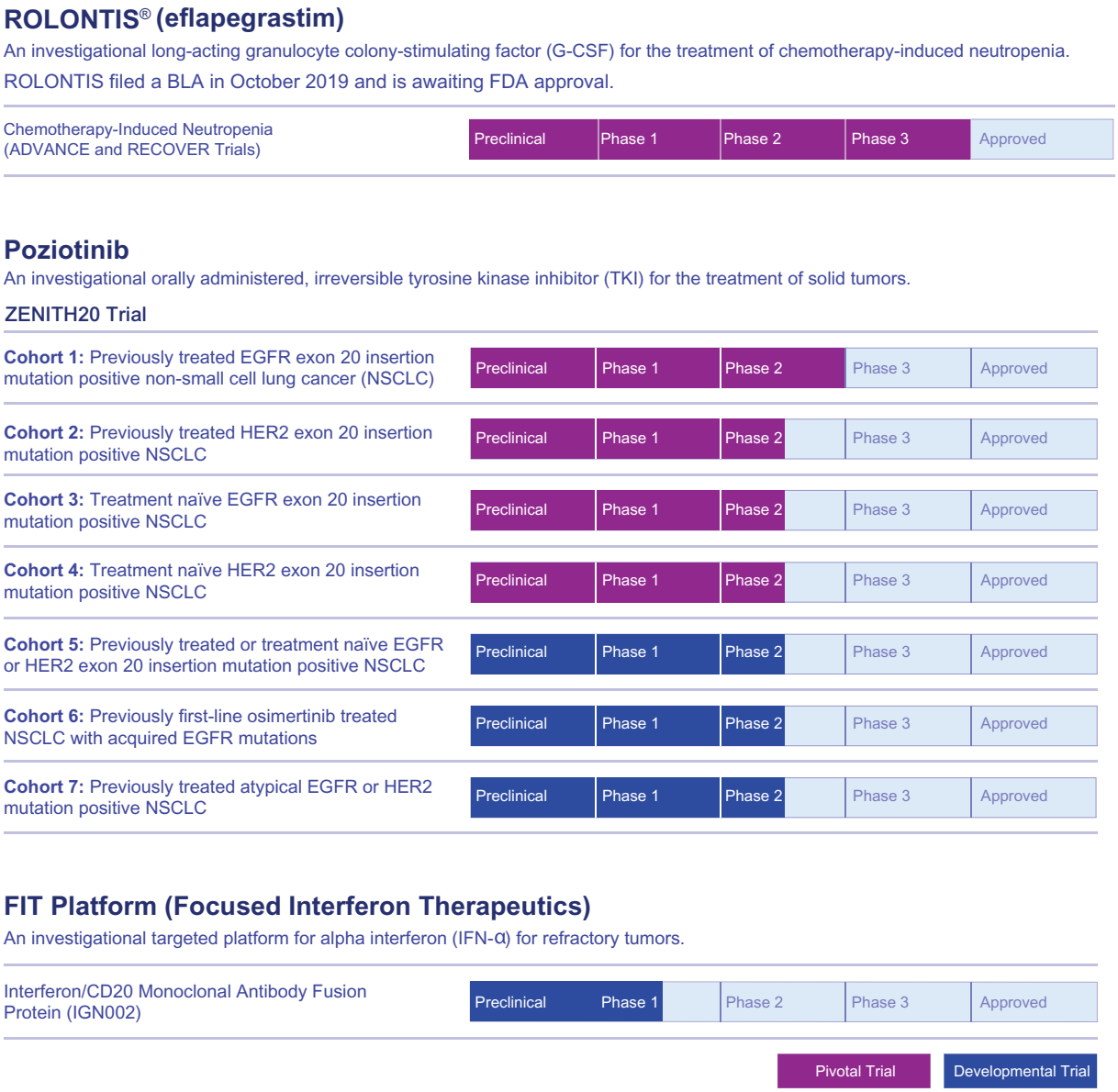
There are a number of other targeted therapies focused on this subtype of NSCLC that are in early clinical investigation by our potential competitors, including: TAK788 — Takeda Pharmaceutical Company Ltd, TAGRISSO (Osimertinib) — AstraZeneca, Tarlox (tarloxotinib) — Rain Therapeutics Inc., DS-8201a — Daiichi Sankyo, JNJ-61186372 — Janssen Research & Development, and CLN081 — Taiho Pharmaceutical Co., Ltd., and Cullinan Oncology, LLC.

(c) **Anti-CD20-IFNá** is in Phase 1 development for treating relapsed or refractory NHL, including diffuse large B-cell lymphoma. There are a number of targeted and immune-therapies approved for NHL, including Rituxan (rituximab) and Polivy (polatuzumab-vedotin-piiq) — Genentech, Inc., Yescarta (axicabtagene ciloleucel) — Gilead Sciences, Inc., and Kymriah (tisagenlecleucel) — Novartis International AG, as well as many other targeted and immune-therapies in clinical investigation for NHL.

Research and Development

New drug development is the process whereby drug product candidates are tested for the purpose of filing a New Drug Application ("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:



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 2019, 2018, and 2017:

	Research and Development Expenses for the Year Ended December 31, (in thousands)		
	2019	2018	2017
ROLONTIS	$ 21,920	$ 31,612	$20,254
Poziotinib	28,092	18,272	6,761
Anti-CD20-IFNá	3,428	—	—
Other in-development indications/drugs	145	151	153
Total — Direct costs	53,585	50,035	27,168
Add: General research and development expenses (including personnel costs that correspond to more than one in-development project)	25,747	25,122	24,357
(Less): Reimbursements from development partners	(7)	—	—
Total research and development expenses from continuing operations	$ 79,325	$ 75,157	$51,525
Total research and development expenses included in discontinued operations (*Note 12*) for drug products sold as part of Commercial Product Portfolio Transaction	$ 2,624	$ 19,799	$14,370

Patents and Proprietary Rights

Overview

We in-license from third parties certain patents 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, prosecution, 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 10(b), "Financial Commitments & Contingencies and Key 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 in a court of law or in administrative proceedings, including oppositions, re-examinations or inter parties review ("IPR"), 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.

In-Development Drug Products — Patents and Licenses Summary

We believe that our patents and licenses are critical to operating our business, as summarized below.

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 in the U.S. until 2031. One of these patents is eligible for possible patent term extension following regulatory approval of ROLONTIS. ROLONTIS is also covered by additional patents and pending applications claiming various aspects of the technology and formulation that are due to expire between 2024 and 2030.

Poziotinib*:* A composition of matter patent covering poziotinib is due to expire in 2028. Poziotinib is also covered by additional patents and patent applications covering its formulations and synthetic processes which will expire between 2032 and 2034. We have licensed patent applications covering the use of poziotinib that if granted, would expire in 2037.

Anti-CD20-IFNá*:* We currently have licensed patents covering products derived from the FIT platform that will last through 2032.

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.

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.®, and ROLONTIS®. We also have trademarks for the Spectrum Pharmaceuticals' logos. Any other trademarks are the property of their respective owners.

Product Exclusivity

The Patent Protection and Affordable Care Act ("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 the first licensure. Products deemed interchangeable (as opposed to biosimilar) are also eligible for certain exclusivity.

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.

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.

Abbreviated New Drug Application (*"ANDA"*)*:* 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 (*"BTD"*)*:* 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.

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 (the "Generic Drug Enforcement Act") established penalties for wrongdoing in connection with the development or submission of an ANDA. Under the Generic Drug Enforcement 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.

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, 2019, we had 146 employees (as compared to 235 employees as of December 31, 2018), 6 of whom hold an M.D. degree and 24 of whom hold a Ph.D. degree. Upon the closing of the Commercial Product Portfolio Transaction on March 1, 2019, we reduced our staff by 87 employees, the majority of which transitioned to Acrotech.

We believe that the success of our business will depend, in part, on 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.

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.

On March 1, 2019, we completed the sale of our Commercial Product Portfolio to Acrotech. Though we presently do not have product sales, our business strategy continues to involve the development of our late-stage assets through commercialization (upon potential FDA approval) and sourcing of additional assets that are synergistic with our existing portfolio.

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

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. We submitted our updated BLA for ROLONTIS with the FDA on October 24, 2019 in response to the FDA's request for additional information in the Chemistry, Manufacturing, and Controls (CMC) section. This BLA was accepted by the FDA for review on December 20, 2019.

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.

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 and may cause our stock price to decline. 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;
- 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, good clinical practice, 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.

We currently generate no revenue from commercial sales and the proceeds from our recent asset sale may not be sufficient to sustain our business operations.

We recently completed the sale of the Commercial Product Portfolio in the Commercial Product Portfolio Transaction. These product sales and royalties represented all of our revenue from commercial operations. We will not generate any further revenue until our pipeline products, including the late-stage development products ROLONTIS and poziotinib, are approved for commercial sale by the FDA and/or other regulatory agencies. There is no guarantee as to when, if ever, our pipeline products will be approved for commercial sale. Accordingly, while we have significant capital resources from this recent sale, we may need to raise additional capital to fund our business operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, it could result in further dilution to our stockholders and adversely impact our stock price.

The pharmaceutical and biotechnology industries are intensely competitive. We are aware of several competitors attempting to develop and market products competitive to our in-development products, which may reduce or eliminate our commercial opportunities in the future.

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological changes. A number of companies are pursuing the development of pharmaceuticals and products that target the same diseases and conditions that our pipeline products target. We cannot predict with accuracy the timing or impact of the introduction of potentially competitive products or their possible effect on our future sales. Certain potentially competitive products to our in-development 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 upon potential FDA approval. The introduction of competitive products or the development of technological advances that compete with our products could significantly reduce anticipated future sales, which, in turn would adversely impact our financial and operating results.

Our supply of APIs, and drug products are and will remain dependent upon the production capabilities of contract manufacturing organizations (CMOs) and other third-parties for related supplies and logistical services. Some of these vendors are based overseas. If they are not able to meet our requirements and/or FDA scrutiny, we may be limited in our ability to meet demand for our products, ensure regulatory compliance, or maximize profit on the future sale of our products. In addition, our dependence on these ex-U.S. vendors also subjects us to business interruption risks related to coronavirus (COVID-19), and/or similar outbreaks, which could have a material adverse impact on us.

We have no internal manufacturing capacity for APIs or our drug products. We therefore 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. and require FDA approval of each manufacturing site. 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 favorable pricing for these arrangements.

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.

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 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.

Finally, our business could be adversely impacted by the effects of the coronavirus outbreak originating in China, or by other epidemics. We source some of our APIs and other materials from Asia, including China and South Korea. Due to our current reliance on these vendors for ROLONTIS and poziotinib supply, we risk disruption in our supply chain (including restrictions on export or shipment), depending on the severity of the coronavirus outbreak and the potential government restrictions placed on our vendors.

Our efforts to acquire or in-license and develop additional drug products may fail and/or our 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.

Our future sales will 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.

Upon FDA approval, 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 is expected to rely 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 will be reimbursed under the Medicare Part B Average Sales Price ("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 based on a formula defined by statute and regulation and are then submitted to the Centers for Medicare & Medicaid Services ("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.

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.

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 are also subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. We are subject to the EU's General Data Protection Regulation, which became effective in May 2018, and the California Consumer Privacy Act of 2018, which became effective in January 2020, each of which contemplate substantial penalties. Failure to comply with these laws could result in significant penalties and could have a material adverse effect on our business and results of operations.

Reports of adverse events or safety concerns involving our in-development products or similar agents, could delay or prevent us from obtaining or maintaining regulatory approval or negatively impact sales.

Our in-development 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.

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, though have employment agreements with each of our named executive officers. Furthermore, our common stock is currently trading at a price below the exercise price of most of our outstanding stock options. As a result, these "underwater" options are less useful as a motivation and retention tool for our existing employees.

A significant portion of our revenue has historically been derived from a limited number of distributors — and is expected to persist for our in-development drugs upon potential FDA approval.

We expect that a significant portion of our future revenue will depend on sales to a limited number of distributors. Any distributors we may use 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 future significant distributors, we would experience 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.

Our business depends upon the continued customer support efforts of distributors.

In the U.S., we plan to sell our products to a small number of distributors who in turn will sell-through to patient health care providers. These distributors will also provide multiple logistics services relating to the distribution of drug products,

including transportation, warehousing, cross-docking, inventory management, packaging and freight-forwarding. We will 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, upon potential FDA approval, 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 future 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 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: Amgen, Inc., Coherus BioSciences, Mylan Pharmaceuticals, Inc., Sandoz, AstraZeneca plc, Takeda Pharmaceutical Company Ltd, Rain Therapeutics Inc., Janssen Research & Development, Taiho Pharmaceutical Co., Ltd., Cullinan Oncology, LLC, Genetech, Inc., Gilead Sciences, Inc., and Novartis International AG.

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, our financial position, results of operations, and cash flows may be materially and negatively impacted.

On March 1, 2019, we completed the sale of the "Commercial Product Portfolio to Acrotech. We contractually retained all obligations related to our estimated allowances for discounts, returns, rebates and chargebacks for sales made on and prior to such date. Our former FUSILEV, MARQIBO, and BELEODAQ customers are permitted to return purchased products to us beginning at its expiration date and within six months thereafter. Our former 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. The product revenue we recognized through March 1, 2019 was net of estimated allowances for discounts, returns, rebates and chargebacks. Such estimates required 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.

A chargeback is the difference between the price the wholesaler pays us (wholesale acquisition cost, or WAC) and the price that the wholesaler's customer pays for our product (contracted customer). Our products were 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, or for us to bill certain qualifying Public Health Service end-users at government-mandated pricing. To the extent that our sales to discount purchasers, such as federal government qualified entities, increases, chargeback claims 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 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 upon applicable regulatory approval 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 can market and sell the same products in other parts of the world upon local regulatory approvals. If negative publicity is associated with our products or similar products sold by third parties in their territories, our own efforts to successfully market and sell our products in our territories may be adversely impacted.

Our business strategy requires that we engage in transactions that increase our capital requirements, cause us to incur debt or assume contingent liabilities, and possibly dilute our stockholders.

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.

Accordingly, 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 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 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.

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.

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.

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.

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, 2019, 2018, and 2017, 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, ROLONTIS, and our FIT platform. 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.

Our future sales and operations will be subject to the risks of doing business internationally.

International markets may subject 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;
- 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.

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.

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 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.

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 future drug products obsolete before we are able to recover expenses incurred in connection with their development. As a result, we 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 in-development products and thereby cause our future

products to become commercially obsolete. Some of our in-development 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 future product candidates in and outside of the U.S. In order to market our 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 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 future sale of our products will be (and has historically been) subject to regulatory approvals and requirements. 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 will be subject 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.

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 potential drug products approved to go to 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.

The later discovery of previously unknown safety risks with our potential drug 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 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 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.

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, 2019, an aggregate 5.2 million shares of common stock were issuable pursuant to the exercise of outstanding options and the vesting of restricted stock units. Any restricted stock awards that we have granted are included within our outstanding share count even though such awards are subject to service conditions for vesting. Further, 5.9 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:

- 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 in-development products being reimbursed at requisite levels in the future;
- 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;
- 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; 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, 2019 through February 21, 2020, the closing price of our common stock ranged between $2.53 and $11.84, and the daily trading volume was as high as 21.3 million shares and as low as 0.3 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 8,000 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 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 10(g) — Litigation* to our accompanying Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

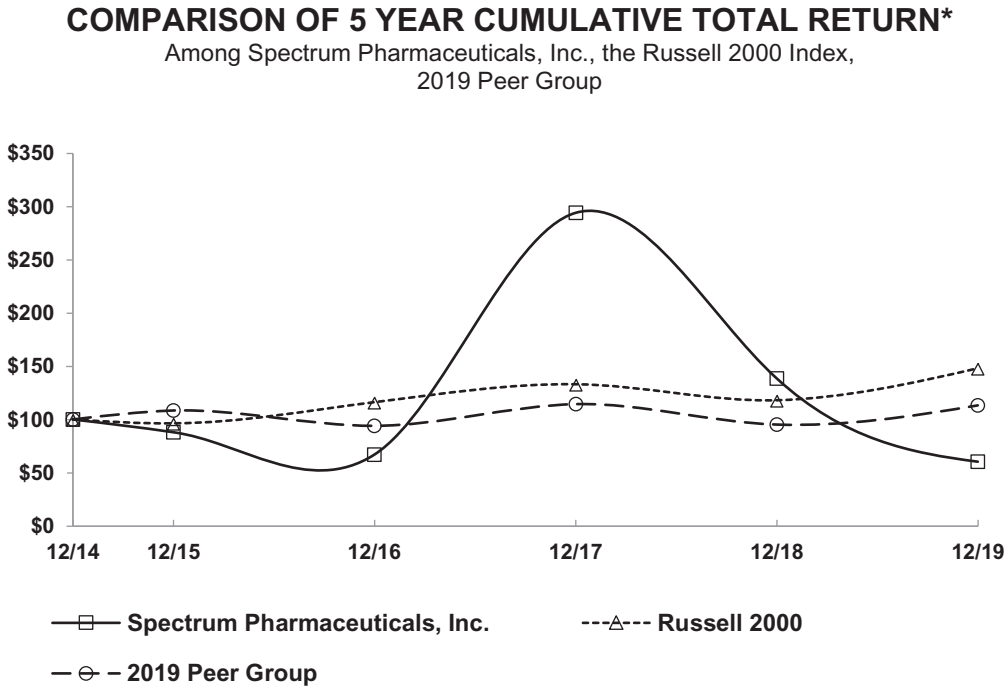
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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

On February 21, 2020, the closing price of our common stock on the NASDAQ Global Select Market was $3.04 per share, and there were 154 holders of record of our common stock.

Stock Performance Graph (1)

The graph below compares the cumulative total stockholder return on $100 invested in our stock on December 31, 2014, the last trading day before our 2015 fiscal year, through the end of fiscal 2019, as compared to the cumulative total return on $100 invested for the same period in the Russell 2000 index and our Peer Group (assuming the reinvestment of all dividends).



*$100 invested on 12/31/14 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

In November 2018, the Compensation Committee engaged with two independent executive compensation firms, Radford and Equilar, to conduct an updated review of our executive compensation program, which included an evaluation of our peer group companies. Specifically, the Compensation Committee focused on selecting a comparably sized, industry-affiliated peer group of companies operating within the biotechnology or pharmaceutical industries.

As of December 31, 2019, our peer group consists of the following publicly-traded companies:

ACADIA Pharmaceuticals
Aerie Pharmaceuticals
Amicus Therapeutics
Clovis Oncology
Corcept Therapeutics
Eagle Pharmaceuticals
Halozyme Therapeutics
Heron Therapeutics
Intercept Pharmaceuticals
Ironwood Pharmaceuticals
Lexicon Pharmaceuticals
Luminex
Momenta Pharmaceuticals
Omeros
Pacira Pharmaceuticals
PTC Therapeutics
Repligen
Retrophin
Supernus Pharmaticeuticals
Theravance Biopharma
Vanda Pharmaceuticals

	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019
Spectrum Pharmaceuticals, Inc.	$ 88	$ 67	$294	$138	$ 60
Russell 2000	$ 96	$116	$133	$118	$148
2019 Peer Group	$108	$ 94	$114	$ 95	$113

(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.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 201(d) of Regulation S-K is incorporated by reference to our definitive proxy statement related to our 2020 Annual Meeting of Stockholders, or the Proxy Statement, to be filed pursuant to Regulation 14A, on our before April 29, 2020.

Sale of Equity Securities During the Period

All equity securities that we sold during the period covered by this Form 10-K that were not registered under the Securities Act have been previously reported in our quarterly reports on Form 10-Q or on our current reports on Form 8-K.

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, 2019, 2018, and 2017 are included elsewhere in this Annual Report on Form 10-K. The below selected financial data is recast for all periods presented to reflect the sale of the assets and liabilities associated with our Commercial Product Portfolio — see *Note 12*. We also made certain immaterial corrections to "accounts payable and other accrued liabilities" affecting 2018 and earlier-reported years. These corrections are reflected in the "Selected Balance Sheet Data" below and are further discussed in *Note 15* to the accompanying Consolidated Financial Statements.

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.

Selected Statement of Operations Data:	Year ended December 31, 2019	2018	2017	2016	2015
	(In thousands, except per share data)				
Revenues (*Note 1(b)*)	$ —	$ —	$ —	$ —	$ —
Operating costs and expenses:					
Selling, general and administrative	61,373	62,690	64,759	60,322	63,986
Research and development	79,325	75,157	51,525	42,436	39,781
Loss from continuing operations before other (expense) income and income taxes	(140,698)	(137,847)	(116,284)	(102,758)	(103,767)
Basic and diluted loss per share:					
Loss per common share from continuing operations before other (expense) income and income taxes	$ (1.27)	$ (1.33)	$ (1.37)	$ (1.41)	$ (1.60)

Selected Balance Sheet Data:	As of December 31, 2019	2018	2017	2016	2015
	(In thousands)				
Cash, cash equivalents and marketable securities	$223,873	$203,988	$227,571	$158,469	$139,986
Total assets	$263,433	$390,886	$487,439	$428,768	$419,049
Long term obligations, less current portion	$ 11,070	$ 21,150	$ 26,351	$127,229	$129,849

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. We made certain immaterial corrections to our previously-reported 2018 and 2017 operating results. These corrections are reflected in the below tables and are further discussed in *Note 15* to the accompanying Consolidated Financial Statements.

OVERVIEW

Our Business

We are a biopharma company, with a primary strategy comprised of acquiring, developing, and commercializing novel and targeted oncology therapies. Our in-house development organization includes clinical development, regulatory, quality and data management. We plan to build out our commercial and marketing capabilities in the second half of 2020 to prepare for the launch of ROLONTIS.

We have three drugs in development:

- ROLONTIS, a novel long-acting granulocyte colony-stimulating ("G-CSF") for chemotherapy-induced neutropenia which has been filed with the FDA and has a Prescription Drug User Fee Act ("PDUFA") date of October 24, 2020;
- Poziotinib, a novel irreversible tyrosine kinase inhibitor under investigation for non-small cell lung cancer ("NSCLC") tumors with various mutations; and
- Anti-CD20-IFNá, an antibody-interferon fusion molecule directed against CD20 that is in Phase 1 development for treating relapsed or refractory non-Hodgkin's lymphoma patients (including diffuse large B-cell lymphoma).

Our business strategy is the development of our late-stage assets through commercialization and the sourcing of additional assets that are synergistic with our existing portfolio (through purchase acquisitions, in-licensing transactions, or co-development and marketing arrangements).

See *Item 1. Business*, for our discussion of:

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

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

During the year ended December 31, 2019 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:

Sale of our Commercial Product Portfolio:

On March 1, 2019, we completed the sale of our Commercial Product Portfolio to Acrotech. Upon closing we received $158.8 million in an upfront cash payment (of which $4 million was held in escrow until November 5, 2019). We are also entitled to receive up to an aggregate of $140 million upon Acrotech's future achievement of certain regulatory milestones (totaling $40 million) and sales-based milestones (totaling $100 million) relating to the Commercial Product Portfolio.

ROLONTIS, a novel long-acting G-CSF:

We submitted our updated BLA for ROLONTIS with the FDA on October 24, 2019 due to the FDA's request for additional information in the Chemistry, Manufacturing, and Controls section. The updated BLA was accepted by the FDA for review on December 20, 2019. Our BLA is supported by data from two identically designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy. Our PDUFA date for the potential approval of ROLONTIS by the FDA has been set for October 24, 2020.

In October 2019, integrated results from ADVANCE and RECOVER were presented during a poster session at the 2019 Meeting of the American Society of Clinical Oncology (ASCO) Symposium in San Francisco. The integrated efficacy and safety data from both trials were consistent with results from the individual trials, demonstrating that ROLONTIS was non-inferior to pegfilgrastim in the reduction of duration of severe neutropenia in all four cycles of treatment. The integrated data also demonstrated that eflapegrastim provided an absolute risk reduction of severe neutropenia of 6.5% compared to pegfilgrastim in Cycle 1.

Poziotinib, an irreversible tyrosine kinase inhibitor:

In October 2017, we announced the start of a pivotal Phase 2 global study with active sites in the U.S., Canada and Europe ("ZENITH20"). The ZENITH20 study consists of seven cohorts of NSCLC patients. Cohorts 1 (EGFR) and 2 (HER2) have completed enrollment of previously treated NSCLC patients with exon 20 mutations. Cohort 3 (EGFR) and 4 (HER2) are currently enrolling first-line NSCLC patients with exon 20 mutations. Cohorts 1- 4 are each independently powered for a pre-specified statistical hypothesis and the primary endpoint is objective response rate (ORR). Cohort 5 includes previously treated or treatment-naïve NSCLC patients with EGFR or HER2 exon 20 insertion mutations. Cohort 6 includes NSCLC patients with classical EGFR mutations who progressed while on treatment with first-line osimertinib and developed an additional EGFR mutation. Cohort 7 includes NSCLC patients with a variety of less common mutations in EGFR or HER2 exons 18-21 or the extracellular or transmembrane domains.

On December 26, 2019, we announced that the pre-specified primary endpoint in its Phase 2 clinical trial evaluating poziotinib in previously treated NSCLC patients with EGFR exon 20 insertion mutations was not met in Cohort 1 of the ZENITH20 trial. Cohort 1 enrolled a total of 115 patients who received 16 mg/day of poziotinib. The intent-to-treat analysis showed that 17 patients had a response (by RECIST) and 62 patients had stable disease for a 68.7% disease control rate (DCR). The confirmed objective response rate (ORR) was 14.8% (95% Confidence Interval (CI) 8.9%-22.6%). The median duration of response was 7.4 months and progression free survival was 4.2 months. The safety profile was in-line with other second-generation EGFR tyrosine kinase inhibitors. The results for this cohort have been accepted for a podium presentation

at the 11th Annual Congress on Pulmonary and Respiratory Medicine in Amsterdam in March 2020. We expect to announce topline results for Cohort 2 in mid-2020 and for Cohort 3 by the end of 2020.

In addition, a basket study has been initiated to investigate poziotinib in patients with EGFR or HER2 mutation-positive malignant solid tumors in an investigator-led study, with the first patient enrolled by MD Anderson in late 2019.

In-License of Anti-CD20-IFNá, an antibody-interferon fusion molecule:

In April 2019, we executed an asset transfer, license, and sublicense agreement for an exclusive license for Anti-CD20-IFNá, an antibody-interferon fusion molecule directed against CD20 that is in Phase 1 development for treating relapsed or refractory non-Hodgkin's lymphoma patients (including diffuse large B-cell lymphoma), representing a considerable unmet medical need.

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

On March 1, 2019, we completed the Commercial Product Portfolio Transaction. In accordance with applicable GAAP, the revenue-deriving activities of our sold commercial operation are separately classified as "discontinued" for all periods presented within the accompanying Consolidated Statements of Operations.

The majority of our revenue was derived from sales of our drug products to large pharmaceutical wholesalers and distributors, which we recognized upon title transfer (which is typically at time of delivery), provided our other revenue recognition criteria have been met. We expect that this revenue source and recognition will persist upon the potential FDA approval of ROLONTIS and poziotinib.

To a lesser extent we also derived revenue from (i) upfront license fees, (ii) milestone receipts from our licensees' sales or regulatory achievements, and royalties from out-licensing our licensees' sales in applicable territories, and (iii) 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 expect that this revenue source and recognition will persist from our current and future out-license arrangements.

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.

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 of new drugs and costs associated with at-risk manufacture of drug products prior to FDA approval .

These clinical development expenses specifically consist of (i) compensation (including stock-based compensation) and benefits for research and development and clinical and regulatory personnel, (ii) materials and supplies for each project, (iii) consultants, and (iv) associated regulatory and clinical site expenses.

Our research and development manufacture expenses are recognized in the period which the activity occurs and includes (i) our technology transfer costs for production, (ii) FDA qualification costs of our contract manufacturers' sites, and (iii) material and service costs associated with our inventory build in anticipation of FDA approval and subsequent commercial launch.

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 ("U.S. 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, consistently applied, and in accordance with U.S. GAAP. 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;
- Income taxes;
- Stock-based compensation; and
- Litigation accruals (as required).

Revenue Recognition

On March 1, 2019, we completed our Commercial Product Portfolio Transaction — see *Note 1(b)*. In accordance with applicable GAAP (*ASC 205-20, Presentation of Financial Statements*), the revenue-deriving activities of our sold commercial operation are separately classified as "discontinued" for all periods presented within the accompanying Consolidated Statements of Operations — see *Note 12*.

***Required Elements of Our Revenue Recognition*:** Revenue from our (a) product sales, (b) out-license arrangements, and (c) service arrangements is recognized under *ASU No. 2014-09*, *Revenue from Contracts with Customers* (*ASC 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 or to our product licensees (i.e., our customers). 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" that reflects 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 customers are contractually permitted to return certain purchased products within the contractual allowable time before/after its applicable expiration date. Returns outside of this aforementioned criteria are not customarily allowed. We estimate expected product returns using our historical return rates. Returned products are typically destroyed since substantially all returns are due to their imminent 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 our 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 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.

(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.

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 "benefit for income taxes from continuing operations" 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 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 – 2019, 2018, and 2017

We made certain immaterial corrections to our previously-reported 2018 and 2017 operating results. These corrections are reflected in the below tables and are further discussed in *Note 15* to the accompanying Consolidated Financial Statements.

	Year Ended December 31,		
	2019	2018	2017
		($ in thousands)	
Revenues (*Note 1(b)*)	$ —	$ —	$ —
Operating costs and expenses:			
Selling, general and administrative	61,373	62,690	64,759
Research and development	79,325	75,157	51,525
Total operating costs and expenses	140,698	137,847	116,284
Loss from continuing operations before other (expense) income and income taxes	(140,698)	(137,847)	(116,284)
Other (expense) income :			
Interest income (expense), net	4,996	(340)	(6,798)
Other (expense) income, net	(8,892)	9,580	389
Total other (expense) income	(3,896)	9,240	(6,409)
Loss from continuing operations before income taxes	(144,594)	(128,607)	(122,693)
Benefit for income taxes from continuing operations	9,208	1,901	21,941
Loss from continuing operations	(135,386)	(126,706)	(100,752)
Income from discontinued operations, net of income taxes (*Notes 12* and *15*)	22,697	5,965	8,563
Net loss	$ (112,689)	$ (120,741)	$ (92,189)

YEAR ENDED DECEMBER 31, 2019 VERSUS DECEMBER 31, 2018

Operating Expenses

	Year Ended December 31,			
	2019	2018	$ Change	% Change
	($ in millions)			
Operating expenses:				
Selling, general and administrative	61.4	62.7	(1.3)	(2.1)%
Research and development	79.3	75.2	4.1	5.5%
Total operating costs and expenses	$ 140.7	$ 137.8	$ 2.9	2.1%

Selling, General and Administrative. Selling, general and administrative expenses decreased $1.3 million in 2019. This decrease is primarily due to (i) $2.8 million of decreased legal and consulting costs (substantially related to non-recurring expenses associated with the termination of our former chief executive officer and reimbursed legal expenses by our insurance carriers) and (ii) $0.3 million of decreased market research expenses. This decrease was partially offset by (i) $1.5 million of employee severance expense and (ii) $0.2 million of various costs related to the Commercial Product Portfolio Transaction.

Research and Development. Research and development expenses increased $4.1 million in 2019. Our increase in 2019 poziotinib expenses were near equal to the 2019 decrease in ROLONTIS expenses; this was due to offsetting activities within clinical and manufacturing operations. Accordingly, the $4.1 million increase is primarily due to (i) $3.3 million of costs associated with our in-license for Anti-CD20-IFNá in April 2019 (see *Note 10(b)(iii)*), (ii) $0.3 million of severance expense for research and development employees as part of the Commercial Product Portfolio Transaction, and (iii) $0.5 million of costs for our various other research and development projects.

Total Other (Expense) Income

	Year Ended December 31,			
	2019	2018	$ Change	% Change
	($ in millions)			
Total other (expense) income	$ (3.9)	$ 9.2	$ (13.1)	142.4%

Total other (expense) income decreased by $13.1 million primarily due to $12.7 million of unrealized loss for the mark-to-market of our CASI equity securities in the current period (see *Note 3(a)* to the accompanying Consolidated Financial Statements), as compared to $10.5 million of unrealized gain in the prior year period. The recognized expense from this decline in CASI stock value was partially offset in the current period by (i) $2.7 million of realized gain from the sale of 1.5 million shares of CASI through a forward-sales contract that settled in April 2019 (see *Note 8*), (ii) $3.3 million interest expense decrease due to the December 2018 maturity of our 2013 Convertible Notes (see *Note 9*), (iii) $2.0 million increase in interest income on our other marketable securities, (iv) $1.1 million increase in the value of our deferred compensation plan assets (see *Notes 3(f)*), and (v) $0.7 million of billable services rendered to Acrotech as part of a transition services agreement that expired in May 2019 (see *Note 13)*.

Income Taxes

	Year Ended December 31,			
	2019	2018	$ Change	% Change
	($ in millions)			
Benefit for income taxes from continuing operations	$ 9.2	$ 1.9	$ 7.3	384.2%

We reported pre-tax losses from continuing operations and pre-tax income from discontinued operations on the Consolidated Statements of Operations for the years ended December 31, 2019 and 2018. Under applicable intraperiod tax allocation guidance (see *Note 11* to the accompanying Consolidated Financial Statements) we are required to allocate income taxes between continuing operations and other categories of earnings. Due to the required allocation, we recorded an income tax benefit of $7.7 million and $1.9 million from continuing operations (though such amounts are not indicative of income tax refunds due to us), income tax expense of $7.5 million and $1.9 million within income from discontinued operations, net of income taxes, and income tax expense of $0.2 million and $0 within other comprehensive income (loss) on the Consolidated Statements of Comprehensive Loss for the years ended December 31, 2019 and 2018, respectively.

Our net tax benefit for the year ended December 31, 2019 prior to the application of intraperiod allocation guidance was $1.5 million. This tax benefit arose from the reversal of deferred tax liabilities recorded on our Consolidated Balance Sheets as of December 31, 2018 that were associated with indefinite-lived intangible assets that were sold as part of the Commercial Product Portfolio Transaction. The tax benefit for the year ended December 31, 2018, prior to the application of intraperiod tax allocation guidance was $0.

YEAR ENDED DECEMBER 31, 2018 VERSUS DECEMBER 31, 2017

Operating Expenses

	Year Ended December 31,			
	2018	2017	$ Change	% Change
	($ in millions)			
Operating expenses:				
Selling, general and administrative	$ 62.7	$ 64.8	$ (2.1)	(3.2)%
Research and development	75.2	51.5	23.7	46.0%
Total operating costs and expenses	$ 137.8	$ 116.3	$ 21.5	18.5%

Selling, General and Administrative. Selling, general and administrative expenses decreased $2.1 million primarily due to a $7 million decrease in personnel and benefit-related costs as compared to prior year, largely attributed to the one-time contractual amounts due to our former chief executive officer upon his termination in December 2017. This decrease was partially offset by the following: (i) $3.3 million increase in legal expenses that were primarily associated with the departure of our former chief executive officer, as well as various corporate development initiatives, and (ii) $2.1 million increase in employer payroll tax expenses primarily related to significant stock option exercises in 2018 by our former chief executive officer.

Research and Development. Research and development expenses increased in 2018 by $23.7 million compared to the prior year, primarily due to the following factors: (i) $19.1 million increase in product manufacturing costs for the eventual commercial launch of ROLONTIS, (ii) $2.9 million increase in FDA regulatory costs associated with the BLA submission for ROLONTIS, (iii) $10.8 million increase in clinical initiatives related to poziotinib, (iv) $0.5 million upfront payment to MD Anderson upon execution of the Exclusive Patent and Technology License Agreement for poziotinib (see *Note 10(b)(ii)*). These increases were partially offset by $10.1 million decrease in clinical related expenses associated with ROLONTIS, as both the ADVANCE and RECOVER studies completed enrollment during the first quarter of 2018 and associated costs were down significantly compared to 2017.

Total Other Income (Expense)

	Year Ended December 31,			
	2018	2017	$ Change	% Change
	($in millions)			
Total other income (expense)	$ 9.2	$ (6.4)	$ 15.6	(243.8)%

Total other income (expense) increased by $15.6 million due to multiple offsetting components, including: (i) $10.5 million increase in the unrealized gain on our CASI stock, which beginning January 1, 2018 are recorded within "other income (expense), net" rather than "other comprehensive (loss) income" upon adoption of *ASU 2016-01* (see *Note 3(a)* to our accompanying Consolidated Financial Statements); and (ii) $7.3 million aggregate decrease of interest expense related to our 2018 Convertible Notes (see *Note 9*). These increases in other income were partially offset by $2 million additional expense for executive deferred compensation for plan liability increases (see *Note 10(f)*).

Income Taxes

	Year Ended December 31,			
	2018	2017	$ Change	% Change
	($in millions)			
Benefit for income taxes from continuing operations	$ 1.9	$ 21.9	$ (20.0)	(91.3)%

We reported pre-tax losses from continuing operations and pre-tax income from discontinued operations on the Consolidated Statements of Operations for the years ended December 31, 2018 and 2017. Under applicable intraperiod tax

allocation guidance (see *Note 11* to the accompanying Consolidated Financial Statements), we are required to allocate income taxes between continuing operations and other categories of earnings. Due to the required allocation, we recorded an income tax benefit of $1.9 million and $14.8 million from continuing operations (though such amounts are not indicative of income tax refunds due to us), income tax expense of $1.9 million and $5.2 million within income from discontinued operations, net of income taxes, and income tax expense of $0 and $9.7 million within other comprehensive income (loss) on the Consolidated Statements of Comprehensive Loss for the years ended December 31, 2018 and 2017, respectively.

Our net tax benefit for the year ended December 31, 2018 prior to the application of intraperiod allocation guidance was $0. Our net tax benefit for the year ended December 31, 2017 prior to the application of intraperiod tax allocation guidance was $7.1 million. The 2017 tax benefit 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.

LIQUIDITY AND CAPITAL RESOURCES

	December 31,		
	2019	2018	2017
	(in thousands, except financial metrics data)		
Cash, cash equivalents and marketable securities	$223,873	$203,988	$227,571
Accounts receivable, net	$ 441	$ 29,873	$ 32,260
Total current assets	$244,020	$250,688	$277,746
Total current liabilities	$ 61,970	$ 98,326	$120,870
Working capital surplus (a)	$182,050	$152,362	$156,876
Current ratio (b)	3.9	2.5	2.3

(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 $134.6 million in 2019, as compared to $62.4 million and $38.9 million in 2018 and 2017, respectively.

For the years ended December 31, 2019, 2018, and 2017, our cash collections from customers totaled $40.7 million, $126.3 million, and $161.5 million respectively.

For the years ended December 31, 2019, 2018, and 2017, cash payments to our employees and vendors for products, services, and rebates totaled $203.6 million, $209.7 million, and $210.2 million, respectively.

Net Cash Provided By (Used In) Investing Activities

Net cash provided by investing activities was $32.0 million and $1.4 million for the years ended December 31, 2019 and 2018, respectively, as compared to $1.1 million of cash used in investing activities for the year ended December 31, 2017.

Our cash provided by investing activities in 2019 primarily relates to (i) $158.6 million of proceeds received from the sale of our Commercial Product Portfolio (see *Note 12* to the accompanying Consolidated Financial Statements), (ii) $77.5 million of proceeds from maturities of our marketable securities (see *Note 3(a)*), and (iii) $5.1 million of proceeds received from our sale of CASI stock (see *Note 8*). Partially offsetting these inflow amounts, we acquired (i) $200.2 million of investment instruments (see *Note 3(a)*) and (ii) we purchased $9.0 million of equipment substantially related to ROLONTIS manufacture (see *Note 3(b)*).

Net Cash Provided By (Used In) Financing Activities

Net cash provided by financing activities was $9.6 million for the year ended December 31, 2019, as compared to $8.5 million of cash used and $108.7 million of cash provided for the years ended December 31, 2018 and 2017, respectively.

Our cash provided by financing activities during the year ended December 31, 2019 was attributable to: (i) $7.1 million of proceeds from the issuance of common stock at the time of exercise of employee stock options, (ii) $1.8 million of proceeds received from our shares sold under an at-the-market-issuance sales agreement (see *Note 5*), and (iii) $0.7 million of proceeds from employee stock purchases under our employee stock purchase plan.

In prior years, we operated as the counterparty (rather than facilitating the stock sale on the open market through our designated broker) when our employees exercised stock options or upon vesting of employees' restricted stock. At that time, we concurrently retired enough shares to cover the federal and state tax due for applicable employees. This resulted in cash use of $27.7 million during 2018 that did not recur in the current year period with our change in policy.

Sale of Common Stock Under ATM Agreements

In December 2015, and August 2017, we entered into a new collective at-market-issuance (ATM) sales agreement with FBR Capital Markets & Co., MLV & Co. LLC, and H.C. Wainwright & Co., LLC. ("December 2015 ATM Agreement" and the "August 2017 ATM Agreement", respectively). 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. During the year ended December 31, 2017 we raised net proceeds of $128.3 million. We had no sales under the ATM during the year ended December 31, 2018.

In April 2019, we entered into a new collective at-market-issuance sales agreement with Cantor Fitzgerald & Co., H.C. Wainwright & Co., LLC and B. Riley FBR, Inc. (the "April 2019 ATM Agreement") connected to our automatic shelf registration statement on Form S-3ASR, filed with the SEC on April 5, 2019.

The April 2019 ATM Agreement allows us to raise aggregate gross proceeds of $150 million from the periodic sales of our common stock on the public market. Through December 31, 2019, we raised aggregate proceeds of $1.8 million net under this at-the-market offering. These proceeds and any future proceeds raised will support the advancement of our in-development drug candidates, activities in connection with the launch of these drugs (including the hiring of personnel, building of inventory supply, and equipment purchases), completing acquisitions of assets, businesses, or securities, and for all other working capital purposes.

Sale of Our Commercialized Drug Portfolio and Future Proceeds

On March 1, 2019, we completed the sale of our Commercial Product Portfolio to Acrotech. Upon closing we received $158.8 million in an upfront cash payment (of which $4 million was held in escrow until November 5, 2019). We are also entitled to receive up to an aggregate of $140 million upon Acrotech's future achievement of certain regulatory milestones (totaling $40 million) and sales-based milestones (totaling $100 million) relating to the Commercial Product Portfolio.

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 $224 million in aggregate cash and cash equivalents, and marketable securities as of December 31, 2019 is sufficient to fund our current and planned operations. 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 5* to the accompanying Consolidated Financial Statements).

However, we cannot provide assurance that we will be able to obtain this additional liquidity on terms favorable to us or our current stockholders, if at all. Additionally, our liquidity and our ability to fund our capital requirements are also dependent on our future financial performance which is subject to various market and economic 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, 2019:

	Total	Less than 1 Year	1-3 Years	3-5 Years	After 5 Years
			(in thousands)		
Operating lease obligations (1)	$ 4,520	$ 1,934	$ 2,499	$ 87	$ —
Purchase obligations (2)	77,413	39,910	24,385	10,884	2,234
Contingent milestone obligations (3)	571,912	10,250	18,100	7,750	535,812
Total	$ 653,845	$ 52,094	$ 44,984	$ 18,721	$ 538,046

(1) The operating lease obligations are primarily related to the facility lease for our corporate headquarters in Henderson, Nevada, expiring October 31, 2021; 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, 2019.

(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.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements 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, 2019, 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 foreign currency exchange rates, prices of raw materials for drug production, and changes in the value of our equity holdings. We believe that these risks have been appropriately addressed for our business as further discussed below.

Foreign currency: We have limited exposure to currency exchange rate fluctuations for our cash receipts in foreign currency from license partners, as well as payments we make to employees, vendors, and license partners in foreign currency (typically in Euros, Canadian dollars, or Indian rupees). We further mitigate this limited risk by maintaining a fraction of our cash in these foreign currencies for our current operational needs. A hypothetical 10% change in these foreign exchange rates would not be material to our reported operating results and period-end financial position due to minimal amounts held in foreign currency-denominated bank accounts during 2019.

Raw materials: Our in-development drug products are produced with active pharmaceutical ingredients (API). These raw material prices are not highly volatile for us. A hypothetical 10% change in API costs would not be material to our reported operating results and period-end financial position. Our current year API purchases for the year ended December 31, 2019 aggregated $11.2 million. To secure required drug supply and raw material pricing, we enter into various agreements that provide stable and predictable pricing for our planned clinical and commercial business needs.

Equity price: We hold publicly-traded equity securities, received as part of out-license consideration (see *Note 3(a)* to our accompanying Consolidated Financial Statements). At December 31, 2019, the market value of these equity holdings was $31.0 million. Our monetization of this value is subject to changes in market prices at the time of sale, thus a hypothetical 10% change in market value (whether realized or unrealized) would be material to our reported operating results and period-end financial position in 2019. We have evaluated this share price risk and decided to not enter into derivative contracts for potential risk mitigation.

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: March 2, 2020

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:

Signature	Title	Dates
/s/ JOSEPH W. TURGEON Joseph W. Turgeon	President and Chief Executive Officer	March 2, 2020
/s/ KURT A. GUSTAFSON Kurt A. Gustafson	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 2, 2020
/s/ WILLIAM L. ASHTON William L. Ashton	Chairman of the Board	March 2, 2020
/s/ DOLATRAI M. VYAS, PH.D. Dolatrai M. Vyas, Ph.D.	Director	March 2, 2020
/s/ BERNICE R. WELLES, M.D., M.B.A. Bernice R. Welles, M.D., M.B.A.	Director	March 2, 2020
/s/ ELIZABETH A. CZEREPAK Elizabeth A. Czerepak	Director	March 2, 2020
/s/ RAYMOND W. COHEN Raymond W. Cohen	Director	March 2, 2020
/s/ JEFFREY L. VACIRCA, M.D., F.A.C.P. Jeffrey L. Vacirca, M.D., F.A.C.P.	Director	March 2, 2020

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

SPECTRUM PHARMACEUTICALS, INC.
FORM 10-K ANNUAL REPORT
For the Fiscal Years Ended December 31, 2019, 2018, and 2017

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 2, 2020, expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 10 to the financial statements, the Company has changed its method of accounting for leases in 2019 due to adoption of Accounting Standards Update 2016-02, *Leases* ("Topic 842").

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Discontinued Operations -Refer to Notes 1 and 12 to the financial statements

Critical Audit Matter Description

On March 1, 2019, the Company completed the sale of their then-commercialized drugs, including FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA (the "Commercial Product Portfolio") to Acrotech Biopharma LLC (the "Commercial Product Portfolio Transaction"). In accordance ASC 205-20, *Presentation of Financial Statements-Discontinued Operations* ("ASC 205-20"), management concluded that the revenue-deriving activities and allocable expenses of the Company's sold commercial operation, as well as the assets and liabilities connected to the Commercial Product Portfolio, are separately classified as "discontinued" for all periods presented within the accompanying financial statements.

Given the significant judgments made by management to apply ASC 205-20 as a result of the Commercial Product Portfolio Transaction, performing audit procedures to evaluate management's identification of the disposal group, specifically expenses allocable to the disposal group, and the classification of the Company's supply agreement with CASI Pharmaceuticals, Inc. for EVOMELA ("EVOMELA Supply Contract") retained in the Commercial Product Portfolio Transaction, required a high degree of auditor judgement and increased extent of audit effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the identification of the disposal group, specifically expenses allocable to the disposal group and the classification of the EVOMELA Supply Contract, included the following:

- We tested the design and effectiveness of controls over management's accounting for discontinued operations, including those over the determination of the expenses allocable to the disposal group and the classification of the EVOMELA Supply Contract.
- We evaluated management's judgments over the identification of the disposal group by obtaining an understanding of management's judgments, reading the asset purchase agreement and relevant supporting documentation, and inquiring of management regarding specific assumptions made such as allocation of personnel expenses.
- We tested the recognition and classification of amounts included in discontinued operations by recalculating allocable expenses using the Company's historical accounting records and the asset purchase agreement, and assessing the Company's ongoing involvement with the EVOMELA Supply Contract.

/s/ Deloitte & Touche LLP

Costa Mesa, California
March 2, 2020

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

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share and par value amounts)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 64,418	$ 157,480
Marketable securities	159,455	46,508
Accounts receivable, net of allowance for doubtful accounts of $43 and $67, respectively	441	29,873
Other receivables	9,558	3,698
Prepaid expenses and other assets	10,148	7,574
Discontinued operations, current assets (*Note 12*)	—	5,555
Total current assets	244,020	250,688
Property and equipment, net of accumulated depreciation	11,607	385
Other assets	4,000	7,188
Facility and equipment under lease	3,806	—
Discontinued operations, non-current assets	—	132,625
Total assets	$ 263,433	$ 390,886
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 54,284	$ 81,312
Accrued payroll and benefits	7,686	9,853
Contract liabilities	—	4,850
Discontinued operations, current liabilities (*Note 12*)	—	2,311
Total current liabilities	61,970	98,326
Deferred tax liabilities, net	—	1,469
Other long-term liabilities	11,070	5,650
Discontinued operations, non-current liabilities	—	14,031
Total liabilities	73,040	119,476
Commitments and contingencies (*Note 10*)		
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; 113,299,612 and 110,525,141 issued and outstanding at December 31, 2019 and 2018, respectively	113	110
Additional paid-in capital	918,205	886,740
Accumulated other comprehensive loss	(3,498)	(3,702)
Accumulated deficit	(724,427)	(611,738)
Total stockholders' equity	190,393	271,410
Total liabilities and stockholders' equity	$ 263,433	$ 390,886

See accompanying notes to these consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2019	2018	2017
Revenues (*Note 1(b)*)	$ —	$ —	$ —
Operating costs and expenses:			
Selling, general and administrative	61,373	62,690	64,759
Research and development	79,325	75,157	51,525
Total operating costs and expenses	140,698	137,847	116,284
Loss from continuing operations before other (expense) income and income taxes	(140,698)	(137,847)	(116,284)
Other (expense) income :			
Interest income (expense), net	4,996	(340)	(6,798)
Other (expense) income, net	(8,892)	9,580	389
Total other (expense) income	(3,896)	9,240	(6,409)
Loss from continuing operations before income taxes	(144,594)	(128,607)	(122,693)
Benefit for income taxes from continuing operations	9,208	1,901	21,941
Loss from continuing operations	$ (135,386)	$ (126,706)	$ (100,752)
Income from discontinued operations, net of income taxes (*Notes 12 and 15*)	22,697	5,965	8,563
Net loss	$ (112,689)	$ (120,741)	$ (92,189)
Basic and diluted (loss) income per share:			
Loss per common share from continuing operations	$ (1.22)	$ (1.23)	$ (1.18)
Income per common share from discontinued operations	$ 0.21	$ 0.06	$ 0.10
Net loss per common share	$ (1.02)	$ (1.17)	$ (1.08)
Weighted average shares outstanding:			
Basic	110,585,768	103,305,911	85,115,592
Diluted	110,585,768	103,305,911	85,115,592

See accompanying notes to these consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31,		
	2019	**2018**	**2017**
Net loss	$(112,689)	$(120,741)	$(92,189)
Other comprehensive income (loss):			
Unrealized gain on available-for-sale securities, net of income tax expense of $0.2 million, $0, and $9.7 million for the years ended December 31, 2019, 2018, and 2017, respectively (see *Note 3(a)*)	622	—	16,039
Foreign currency translation adjustments	(418)	(2,490)	1,539
Other comprehensive income (loss)	204	(2,490)	17,578
Total comprehensive loss	$(112,485)	$(123,231)	$(74,611)

See accompanying notes to these consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2016	80,466,735	$ 80	$ 648,384	$ (1,579)	$ (421,040)	$ 225,845
Net loss	—	—	—	—	(92,189)	(92,189)
Other comprehensive income, net	—	—	—	17,578	—	17,578
Recognition of stock-based compensation expense	—	—	14,227	—	—	14,227
Issuance of common stock to 401(k) plan for employees	102,874	—	912	—	—	912
Issuance of common stock for employee stock purchase plan	203,229	—	1,010	—	—	1,010
Issuance of common stock upon exercise of stock options, net	864,897	1	5,477	—	—	5,478
Restricted stock award grants, net of forfeitures	548,394	—	—	—	—	—
Repurchase/retirement of restricted stock awards to satisfy employee tax withholding	(373,822)	—	(4,331)	—	—	(4,331)
Issuance of common shares under an at-the-market sales agreement (*Note 5*)	13,558,132	14	128,258	—	—	128,272
Conversion hedge unwind in connection with open market purchases of 2018 Convertible Notes (*Note 9*)	5,372,296	5	43,410	—	—	43,415
Balance as of December 31, 2017	100,742,735	$ 100	$ 837,347	$ 15,999	$ (513,229)	$ 340,217
Net loss	—	—	—	—	(120,741)	(120,741)
Cumulative-effect adjustment of ASU 2016-01 adoption (*Note 3(a)*)	—	—	—	(17,211)	17,211	—
Cumulative-effect adjustment of Topic 606 adoption	—	—	—	—	4,678	4,678
Foreign currency adjustment related to new adoptions	—	—	—	—	343	343
Other comprehensive loss, net	—	—	—	(2,490)	—	(2,490)
Recognition of stock-based compensation expense	—	—	16,309	—	—	16,309
Issuance of common stock to 401(k) plan for employees	70,379	—	1,175	—	—	1,175
Issuance of common stock for employee stock purchase plan	97,804	—	1,122	—	—	1,122
Issuance of common stock upon exercise of stock options	7,858,141	8	52,977	—	—	52,985
Restricted stock award grants, net of forfeitures	874,532	1	—	—	—	1
Repurchase/retirement of restricted stock awards to satisfy employee tax withholding	(3,463,873)	(3)	(62,541)	—	—	(62,544)
Issuance of common stock upon vesting of restricted stock units	200,652	—	—	—	—	—
Issuance of common stock upon exercise of warrants	292,575	—	—	—	—	—
Common stock redeemed on 2018 Convertible Notes (*Note 9*)	3,852,196	4	40,351	—	—	40,355
Balance as of December 31, 2018	110,525,141	$ 110	$ 886,740	$ (3,702)	$ (611,738)	$ 271,410
Net loss	—	—	—	—	(112,689)	(112,689)
Other comprehensive loss, net	—	—	—	204	—	204
Recognition of stock-based compensation expense	—	—	20,416	—	—	20,416
Issuance of common stock to 401(k) plan for employees	225,780	—	1,422	—	—	1,422
Issuance of common stock for employee stock purchase plan	131,966	—	663	—	—	663
Issuance of common stock upon exercise of stock options	1,121,403	2	7,147	—	—	7,149
Restricted stock award grants, net of forfeitures	830,033	1	—	—	—	1
Issuance of common stock upon vesting of restricted stock units	243,760	—	—	—	—	—
Issuance of common shares under an at-the-market sales agreement (*Note 5*)	221,529		1,817	—	—	1,817
Balance as of December 31, 2019	113,299,612	$ 113	$ 918,205	$ (3,498)	$ (724,427)	$ 190,393

See accompanying notes to these consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Cash Flows From Operating Activities:			
Loss from continuing operations	(135,386)	(126,706)	(100,752)
Income from discontinued operations, net of income taxes (*Note 12*)	22,697	5,965	8,563
Net loss	(112,689)	(120,741)	(92,189)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,620	28,409	27,972
Stock-based compensation (*Note 4*)	21,838	17,483	15,139
Recognized gain on Commercial Product Portfolio Transaction (*Note 12*)	(34,568)	—	—
Amortization of operating leases (*Note 10(a)*)	1,715	—	—
Amortization of discount on investments in debt securities, recorded to interest income (*Note 3(a)*)	(431)	—	—
Income tax benefit recognition on unrealized gain for available-for-sale securities	(205)	—	(9,651)
Realized gain on sale of CASI stock (*Note 8*)	(2,674)	—	—
Unrealized loss (gain) on CASI stock holdings (*Note 3(a) and Note 8*)	12,665	(10,458)	—
Unrealized (gain) loss from transactions denominated in foreign currency	(6)	10	(23)
Change in deferred taxes	(1,469)	31	(5,237)
Change in fair value of contingent consideration	1,478	(1,927)	4,957
Accretion of debt discount on 2018 Convertible Notes, recorded to interest expense (*Note 9*)	—	1,931	4,890
Amortization of deferred financing costs on 2018 Convertible Notes, recorded to interest expense (*Note 9*)	—	220	567
Bad debt expense (recovery)	(12)	12	(17)
Loss on 2018 Convertible Note purchase (*Note 9*)	—	—	845
Change in cash surrender value of corporate-owned life insurance policy	—	(5)	(418)
Changes in operating assets and liabilities:			
Accounts receivable, net	29,420	2,844	7,694
Other receivables	(5,871)	(1,571)	3,663
Inventories	(2,037)	3,390	4,318
Prepaid expenses and other assets	(2,473)	(3,642)	(6,137)
Other assets	(1,188)	5,010	1,573
Accounts payable and other accrued liabilities	(35,769)	12,112	6,459
Accrued payroll and benefits	(2,168)	592	280
FOLOTYN development liability	(4)	(389)	(744)
Contract liabilities (*Note 3(i)*)	(4,850)	4,850	—
Other long-term liabilities	3,047	(564)	(3,389)
Deferred revenue	—	—	593
Net cash used in operating activities	(134,631)	(62,403)	(38,855)
Cash Flows From Investing Activities:			
Proceeds from Commercial Product Portfolio Transaction (*Note 1(b)*)	158,571	—	—
Proceeds from maturities of marketable securities	77,475	—	—
Proceeds from sale of CASI stock (*Note 8*)	5,074	—	—
Purchase of investment securities available-for-sale (*Note 3(a)*)	(200,160)	—	—
Purchases of property and equipment (*Note 3(b)*)	(9,018)	(107)	(465)
Proceeds from sale of property and equipment	50	—	—
Proceeds from redemption of corporate-owned life insurance policy	—	4,130	—
Cash paid for KHAPZORY distribution rights	—	(2,650)	—
Payment for corporate-owned life insurance premiums	—	—	(601)
Purchase of equity securities (*Note 8*)	—	—	(15)
Net cash provided by (used in) investing activities	31,992	1,373	(1,081)
Cash Flows From Financing Activities:			
Proceeds from employees for exercises of stock options	7,147	13,475	5,477
Proceeds from sale of stock under our employee stock purchase plan	663	1,122	1,010
Proceeds from sale of common stock under an at-the-market sales agreement (*Note 5*)	1,817	—	128,272
Proceeds from employees, for our remittance to tax authorities, upon vesting of restricted stock and upon exercises of stock options	—	4,645	—
Payments to tax authorities upon employees' surrender of restricted stock upon vesting and upon exercises of stock options	—	(27,679)	(4,331)
Payment of principal upon the maturity of the 2018 Convertible Notes (*Note 9*)	—	(20)	—
Purchase of 2018 Convertible Notes (*Note 9*)	—	—	(27,500)
Purchase of warrants related to the conversion hedge of 2018 Convertible Notes (*Note 9*)	—	—	(27,189)
Proceeds from sale of call options related to the conversion hedge of 2018 Convertible Notes (*Note 9*)	—	—	32,982
Net cash provided by (used in) financing activities	9,627	(8,457)	108,721
Effect of exchange rates on cash and equivalents	(50)	(356)	316
Net (decrease) increase in cash and cash equivalents	(93,062)	(69,843)	69,101
Cash and cash equivalents — beginning of year	157,480	227,323	158,222
Cash and cash equivalents — end of year	$ 64,418	$ 157,480	$ 227,323
Supplemental Disclosure of Cash Flow Information:			
Cash paid for facility and equipment under operating leases	$ 1,835	$ —	$ —
Cash paid for income taxes	$ 38	$ 45	$ 17
Cash paid for interest	$ —	$ 1,031	$ 2,692
Noncash investing activities:			
Additions of property and equipment that remain in accounts payable and other accrued liabilities (*Note 3(b)*)	$ 2,760	$ —	$ —

See accompanying notes to these consolidated financial statements.

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 novel and targeted oncology therapies. Our in-house development organization includes clinical development, regulatory, quality and data management. We plan to build out our commercial and marketing capabilities in the second half of 2020 to prepare for the launch of ROLONTIS.

We have three drugs in development:

- ROLONTIS, a novel long-acting granulocyte colony-stimulating ("G-CSF") for chemotherapy-induced neutropenia which has been filed with the FDA and has a Prescription Drug User Fee Act date of October 24, 2020;
- Poziotinib, a novel irreversible tyrosine kinase inhibitor under investigation for non-small cell lung cancer tumors with various mutations; and
- Anti-CD20-IFNá, an antibody-interferon fusion molecule directed against CD20 that is in Phase 1 development for treating relapsed or refractory non-Hodgkin's lymphoma ("NHL") patients (including diffuse large B-cell lymphoma).

Our business strategy is the development of our late-stage assets through commercialization and the sourcing of additional assets that are synergistic with our existing portfolio (through purchase acquisitions, in-licensing transactions, or co-development and marketing arrangements).

(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. All inter-company accounts and transactions among these legal entities have been eliminated in consolidation. In May 2019, we dissolved Spectrum Pharma Canada Inc., previously consolidated as a "variable interest entity" (as defined under applicable GAAP).

Discontinued Operations-Sale of our Commercial Product Portfolio

On March 1, 2019, we completed the sale of our seven then-commercialized drugs, including FUSILEV, KHAPZORY, FOLOTYN, ZEVALIN, MARQIBO, BELEODAQ, and EVOMELA (the "Commercial Product Portfolio") to Acrotech Biopharma LLC ("Acrotech") (the "Commercial Product Portfolio Transaction"). Upon closing we received $158.8 million in an upfront cash payment (of which $4 million was held in escrow until November 5, 2019). We are also entitled to receive up to an aggregate of $140 million upon Acrotech's future achievement of certain regulatory milestones (totaling $40 million) and sales-based milestones (totaling $100 million) relating to the Commercial Product Portfolio.

These Consolidated Financial Statements are recast for all periods presented to reflect the sale of the assets and liabilities associated with our Commercial Product Portfolio, as well as the corresponding revenue-deriving activities and allocable expenses of this commercial business within "discontinued operations" — see *Note 12*. We have presented our face financial statements in general conformity with our historical format, even where presented values are $-0- within continuing operations due to required discontinued operations classification for all periods presented. We believe this format provides increased clarity and comparability with our previously filed financial statements, as well as our expectation that these financial statement captions and associated footnote disclosures will remain relevant to our future business activities.

(c) Operating Segment

We operate in one reportable operating segment that is focused exclusively on developing (and eventually marketing) oncology and hematology drug products. For the years ended December 31, 2019, 2018, and 2017, all of our revenue and

operating costs and expenses were solely attributable to these activities (and as applicable, currently and retrospectively classified as "discontinued" within the accompanying Consolidated Balance Sheets and Consolidated Statements of Operations — see *Note 12*). All of our assets are held in the U.S, except for cash held in certain foreign bank accounts.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND USE OF ESTIMATES

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 (as applicable) 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 realization of our tax assets and estimates of our tax liabilities; (vi) the fair value of our investments; (vii) the valuation of our stock options and the periodic expense recognition of stock-based compensation; and (viii) 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

On March 1, 2019, we completed the Commercial Product Portfolio Transaction — see *Note 1(b)*. In accordance with applicable GAAP (*ASC 205-20, Presentation of Financial Statements*), the revenue-deriving activities of our sold commercial operation are separately classified as "discontinued" for all periods presented within the accompanying Consolidated Statements of Operations — see *Note 12*.

Impact of the Adoption of the New Revenue Recognition Standard**:** *ASU No. 2014-09*, *Revenue from Contracts with Customers* (*"ASC 606"*), became effective for us on January 1, 2018. 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").*

Required Elements of Our Revenue Recognition**:** Revenue from our (a) product sales, (b) out-license arrangements, and (c) service arrangements is recognized under *ASC 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 or to our product licensees (i.e., our customers). 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" that reflects 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 (that comprise our GTN liabilities within *Note 3(h)*) are each discussed below:

Product Returns Allowances: Our customers are contractually permitted to return certain purchased products within the contractual allowable time before/after its applicable expiration date. Returns outside of this aforementioned criteria are not customarily allowed. We estimate expected product returns using our historical return rates. Returned products are typically destroyed since substantially all returns are due to its imminent 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 our 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 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.

(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

Marketable securities consist of our holdings in equity securities, mutual funds, bank certificates of deposit ("Bank CDs"), government-related debt securities, and corporate debt securities. Since we classify these investments as "available-for-sale" any (1) realized gains (losses) or (2) unrealized gains (losses) on these securities are respectively recognized in (1) "other (expense) income, net" on the accompanying Consolidated Statements of Operations, or (2) depending on the nature of the marketable securities recognized in "accumulated other comprehensive loss" as a separate component of stockholder's equity on the accompanying Consolidated Statements of Stockholders' Equity, or in "other (expense) income, net" on the accompanying Consolidated Statements of Operations.

(iv) Accounts Receivable

Our accounts receivable, net of allowance for doubtful accounts 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 written 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 net realizable value, 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 during clinical development and trials, and at-risk inventory build in anticipation of commercialization, are exclusively recognized through "research and development" expense 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) 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 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.

(viii) 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.

(ix) 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 "benefit for income taxes from continuing operations" within the Consolidated Statements of Operations in the period the notice was received.

(x) Research and Development Costs

Our research and development costs are expensed as incurred (see *Note 10(c)*), or as certain milestone payments become contractually due to our licensors, as triggered by the achievement of clinical or regulatory events.

(xi) 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:

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, 2019 and December 31, 2018, our "cash and cash equivalents" were held with major financial institutions. As of December 31, 2019, our "marketable securities" include our equity holdings in CASI Pharmaceuticals, Inc. ("CASI"), mutual funds, government-related debt securities, corporate debt securities, and bank certificates of deposits ("bank CDs").

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

We maintain cash balances with select financial institutions. The Federal Deposit Insurance Corporation (FDIC) and other third parties insure a fraction of these deposits. Accordingly, these cash deposits are not insured against the possibility of a substantial or complete loss of principal and are inherently subject to the credit risk of the corresponding financial institution.

Our investment policy requires that purchased investments may only be in highly-rated and liquid financial instruments and limits our holdings 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 8*).

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(xi)*) because of our ability to immediately convert these instruments into cash with minimal expected change in value. As of December 31, 2019, our held securities that remain in an unrealized loss position for less than one year were insignificant and are presented in the table below.

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

	Historical or Amortized Cost	Foreign Currency Translation	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash equivalents	Marketable Securities
December 31, 2019							
Equity securities* (see *Note 8*)	$ 6,310	$(2,477)	$27,214	$ —	$ 31,047	$ —	$ 31,047
Money market funds	54,199	—	—	—	54,199	54,199	—
Government-related debt securities**	62,617	—	19	(10)	62,626	—	62,626
Corporate debt securities**	58,235	—	38	(25)	58,248	5,000	53,248
Bank deposits	5,219	—	—	—	5,219	5,219	—
Mutual funds	4,375	—	783	—	5,158	—	5,158
Bank CDs	7,354	—	22	—	7,376	—	7,376
Total cash and cash equivalents and marketable securities	$198,309	$(2,477)	$28,076	$(35)	$223,873	$ 64,418	$159,455
December 31, 2018							
Equity securities*	$ 8,710	$(2,168)	$39,880	$ —	$ 46,422	$ —	$ 46,422
Money market funds	142,745	—	—	—	142,745	142,745	—
Bank deposits	14,735	—	—	—	14,735	14,735	—
Bank CDs	86	—	—	—	86	—	86
Total cash and cash equivalents and marketable securities	$166,276	$(2,168)	$39,880	$ —	$203,988	$157,480	$ 46,508

* Beginning January 1, 2018, under the new requirements of *ASU 2016-01, Recognition and Measurement of Financial Assets and Liabilities*, the unrealized gains (losses) on our CASI equity securities are recognized as an increase (decrease) to "other (expense) income, net" on the Consolidated Statements of Operations (rather than through "other comprehensive loss" 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, reported as a decrease to "accumulated other comprehensive loss" and a decrease to "accumulated deficit" on the accompanying Consolidated Balance Sheets. Our unrealized (losses) gains on these equity securities for the year ended December 31, 2019 and 2018 was $(12.7) million and 10.5 million, respectively, as reported in "other (expense) income, net" on the accompanying Consolidated Statements of Operations.

** Beginning in the second quarter of 2019, we purchased certain government-related and corporate debt securities. We have classified these as "available-for-sale" since we may redeem or sell these investments before their stated maturity to

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

fund our operations. Under the requirements of *ASC 320, Investments — Debt and Equity Securities:* (i) we recorded these securities at initial "book value" and then amortize, through maturity, the determined "discount" or "premium" within "interest income" on the accompanying Consolidated Statements of Operations, and (ii) we recognize the "unrealized gains (loss)" of these securities (i.e., fair value *versus* amortized book value) as a separate component of "other comprehensive loss" on the accompanying Consolidated Statements of Comprehensive Loss for the year ended December 31, 2019.

(b) Property and Equipment, net of Accumulated Depreciation

"Property and equipment, net of accumulated depreciation" consists of the following:

	December 31,	
	2019	2018
Manufacturing equipment*	$10,355	$ —
Computers hardware and software	3,606	3,079
Laboratory equipment	36	635
Office furniture	248	212
Leasehold improvements	3,374	2,957
Property and equipment, at cost	17,619	6,883
(Less): Accumulated depreciation	(6,012)	(6,498)
Property and equipment, net of accumulated depreciation	$11,607	$ 385

* This account is comprised of our owned ROLONTIS production equipment on location at our contract manufacturer. This equipment has alternative future use for the general production of various biologic agents. Accordingly, we have capitalized these purchases, rather than recording it as "research and development" expense, despite its current designation for the manufacture of pre-FDA approved product. The majority of this manufacturing equipment was not in use and therefore not being depreciated as of December 31, 2019.

Depreciation expense (included within "total operating costs and expenses" in the accompanying Consolidated Statements of Operations) for the years ended December 31, 2019, 2018, and 2017 was $0.4 million, $0.2 million, and $0.3 million, respectively.

(c) 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, 2019 and 2018, are as follows:

	December 31,			
	2019		2018	
McKesson Corporation and its affiliates	$ 9	2.0%	$ 7,615	25.5%
AmerisourceBergen Corporation, and its affiliates	—	—%	10,448	35.0%
Cardinal Health, Inc. and its affiliates	—	—%	8,228	27.5%
All other customers	432	98.0%	3,582	12.0%
Accounts receivable, net	$ 441	100.0%	$ 29,873	100.0%

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

(d) Prepaid Expenses and Other Assets

"Prepaid expenses and other assets" consists of the following:

	December 31, 2019	December 31, 2018
Vendor deposits	$ 8,740	$6,792
Prepaid insurance	1,408	782
Prepaid expenses and other assets	$10,148	$7,574

(e) Other Receivables

"Other receivables" consists of the following:

	December 31, 2019	December 31, 2018
CASI other receivables	$2,393	$ —
Other miscellaneous receivables (including Medicaid rebate credits and royalty receivables from licensees)	1,490	1,189
Insurance receivable*	4,015	206
Income tax receivable — current portion	973	643
Interest receivable from marketable securities (see *Note 3(a)*)	561	—
Reimbursements due from development partners for incurred research and development expenses	126	135
Secured promissory note (see *Note 8*)	—	1,525
Other receivables	$9,558	$3,698

* This insurance receivable balance represents our incurred legal fees and pending and completed settlements that are expected to be reimbursed by our insurance carriers.

(f) Other Assets

"Other assets" consists of the following:

	December 31, 2019	December 31, 2018
Key employee life insurance — cash surrender value (associated with our deferred compensation plan — see *Note 7*	$3,547	$6,274
Research & development supplies and other	119	246
Income tax receivable — non-current portion*	334	668
Other assets	$4,000	$7,188

* This value represents the non-current portion of refundable alternative minimum tax payments that are expected to be received over the next few years (see *Note 11*).

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

(g) Facility and Equipment Under Lease

"Facility and equipment under lease" consists of the following:

	December 31, 2019	December 31, 2018
Office and research facilities	$3,391	$ —
Office equipment	415	—
Facility and equipment under lease	$3,806	$ —

(h) Accounts Payable and Other Accrued Liabilities

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

	December 31,	
	2019	2018
Trade accounts payable and other	$32,012	$44,919
Lease liability — current portion	1,683	—
Accrued commercial/Medicaid rebates*	2,925	8,580
Accrued product royalty due to licensors	66	4,337
Allowance for product returns	4,714	5,171
Accrued data and distribution fees	768	3,248
Accrued GPO administrative fees	6	296
Accrued inventory management fees	364	388
Allowance for government chargebacks*	11,746	14,373
Accounts payable and other accrued liabilities	$54,284	$81,312

* The values in 2018 have been restated for certain immaterial corrections related to "Accrued commercial/Medicaid rebates" and "Allowance for government chargebacks." (see *Note 15*).

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	Commercial/Medicaid Rebates and Government Chargebacks*	Distribution, Data, Inventory, and GPO Administrative Fees	Product Return Allowances
Balance as of December 31, 2017	$ 21,480	$ 5,727	$ 4,045
Add: GTN accruals recorded for product sales	69,704	13,962	1,700
(Less): Payments made and credits against GTN accruals	(68,232)	(15,757)	(574)
Balance as of December 31, 2018	22,952	3,932	5,171
Add: GTN accruals recorded for product sales	7,702	1,209	167
(Less): Payments made and credits against GTN accruals	(15,983)	(4,003)	(624)
Balance as of December 31, 2019	$ 14,671	$ 1,138	$ 4,714

* The values in 2018 and 2017 have been restated for certain immaterial corrections related to "Commercial/Medicaid Rebates and Government Chargebacks." (see *Note 15*).

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

(i) Contract Liabilities

"Contract liabilities" consists of the following:

	December 31, 2019	December 31, 2018
Customer deposit for EVOMELA supply in China territory (see *Note 8*)	$ —	$4,850
Contract liabilities	$ —	$4,850

(j) Other Long-Term Liabilities

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

	December 31, 2019	December 31, 2018
Deferred compensation liability (*Note 10(f)*)	$ 8,597	$5,474
Lease liability — non-current portion (*Note 10(a)*)	2,372	—
Other tax liabilities	101	176
Other long-term liabilities	$11,070	$5,650

4. STOCK-BASED COMPENSATION

2018 Long-Term Incentive Plan

We have one active stockholder-approved stock-based compensation plan, the 2018 Long- Term Incentive Plan (the "2018 Plan"). In June 2018, the 2018 Plan replaced our former 2009 Incentive Award Plan (the "2009 Plan"). 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 stated maximum availability of common stock under the 2018 Plan is 9.5 million shares, except for additional availability provided on a one-for-one basis for awards formerly issued under the 2009 Plan that are terminated, forfeited, cancelled or expire unexercised. Awards issued under the 2018 Plan reduce share availability on a one-to-one basis for stock options and on a 1.5-to-one basis for restricted stock awards and restricted stock units. Accordingly, as of December 31, 2019, 5.9 million awards were available for grant under the 2018 Plan, assuming all were issued in the form of stock options, though would be reduced to 4.0 million awards available for grant if all were issued in the form of restricted stock.

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). At the time of vesting of restricted stock, by our policy, requisite shares are automatically sold on the open market by our designated broker to the extent required to cover the employee's federal and state taxes due.

Stock-based awards are governed by agreements between us and the recipients. Incentive stock options ("ISOs") 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 for certain recipients may not be less than 110% of such fair market value. The grant date is generally the date the terms of the award are approved by the Compensation Committee of our Board of Directors.

Stock-based awards generally vest at 25% to 33% on the first anniversary following the date of grant. 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; 12 months after the date of termination upon disability or death; ninety days after the date of termination for all other separations (though whether vested or unvested, stock options of the employee recipient are immediately forfeited upon termination for "Cause" as defined in the 2018 Plan).

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

Employee Stock Purchase Plan

Under the terms of our 2009 Employee Stock Purchase Plan (the "ESPP"), eligible employees can purchase common stock through scheduled 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 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 at full market value on the offering date during each plan year.

As of December 31, 2019, a total of 8.7 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, 2019, 2018, and 2017, was as follows:

	Year Ended December 31,		
	2019	2018	2017
Selling, general and administrative	$14,118	$ 9,268	$ 9,178
Research and development	4,316	2,566	1,885
Total stock-based compensation	$18,434	$11,834	$11,063

Employee stock-based compensation expense for the years ended December 31, 2019, 2018, and 2017 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 16%, 15%, and 14% for the years ended December 31, 2019, 2018, and 2017, 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,		
	2019	2018	2017
Expected option life (in years) (a)	5.34	4.73	4.84
Risk-free interest rate (b)	1.47% - 2.49%	1.81% - 2.75%	0.82% - 1.90%
Volatility (c)	61.6% - 76.1%	50.0% - 56.2%	49.3% - 61.4%
Dividend yield (d)	—%	—%	—%
Weighted-average grant-date fair value per stock option	$5.85	$8.64	$2.89

(a) Determined by the historical stock option exercise behavior of our employees (maximum term is 10 years).

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

Stock option activity during the years ended December 31, 2019, 2018, and 2017 was as follows:

	Number of Shares	Weighted-Average Exercise Price/Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding — December 31, 2016	14,340,582	$ 6.86		
Granted	1,223,483	6.51		
Exercised	(937,482)	6.40		$ 6,813(1)
Forfeited	(244,793)	6.26		
Expired	(524,577)	6.27		
Outstanding — December 31, 2017	13,857,213	6.89		
Granted	1,094,358	18.87		
Exercised	(7,858,141)	6.74		$84,758(1)
Forfeited	(214,464)	6.54		
Expired	(35,381)	6.94		
Outstanding — December 31, 2018	6,843,585	8.98		
Granted	1,113,081	10.54		
Exercised	(1,121,403)	6.38		$ 2,919(1)
Forfeited	(172,074)	9.84		
Expired	(223,253)	11.09		
Outstanding — December 31, 2019	6,439,936	$ 9.61	6.16	$ 1(2)
Vested (exercisable) — December 31, 2019	4,682,766	$ 8.66	5.29	$ 1(2)
Unvested (unexercisable) — December 31, 2019	1,757,170	$ 12.14	8.47	$ —(2)

(1) Represents the total *difference* between our closing stock price at the time of exercise and the stock option exercise price, multiplied by the number of options exercised.
(2) Represents the total *difference* between our closing stock price on the last trading day of 2019 and the stock option exercise price, *multiplied by* the number of in-the-money options as of December 31, 2019. The amount of intrinsic value will change based on the fair market value of our stock.

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

The following table summarizes information with respect to stock option grants as of December 31, 2019:

	Outstanding			Exercisable	
Exercise Price	Granted Stock Options Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Granted Stock Options Exercisable	Weighted-Average Exercise Price
$1.47 – 4.96	91,599	2.80	$ 4.16	82,428	$ 4.15
$4.97 – 6.91	2,210,050	6.18	6.00	1,866,277	5.97
$6.92 – 9.00	1,801,136	4.91	7.84	1,565,804	7.76
$9.01 – 12.00	1,135,793	7.23	11.03	509,250	10.70
$12.01 – 22.64	1,201,358	7.24	17.97	659,007	17.39
	6,439,936	6.16	$ 9.61	4,682,766	$ 8.66

As of December 31, 2019, there was unrecognized compensation expense of $7.3 million related to unvested stock options, which we expect to recognize over a weighted average period of 2.0 years.

Restricted Stock Award Activity

A summary of restricted stock award activity is as follows:

	Number of Restricted Stock Awards	Weighted Average Fair Value per Share at Grant Date
Unvested — December 31, 2016	2,152,157	$ 6.29
Granted	927,306	6.22
Vested	(1,137,555)	6.38
Forfeited	(378,990)	5.95
Unvested — December 31, 2017	1,562,918	6.27
Granted	1,092,534	17.35
Vested	(635,320)	6.51
Forfeited	(218,002)	7.56
Unvested — December 31, 2018	1,802,130	12.75
Granted	1,091,353	10.50
Vested	(972,404)	11.70
Forfeited	(261,320)	11.48
Unvested — December 31, 2019	1,659,759	$ 11.67

	Year Ended December 31,		
	2019	2018	2017
Restricted stock award expense	$9,170	$5,180	$4,985

As of December 31, 2019, there was approximately $13.5 million of unrecorded expense related to issued restricted stock awards that will be recognized over an estimated weighted average period of 1.9 years. These unvested shares are included in our reported issued and outstanding common stock as of December 31, 2019.

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

Restricted Stock Unit Activity

Our outstanding restricted stock units substantially relate to awards that contain "market-based" vesting conditions that are issued to our executive officers. These conditions are specified in each award agreement and result in a variable number of shares that become issuable at the assessment date, after review and approval by our Compensation Committee. A summary of restricted stock unit activity is as follows:

	Number of Restricted Stock Units	Weighted Average Fair Value per Share at Grant Date
Outstanding — December 31, 2017	217,206	$ 6.49
Granted	138,334	28.31
Market-based achievement adjustment at vesting	100,326	6.49
Share issuance upon approved achievement date	(200,652)	6.49
Outstanding — December 31, 2018	255,214	17.91
Granted	257,585	12.87
Market-based achievement adjustment at vesting	116,880	6.49
Share issuance	(243,760)	7.04
Outstanding — December 31, 2019	385,919	$18.00

	2019	2018	2017
Restricted stock unit expense	$3,019	$2,301	$1,030

401(k) Plan — Stock Matching Contribution

We issued shares of common stock to our employees in connection with our 401(k) program, partially matching our employees' annual 401(k) contributions, as summarized below:

	Year Ended December 31,		
	2019	2018	2017
Shares of common stock issued	225,780	70,379	102,874
Value of employer match in shares	$ 1,289	$ 762	$ 639

5. STOCKHOLDERS' EQUITY

Authorized Stock

In June 2018, our stockholders approved an amendment and restatement of our Certificate of Incorporation to reflect an increase in the number of authorized shares of our common stock from 175 million shares to 300 million shares. In addition to the increase in the authorized number of shares of common stock, the amendment eliminates designated series of preferred stock that are obsolete and are no longer outstanding or issuable, including Series B Junior Participating Preferred Stock and Series E Convertible Voting Preferred Stock. As of December 31, 2019, we had five million shares of preferred stock authorized and no shares of preferred stock outstanding. The amendment was filed with the Delaware Secretary of State in June 2018.

Stockholder Rights Agreement

On November 29, 2010, our Board of Directors approved a stockholder rights agreement (the "Stockholder Rights Agreement"), effective December 13, 2010. A stockholder rights agreement is designed to deter coercive, unfair, or

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inadequate takeovers and other abusive tactics that might be used in an attempt to gain control of our company. A stockholder rights agreement will not prevent takeovers at a full and fair price, but rather is designed to deter coercive takeover tactics and to encourage anyone attempting to acquire our company to first negotiate with our Board of Directors.

On March 27, 2018, we entered into a Second Amendment to Rights Agreement which had the effect of suspending the Stockholders Rights Agreement as of March 30, 2018, though it will expire under its terms on December 13, 2020.

Common Stock Issuable Upon Exercise of Stock Options and Vesting of Restricted Stock Units

As of December 31, 2019, (i) 4.7 million shares of our common stock are issuable upon the exercise of outstanding stock options (regardless of whether in or out-of-the-money) and (ii) 0.5 million shares of our common stock are issuable if the maximum market conditions of our outstanding restricted stock unit agreements are met.

Stock Warrant Activity

We typically issue warrants to purchase shares of our common stock to investors as part of a financing transaction or in connection with services rendered by placement agents or consultants. During 2018, our previously outstanding warrants were exercised, and therefore no outstanding warrants remained as of December 31, 2019. A summary of warrant activity is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding — December 31, 2016	445,000	$ 6.78
Outstanding — December 31, 2017	445,000	6.78
Exercised	(445,000)	6.78
Outstanding — December 31, 2018	—	$ —

Sale of Common Stock Under ATM Agreements

In December 2015, and August 2017, we entered into a new collective at-market-issuance (ATM) sales agreement with FBR Capital Markets & Co., MLV & Co. LLC, and H.C. Wainwright & Co., LLC. ("December 2015 ATM Agreement" and the "August 2017 ATM Agreement", respectively). 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. During the year ended December 31, 2017 we raised net proceeds of $128.3 million. We had no sales under the ATM during the year ended December 31, 2018.

In April 2019, we entered into a new collective at-market-issuance sales agreement with Cantor Fitzgerald & Co., H.C. Wainwright & Co., LLC and B. Riley FBR, Inc. (the "April 2019 ATM Agreement") connected to our automatic shelf registration statement on Form S-3ASR, filed with the SEC on April 5, 2019.

The April 2019 ATM Agreement allows us to raise aggregate gross proceeds of $150 million from the periodic sales of our common stock on the public market. Through December 31, 2019, we raised aggregate net proceeds of $1.8 million under this ATM. These proceeds and any future proceeds raised will support the advancement of our in-development drug candidates, activities in connection with the launch of our in-development drug candidates, including hiring and building inventory supply, making acquisitions of assets, businesses, companies or securities, capital expenditures, and for other working capital purposes.

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

Description of Financing Transaction	No. of Common Shares Issued	Proceeds Received (Net of Broker Commissions and Fees)
Common shares issued pursuant to the December 2015 ATM Agreement between July 1, 2017 and July 31, 2017	3,243,882	$ 23,745
Common shares issued pursuant to the August 2017 ATM Agreement between August 1, 2017 and December 31, 2017	10,314,250	$ 104,527
Common shares issued pursuant to the April 2019 ATM Agreement during the year ended December 31, 2019	221,529	$ 1,814

There were no sales of our common stock under the April 2019 ATM Agreement during the three months ended December 31, 2019.

6. NET LOSS PER SHARE

Net loss per share was computed by dividing net loss by the weighted average number of common shares outstanding for the years ended December 31, 2019, 2018, and 2017:

	Year Ended December 31,		
	2019	2018	2017
Net loss	$ (112,689)	$ (120,741)	$ (92,189)
Weighted average shares — basic and diluted	110,585,768	103,305,911	85,115,592
Net loss per share — basic and diluted	$ (1.02)	$ (1.17)	$ (1.08)

The below outstanding securities were excluded from the above calculation of net loss per share because their impact under the “treasury stock method” and “if-converted method” would have been anti-dilutive due to our net loss per share for the years ended December 31, 2019, 2018, and 2017, as summarized below:

	Year Ended December 31,		
	2019	2018	2017
Common stock options issued	1,059,846	4,407,765	3,668,662
Restricted stock awards issued	1,659,759	1,802,130	1,562,918
Restricted stock units issued	385,919	255,214	217,206
2013 Convertible Notes outstanding — if converted into common shares	—	—	3,854,959
Common stock warrants issued	—	—	138,277
Total	3,105,524	6,465,109	9,442,022

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

7. FAIR VALUE MEASUREMENTS

The table below summarizes certain asset and liability fair values that are included within our accompanying Consolidated Balance Sheets, and their designations among the three fair value measurement categories (see *Note 2(xi)*):

	December 31, 2019 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Assets:				
Equity securities (*Note 8*)	$ 31,047	$ —	$ —	$ 31,047
Bank CDs	—	7,376	—	7,376
Mutual funds	5,158	11	—	5,169
Key employee life insurance, cash surrender value — *Note 3(f)*)	—	3,547	—	3,547*
Money market funds	54,199	—	—	54,199
Government-related debt securities	47,636	14,990	—	62,626
Corporate debt securities	—	58,248	—	58,248
	$138,040	$84,172	$ —	$222,212
Liabilities:				
Deferred executive compensation liability (*Note 10(f)*)	$ —	$ 8,746	$ —	$ 8,746*
	$ —	$ 8,746	$ —	$ 8,746

	December 31, 2018 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Assets:				
Equity securities *(Note 8)*	$46,422	$ —	$ —	$ 46,422
Bank CDs	—	86	—	86
Mutual funds	—	78	—	78
Key employee life insurance, cash surrender value	—	6,274	—	6,274*
Money market funds	—	142,745	—	142,745
	$46,422	$149,183	$ —	$195,605
Liabilities:				
Deferred executive compensation liability *(Note 10(f))*	$ —	$ 6,167	$ —	$ 6,167*
	$ —	$ 6,167	$ —	$ 6,167

* The reported amount of "key employee life insurance, cash surrender value" is based on the cash surrender value of life insurance policies of named current and former employees at each period-end. The reported amount of "deferred executive compensation liability" is based on the period-end market value of mutual fund investments selected by employee participants of the deferred compensation plan.

We did not have any transfers between *"Level 1"* and *"Level 2"* (see *Note 2(xi)*) measurement categories for any periods presented except for "money market funds" included within *Level 1* as of December 31, 2019 that were presented within *Level 2* as of December 31, 2018. We believe this change is appropriate since these money market funds have quoted daily prices in active markets that are publicly accessible.

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

Our carrying amounts of financial instruments such as cash equivalents, accounts receivable, prepaid expenses, accounts payable and other accrued liabilities approximate their fair values due to their short-term nature of settlement.

8. CASI HOLDINGS AND EVOMELA SUPPLY CONTRACT

Overview of CASI Transaction

In 2014, we executed three perpetual out-license agreements for our former products ZEVALIN, MARQIBO, and EVOMELA ("CASI Out-Licensed Products") with CASI, a publicly-traded biopharmaceutical company (NASDAQ: CASI) with a primary focus on the China market (collectively, the "CASI Out-License"). Under the CASI Out-License, we received CASI common stock and a secured promissory note and CASI gained the exclusive rights to distribute the CASI Out-Licensed Products in greater China (which includes Taiwan, Hong Kong and Macau).

On March 1, 2019, we completed the Commercial Product Portfolio Transaction (see *Note 1(b)*) and substantially all of the contractual rights and obligations associated with these products, including the CASI Out-License, were transferred to Acrotech at closing. However, on an interim basis we retained our original supply agreement with CASI for EVOMELA. Corresponding revenue for shipped product has been recognized within discontinued operations "product sales, net" (see *Note 12*). With our fulfillment of this order in October 2019, we will not have any further involvement with this arrangement.

Our Ownership in CASI at December 31, 2019

Under certain conditions that expired in December 2017, we exercised our rights during 2016 and 2017 to purchase additional shares of CASI common stock at par value in order to maintain our post-investment ownership percentage. Our aggregate holding of 10.0 million CASI common shares as of December 31, 2019 represented an approximate 10.3% ownership with a fair market value of $31.0 million (see *Note 3(a)*). In April 2019, we completed the sale of 1.5 million shares for $5.1 million of cash and recognized a $2.7 million gain within "other (expense) income, net" within the accompanying Consolidated Statements of Operations for the year ended December 31, 2019.

9. CONVERTIBLE SENIOR NOTES

Overview of 2013 Convertible Notes

On December 17, 2013, we entered into an agreement for the sale of $120 million aggregate principal amount of 2.75% Convertible Senior Notes (the "2013 Convertible Notes"). During 2016 and 2017, we completed certain open market purchases to retire $79.5 million of note principal.

The 2013 Convertible Notes matured on December 15, 2018. Substantially all then-outstanding notes were converted into our common stock at a rate of 95 shares per $1,000 principal units.

Components of Interest Expense on 2013 Convertible Notes

The following table sets forth the components of interest expense recognized in the accompanying Consolidated Statements of Operations for the 2013 Convertible Notes:

	December 31,	
	2018	2017
Stated coupon interest expense	$ 981	$2,615
Amortization of debt issuance costs	220	567
Accretion of debt discount	1,931	4,890
Total interest expense	$3,132	$8,072
Effective interest rate	8.41%	8.41%

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

10. FINANCIAL COMMITMENTS & CONTINGENCIES AND KEY LICENSE AGREEMENTS

(a) Facility and Equipment Leases

Overview

In the ordinary course of our business, we enter into leases with unaffiliated parties for the use of (i) office and research facilities and (ii) office equipment. Our current leases have remaining terms ranging from one year to four years and none include any residual value guarantees, restrictive covenants, term extensions, or early-termination options.

Our facility leases have minimum annual rents, payable monthly, and some carry fixed annual rent increases. Under some of these arrangements, real estate taxes, insurance, certain operating expenses, and common area maintenance are reimbursable to the lessor. These amounts are expensed as incurred, as they are variable in nature and therefore excluded from the measurement of our reported lease asset and liability discussed below. During the year ended December 31, 2019, 2018 and 2017, we had no sublease arrangements with us as lessor.

We lease our principal executive office in Henderson, Nevada under a non-cancelable operating lease expiring October 31, 2021. We also lease our research and development facility in Irvine, California under a non-cancelable operating lease expiring July 31, 2022, in addition to other administrative office leases. We recognize lease expense on a straight-line basis over the expected term of these operating leases, as reported within "selling, general and administrative" expense on the accompanying Consolidated Statements of Operations. For the year ended December 31, 2019, 2018, and 2017 this expense aggregated $2.2 million, $1.6 million, and $1.6 million, respectively.

Adoption of the New Lease Accounting Standard

Beginning January 1, 2019, we adopted *ASU 2016-02, Leases* ("*Topic 842*"). Under this new lease accounting standard, we recognized a right-of-use asset ("ROU") and lease liability on our accompanying Consolidated Balance Sheets for all leases (except for any lease with an original term of less than 12 months). We elected the "optional transition method" upon adoption of *Topic 842* and the available practical expedients. Accordingly, we did not reassess (i) lease classification (as either operating or financing) or (ii) initial direct costs for existing leases.

This reported asset and liability, respectively, represents (i) the economic benefit of our use of leased facilities and equipment and (ii) the present-value of our contractual minimum lease payments, applying our estimated incremental borrowing rate as of the lease commencement date (since an implicit interest rate is not readily determinable in any of our leases). We recorded $4.2 million to our January 1, 2019 balance sheet for both (i) our right-of-use asset within "facility and equipment under lease" and (ii) our lease liability within "accounts payable and other accrued liabilities" and "other long-term liabilities." The recorded asset and liability associated with each lease is amortized over the respective lease term using the "effective interest rate" method. For the year ended December 31, 2019, we recognized an additional $1.1 million of ROU assets in exchange for $1.1 million of additional lease liabilities.

We elected to (1) not separate "lease components" from "non-lease components" in our measurement of minimum payments for (i) facility leases and (ii) office equipment leases and (2) not recognize a lease asset and liability for a term of 12 months or less.

Financial Reporting Captions

The below table summarizes these lease asset and liability accounts presented on our accompanying Consolidated Balance Sheets:

Operating Leases*	Consolidated Balance Sheet Caption	December 31, 2019
Operating lease right-of-use assets — non-current	Facility and equipment under lease	$ 3,806
Operating lease liabilities — current	Accounts payable and other accrued liabilities	$ 1,683
Operating lease liabilities — non-current	Other long-term liabilities	2,372
Total lease liabilities		$ 4,055

* As of December 31, 2019, we have no "finance leases" as defined in *Topic 842*.

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

Components of Lease Expense

We recognize lease expense on a straight-line basis over the term of our operating leases, as reported within "selling, general and administrative" expense on the accompanying Consolidated Statements of Operations. The components of our aggregate lease expense are summarized below:

	Year Ended December 31, 2019
Operating lease cost	$1,660
Variable lease cost	470
Short-term lease cost	77
Total lease cost	$2,207

Weighted Average Remaining Lease Term and Applied Discount Rate

	Weighted Average Remaining Lease Term	Weighted Average Discount Rate
Operating leases as of December 31, 2019	2.5 years	7.8%

Future Contractual Lease Payments as of December 31, 2019

The below table summarizes our (i) minimum lease payments over the next five years, (ii) lease arrangement implied interest, and (iii) present value of future lease payments:

Operating Leases — future payments	December 31, 2019
2020	$1,934
2021	1,671
2022	828
2023	87
2024	—
Total future lease payments, undiscounted	$4,520
(Less): Implied interest	(465)
Present value of operating lease payments	$4,055

Future Contractual Lease Payments as of December 31, 2018

The below is required tabular disclosure for comparative purposes with our current period-end balance sheet date above:

Operating Leases — future payments	December 31, 2018
2019	$1,486
2020	1,441
2021	1,465
2022	828
2023 and thereafter	87
	$5,308

(b) In/Out Licensing Agreements and Co-Development Arrangements

Overview

The in-license agreements for our development-stage drug products provide us with territory-specific rights to their manufacture and distribution (including further sub-licensing/out-licensing rights). We are generally responsible for all related clinical development costs, patent filings and maintenance costs, marketing costs, and liability insurance costs. We are also obligated to make specified milestone payments to our licensors upon the achievement of certain regulatory and sales milestones, and to pay royalties based on our net sales of all in-licensed products. We also may enter into out-license agreements for territory-specific rights to these drug products which include one or more of: upfront license fees, royalties from our licensees' sales, and/or milestone payments based on our licensees' sales or regulatory achievements. For certain drug products, we may enter into cost-sharing arrangements with licensees and licensors.

Impact of Commercial Product Portfolio Transaction on Rights and Obligations Associated with the Product Portfolio

On March 1, 2019, we completed the Commercial Product Portfolio Transaction and substantially all of the contractual rights and obligations associated with the Commercial Product Portfolio that were previously disclosed in *Note 17(b)* to our 2018 Annual Report on Form 10-K were transferred to Acrotech at the closing of the Commercial Product Portfolio Transaction. However, under the terms of this transaction we retained our trade "accounts receivable" and GTN liabilities included within "accounts payable and other accrued liabilities" (see *Note 3(h)*) associated with our product sales made on and prior to February 28, 2019.

Accordingly, these Consolidated Financial Statements are recast for all periods presented to reflect the sale of the assets and liabilities associated with our Product Portfolio, as well as the corresponding revenue-deriving activities and allocable expenses of this commercial business within "discontinued operations" — see *Notes 1* and *12*. The most significant agreements associated with our *continuing operations* are listed below, along with the key financial terms and our corresponding accounting and reporting conventions for each:

(i) ROLONTIS: Co-Development and Commercialization Agreement with Hanmi Pharmaceutical Co. Ltd

In October 2014, we exercised our option under a License Option and Research Collaboration Agreement dated January 2012 (as amended) with Hanmi Pharmaceutical Co. Ltd., or Hanmi, for ROLONTIS, a drug based on Hanmi's proprietary LAPSCOVERY™ technology for the treatment of chemotherapy induced neutropenia. Under the terms of this agreement, as amended, we have primary financial responsibility for the ROLONTIS development plan and hold its worldwide rights (except for Korea, China, and Japan). We are contractually obligated to pay Hanmi tiered royalties that range from the low double-digits to mid-teens on our annual net sales of ROLONTIS.

In January 2016, the first patient was dosed with ROLONTIS in a clinical trial. This triggered our contractual milestone payment to Hanmi, and in April 2016, we issued 318,750 shares of our common stock to Hanmi. We are responsible for further contractual payments upon our achievement of a regulatory milestone (triggering a payment of $10 million to Hanmi) and sales milestone payments of up to $120 million per calendar year based on our annual net sales of ROLONTIS.

Depending on the milestone achievement type we will either (a) capitalize the payment value to "intangible assets" in the Consolidated Balance Sheets or (b) recognize the payment value within "research and development" or "cost of sales" on the Consolidated Statements of Operations. The corresponding liability for the payment due to the licensor will be recognized in the Consolidated Balance Sheets within "accounts payable and other accrued liabilities" in the earliest period that we determine the respective milestone achievement is probable or occurs.

(ii) Poziotinib: In-License Agreement with Hanmi and Exclusive Patent and Technology License Agreement with MD Anderson

In February 2015, we executed an in-license agreement with Hanmi for poziotinib, a pan-HER inhibitor in Phase 2 clinical trials (which has also shown single agent activity in the treatment of various cancer types during Phase 1 studies, including breast, gastric, colorectal, and lung cancers) and made an upfront payment to Hanmi for distribution rights.

Under the terms of this agreement, we received the exclusive global rights to commercialize poziotinib, except for Korea and China. Hanmi and its development partners are fully responsible for the completion of on-going Phase 2 trials in Korea. We are financially responsible for all other clinical studies. We are obligated to make contractual payments to Hanmi upon our achievement of various regulatory milestones that aggregate $33 million. We are also obligated to pay Hanmi net sales milestones of up to $325 million annually and pay royalties in the low to mid-teen digits on our net sales of poziotinib, potentially reduced by royalties due to other third parties.

In April 2018, we executed an exclusive patent and technology agreement for the use of poziotinib in treating patients with EGFR and HER2 exon 20 mutations in cancer and HER2 exon 19 mutations in cancer with The University of Texas M.D. Anderson Cancer Center ("MD Anderson"). MD Anderson discovered poziotinib's use in treating these patient-types ("Exon 19/20 Patients"). We made an upfront payment to MD Anderson of $0.5 million upon the execution of this agreement that we recognized within "research and development" expense in the accompanying Consolidated Statements of Operations for the year ended December 31, 2018.

We are contractually obligated to pay nominal fixed annual license maintenance fees to MD Anderson and pay additional fees upon our achievement of various regulatory and sales milestones. These regulatory milestones aggregate $6 million and the sales milestones aggregate $24 million. We are also contractually obligated to pay MD Anderson royalties in the low single-digits on our net sales of poziotinib.

Depending on the milestone achievement type we will either (a) capitalize the payment value to "intangible assets" in the Consolidated Balance Sheets or (b) recognize the payment value within "research and development" or "cost of sales" on the Consolidated Statements of Operations. The corresponding liability for the payment due to the licensor will be recognized in the Consolidated Balance Sheets within "accounts payable and other accrued liabilities" in the earliest period that we determine the respective milestone achievement is probable or occurs.

(iii) In-License Agreement with ImmunGene for FIT Drug Delivery Platform

In April 2019, we executed an asset transfer, license, and sublicense agreement with ImmunGene, Inc. ("ImmunGene") for an exclusive license for the intellectual property related to (i) Anti-CD20-IFNá, an antibody-interferon fusion molecule directed against CD20 that is in Phase 1 development for treating relapsed or refractory non-Hodgkin lymphoma, including diffuse large b-cell lymphoma patients, representing a considerable unmet medical need; and (ii) an antibody-interferon fusion molecule directed against GRP94, a target for which currently there are no existing approved therapies that has the potential for treating both solid and hematologic malignancies. Both molecules are based on the Focused Interferon Therapeutics ("FIT") drug delivery platform.

We made upfront payments aggregating $2.8 million to ImmunGene and to several other third parties, all of which were recorded within "research and development" expense within our accompanying Consolidated Statements of Operations for the year ended December 31, 2019. We will make further payments to ImmunGene upon our achievement of various regulatory milestones that aggregate $26.1 million, plus an additional $5 million milestone payment for each new indication (beyond those described above) approved for either drug in the U.S., Europe, or Japan.

Our contractual royalties to ImmunGene are in the high-single digits on our net sales of each drug, potentially reduced by our royalties due to other third parties. We are also contractually obligated to pay nominal fixed annual license maintenance fees to two licensors.

Depending on the milestone achievement type we will either (a) capitalize the payment value to "intangible assets" in the Consolidated Balance Sheets or (b) recognize the payment value within "research and development" or "cost of sales" on the Consolidated Statements of Operations. The corresponding liability for the payment due to the licensor will be recognized in the Consolidated Balance Sheets within "accounts payable and other accrued liabilities" in the earliest period that we determine the respective milestone achievement is probable or occurs.

(c) Service Agreements for our Research and Development Activities

We have entered into various contracts with numerous third party service providers for the execution of our research and development initiatives (to which we assign discrete project codes in order to compile and monitor such expenses).

These vendors include raw material suppliers, clinical trial sites, clinical research organizations, and data monitoring centers, among others. The financial terms of these agreements are varied and generally obligate us to pay in stages, depending on the achievement of certain events specified in the agreements — such as contract execution, progress of service completion, delivery of drug supply, and the dosing of patients in clinical studies.

We recognize these "research and development" expenses and corresponding "accounts payable and other accrued liabilities" in the accompanying financial statements based on estimates of our vendors' progress of performed services, patient enrollments and dosing, completion of clinical studies, and other events. Should we decide to discontinue and/or slow-down the work on any project, the associated costs for those projects would typically be limited to the extent of the work completed, as we are generally able to terminate these contracts with adequate notice.

(d) Supply and Service Agreements Associated with Product Production

We have various product supply agreements and/or have issued vendor purchase orders that obligate us to agreed-upon raw material purchases from certain vendors. We also have certain drug production service agreements with select contract manufacturers that obligate us to service fees during the contractual period. These collective commitments do not exceed our planned commercial requirements; the corresponding contracted prices do not exceed their current fair market values.

(e) Employment Agreement

We entered into revised employment agreements with each of our named executive officers (chief executive officer, chief operating officer, chief financial officer, chief legal officer, and chief medical officer) in April/June 2018 and June 2019, which supersede any prior Change in Control Severance Agreements with such individuals. These agreements provide for the payment of certain benefits to each executive upon his separation of employment under specified circumstances. These arrangements are designed to encourage each to act in the best interests of our stockholders at all times during the course of a change in control event or other significant transaction.

(f) Deferred Compensation Plan

The Spectrum Pharmaceuticals, Inc. Deferred Compensation Plan (the "DC Plan") is administered by the Compensation Committee of our Board of Directors and is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended.

The DC Plan is maintained to provide special deferred benefits for a select group of our employees (the "DC Participants"). DC Participants make annual elections to defer a portion of their eligible cash compensation which is then placed into their DC Plan accounts. We match a fixed percentage of these deferrals and may make additional discretionary contributions. At December 31, 2019 and December 31, 2018, the aggregate value of this DC Plan liability was $8.7 million and $6.2 million, respectively, and is included within "accounts payable and other accrued liabilities" and "other long-term liabilities" in the accompanying Consolidated Balance Sheets.

(g) Litigation

We are involved from time-to-time with various legal matters arising in the ordinary course of business. These claims and legal proceedings are of a nature we believe are normal and incidental to a pharmaceutical business, and may include product liability, intellectual property, employment matters, and other general claims. We may also be subject to derivative lawsuits from time to time.

We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are assessed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our consolidated results of operations, cash flows, or financial condition.

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

Shareholder Litigation

Olutayo Ayeni v. Spectrum Pharmaceuticals, Inc., et al. (Filed September 21, 2016 in the United States District Court, Central District of California; Case No. 2:16-cv-07074) (the "Ayeni Action") and Glen Hartsock v. Spectrum Pharmaceuticals, Inc., et al. (Filed September 28, 2016 in the United States District Court, District Court of Nevada Case; No. 2:16-cv-02279-RFB-GWF) (the "Hartsock Action"). On November 15, 2016, the Ayeni Action was transferred to the United States District Court for the District of Nevada. The parties have stipulated to a consolidation of the Ayeni Action with the Hartsock Action. These class action lawsuits allege that we and certain of our executive officers made false or misleading statements and failed to disclose material facts about our business and the prospects of approval for our New Drug Application to the FDA for QAPZOLA in violation of Section 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Securities Exchange Act of 1934, as amended.

On July 23, 2019, we entered into a memorandum of understanding with these plaintiffs for a collective settlement that is pending court approval. The value of this proposed settlement is included within "other receivables" (see *Note 3(e)*) and "accounts payable and other accrued liabilities" (see *Note 3(h)*) on the accompanying Consolidated Balance Sheet as of December 31, 2019.

11. INCOME TAXES

The components of loss before benefit for income taxes from continuing operations are as follows:

	Year Ended December 31,		
	2019	2018	2017
United States	$ (139,682)	$ (133,165)	$ (121,507)
Foreign	(4,912)	4,558	(1,185)
Total	$ (144,594)	$ (128,607)	$ (122,692)

The benefit for income taxes from continuing operations consist of the following:

	Year Ended December 31,		
	2019	2018	2017
Current:			
Federal	$(6,584)	$(1,663)	$(15,412)
State	(1,166)	(269)	(1,298)
Foreign	11	—	6
	$(7,739)	$(1,932)	$(16,704)
Deferred:			
Federal	(781)	12	(5,256)
State	(688)	19	19
	(1,469)	31	(5,237)
Total income tax benefit	$(9,208)	$(1,901)	$(21,941)

For the fiscal years ended December 31, 2019, 2018 and 2017, we generated losses from continuing operations and recognized income from other financial statement categories such as "income from discontinued operations" and "other comprehensive income (loss)". Under *ASC 740-20-45-7* and applicable intra-period income tax allocation guidance, companies are required to consider all sources of income in determining the tax benefit to be recognized from its losses from continuing operations.

As a result of the required intra-period allocation, we recognized $7,675, $1,902 and $14,813 of tax benefits for our losses from continuing operations during the years ended December 31, 2019, 2018 and 2017, respectively. Tax charges equal to the tax benefits recognized within "loss from continuing operations" were recorded within "income from

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

discontinued operations" on the accompanying Consolidated Statements of Operations for the years ended December 31, 2019, 2018 and 2017, and other comprehensive income (loss) on the accompanying Statements of Comprehensive Loss for the years ended December 31, 2019, 2018 and 2017.

The income tax benefit differs from that computed using the applicable federal statutory rate, as applied to our income before taxes in each year as follows:

	Year Ended December 31,		
	2019	2018	2017
Tax provision computed at the federal statutory rate	$(30,365)	$(26,854)	$(42,614)
State tax, net of federal benefit	(4,126)	(5,077)	(2,207)
Research and development expense tax credits	(2,526)	(4,884)	(1,176)
Change in uncertain tax benefit reserve	—	—	(561)
Change in tax credit carryforwards	81	(3,056)	386
Officers compensation	1,506	600	(9,292)
Stock based compensation	(230)	(12,610)	(2,734)
Permanent items and other	267	(116)	1,450
Tax differential on foreign earnings	(31)	(32)	33
Change in tax rate	1,126	(1,329)	37,768
Refundable alternative minimum tax credit	—	—	(1,336)
Change in prior year deferred taxes	1,170	6,595	(1,218)
Valuation allowance	23,920	44,862	(440)
Income tax benefit	$ (9,208)	$ (1,901)	$(21,941)

Significant components of our deferred tax assets and liabilities as of December 31, 2019 and 2018 are presented below. A valuation allowance has been recognized to offset the net deferred tax assets as realization of such deferred tax assets did not meet our "more-likely-than-not" assessment threshold, as required under GAAP.

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carry forwards	$ 118,163	$ 103,582
Research and development expense tax credits	22,724	21,618
Stock based compensation	4,385	5,057
Lease obligation	919	—
Development costs	704	3,938
Returns and allowances	1,069	1,976
Other, net	11,861	7,185
Total deferred tax assets before valuation allowance	159,825	143,356
Valuation allowance	(152,966)	(131,042)
Total deferred tax assets	6,859	12,314
Deferred tax liabilities, net:		
Unrealized gains	(5,607)	(9,387)
Depreciation and amortization differences	(389)	(4,396)
Right-of-use asset	(863)	—
Net deferred tax liabilities	$ —	$ (1,469)

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

At December 31, 2019 and 2018, we recorded a valuation allowance of $153.0 million and $131.0 million, respectively. The valuation allowance increased by $21.9 million and $45.0 million during 2019 and 2018, respectively. The increase in the valuation allowance in 2019 and 2018 was due to an increase in net operating loss carryforwards and the reversal of deferred tax liabilities from our amortization of intangible assets which have no tax basis, partially offset by a $2.0 million valuation allowance release in 2019 related to our discontinued operations.

We had federal and state net operating loss carryforwards of approximately $497.0 million and $266.9 million, at December 31, 2019, respectively. We have approximately $5.2 million of foreign loss carryforwards that will begin to expire in 2028. The federal and state loss carry forwards began to expire in 2020 unless previously utilized. Federal loss carryforwards generated in 2018 and beyond will be carried forward indefinitely. At December 31, 2019, we had federal and state tax credits of approximately $15.9 million and $8.6 million, respectively. The federal tax credit carryovers begin to expire in 2027 unless previously utilized. The state research and development credit carryforwards have an indefinite carryover period.

Our utilization of certain net operating loss and research and development expense tax credit carryforwards, including those acquired in connection with the acquisition of Allos Therapeutics, Inc. in April 2012 and Talon Therapeutics, Inc. in July 2016, are subject to annual limitations under Sections 382 and 383 of the Internal Revenue Code of 1986 and similar state provisions. Any net operating losses or credits that would expire unutilized as a result of Section 382 and 383 limitations have been removed from the table of deferred tax assets and the accompanying disclosures of net operating loss and research and development carryforwards.

The following tabular reconciliation summarizes the activity related to our unrecognized tax benefits:

	Year Ended December 31,		
	2019	2018	2017
Balance at beginning of year	$3,248	$2,715	$3,271
Adjustments related to prior year tax positions	(392)	(551)	(39)
Increases related to current year tax positions	692	1,084	374
Decreases due to expiration of tax statutes	(75)	—	(891)
Balance at end of year	$3,473	$3,248	$2,715

We continue to believe that our tax positions meet the “more-likely-than-not” standard and as part of that analysis, we considered the amounts and probabilities from ultimate settlement with the tax authorities.

Approximately $0.1 million, $0.2 million, and $0.2 million of the total unrecognized tax benefits as of December 31, 2019, 2018, and 2017, respectively, would reduce our annual effective tax rate if recognized. Additional amounts in the summary rollforward could impact our effective tax rate if we did not maintain a full valuation allowance on our net deferred tax assets.

We do not expect our unrecognized tax benefits to change significantly over the next 12 months. With a few exceptions, we are no longer subject to U.S. federal, state and local income tax examinations for years before 2015. Our policy is to recognize interest and/or penalties related to unrecognized tax benefits in income tax expense in the Consolidated Statements of Operations.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning in 2018, the transition of U.S international taxation from a worldwide tax system to a territorial system, which includes a new federal tax on global intangible low-taxed income (Global Minimum Tax, or GMT), and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017. The Company calculated its best estimate of the impact of the Tax Act in its 2017 income tax provision in accordance with its understanding of the Tax Act and guidance available as of the date of the 10-K filing for the year ended December 31, 2017.

In addition, the SEC Staff issued *SAB 118*, which provides guidance on accounting for the tax effects of the Tax Act. *SAB 118* provides a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under *ASC 740*. In accordance with *SAB 118*, a company must reflect the income tax effects of those aspects of the Tax Act for which the accounting under *ASC 740* is complete. To the extent that a company's accounting for certain income tax effects of the Tax Act is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate in the financial statements. If a company cannot determine a provisional estimate to be included in the financial statements, it should continue to apply *ASC 740* on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the Tax Act.

The provisional amounts were subject to revisions as we completed its analysis of the Tax Act, collected and prepared necessary data, and interpreted any additional guidance issued by the U.S. Treasury Department, Internal Revenue Service, or IRS, FASB, and other standard-setting and regulatory bodies. The measurement period expired as of December 31, 2018 and our accounting for the Tax Act is complete. The changes in 2018 to provisional amounts recorded in 2017 for the effects of the Tax Act were not material.

12. DISCONTINUED OPERATIONS

Overview

On March 1, 2019, we completed the Commercial Product Portfolio Transaction — see *Note 1(b)* (as we first announced on January 17, 2019 on Form 8-K, upon the signing of the definitive asset purchase agreement).

In accordance with applicable GAAP (*ASC 205-20, Presentation of Financial Statements*), the revenue-deriving activities and allocable expenses of our sold commercial operation, as well as the assets and liabilities connected to the Commercial Product Portfolio, are separately classified as "discontinued" for all periods presented within the accompanying Consolidated Statements of Operations and Consolidated Balance Sheets. See *Note 15* for a discussion of certain immaterial corrections affecting the presented amounts below.

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

Consolidated Statement of Operations

The following table presents the various elements of "income from discontinued operations, net of income taxes" as reported in the accompanying Consolidated Statements of Operations:

	Year ended December 31,		
	2019	2018	2017
Revenues:			
Product sales, net*	$22,325	$103,736	$115,237
License fees and service revenue	290	4,867	12,189
Total revenues	$22,615	$108,603	$127,426
Operating costs and expenses:			
Cost of sales (excluding amortization of intangible assets)	12,007	26,756	42,859
Cost of service revenue	—	—	4,359
Selling, general and administrative	5,801	28,010	19,508
Research and development	2,624	19,799	14,370
Amortization of intangible assets	1,248	28,098	27,647
Restructuring charges — employee severance (*Note 13*)	3,858	—	—
Total operating costs and expenses	$25,538	$102,663	$108,743
Income (loss) from discontinued operations	$ (2,923)	$ 5,940	$ 18,683
Other income (expense):			
Change in fair value of contingent consideration	(1,478)	1,927	(4,957)
Gain on sale of Commercial Product Portfolio**	34,568	—	—
Total other income (expense)	$33,090	$ 1,927	$ (4,957)
Income from discontinued operations before income taxes	30,167	7,867	13,726
Provision for income taxes from discontinued operations***	(7,470)	(1,902)	(5,163)
Income from discontinued operations, net of income taxes	$22,697	$ 5,965	$ 8,563

* This revenue for the year ended December 31, 2019 includes: (i) sales from our Commercial Product Portfolio in January and February 2019 (prior to the completion of the Commercial Product Portfolio Transaction) and (ii) EVOMELA sales to a specific licensee through October 2019 (see *Note 8*).

** This pre-tax gain on sale represents the $158.8 million gross proceeds from the Commercial Product Portfolio Transaction *less* our $121.2 book value of transferred net assets (inclusive of assumed liabilities) to Acrotech on the March 1, 2019 closing date *less* legal and banker fees aggregating $3.9 million. In the third quarter of 2019, we reduced this gain for a $0.2 million contract cancellation fee associated with our sold commercial operations; this value was deducted from the $4.0 million escrow account (reported as "restricted cash" on the Consolidated Balance Sheets until its release on November 5, 2019). In the fourth quarter of 2019, we increased this gain by $1.1 million to correct for certain inventory that did not contractually transfer to the buyer.

*** This income tax provision represents an allocation of taxes as required under intraperiod allocation guidance (see *Note 11*). Due to our aggregate net operating loss-carryforwards, no federal or state income tax payments are expected to be made relating to our current year activity, inclusive of our recognized gain on sale of the Commercial Product Portfolio.

Consolidated Balance Sheets

Accounts receivable derived from our product sales on and prior to February 28, 2019 were not transferred to Acrotech as part of the Commercial Product Portfolio Transaction, nor were our GTN liabilities and trade accounts payable assumed

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

by Acrotech that were associated with our commercial activities on and prior to February 28, 2019 (see *Note 3(h)*). Accordingly, these specific assets and liabilities remain presented within "accounts receivable, net of allowance for doubtful accounts" and "accounts payable and other accrued liabilities" on the accompanying Consolidated Balance Sheets.

The following table presents a summary of our "discontinued operations, assets" and "discontinued operations, liabilities" as of December 31, 2018 within the accompanying Consolidated Balance Sheets (representing those assets and liabilities transferred to Acrotech as part of the Commercial Product Portfolio Transaction):

	December 31, 2018
Inventories	$ 3,550
Prepaid expenses and other assets	2,005
Discontinued operations, current assets	5,555
Intangible assets, net of accumulated amortization	111,594
Goodwill	18,061
Other assets	2,970
Discontinued operations, non-current assets	132,625
FOLOTYN development liability	2,311
Discontinued operations, current liabilities	2,311
FOLOTYN development liability, less current portion	9,686
Acquisition-related contingent obligations	4,345
Discontinued operations, non-current liabilities	$ 14,031

Consolidated Statement of Cash Flows

The following table presents significant non-cash items for our discontinued operations that are included as adjustments in the accompanying Consolidated Statements of Cash Flows:

	Year ended December 31,		
	2019	2018	2017
Depreciation and amortization	$1,263	$28,187	$27,661
Stock-based compensation	$3,404	$ 5,649	$ 4,076
Change in fair value of contingent consideration	$1,478	$ (1,927)	$ 4,957

13. RESTRUCTURING COSTS RELATED TO SALE OF COMMERCIAL PRODUCT PORTFOLIO

Employee Severance

On March 1, 2019, we completed the Commercial Product Portfolio Transaction (see *Note 1(b)*) and 87 of our employees were (1) terminated March 1, 2019 or (2) given notice of May 31, 2019 termination and asked to provide transition services for the benefit of Acrotech through that date (as provided by a transition services agreement with Acrotech entered contemporaneously with our sale). For the year ended December 31, 2019, we recognized $0.7 million of income for services rendered to Acrotech under this agreement within "other income (expense), net" on our accompanying Consolidated Statements of Operations.

The employees in (1) above were entitled to cash severance payments and acceleration of their unvested restricted stock awards and stock options. For the year ended December 31, 2019, we fully recognized the aggregate value of $5.1 million for this severance benefit, of which $3.9 million, $1.0 million, and $0.2 million is included on the accompanying Consolidated Statements of Operations within "income from discontinued operations, net of income taxes" (see *Note 12*), "selling, general, and administrative" expenses and "research and development" expenses, respectively.

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

The employees in (2) above were also entitled to cash severance payments and acceleration of their unvested restricted stock awards and stock options, though on May 31, 2019. The aggregate value of these one-time cash payments and stock-based award accelerations was $0.5 million. Due to then ongoing service requirements of these employees, we amortized this value through expense on a ratable basis beginning March 1, 2019 through May 31, 2019. For the year ended December 31, 2019, we recognized $0.5 million for this severance benefit, which is included within "selling, general, and administrative" expenses on the accompanying Consolidated Statements of Operations, and within "accrued payroll and benefits" and "additional paid-in capital" (for stock-based awards) on the accompanying Consolidated Balance Sheets as of December 31, 2019.

Unpaid cash severance for our former employees was $0.3 million at December 31, 2019 and is recorded within "accrued payroll and benefits" on the accompanying Consolidated Balance Sheets.

14. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly financial data (unaudited) for the year ended December 31, 2019 and 2018 is presented below:

	Quarter Ended (Unaudited)			
	March 31,	June 30,	September 30,	December 31,
2019				
Total revenues	$ —	$ —	$ —	$ —
Loss from continuing operations before other income (expense) and income taxes	$(37,838)	$(34,212)	$(30,293)	$(38,355)
Loss from continuing operations*	$(39,846)	$(28,783)	$(26,557)	$(40,200)
Basic and diluted loss per common share from continuing operations***	$ (0.36)	$ (0.26)	$ (0.24)	$ (0.36)

	Quarter Ended (Unaudited)			
	March 31,	June 30,	September 30,	December 31,
2018				
Total revenues	$ —	$ —	$ —	$ —
Loss from continuing operations before other income (expense) and income taxes	$(29,981)	$(32,986)	$(28,422)	$(46,458)
(Loss) income from continuing operations**	$(19,243)	$ 14,863	$(69,209)	$(53,117)
Basic and diluted (loss) income per common share from continuing operations***	$ (0.19)	$ 0.14	$ (0.66)	$ (0.52)

* Loss from continuing operations for the quarter ended March 31, 2019 was adjusted by $26 thousand from amounts previously reported on Form 10-Q as a result of correcting the immaterial errors discussed in *Note 15*.

** (Loss) income from continuing operations for each of the quarters ended March 31, June 30, September 30, and December 31, 2018 were adjusted by $71 thousand, $31 thousand, $37 thousand, and $38 thousand, respectively, from amounts previously reported on Form 10-Q as a result of correcting the immaterial errors discussed in *Note 15*.

*** There was no impact on previously disclosed basic and diluted (loss) income per common share from continuing operations.

Net loss per basic and diluted shares are computed independently for each of the quarters presented, based on basic and diluted shares outstanding per quarter, and therefore, it may not sum to the value for the full year.

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

15. IMMATERIAL RESTATEMENT OF PRIOR PERIOD FINANCIAL STATEMENTS

PHS pricing for certain qualifying end-users of ZEVALIN

Subsequent to the issuance of our Form 10-K for the year ended December 31, 2018, management identified certain immaterial errors aggregating to $12.0 million that substantially relates to our ZEVALIN pricing to qualifying Public Health Service ("PHS") hospitals from 2009 through the first quarter of 2019. This accumulated value resulted from a mistaken one-time "market date" load into the Centers for Medicare and Medicaid Services ("CMS") system for this drug. We erroneously used the year we in-licensed this product of 2009, rather than its original sale year of 2002.

In our 2018 Annual Report on Form 10-K and earlier filings, we reported our GTN estimates as a reduction to "product sales, net" in our Consolidated Statements of Operations. We have restated our accompanying Consolidated Financial Statements to correct for these immaterial errors for all annual periods presented on each face financial statement (as summarized below), as well as the correction of "product sales, net" presented within *Note 12* for our discontinued operations summary.

Consolidated Balance Sheet as of December 31, 2018:

	As Previously Reported	Adjustments for Error Correction	As Restated
Accounts payable and other accrued liabilities	$ 69,460	$ 11,852	$ 81,312
Total current liabilities	86,474	11,852	98,326
Total liabilities	107,624	11,852	119,476
Accumulated deficit	(599,886)	(11,852)	(611,738)
Total stockholders' equity	283,262	(11,852)	271,410

Consolidated Statements of Operations for the years ended December 31, 2018 and 2017:

	2018			
	As Previously Reported	Adjustments for Error Correction	Reclassification for Discontinued Operations	As Restated
Product sales, net	$ 104,466	$ (730)	$(103,736)	$ —
Total revenues	109,333	(730)	(108,603)	—
Loss from continuing operations before other (expense) income and income taxes	(131,177)	(730)	(5,940)	(137,847)
Loss from continuing operations before income taxes	(120,010)	(730)	(7,867)	(128,607)
Benefit for income taxes from continuing operations	(1)	—	1,902	1,901
Loss from continuing operations	(120,011)	(730)	(5,965)	(126,706)
Loss per common share from continuing operations	(1.16)	(0.01)	(0.06)	(1.23)

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

	2017			
	As Previously Reported	Adjustments for Error Correction	Reclassification for Discontinued Operations	As Restated
Product sales, net	$ 116,178	$ (941)	$(115,237)	$ —
Total revenues	128,367	(941)	(127,426)	—
Loss from continuing operations before other (expense) income and income taxes	(96,660)	(941)	(18,683)	(116,284)
Loss from continuing operations before income taxes	(108,026)	(941)	(13,726)	(122,693)
Benefit for income taxes from continuing operations	16,778	—	5,163	21,941
Loss from continuing operations	(91,248)	(941)	(8,563)	(100,752)
Loss per common share from continuing operations	(1.07)	(0.01)	(0.10)	(1.18)

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2018 and 2017:

	2018		
	As Previously Reported	Adjustments for Error Correction	As Restated
Net loss	$(120,011)	$(730)	$(120,741)
Total comprehensive loss	(122,501)	(730)	(123,231)

	2017		
	As Previously Reported	Adjustments for Error Correction	As Restated
Net loss	$(91,248)	$(941)	$(92,189)
Total comprehensive loss	(73,670)	(941)	(74,611)

Consolidated Statements of Stockholders' Equity and Cash Flows:

The Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018 and 2017 have also been restated to include the changes to "net loss" summarized above, as well as an $10.2 million increase to the beginning "accumulated deficit" as of January 1, 2017, representing the accumulated error through that date.

This error had no impact on our Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017, except for the offsetting correction between "net loss" and changes in "accounts payable and other accrued liabilities" presented within "net cash used in operating activities" in each year, as summarized in the above tables.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None

Item 9A. Controls and Procedures

Our principal executive officer and principal financial officer have provided certifications filed as *Exhibits 31.1* and *32.1*, and *31.2*, and *32.2*, respectively. Such certifications should be read in conjunction with the information contained in this *Item 9A* for a more complete understanding of the matters covered by those certifications.

(a) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in *Rule 13a-15(f)* of the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of the financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. This process includes those policies and procedures (i) that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) that receipts and expenditures are being made only in accordance with authorizations of our management and directors; (iii) that provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements; and (iv) that provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP.

We continuously seek to improve the efficiency and effectiveness of our business operations and accompanying internal controls. An internal control system, no matter how well conceived and operated, can provide only reasonable assurance that its objectives are met. Because of inherent limitations in any control system, no evaluation can provide absolute assurance that all control issues within a company have been detected. In addition, internal controls are subject to the risk of inadequacy because of changes in business conditions and/or the risk that compliance with a company's policies or procedures may deteriorate over time.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 framework) ("2013 COSO"). Based on our management's assessment, we have concluded that as of December 31, 2019, our internal control over financial reporting was effective, as evaluated under the 2013 COSO criteria. Our independent registered public accounting firm, Deloitte & Touche LLP, has issued a report on our internal control over financial reporting. Deloitte & Touche LLP's report appears within *Item 9A* in this Annual Report on Form 10-K and expresses an unqualified opinion on the effectiveness of our internal control over financial reporting.

(b) Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of December 31, 2019, pursuant to Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures, as of such date, were effective.

(c) Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the fiscal fourth quarter of the year ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Spectrum Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2019, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2019, of the Company and our report dated March 2, 2020, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP
Costa Mesa, California
March 2, 2020

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required under this item is incorporated by reference from our definitive proxy statement related to our 2020 Annual Meeting of Stockholders, or the Proxy Statement, to be filed pursuant to Regulation 14A, on or before April 30, 2020.

Item 11. ***Executive Compensation***

The information required under this item is incorporated herein by reference from the Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

The information required under this item is incorporated herein by reference from the Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence.***

The information required under this item is incorporated herein by reference from the Proxy Statement.

Item 14. ***Principal Accounting Fees and Services***

The information required under this item is incorporated herein by reference from the Proxy Statement.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) Financial Statements and Schedules

The following financial statements and schedules listed below are included in this Annual Report on Form 10-K:

(All other schedules are omitted, as required information is either not applicable or the information is presented in the consolidated financial statements).

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

Years Ended December 31, 2019, 2018, and 2017

Description	Balance at Beginning of Period	Additions (Reductions) ($ in thousands) Additions (Recovery) to Bad Debt Expense	Charged to Other Accounts (in thousands)	Deductions (1)	Balance at End of Period
December 31, 2019					
Allowance for doubtful accounts	$ 67	$ (12)	$ 43	$ (55)	$ 43
December 31, 2018					
Allowance for doubtful accounts	$ 71	$ 12	$ —	$ (16)	$ 67
December 31, 2017					
Allowance for doubtful accounts	$ 88	$ (17)	$ —	$ —	$ 71

(1) Deductions represent the actual write-off of accounts receivable balances.

(b) Exhibits

The following is a list of exhibits required by Item 601 of Regulation S-K filed as part of this Annual Report on Form 10-K. For exhibits that previously have been filed, the Company incorporates those exhibits herein by reference. The exhibit table below includes the Form Type and Filing Date of the previous filing and the original exhibit number in the previous filing which is being incorporated by reference herein.

Exhibit No.	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
2.1	Agreement and Plan of Merger, dated April 4, 2012, by and among Spectrum Pharmaceuticals, Inc., Sapphire Acquisition Sub, Inc. and Allos Therapeutics, Inc., including a Form of Contingent Value Rights Agreement and a Form of Tender and Voting Agreement.	8-K	001-35006	2.1, 2.2, and 2.3	4/5/12	
2.2	Securities Purchase Agreement, dated July 16, 2013, by and among Spectrum Pharmaceuticals, Inc., Eagle Acquisition Merger Sub, Inc., certain entities affiliated with Warburg Pincus & Co. and certain entities affiliated with Deerfield Management, LLC.	8-K	001-35006	2.1	7/19/13	
2.3	Stock Purchase Agreement, dated July 16, 2013, by and among Spectrum Pharmaceuticals, Inc., Eagle Acquisition Merger Sub, Inc. and Talon Therapeutics, Inc.	8-K	001-35006	2.2	7/19/13	
2.4	Exchange Agreement, dated July 16, 2013, by and among Spectrum Pharmaceuticals, Inc., Talon Therapeutics, Inc. and certain entities affiliated with Deerfield Management, LLC, including the Registration Rights Agreement by and among Spectrum Pharmaceuticals, Inc. and certain entities affiliated with Deerfield Management, LLC, as Exhibit A thereto.	8-K	001-35006	2.4	7/19/13	
2.5	Asset Purchase Agreement, dated January 17, 2019, by and among Spectrum Pharmaceuticals, Inc., Acrotech Biopharma LLC and Aurobindo Pharma USA, Inc.	8-K	001-35006	10.1	1/17/19	
3.1	Restated Certificate of Incorporation, as filed on June 18, 2018.	8-K	001-35006	3.1	6/18/18	

Exhibit No.	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.2	Third Amended and Restated Bylaws of Spectrum Pharmaceuticals, Inc.	8-K	001-35006	3.1	3/29/18	
4.1	Rights Agreement, dated December 13, 2010, between Spectrum Pharmaceuticals, Inc. and ComputerShare Trust Company, N.A. (formerly U.S. Stock Transfer Corporation), as Rights Agent, which includes as Exhibit A thereto the form of Certificate of Designation for the Series B Junior Participating Preferred Stock, as Exhibit B thereto the Form of Rights Certificate and as Exhibit C thereto a Summary of Rights of Stockholder Rights Plan.	8-K	000-28782	4.1	12/13/10	
4.2	First Amendment to Rights Agreement, dated October 13, 2017, by and between Spectrum Pharmaceuticals, Inc. and Computershare Trust Company, N.A., as Rights Agent.	8-K	001-35006	4.1	10/13/17	
4.3	Second Amendment to Rights Agreement, dated March 27, 2018, by and between Spectrum Pharmaceuticals, Inc. and Computershare Trust Company, N.A., as Rights Agent.	8-K	001-35006	4.1	3/29/18	
4.4	Registration Rights and Stockholder Agreement, dated February 2, 2010, by and between Spectrum Pharmaceuticals, Inc. and TopoTarget A/S.	10-K	001-35006	4.2	3/12/14	
4.5	Description of Equity Securities Registered under Section 12 of the Exchange Act.					X
10.1	Industrial Lease Agreement, dated January 16, 1997, between Spectrum Pharmaceuticals, Inc. and the Irvine Company.	10-KSB	000-28782	10.11	3/31/97	
10.2	First Amendment to Lease, dated March 25, 2004, by and between Spectrum Pharmaceuticals, Inc. and the Irvine Company.	10-Q	000-28782	10.1	5/17/04	
10.3	Second Amendment to Lease, dated March 7, 2006, by and between Spectrum Pharmaceuticals, Inc. and the Irvine Company.	10-K	001-35006	10.6	3/12/14	
10.4	Third Amendment to Lease, dated February 12, 2006, by and between Spectrum Pharmaceuticals, Inc. and the Irvine Company LLC.	10-K	001-35006	10.7	3/12/14	
10.5	Fourth Amendment to Lease, dated July 29, 2009, by and between Spectrum Pharmaceuticals, Inc. and the Irvine Company LLC.	10-K	000-28782	10.29	4/5/10	
10.6	Fifth Amendment to Lease, dated November 21, 2013, by and between Spectrum Pharmaceuticals, Inc. and the Irvine Company LLC.	10-K	001-35006	10.9	3/12/14	
10.7	Sixth Amendment to Lease, dated January 31, 2014, by and between Spectrum Pharmaceuticals, Inc. and the Irvine Company LLC.	10-K	001-35006	10.10	3/12/14	
10.8	Seventh Amendment to Lease, dated August 7, 2018, by and between Spectrum Pharmaceuticals, Inc. and the Irvine Company LLC.					X
10.9	Eighth Amendment to Lease, dated October 10, 2018, by and between Spectrum Pharmaceuticals, Inc. and the Irvine Company LLC.					X

Exhibit No.	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.10*	Spectrum Pharmaceuticals, Inc. Deferred Compensation Plan.	S-8	333-176681	4.1	9/6/11	
10.11*	Form of Indemnification Agreement of Spectrum Pharmaceuticals, Inc.					X
10.12*	Amended and Restated Spectrum Pharmaceuticals, Inc. 2009 Employee Stock Purchase Plan.					X
10.13*	Spectrum Pharmaceuticals, Inc. 2009 Incentive Award Plan.	S-8	333-160 312	99.2	6/29/09	
10.14*	Term Sheet for 2009 Incentive Award Plan Stock Option Award.	10-Q	000-287 82	10.8	8/13/09	
10.15*	Term Sheet for 2009 Incentive Award Plan, Nonqualified Stock Option Award Awarded to Non-Employee Directors (Revised July 2012).	10-Q	001-350 06	10.2	11/9/12	
10.16*	Term Sheet for 2009 Incentive Award Plan, Restricted Stock Award.	10-Q	000-287 82	10.10	8/13/09	
10.17*	Amendment No. 1 to 2009 Incentive Award Plan.	10-Q	001-350 06	10.2	11/6/15	
10.18*	Form of Performance Unit Award Agreement under 2009 Incentive Award Plan	10-Q	001-350 06	10.2	5/4/17	
10.19	At Market Issuance Sales Agreement dated December 23, 2015, by and among Spectrum Pharmaceuticals, Inc., FBR Capital Markets & Co., MLV & Co. LLC and H.C. Wainwright & Co., LLC.	S-3	333-208760	1.2	12/23/15	
10.20	At Market Issuance Sales Agreement, dated August 4, 2017, between Spectrum Pharmaceuticals, Inc., H.C. Wainwright & Co., LLC, FBR Capital Markets & Co. and MLV & Co. LLC.	8-K	001-350 06	1.1	8/4/17	
10.21	Controlled Equity Offering Sales Agreement, dated as of April 5, 2019 among Registrant, Cantor Fitzgerald & Co., H.C. Wainwright & Co., LLC and B. Riley FBR, Inc.	S-3ASR	333-230821	1.2	4/5/19	
10.22*	Executive Employment Agreement, dated as of April 10, 2018, by and between Spectrum Pharmaceuticals, Inc. and Kurt A. Gustafson.	10-Q	001-35006	10.6	8/9/18	
10.23*	Executive Employment Agreement, dated as of April 10, 2018, by and between Spectrum Pharmaceuticals, Inc. and Thomas J. Riga.	10-Q	001-35006	10.7	8/9/18	
10.24*	Executive Employment Agreement, dated as of April 10, 2018, by and between Spectrum Pharmaceuticals, Inc. and Joseph W. Turgeon.	10-Q	001-35006	10.8	8/9/18	
10.25*	Executive Employment Agreement, dated as of June 18, 2018, by and between Spectrum Pharmaceuticals, Inc. and Keith McGahan.	10-Q	001-35006	10.9	8/9/18	
10.26*	Executive Employment Agreement, dated as of June 19, 2019, by and between Spectrum Pharmaceuticals, Inc. and Dr. Francois Lebel.	10-Q	001-35006	10.1	8/9/19	
10.27*	Spectrum Pharmaceuticals, Inc. 2018 Long-Term Incentive Plan	8-K	001-35006	10.1	6/18/18	

Exhibit No.	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.28*	Form of Stock Option Award Spectrum Pharmaceuticals, Inc. 2018 Long-Term Incentive Plan	8-K	001-35006	10.2	6/18/18	
10.29*	Form of Restricted Stock Award under the Spectrum Pharmaceuticals, Inc. 2018 Long-Term Incentive Plan.	8-K	001-35006	10.3	6/18/18	
10.30*	Form of Restricted Stock Unit Award for Canadian Resident Employees and Directors under the Spectrum Pharmaceuticals, Inc. 2018 Long-Term Incentive Plan.	8-K	001-35006	10.4	6/18/18	
10.31*	Form of Performance Unit Award under the Spectrum Pharmaceuticals, Inc. 2018 Long-Term Incentive Plan.	8-K	001-35006	10.5	6/18/18	
21.1	Subsidiaries of Registrant.					X
23.1	Consent of Independent Registered Public Accounting Firm (Deloitte & Touche LLP).					X
24.1	Power of Attorney (included in the signature page)					X
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.					X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/ 15d-14(a) of the Securities Exchange Act of 1934.					X
32.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(b)/15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.					X
32.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(b)/ 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.					X
101.INS	Inline XBRL Instance Document — the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 filed herewith)					

* Indicates a management contract or compensatory plan or arrangement.

\# Confidential portions omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary

None.

EXHIBIT 21.1

List of Subsidiaries

SUBSIDIARY/AFFILIATE NAME	INCORPORATION
Spectrum Oncology Private Limited	India
Spectrum Pharmaceuticals International Holdings, LLC	Delaware
Allos Therapeutics, Inc.	Delaware
Spectrum Pharmaceuticals Cayman, L.P. (1% Spectrum Pharmaceuticals International Holdings, LLC and 99% Spectrum Pharmaceuticals, Inc.)	Cayman Islands
Spectrum Pharmaceuticals, B.V.	Netherlands
Spectrum Pharmaceuticals Canada, Inc.	Canada
Talon Therapeutics, Inc.	Delaware

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-185115, 333-163366, 333-37585, 333-52331, 333-73009, 333-92855, 333-37180, 333-38710, 333-42852, 333-51388, 333-60966, 333-64432, 333-64444, 333-102587, 333-105814, 333-108658, 333-110103, 333-115759, 333-121612, 333-125208, 333-135029, 333-142628, 333-150260, 333-190413, 333-194823, and 333-208760 on Form S-3, and Registration Statement Nos. 333-225704, 333-30321, 333-30345, 333-54246, 333-106427, 333-119833, 333-134566, 333-160312, 333-160705, 333-164014, 333-176681, 333-202761 and 333-216692 on Form S-8 of our reports dated March 2, 2020, relating to the financial statements and financial statement schedule of Spectrum Pharmaceuticals, Inc. and subsidiaries (which report expresses an unqualified opinion and includes explanatory paragraphs related to a change in method of accounting for revenue from contracts with customers, and a change in method of accounting for unrealized gains and losses on equity securities), and the effectiveness of Spectrum Pharmaceuticals, Inc. and subsidiaries' internal control over financial reporting, appearing in this Annual Report on Form 10-K of Spectrum Pharmaceuticals, Inc. for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP

Costa Mesa, California
March 2, 2020

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Joseph W. Turgeon, certify that:

1. I have reviewed this Annual Report on Form 10-K of Spectrum Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2020

/s/ JOSEPH W. TURGEON

Joseph W. Turgeon
President and Chief Executive Officer
(Chief Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Kurt A. Gustafson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Spectrum Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2020

/s/ KURT A. GUSTAFSON

Kurt A. Gustafson
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Spectrum Pharmaceuticals, Inc. (the "Company"), hereby certifies, to such officer's knowledge, that:

(i) the accompanying Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 2, 2020

/s/ JOSEPH W. TURGEON

Joseph W. Turgeon
Chief Executive Officer and President

This certification accompanies this Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Spectrum Pharmaceuticals, Inc. (the "Company"), hereby certifies, to such officer's knowledge, that:

(i) the accompanying Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 2, 2020

/s/ KURT A. GUSTAFSON

Kurt A. Gustafson
Executive Vice President and Chief Financial Officer

This certification accompanies this Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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