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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, 2023

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

Commission File No. 001-34186

VANDA PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware	**03-0491827**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2200 Pennsylvania Avenue NW, Suite 300 E
Washington, DC 20037
(Address of principal executive offices)

(202) 734-3400
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	VNDA	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Exchange 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 Exchange 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

As of June 30, 2023, the last business day of the registrant's last completed second quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $368.7 million based on the closing price of the registrant's Common Stock, as reported by The Nasdaq Global Market, on such date. Shares of Common Stock held by each executive officer and director have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the registrant's Common Stock, par value $0.001 per share, outstanding as of February 1, 2024 was 57,537,499.

The Exhibit Index as required by Item 601(a) of Regulation S-K is included in Item 15 of Part IV of this report.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement with respect to the registrant's 2024 Annual Meeting of Stockholders, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Form 10-K.

Vanda Pharmaceuticals Inc.
Form 10-K

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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K (Annual Report) contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "project," "target," "goal," "likely," "will," "would," and "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances and uncertainties. If the risks, changes in circumstances or uncertainties materialize or the assumptions prove incorrect, the results of Vanda Pharmaceuticals Inc. (we, our, the Company or Vanda) may differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements in this Annual Report may include, but are not limited to, statements about:

- our ability to continue to commercialize HETLIOZ® (tasimelteon) capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the United States (U.S.), in light of existing and potential generic competition, and Europe and HETLIOZ® capsules and oral suspension (HETLIOZ LQ®) for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in the U.S.;
- our ability to increase market awareness of Non-24 and SMS and market acceptance of HETLIOZ®;
- our ability to overcome the continued reimbursement and patient access challenges we face as a result of third-party payor coverage;
- our ability to continue to generate U.S. sales of Fanapt® (iloperidone) oral tablets for the treatment of schizophrenia;
- our ability to obtain approval from the U.S. Food and Drug Administration (FDA) for Fanapt® beyond the currently approved indications;
- our ability to commercialize PONVORY® (ponesimod) tablets for the treatment of adults with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease in the U.S. and Canada and our ability to transition regulatory and manufacturing responsibility to us;
- our ability to obtain regulatory approval for tradipitant from the FDA;
- the impact of public health crises, epidemics, pandemics or similar events on our business and operations, including our revenue, our supply chain, our commercial activities, our ongoing and planned clinical trials and our regulatory activities;
- our dependence on third-party manufacturers to manufacture HETLIOZ®, HETLIOZ LQ®, and Fanapt® in sufficient quantities and quality;
- our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;
- our ability to maintain rights to develop and commercialize our products under our license agreements;
- our ability to obtain and maintain regulatory approval of our products, and the labeling for any approved products;
- our level of success in commercializing HETLIOZ® and Fanapt® in new markets;
- our ability to obtain approval from the FDA for HETLIOZ® beyond the currently approved indications;
- our ability to obtain approval from the FDA for PONVORY® beyond the currently approved indications;
- our expectations regarding the timing and success of preclinical studies and clinical trials;
- the safety and efficacy of our products;
- regulatory developments in the U.S., Europe and other jurisdictions;
- limitations on our ability to utilize some or all of our prior net operating losses and orphan drug and research and development credits;
- the size and growth of the potential markets for our products and our ability to serve those markets;
- our expectations regarding trends with respect to our revenues, costs, expenses, liabilities and cash, cash equivalents and marketable securities;

- our ability to identify or obtain rights to new products;
- our ability to attract and retain key scientific or management personnel;
- the cost and effects of litigation;
- our ability to obtain the capital necessary to fund our research and development or commercial activities;
- potential losses incurred from product liability claims made against us; and
- the use of our existing cash, cash equivalents and marketable securities.

All forward-looking statements in this report are expressly qualified in their entirety by the cautionary statements contained throughout this report. We caution you not to rely too heavily on such forward-looking statements. Each forward-looking statement speaks only as of the date of this Annual Report, and we undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

We encourage you to read Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations,* and our consolidated financial statements contained in this Annual Report. We also encourage you to read *Summary of Principal Risk Factors* below and Part I, Item 1A of this Annual Report, entitled *Risk Factors*, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described in this Annual Report, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

SUMMARY OF PRINCIPAL RISK FACTORS

This summary briefly lists the principal risks and uncertainties facing our business, which are only a select portion of those risks. A more complete discussion of those risks and uncertainties is set forth in Part I, Item 1A of this Annual Report, entitled *Risk Factors*. Additional risks not presently known to us or that we currently deem immaterial may also affect us. If any of these risks occur, our business, financial condition or results of operations could be materially and adversely affected.

Our business is subject to the following principal risks and uncertainties:

Risks Related to our Business and Industry

- We are dependent on the commercial success of HETLIOZ®, Fanapt® and PONVORY®.
- We face generic competition for HETLIOZ®.
- Future performance of HETLIOZ®, Fanapt®, and PONVORY® may be impacted by a number of factors including competing products or unanticipated safety issues.
- We are subject to uncertainty relating to pricing and reimbursement policies in the U.S.
- We have encountered third-party payors that refuse to cover or reimburse prescriptions written for HETLIOZ®.
- The FDA may not approve our tradipitant New Drug Application (NDA) filing for the use of tradipitant for patients with gastroparesis or accept our supplemental New Drug Application (sNDA) filing for the use of tradipitant for patients with motion sickness, or the FDA may determine that our clinical trial results for tradipitant for these indications do not demonstrate adequate safety and substantial evidence of efficacy.
- Global economic conditions may have an adverse effect on our business.
- Global health crises and pandemics may adversely impact our business.
- The FDA may not approve our supplemental New Drug Applications (sNDA) for HETLIOZ® for the treatment of jet lag disorder or insomnia.
- The FDA may not approve our sNDA for Fanapt® for the treatment of bipolar I disorder.
- We may be unable to enter into third-party collaborations to develop and commercialize our products, or collaborations we enter into with any such third party may not be commercially successful.
- Even after we obtain regulatory approvals of a product, acceptance of the product in the marketplace is uncertain.
- We may not be able to successfully transition regulatory and supply responsibility for PONVORY® from Janssen to us.
- We rely on, and will continue to rely on, outsourcing arrangements for many of our activities, including preclinical and clinical development and supply of HETLIOZ®, HETLIOZ LQ®, Fanapt®, PONVORY® and our other products.
- We may experience disruptions to our HETLIOZ®, HETLIOZ LQ®, Fanapt® or PONVORY® supply chains.
- We may fail to comply with government regulations regarding the sale and marketing of our products.
- We may fail to comply with regulations and obligations related to the ongoing oversight of our products regarding, among other things, development, manufacturing, labeling, recordkeeping and reporting.
- We may not market or distribute our products in a manner compliant with federal or state healthcare fraud and abuse laws.
- We rely on a limited number of specialty pharmacies for distribution of HETLIOZ® in the U.S., and the loss of one or more of these specialty pharmacies or their failure to distribute HETLIOZ® effectively would materially harm our business.
- Our revenues from Fanapt® are substantially dependent on sales through a limited number of wholesalers.
- We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.
- FDA and foreign regulatory approval of our products is uncertain.

- Our products may cause undesirable side effects or have other properties that could delay, prevent or result in the revocation of their regulatory approval or limit their marketability.
- Clinical trials for our products are expensive and their outcomes are uncertain.
- Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income is dependent on generating future taxable income and may be limited, including as a result of transactions involving our common stock.
- Our contract research organizations (CROs) may not successfully carry out their duties or we may lose our relationships with CROs.
- We rely on a limited number of third-party manufacturers to formulate and manufacture our products and these manufacturers may not be able to satisfy our demand and alternative sources may not be available.
- Materials necessary to manufacture our products may not be available on commercially reasonable terms, or at all.
- We may lose key scientists or management personnel or fail to recruit additional highly skilled personnel.
- We may be subject to product liability lawsuits.
- European Union (E.U.) Member States tend to impose strict price controls, which may delay or prevent the further commercial launch or impede the commercial success of HETLIOZ® in Europe and adversely affect our future results of operations.
- We may not be able to effectively market and sell our future products, if approved, in the U.S.
- Healthcare legislative reform measures or developments arising from changes in political climate may have a material adverse effect on our business and results of operations.
- We are subject to stringent laws, rules, regulations, policies, industry standards and contractual obligations regarding data privacy and security in foreign jurisdictions which are subject to change and reinterpretation.

Risks Related to Intellectual Property and Other Legal Matters

- Our rights to develop and commercialize our products are subject in part to the terms and conditions of licenses or sublicenses granted to us by other pharmaceutical companies.
- Our efforts to protect the proprietary nature of the intellectual property related to our products may not be adequate.
- We are, have been, and may continue to be, involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful.
- We may not be able to obtain protection under the Hatch-Waxman Act and similar foreign legislation to extend our patents and to obtain market exclusivity for our products.
- Generic competitors have obtained FDA approval of generic versions of HETLIOZ® in the U.S.
- We may not be successful in the development of products for our own account.
- Litigation or third-party claims of intellectual property infringement could require us to divert resources and may prevent or delay our drug discovery and development efforts.

ITEM 1. BUSINESS

Overview

Vanda Pharmaceuticals Inc. (we, our, the Company or Vanda) is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients.

We strive to advance novel approaches to bring important new medicines to market through responsible innovation. We are committed to the use of technologies that support sound science, including genetics and genomics, in drug discovery, clinical trials and the commercial positioning of our products.

Our commercial portfolio is currently comprised of three products, HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS), Fanapt® for the treatment of schizophrenia and PONVORY®, which we acquired the U.S. and Canadian rights to on December 7, 2023, for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease, in adults. HETLIOZ® is the first product approved by the FDA for patients with Non-24 and for patients with SMS. In addition, we have a number of drugs in development, including:

- HETLIOZ® (tasimelteon) for the treatment of jet lag disorder, insomnia, delayed sleep phase disorder (DSPD) and pediatric Non-24;
- Fanapt® (iloperidone) for the treatment of bipolar I disorder and a long acting injectable (LAI) formulation for the treatment of schizophrenia;
- PONVORY (ponesimod) for the treatment of inflammatory/autoimmune disorders, including but not limited to ulcerative colitis, psoriasis, Crohn's disease, atopic dermatitis, eosinophilic esophagitis and alopecia areata;
- Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness and atopic dermatitis;
- VHX-896, the active metabolite of iloperidone;
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors, including VSJ-110 for the treatment of dry eye and ocular inflammation and VPO-227 for the treatment of secretory diarrhea disorders, including cholera;
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of onychomycosis, hematologic malignancies and with potential use as a treatment for several oncology indications;
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, for the treatment of social/performance anxiety and psychiatric disorders; and
- Antisense oligonucleotide (ASO) molecules, including VCA-894A for the treatment of Charcot-Marie-Tooth Disease, Type 2S (CMT2S), caused by cryptic slice site variants within IGHMBP2.

We were incorporated in 2002 and commenced operations in 2003. We are headquartered in Washington, D.C.

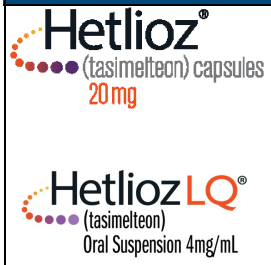
Our Strategy

Our goal is to further solidify our position as a leading global biopharmaceutical company focused on developing and commercializing innovative therapies addressing high unmet medical needs through the application of our drug development expertise and our pharmacogenetics and pharmacogenomics expertise. The key elements of our strategy to accomplish this goal are to:

- *Maximize the commercial success of HETLIOZ®, Fanapt® and PONVORY®;*
- *Enter into strategic partnerships to supplement our capabilities and to extend our commercial reach;*
- *Pursue the clinical development and regulatory approval of our products, including tradipitant;*
- *Apply our pharmacogenetics and pharmacogenomics expertise to differentiate our products;*
- *Expand our product portfolio through the identification and acquisition of additional products; and*
- *Utilize novel and innovative approaches in pursuit of each of these strategies.*

Commercialized Products

Our commercial product portfolio consists of:

Product	Indication	2023 Net Sales (in millions)	Geography
	Non-24 (capsules) Nighttime sleep disturbances in SMS (capsules and HETLIOZ LQ® oral suspension)	$100.2	United States Europe (Non-24 in blind patients only)
	Schizophrenia (tablets)	$90.9	United States Israel
	Relapsing forms of multiple sclerosis (tablets)	$1.6	United States Canada

HETLIOZ® for Non-24 (capsules)

In January 2014, HETLIOZ® capsules were approved in the U.S. for the treatment of adults with Non-24. Non-24 is a serious, rare and chronic circadian rhythm sleep-wake disorder characterized by the inability to entrain (synchronize) the master body clock with the 24-hour day-night cycle. HETLIOZ® is the first FDA approved treatment for Non-24. HETLIOZ® is a melatonin agonist of the human MT1 and MT2 receptors, with greater specificity for MT2. These receptors are thought to be involved in the control of circadian rhythms. HETLIOZ® is believed to reset the master body clock in the suprachiasmatic nucleus, located in the hypothalamus, resulting in the entrainment and alignment of the body's melatonin and cortisol rhythms to the 24-hour day-night cycle.

Most people have a master body clock that naturally runs longer than 24 hours and light is the primary environmental cue that resets it to 24 hours each day. Individuals with Non-24 have a master body clock that is not reset, and continually delays, resulting in prolonged periods of misalignment between their circadian rhythms and the 24-hour day-night cycle, including the timing of melatonin and cortisol secretion. As a result of this misalignment, Non-24 is associated with significant disruption of the sleep-wake cycle and impairments in social and occupational functioning, and marked subjective distress. Individuals with Non-24 cycle in and out of phase and suffer from disrupted nighttime sleep patterns and/or excessive daytime sleepiness.

HETLIOZ® was launched commercially in the U.S. in April 2014. In addition, in July 2015, the European Commission (EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults and included post-marketing commitments related to a pediatric investigation plan. This authorization was renewed in July 2020 for an unlimited duration and is valid in the 27 countries that are members of the European Union (E.U.), as well as European Economic Area members Iceland, Liechtenstein and Norway. HETLIOZ® was launched commercially in Germany in August 2016.

In January 2010, the FDA granted orphan drug designation status for HETLIOZ® in Non-24 in blind individuals. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives, including study design assistance, tax credits, waiver of FDA user fees, and up to seven years of market

exclusivity upon marketing approval. In February 2011, the European Medicines Agency (EMA) designated HETLIOZ® as an orphan medicinal product for the same indication.

Non-24 affects a majority of totally blind individuals, or approximately 80,000 people in the U.S. Blind individuals who develop Non-24 lack the light sensitivity necessary to synchronize the master body clock in the brain with the 24-hour day-night cycle. Non-24 also can affect sighted individuals. As with the totally blind, Non-24 in sighted individuals appears to be a comorbidity with certain other conditions. For example, a comorbidity has been established between psychiatric mood disorders and Non-24. Hospitalized individuals with neurological and psychiatric disorders can become insensitive to social cues, which may predispose them to the development of Non-24. This recognition of comorbidity led us to an initiative to engage with the psychiatric community. Patients diagnosed with traumatic brain injury, including concussions, frequently suffer from sleep disorders, some of which may be circadian rhythm sleep-wake disorders, including Non-24.

While there are no EC approved treatments for Non-24 other than HETLIOZ®, and only recently has the FDA approved generics for the treatment of Non-24, there are a number of drugs approved and prescribed for patients with sleep disorders. The most commonly prescribed drugs are hypnotics. See *Competition* below for a discussion of commonly prescribed drugs for patients with sleep disorders.

HETLIOZ® for SMS (capsules and oral suspension)

In December 2020, HETLIOZ® capsules and oral suspension (HETLIOZ LQ®) were approved in the U.S. for the treatment of adults and children, respectively, with nighttime sleep disturbances in SMS. HETLIOZ® capsules, for adults with SMS, were immediately available after approval and the HETLIOZ LQ® liquid formulation, for children with SMS, became available in the first quarter of 2021. SMS is a developmental disorder that is caused by a small deletion of human chromosome 17p. In more rare cases, SMS is caused by a point mutation in the RAI1 gene, which resides in the deleted region. HETLIOZ® is the first FDA-approved medication for patients with SMS.

In April 2010, the FDA granted orphan drug designation status for HETLIOZ® in the treatment of sleep disorder in SMS. SMS is estimated to affect 1/15,000-25,000 births in the U.S. SMS is not usually inherited but rather is caused by a de-novo deletion. Patients with SMS present with a number of physical, mental and behavioral problems. The most common symptom of SMS is a severe sleep disorder associated with significant disruption in the lives of patients and their families. In September 2023, the EMA designated HETLIOZ® as an orphan medicinal product for the treatment of SMS.

While there are no FDA approved treatments for patients with SMS other than HETLIOZ®, there are a number of drugs approved and prescribed for patients with sleep disorders that may be used to treat patients with SMS. The most commonly prescribed drugs are hypnotics. See *Competition* below for a discussion of commonly prescribed drugs for patients with sleep disorders.

Fanapt® for schizophrenia (tablets)

Fanapt® is a product approved for the treatment of schizophrenia. In May 2009, the FDA granted U.S. marketing approval of Fanapt® for the acute treatment of schizophrenia in adults. At that time, we had certain worldwide exclusive rights relating to Fanapt®, which we obtained pursuant to a sublicense agreement entered into with Novartis Pharma AG (Novartis) in June 2004. In October 2009, we amended and restated our sublicense agreement with Novartis pursuant to which Novartis retained exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. In January 2010, Novartis launched Fanapt® in the U.S. On December 31, 2014, Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to us as part of a settlement agreement. Additionally, our distribution partners launched Fanapt® in Israel in 2014. In May 2016, the FDA approved a supplemental New Drug Application (sNDA) for Fanapt® for the maintenance treatment of schizophrenia in adults.

Schizophrenia is a chronic, debilitating mental disorder characterized by hallucinations, delusions, racing thoughts and other psychotic symptoms (collectively referred to as “positive symptoms”), as well as moodiness, anhedonia (inability to feel pleasure), loss of interest, eating disturbances and withdrawal (collectively referred to as “negative symptoms”), and attention and memory deficits (collectively referred to as “cognitive symptoms”). Schizophrenia develops in late adolescence or early adulthood in approximately 1% of the world’s population. Most schizophrenia patients today are treated with drugs known as “atypical” antipsychotics, which were first approved in the U.S. in the late 1980s. These antipsychotics have been named “atypical” for their ability to treat a broader range of negative symptoms than the first-generation “typical” antipsychotics, which were introduced in the 1950s and are now generic. Atypical antipsychotics are generally regarded as having improved side effect profiles and efficacy relative to typical antipsychotics. See *Competition* below for a discussion of commonly prescribed atypical antipsychotics in addition to Fanapt®.

PONVORY® for relapsing multiple sclerosis (tablets)

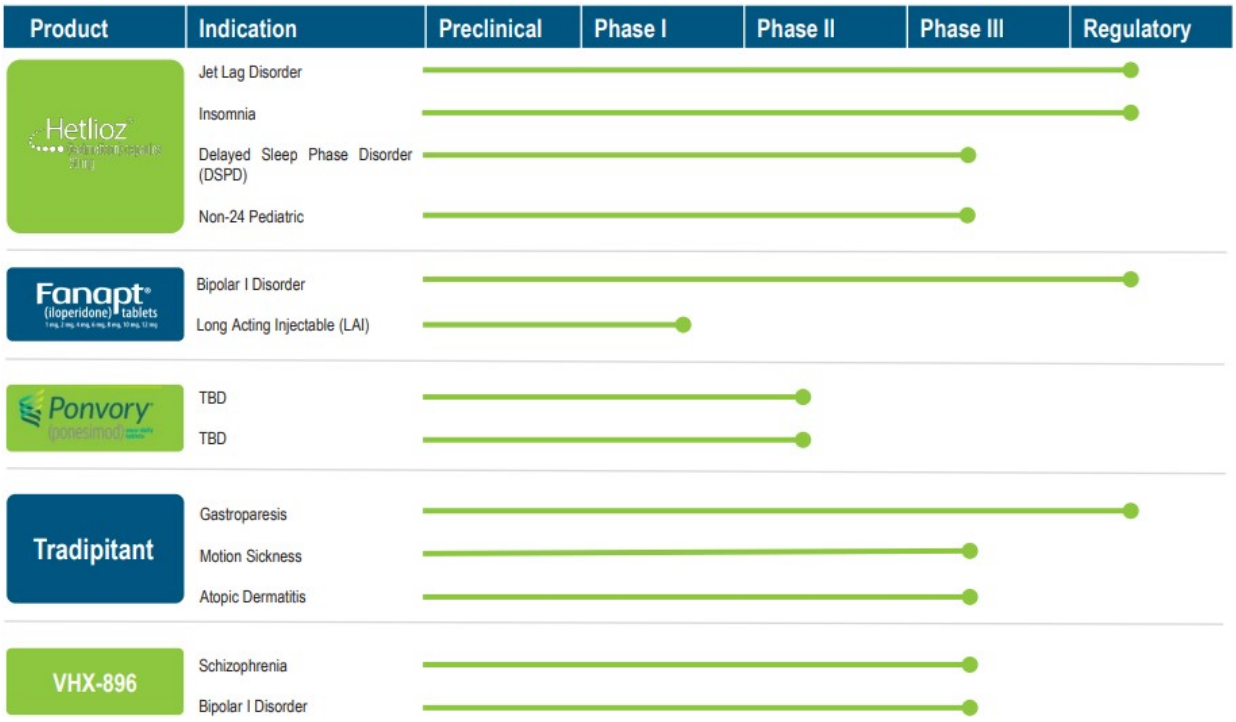
PONVORY® is a product approved for the treatment of relapsing forms of MS (RMS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease, in adults. In December 2023, we purchased the right to market and sell PONVORY® in the U.S. and Canadian markets from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company. In March 2021, the FDA granted U.S. marketing approval of PONVORY® for the treatment of RMS in adults. Health Canada approved PONVORY® for the treatment of RMS in April 2021. MS is a chronic autoimmune inflammatory disease of the central nervous system (CNS) in which immune cells attack myelin (the protective casing that insulates nerve cells), damaging or destroying it and causing inflammation. This affects how the CNS processes information and communicates with the rest of the body, causing the neurologic signs and symptoms of MS. Symptoms vary by person, but common symptoms include fatigue, balance and walking problems, numbness or tingling, dizziness and vertigo, vision problems, bladder and bowel problems and weakness.

PONVORY® was launched commercially in the U.S. in April 2021 and in Canada in November 2021 by one of the Johnson & Johnson Companies. There are a number of drugs approved and prescribed to treat patients with MS. See *Competition* below for a discussion of these commonly prescribed drugs.

Research and Development

We have built a research and development organization that includes extensive expertise in the scientific disciplines of pharmacogenetics and pharmacogenomics. We operate cross-functionally and are led by an experienced research and development management team. We use rigorous project management techniques to assist us in making disciplined strategic research and development program decisions and to help limit the risk profile of our product pipeline. We also access relevant market information and key opinion leaders in creating target product profiles and, when appropriate, as we advance our programs towards commercialization. We engage third parties to conduct portions of our preclinical research. In addition, we utilize multiple clinical sites to conduct our clinical trials; however, we are not substantially dependent upon any one of these sites for our clinical trials nor do any of them conduct a major portion of our clinical trials.

Our product pipeline currently consists of the following products in clinical development or under regulatory review:



HETLIOZ® for jet lag disorder

In March and May 2018, respectively, we announced the results of our JET8 and JET studies for the treatment of jet lag disorder. In the JET8 clinical study, HETLIOZ® demonstrated significant and clinically meaningful benefits in nighttime and daytime symptoms of jet lag disorder, including improvement in sleep time and benefits in measurements of next day alertness. The JET study showed effectiveness in treating travelers who traveled either five or eight time zones from Washington, D.C. to London and San Francisco or Los Angeles to London, respectively. The results support the previously reported pivotal JET5 and JET8 Phase III studies, which demonstrated improvements in patients who experienced circadian advances of five and eight hours, respectively. Additionally, in September 2018, we announced results from a driving study, which demonstrated that tasimelteon did not impair measures of driving performance.

The FDA accepted the filing of our sNDA for HETLIOZ® for the treatment of jet lag disorder in December 2018. The FDA determined the action target action date under the Prescription Drug User Fee Act Amendments of 2017 to be August 16, 2019 and, on that date, we received a complete response letter (CRL) from the FDA. The FDA asserted in the CRL that the measures demonstrating improved sleep were of unclear clinical significance. We met with the FDA to discuss the CRL in a Post Action meeting and in 2022 we requested the opportunity for a hearing with the FDA on the approvability of the jet lag disorder sNDA. We filed a lawsuit against the FDA in September 2022 demanding that the FDA immediately publish in the Federal Register a notice of opportunity for a hearing on the jet lag disorder sNDA. The FDA then published the notice in the Federal Register in October 2022. We have asked the U.S. District Court for the District of Columbia (DC District Court) to, among other things, compel the FDA to comply with its obligations and declare that its lack of compliance violates the FDCA and the FDA regulations. In January 2024, the DC District Court held an oral argument on dispositive cross-motions, following which the DC District Court granted our motion for summary judgment. The DC District Court ruled that the FDA violated the statute and ordered the FDA to either finally resolve our application or commence a hearing on or before March 5, 2024. Our lawsuit remains pending. We have asked the DC District Court to, among other things, compel the FDA to comply with its obligations and declare that its lack of compliance violates the FDCA and the FDA regulations. In January 2024, the DC District Court held an oral argument on dispositive cross-motions, following which the DC District Court granted our motion for summary judgment. The DC District Court ruled that the FDA violated the statute and ordered the FDA to either finally resolve our application or commence a hearing on or before March 5, 2024. Our lawsuit remains pending.

Jet lag disorder is a common circadian disorder frequently observed in millions of travelers who cross multiple time zones. Jet lag disorder is characterized by nighttime sleep disruption, a decrease in daytime alertness and impairment to social and occupational functioning. Jet lag disorder symptoms are more severe during eastward travel. U.S. Department of Commerce, International Trade Administration reports state that more than 20 million U.S. residents make trips abroad each year to overseas destinations in Europe, the Middle East and Asia.

HETLIOZ® for insomnia

HETLIOZ® is effective in improving sleep onset difficulty in people with primary insomnia with the effect observed as early as the first night of treatment. A Phase III, multi-center, placebo-controlled, 4-week trial evaluated patients with chronic primary insomnia. Two transient insomnia studies induced by phase advance of the sleep-wake cycle were also conducted with five-hour and eight-hour phase advance, which showed a significant effect the first night in improving sleep parameters. In July 2023, the FDA accepted our sNDA for HETLIOZ® in insomnia for filing and set a target action date of March 4, 2024 under the Prescription Drug User Fee Act (PDUFA) for its decision.

HETLIOZ® for pediatric Non-24

We plan to develop HETLIOZ® for the treatment of pediatric Non-24. A pharmacokinetic study of the HETLIOZ® pediatric liquid formulation was completed in the first quarter of 2018.

HETLIOZ® for DSPD

A Phase III study of HETLIOZ® in DSPD is ongoing. DSPD is a circadian rhythm disorder in which a person's sleep is delayed beyond the socially acceptable or conventional bedtime. This delay in falling asleep causes difficulty in waking up at the desired time and affects social and occupational functioning. DSPD is likely the most prevalent circadian-rhythm sleep disorder, affecting approximately 1% of the population, and there is no FDA approved treatment at this time.

Fanapt® for bipolar I disorder

In December 2022, we announced Fanapt® was effective in the treatment of acute manic and mixed episodes associated with bipolar I disorder in adults in a randomized double-blind placebo controlled Phase III study. The primary

endpoint measured in Week 4 of treatment was assessed by the Young Mania Rating Scale (YMRS), a rating scale of clinical severity in the core symptoms of mania. At the end of the 4-week study, Fanapt® treated patients showed a larger improvement than placebo treated patients, and this difference was highly statistically significant. Statistically significant benefit in the Fanapt® group over placebo was observed as early as the Week 2 assessment. Consistent with the total YMRS score, the individual YMRS subscale items also showed improvement in the Fanapt® group versus the placebo group over the course of the 4-week study. Other outcomes, such as Clinician Global Impression of Severity (CGI-S) and Clinician Global Impression of Change (CGI-C), also achieved statistical significance.

Bipolar disorders are brain disorders that cause changes in a person's mood, energy and ability to function. Bipolar disorder is a category that includes three different conditions - bipolar I, bipolar II and cyclothymic disorder.

People with bipolar disorders have extreme and intense emotional states that occur at distinct times, called mood episodes. These mood episodes are categorized as manic, hypomanic or depressive. People with bipolar disorders generally have periods of normal mood as well.

In August 2023, the FDA accepted our sNDA for Fanapt® in bipolar I disorder in adults for filing and set a PDUFA target action date of April 2, 2024 for its decision.

Fanapt® for schizophrenia (LAI)

In October 2018, we enrolled our first patient in a pharmacokinetic study of the LAI formulation of Fanapt®. This pharmacokinetic study is ongoing and will serve to inform the dosing for a later clinical study of Fanapt® LAI for the treatment of schizophrenia.

PONVORY®

The mechanism of action of PONVORY® makes it also a potential therapeutic candidate for the treatment of a diverse group of inflammatory/autoimmune disorders including but not limited to ulcerative colitis, psoriasis, Crohn's disease, atopic dermatitis, eosinophilic esophagitis and alopecia areata. In a randomized placebo controlled clinical study, PONVORY® has been shown to reduce the symptoms and signs of psoriasis.

Tradipitant for gastroparesis

In December 2018, we announced results from a Phase II randomized clinical study (2301) of tradipitant as a monotherapy in the treatment of gastroparesis. Several symptom severity scales were used to assess gastroparesis symptoms, including the Gastroparesis Symptom Index (GCSI), Patients Assessment of Upper Gastrointestinal Disorders-Symptoms (PAGI-SYM), and Patient Global Impression of Change (PGI-C) as well as a Clinician Global Impression of Severity (CGI-S). Tradipitant met the primary endpoint of the study of change in nausea score as measured by patient daily diaries and also met the related endpoint of improvement in the number of nausea free days. Tradipitant also showed significant improvement in most of the secondary endpoints studied, including several key scales reflecting overall gastroparesis symptoms, specifically GCSI, PAGI-SYM, CGI-S, and PGI-C.

In February 2022, we announced results from our Phase III clinical study, VP-VLY-686-3301, evaluating the efficacy and safety of tradipitant in treating the symptoms of gastroparesis. The study did not meet its prespecified primary endpoint, which was the difference between drug and placebo on the change of the severity of nausea from baseline at week 12 of treatment. Both treatment arms showed significant improvements from baseline on nausea as well as the other core symptoms of gastroparesis. When restricting the analysis in the group of patients that used no rescue medications at baseline and adjusting for poor compliance, we identified strong evidence of a drug effect across a number of symptoms and across the duration of the study, including a significant and meaningful effect at the prespecified primary endpoint of nausea change at week 12. The FDA may not view this data as constituting substantial evidence of efficacy for tradipitant in any indication for the treatment of gastroparesis or its symptoms, for any length of treatment. The open-label phase of the study remains open.

We believe that tradipitant has a well-established safety profile, as demonstrated by the results of extensive testing in animals and humans. Despite these results, however, the FDA informed us in December 2018 that in order to treat patients beyond 12 weeks, we would have to conduct a nine-month non-rodent chronic toxicity study. This currently limits our ability to collect safety data in humans for more than 12 weeks. The non-rodent study required by the FDA necessitates the sacrifice of dozens of animals and we have disputed the necessity of a nine-month non-rodent chronic toxicity study. In February 2019, we filed a lawsuit in the U.S. District Court for the District of Columbia (DC District Court) challenging the FDA's position, but we ultimately did not prevail. Despite our disagreement with the FDA, the preclinical package has allowed us to continue to

conduct all of the efficacy studies necessary for New Drug Application (NDA) filing. Moreover, in July 2020, the FDA authorized tradipitant through an expanded access program (EAP) for a single patient. An EAP allows a patient to request the use of tradipitant, prior to NDA approval, for up to six months with an option to request renewal. Since then, certain patients who experienced a benefit in tradipitant studies have requested and received expanded access, while others have been denied treatment under the EAP. The EAP is ongoing and a number of patients have initiated treatment. Although this EAP is not intended for data collection, we collect safety data from this cohort of expanded access patients and included this data in the NDA that we submitted for tradipitant for patients with gastroparesis. In December 2023, the FDA accepted our NDA for tradipitant in gastroparesis for filing and set a PDUFA target action date of September 18, 2024. If approved, tradipitant will be the first novel drug to be approved by the FDA for the treatment of gastroparesis in over 40 years and tradipitant is the first novel drug to be accepted for review by the FDA for gastroparesis in over 30 years. The FDA may disregard such safety data when reviewing the NDA. The lack of long-term (i.e., more than 12 weeks in humans) safety data would likely impact the FDA's willingness to approve tradipitant for a chronic indication. However, because long-term safety data is not normally a requirement for short-term indications, and with a preclinical profile that has not precluded clinical development, we believe the package was complete for any NDA filing to treat patients for 12 weeks or less. For example, the FDA has communicated to us that it is considering an indication for the short-term relief of nausea in gastroparesis. While this short-term indication is not preferred, we would consider accepting this limited indication while continuing to pursue a chronic indication. However, the FDA may not deem the safety information sufficient even for a short-term indication. Moreover, FDA authorization of an EAP is not a guarantee of or a step in obtaining full FDA approval of an NDA.

Gastroparesis is a serious medical condition characterized by delayed gastric emptying associated with the symptoms of nausea, vomiting, bloating, fullness after meals and abdominal pain, along with significant impairment of social and occupational functioning. A paper by Rey et al published in the January 2012 Journal of Neurogastroenterology and Motility estimated the prevalence of gastroparesis in the U.S. to be approximately six million patients, many of whom remain undiagnosed.

Tradipitant for motion sickness

In July 2019, we reported tradipitant was effective in treating motion sickness in a randomized double blind placebo controlled Phase II clinical study conducted in the Pacific Ocean. The study had two primary endpoints: percentage of participants vomiting, and Motion Sickness Severity Scale (MSSS) Worst score. In the overall population, a significantly higher percentage of participants experienced vomiting in the placebo arm as compared to the tradipitant arm. The MSSS Worst score endpoint also favored tradipitant, but the difference did not reach statistical significance. The protocol for a pivotal Phase III motion sickness study was discussed with the FDA at the end of Phase II meeting, and the FDA agreed with the adequacy of the program design to support an NDA. In May 2023, we announced positive results from the first Phase III study of tradipitant in motion sickness, confirming the previously reported results demonstrating that tradipitant is effective in the prevention of vomiting associated with motion sickness. A second Phase III study of tradipitant in motion sickness is ongoing.

Motion sickness is a disorder that arises often as a response to real or perceived movement, as occurring during vehicular travel. Vomiting is the most disturbing symptom of motion sickness, although the disorder is often accompanied by a constellation of symptoms that includes nausea, sweating, pallor, headache and anorexia. Motion sickness is one of the most prevalent episodic disorders in the world, whose prevalence has dramatically increased with world population mobility over the last 100 years. It is reported that approximately 30% of the general population suffers from motion sickness under ordinary travel conditions that include sea, air and land travel.

Tradipitant for atopic dermatitis

We announced results in September 2017 from a randomized Phase II clinical study of tradipitant as a monotherapy in the treatment of patients with atopic dermatitis. Tradipitant was shown to improve the intensity of the worst itch patients experienced, as well as atopic dermatitis disease severity. On the pre-specified primary endpoint of Average Itch Visual Analog Scale (VAS), tradipitant showed improvement over placebo, but this improvement was not significant due to high placebo effect and the lack of sensitivity of this measure.

In June 2018, we initiated EPIONE, a Phase III study of tradipitant for pruritus in atopic dermatitis. In October 2019, we began enrolling patients in EPIONE 2, a second Phase III clinical study of tradipitant in atopic dermatitis. We announced results of EPIONE in February 2020. The EPIONE study did not meet its primary endpoint in reduction of pruritus across the overall study population. However, the antipruritic effect of tradipitant was robust in the mild atopic dermatitis population. The EPIONE study continued to demonstrate that tradipitant is safe and well-tolerated. The EPIONE 2 study was placed on hold in 2020.

Atopic dermatitis is a chronic, relapsing inflammatory skin disorder characterized by the symptom of intense and persistent pruritus or itch. Other clinical features include erythema, excoriation, edema, lichenification, oozing and xerosis. Atopic dermatitis is a common skin disorder affecting millions of people worldwide. Currently, there are very few safe systemic treatments available for atopic dermatitis, representing a significant unmet medical need in this population. A 2015 Decision Resources Group report estimated that 9.8 million individuals were diagnosed with atopic dermatitis in the U.S., of which approximately 6.4 million were drug-treated atopic dermatitis patients.

VHX-896

In 2021, we initiated a bioequivalence study of Fanapt® and VHX-896, the active metabolite of iloperidone. We believe that VHX-896 has the potential to improve the clinical profile of Fanapt® and create sustained, long-term value in the treatment of psychiatric disorders, including schizophrenia and bipolar I disorder.

Other products

VTR-297

In the fourth quarter of 2018, we initiated a clinical study in patients with hematologic malignancies. Enrollment in the Phase I/II clinical study (1101) of VTR-297 in hematologic malignancies is ongoing. VTR-297 is a small molecule HDAC inhibitor with potential use as a treatment for several oncology indications.

In January 2024, the FDA approved our Investigational New Drug (IND) application to evaluate VTR-297 for the treatment of onychomycosis.

Portfolio of CFTR activators and inhibitors

A clinical program in VSJ-110 is ongoing. We are evaluating VSJ-110 for the treatment of allergic conjunctivitis. VSJ-110 is a small molecule nanomolar potency CFTR activator. VSJ-110 has shown efficacy in a dry eye model and exhibited anti-inflammatory properties in both in vitro and in vivo assays.

In addition, an early stage CFTR inhibitor program is planned for VPO-227 for the treatment of secretory diarrhea disorders, including cholera. We believe that VPO-227 has the potential to be an orally administered treatment for cholera. In October 2022, VPO-227 was granted orphan drug designation by the FDA for the treatment of cholera.

VQW-765

We are evaluating VQW-765 for the treatment of psychiatric disorders. In December 2022, we announced results from our Phase II study, VP-VQW-765-2201 (Study 2201), of a single-dose treatment to alleviate acute performance anxiety in social situations. In the clinical study, 230 volunteers with prior history of performance anxiety were randomized to receive a single dose of VQW-765 or placebo and were challenged with the standardized Trier Social Stress Test (TSST). The TSST creates an acute stress by requiring participants to make an interview-style presentation in front of a panel who provides no feedback or encouragement. Participants who received VQW-765 showed numerically lower stress levels compared to those who received placebo. A significant relationship was also seen between exposure to VQW-765 (amount of drug measured in blood) and the clinical response.

VQW-765 is a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist that we licensed from Novartis on December 31, 2014 pursuant to a settlement agreement.

ASO Molecules

In 2022, we announced a research and development collaboration agreement with OliPass Corporation (OliPass) to jointly develop a set of ASO molecules based on OliPass' proprietary modified peptide nucleic acids. The collaboration focuses on editing and modifying gene expression using ASOs in disease states where the expression of genes is either altered or the sequence of the expressed genes can be altered for therapeutic benefit. OliPass' unique OliPass Peptide Nucleic Acids technology provides the delivery platform to enable these gene expression modifications.

ASOs may have broad applicability in addressing a number of disorders, from nervous system treatments to systemic treatments. In June 2023, VCA-894A, an ASO molecule, was granted orphan designation by FDA for the treatment of a patient with CMT2S, caused by cryptic splice site variants within IGHMBP2. In January 2024, we announced that the FDA had approved the Investigational New Drug (IND) application to evaluate VCA-894A for the treatment of a patient with CMT2S. CMT2S is a rare subtype of Charcot-Marie-Tooth disease (CMT), an inherited peripheral neuropathy for which there is no available treatment. The estimated prevalence of CMT is 1 in 2,500 individuals, with varying clinical features dependent on the various genetic variants of CMT. The prevalence of CMT2S is estimated to be less than 1 in 1,000,000 worldwide.

For more detailed information regarding our clinical trial results and regulatory activities for our products please refer to our SEC filings and press releases, which can be found on the SEC EDGAR website and on our website www.vandapharma.com. Information contained on those websites is not incorporated by reference into this Annual Report or any other report or document that we file with the SEC.

License Agreements

Our rights to develop and commercialize certain of our products are subject to the terms and conditions of licenses granted to us by other pharmaceutical companies.

HETLIOZ®

In February 2004, we entered into a license agreement with Bristol-Myers Squibb (BMS) under which we received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize HETLIOZ®. We have paid BMS $37.5 million in upfront fees and milestone obligations. We have no remaining milestone obligations to BMS. Additionally, we are obligated to make royalty payments on HETLIOZ® net sales to BMS. The royalty period in each territory where we commercialize HETLIOZ® is 10 years following the first commercial sale in the territory. In territories outside the U.S., the royalty is 5% on net sales. In December 2022, the royalty on net sales in the U.S. decreased from 10% to 5%. This U.S. royalty will end in April 2024. We are also obligated under the license agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that we receive from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. We are obligated to use commercially reasonable efforts to develop and commercialize HETLIOZ®.

Either party may terminate the HETLIOZ® license agreement under certain circumstances, including a material breach of the agreement by the other. In the event we terminate our license, or if BMS terminates our license due to our breach, all rights licensed and developed by us under this agreement will revert or otherwise be licensed back to BMS on an exclusive basis.

Fanapt®

Pursuant to the terms of a settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us on December 31, 2014. We paid directly to Sanofi S.A. (Sanofi) a fixed royalty of 3% of net sales through December 2019 related to manufacturing know-how. No further royalties on manufacturing know-how are payable by us. We are also obligated to pay Sanofi a fixed royalty on Fanapt® net sales equal up to 6% on Sanofi know-how not related to manufacturing under certain conditions for a period of up to 10 years in markets where the NCE patent has expired or was not issued. We are obligated to pay this 6% royalty on net sales in the U.S. through November 2026. No further royalties on know-how not related to manufacturing will be payable by us for net sales in the U.S. after November 2026. We may lose our rights to develop and commercialize Fanapt® if we fail to comply with certain requirements in the Titan license agreement regarding our financial condition, or if we fail to comply with certain diligence obligations regarding our development or commercialization activities.

Tradipitant (VLY-686)

In April 2012, we entered into a license agreement with Eli Lilly and Company (Lilly) pursuant to which we acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1 receptor antagonist, tradipitant, for all human indications. Lilly is eligible to receive future payments based upon achievement of specified development, regulatory approval and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. We have paid Lilly $5.0 million in upfront fees and development milestones, including a $2.0 million development milestone paid in December 2023 for the filing of the first marketing authorization for tradipitant in the U.S. or the E.U. As of December 31, 2023, remaining milestones include $10.0 million and $5.0 million milestones for the first approval of a marketing authorization for tradipitant in the U.S. and the E.U., respectively, and up to $80.0 million for sales milestones. We are obligated to use commercially reasonable efforts to develop and commercialize tradipitant.

Either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other. In the event that we terminate the agreement, or if Lilly terminates the agreement due to our breach or for certain other reasons set forth in the agreement, all rights licensed and developed by us under the agreement will revert or otherwise be licensed back to Lilly on an exclusive basis, subject to payment by Lilly to us of a royalty on net sales of products that contain tradipitant.

Portfolio of CFTR activators and inhibitors

In March 2017, we entered into a license agreement with the University of California San Francisco (UCSF), under which we acquired an exclusive worldwide license to develop and commercialize a portfolio of CFTR activators and inhibitors. Pursuant to the license agreement, we will develop and commercialize the CFTR activators and inhibitors and are responsible for all development costs under the license agreement, including current pre-investigational new drug development work. UCSF is eligible to receive future payments based upon achievement of specified development, regulatory approval and commercialization milestones as well as single-digit tiered-royalties on net sales. We have paid UCSF $1.6 million in upfront fees and development milestones. As of December 31, 2023, remaining milestones include $11.9 million for development milestones and $33.0 million for future regulatory approval and sales milestones. Included in the $11.9 million in development milestones are $1.1 million of milestone obligations due upon the conclusion of clinical studies for each licensed product, not to exceed $3.2 million in total for the CFTR portfolio.

Either party may terminate the agreement under certain circumstances. In the event that we terminate the agreement, or if UCSF terminates the agreement due to our breach or for certain other reasons set forth in the agreement, all rights licensed and developed by us under the agreement will revert or otherwise be licensed back to UCSF. Termination will not relieve us of our obligation to pay royalties or other payments owed, if any, to UCSF under the terms of the agreement.

VQW-765

In connection with the settlement agreement with Novartis relating to Fanapt®, we received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize VQW-765, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist. Pursuant to the license agreement, we are obligated to use commercially reasonable efforts to develop and commercialize VQW-765 and are responsible for all development costs. We have no milestone obligations, but Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens.

Either party may terminate the agreement under certain circumstances, including a material breach of the agreement by the other. In the event that we terminate the agreement, or if Novartis terminates the agreement due to our breach or for certain other reasons set forth in the agreement, all rights licensed and developed by us under the agreement will revert or otherwise be licensed back to Novartis on an exclusive basis, subject to payment by Novartis to us of a royalty on net sales of products that contain VQW-765.

Patents and Proprietary Rights; Hatch-Waxman Protection

Our products are protected from unauthorized use by others only to the extent that our products are covered through regulatory protections or by valid and enforceable patents, either licensed to us by others or generated through our activities internally, that give us sufficient proprietary rights. Accordingly, securing patents, regulatory data package protection, and other proprietary rights are an essential element of our business strategies.

PONVORY®, tradipitant and VQW-765 are covered by NCE and other patents and patent applications related to their respective medicinal uses. In addition, NCE patent protection has been sought for VTR-297 and CFTR. Patent applications for these active ingredients remain pending. Although the NCE patents protecting Fanapt® and HETLIOZ® have expired, Fanapt® remains protected by additional patents and HETLIOZ® remains protected by additional patents, some of which we have asserted against current generic competitors. For more on the license and sublicense arrangements related to these active ingredients, see *License Agreements* above. For more on patent litigation, see Note 17, *Legal Matters*, to the consolidated financial statements in Part II, Item 8 of this Annual Report and the risk factor entitled "*We are, have been, and may continue to be, involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful*," in Part I, Item 1A of this Annual Report, each of which is incorporated herein by reference. In addition, we have filed for patents based on our own discoveries that seek to provide additional protection for HETLIOZ® and Fanapt®.

A comprehensive list of active patents for our U.S. commercial products is available in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for our commercial products and is also provided in the table below. Members of these patent families are also issued or pending in a number of territories, such as Europe and Japan. The patents in the table below that are marked with "*" are the subject of ongoing patent litigation. See Note 17, *Legal Matters*, to the consolidated financial statements in Part II, Item 8 of this Annual Report and the risk factor entitled "*We are, have been, and may continue to be, involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful*," in Part I, Item 1A of this Annual Report, each of which is incorporated herein by reference, for additional information.

Product	Number	Type
HETLIOZ®	US 9,060,995	Method of treatment
	US 9,539,234	Method of treatment
	US 9,549,913	Method of treatment
	US 9,730,910*	Method of treatment
	US 9,855,241	Method of treatment
	US RE46604*	Method of treatment
	US 10,071,977	Drug substance
	US 10,149,829*	Method of treatment
	US 10,179,119	Method of treatment
	US 10,376,487*	Method of treatment
	US 10,449,176	Method of treatment
	US 10,610,510	Method of treatment
	US 10,610,511	Method of treatment
	US 10,829,465	Drug substance
	US 10,945,988	Method of treatment
	US 10,980,770	Method of treatment
	US 11,141,400	Method of treatment
	US 11,266,622	Method of treatment
	US 11,285,129*	Method of treatment
	US 11,566,011	Drug substance
	US 11,633,377	Method of treatment
	US 11,759,446	Method of treatment
	US 11,760,740	Drug substance
	US 11,786,502	Method of treatment
	US 11,833,130	Method of treatment
	US 11,850,229	Method of treatment
HETLIOZ LQ®	US 9,539,234	Method of treatment
	US 9,730,910*	Method of treatment
	US 10,071,977	Drug substance

Product	Number	Type
	US 10,149,829*	Method of treatment
	US 10,179,119	Method of treatment
	US 10,376,487*	Method of treatment
	US 10,610,510	Method of treatment
	US 10,610,511	Method of treatment
	US 10,829,465	Drug substance
	US 10,980,770	Method of treatment
	US 11,141,400	Method of treatment
	US 11,202,770	Drug formulation
	US 11,266,622	Method of treatment
	US 11,285,129*	Method of treatment
	US 11,566,011	Drug substance
	US 11,633,377	Method of treatment
	US 11,759,446	Method of treatment
	US 11,760,740	Drug substance
	US 11,786,502	Method of treatment
	US 11,833,130	Method of treatment
	US 11,850,229	Method of treatment
Fanapt®	US 8,586,610*	Method of treatment
	US 8,652,776	Method of treatment
	US 8,999,638	Method of treatment
	US 9,072,742	Method of treatment
	US 9,074,254	Method of treatment
	US 9,074,255	Method of treatment
	US 9,074,256	Method of treatment
	US 9,138,432*	Method of treatment
	US 9,157,121	Method of treatment
PONVORY®	US 8,273,779	Method of treatment
	US 9,000,018	Method of treatment
	US 9,062,014	Drug substance
	US 10,220,023	Method of treatment
	US RE43728	Drug substance

HETLIOZ® and HETLOZ LQ®

Our rights to the NCE patent covering HETLIOZ® capsules and oral suspension (HETLIOZ LQ®) and related intellectual property have been acquired through a license with BMS. HETLIOZ® and its formulations, genetic markers and uses are the subject of numerous patent filings for which protection has been sought in selected countries worldwide. The NCE patent covering HETLIOZ® expired in December 2022 in the U.S., which is inclusive of a five-year extension granted under the Hatch-Waxman Act in October 2018. Corresponding NCE patent protection has expired in most other markets. The U.S. Patent and Trademark Office has issued 22 method of treatment patents for HETLIOZ® that will expire between 2033 and 2041 and four drug substance patents that will expire in 2035. Additionally, the U.S. Patent and Trademark Office has issued a drug formulation patent for HETLIOZ LQ® that will expire in 2040. We also have other pending patent applications covering methods of treatment and compositions of tasimelteon (HETLIOZ® active ingredient) oral suspensions.

We filed several Hatch-Waxman lawsuits in the U.S. District Court for the District of Delaware (Delaware District Court) against Teva Pharmaceuticals USA, Inc. (Teva), Apotex Inc. (Apotex), MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (MSN) (collectively, the HETLIOZ® Defendants) asserting infringement of patents covering HETLIOZ® 20 mg capsules. In January 2022, we entered into a license agreement with MSN and Impax Laboratories LLC

resolving the lawsuits against MSN. The consolidated lawsuits against the remaining HETLIOZ® Defendants were tried in March 2022. In December 2022, the Delaware District Court ruled that Teva and Apotex did not infringe U.S. Patent No. RE46,604, and that the asserted claims of U.S. Patent Nos. RE46,604; 9,730,910; 10,149,829; and 10,376,487 were invalid. We have appealed the decision to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) and in May 2023, a three-judge panel of the Federal Circuit affirmed the Delaware District Court's ruling. In August 2023, the Federal Circuit denied our request for a rehearing. In January 2024, we filed a petition for a writ of certiorari with the U.S. Supreme Court to review the Federal Circuit's decision. We have also filed Hatch-Waxman lawsuits in U.S. District Court for the District of New Jersey against each of Teva and Apotex and in the U.S. District Court for the Southern District of Florida against Apotex, in each case, asserting infringement of a method of administration patent that was not litigated in the Delaware District Court. The New Jersey cases have been transferred to the Delaware District Court, where they remain pending. This litigation does not affect the sale of HETLIOZ® in the E.U. and there is no generic litigation pending outside of the U.S. with respect to HETLIOZ®. Furthermore, the litigation does not relate to the HETLIOZ LQ® oral suspension formulation. See Note 17, *Legal Matters,* to the consolidated financial statements in Part II, Item 8 of this Annual Report and the risk factor entitled "*We are, have been, and may continue to be, involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful*," in Part I, Item 1A of this Annual Report, each of which is incorporated herein by reference, for additional information.

In Europe, the law provides for 10 years of data exclusivity (with the potential for an additional year if a medicine is developed for a significant new indication). In addition, Europe provides for 10 years of market exclusivity for orphan indications. As such, in Europe, data or market exclusivity will provide protection for HETLIOZ® for at least 10 years from approval. It is also possible that the protection through a basic patent (i.e., a patent that protects a product as such, a process to obtain a product, or an application of a product) in Europe could be extended for up to five years by the issuance of a supplementary protection certificate (SPC). A completed Pediatric Investigation Plan (PIP) could further extend SPC protection for an additional six months or the market exclusivity in an orphan indication for two additional years. Thus, a PIP could provide a total of 12 years of market exclusivity for an orphan indication. The European Patent Office has granted our patent application directed to the 20 mg/day dose. This patent will expire in 2027 and provides the basis for an SPC. Other pending patent applications in Europe, if granted, may offer additional protection for HETLIOZ®.

Outside the U.S. and Europe, data exclusivity will protect HETLIOZ® from generic competition for varying numbers of years depending on the country.

Additional patent applications directed to specific sleep disorders and to methods of treating patients with HETLIOZ®, if issued, could provide exclusivity for such indications and methods of treatment.

Fanapt®

The NCE patent for Fanapt®, which expired in 2016 in the U.S. and in 2010 in other countries, was owned by Sanofi. Other patents and patent applications relating to Fanapt® are owned by us.

Fanapt® metabolites, formulations, genetic markers and uses are the subject of numerous patent filings in which protection has been sought in the U.S., Europe, and other markets. In November 2013, a U.S. patent (U.S. 8,586,610) directed to a method of treating patients with Fanapt® based on genotype was issued to us by the U.S. Patent and Trademark Office. This patent, which was listed in the Orange Book in January 2015, is set to expire in 2027, potentially further extending the U.S. marketing exclusivity for Fanapt®. Additional method of treatment patents have been issued in the U.S. and listed in the Orange Book, with the latest expiration date in December 2031.

We have also filed and plan on filing additional patent applications covering the use of iloperidone (Fanapt® active ingredient) LAI formulations. Patents for the microsphere LAI formulation of Fanapt® expired in 2022 in some markets in Europe and will expire in 2024 in the U.S. Patents for the aqueous microcrystals LAI formulation of Fanapt® expire in 2023 in the U.S. and in some markets in Europe. We have pending patent applications covering the use of iloperidone and plan on filing additional applications based on discoveries made throughout the development plan of this molecule.

We filed several Hatch-Waxman lawsuits in the Delaware District Court against a number of generic company competitors asserting infringement of two of our Fanapt® patents. The litigation has been resolved with respect to all but one of these competitors. See Note 17, *Legal Matters,* to the consolidated financial statements in Part II, Item 8 of this Annual Report and the risk factor entitled "*We are, have been, and may continue to be, involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful*," in Part I, Item 1A of this Annual Report, each of which is incorporated herein by reference, for additional information.

In Europe, the law provides for 10 years of regulatory exclusivity (with the potential for an additional year if the drug is developed for a significant new indication). No generic versions of Fanapt® would be permitted to be marketed or sold during the applicable regulatory exclusivity period in most European countries. Outside the U.S. and Europe, similar regulatory package protection periods may be available and could protect Fanapt® from generic competition for varying numbers of years depending upon the country.

PONVORY®

Janssen has obtained patent protection for PONVORY® and its formulations in selected countries worldwide, including the U.S. and Canada. In December 2023, we acquired all rights that Janssen had in U.S. and Canadian patents related to PONVORY®, pending U.S. and Canada patent applications related to PONVORY®, and any further U.S. and Canadian derivative patents and patent applications arising from the foregoing patents and pending patent applications. Regulatory exclusivity (NCE) protecting PONVORY® in the U.S. will expire on March 18, 2026. The NCE patent covering the active ingredient in PONVORY® (Reissue Patent No. 43,728) is set to expire on November 16, 2024, but an application for term extension pursuant to the Hatch-Waxman Act was submitted, which would extend this patent's term to November 16, 2029 if granted. The U.S. Patent and Trademark Office has granted additional patents, including a further patent directed to a crystalline form of the active ingredient in PONVORY®, which will expire in May 2032 in view of awarded patent term adjustment. The U.S. Patent and Trademark Office has also issued three method of treatment patents for PONVORY®, which will expire between November 2024 and December 2035. Furthermore, on January 24, 2024, the U.S. Patent and Trademark Office issued a Notice of Allowance in the case of U.S. Pat. Appl. No. 17/962,968, which covers other methods of treatment using the active ingredient in PONVORY®. Once issued, this patent would be expected to expire on October 10, 2042. Also, a number of patent applications covering further methods of treatment remain pending at the U.S. Patent and Trademark Office.

In Canada, the Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations) create a regime analogous to the Hatch-Waxman Act and link the regulatory approval process for generic and biosimilar drugs to the adjudication of innovator patent rights. To be eligible for protection under the PM(NOC) Regulations, patents must first be listed on the Patent Register in connection with an innovator's drug submission to Health Canada. A generic or biosimilar manufacturer must then provide notice to the innovator of its plans to market a drug that it compared to the innovator's patented drug in the Health Canada approval process. Within 45 days of receiving such a notice of allegation, an innovator drug company may commence patent infringement proceedings against the generic or biosimilar manufacturer. The commencement of an action by the innovator under the PM(NOC) Regulations may stay Health Canada's regulatory approval of the generic or biosimilar drug for a period of 24 months. It is also possible that protection through a patent (i.e., a patent claiming a medicinal ingredient, or the combination of all medicinal ingredients, or uses thereof) in Canada can be extended for up to two years by the issuance of a Certificate of Supplementary Protection (CSP). Health Canada's Patent Register lists Canadian Patent Nos. 2545582, 2740313, and 2968180 for PONVORY®, which are respectively directed to the active ingredient in PONVORY®, the crystalline form of that active ingredient, and methods of treatment. These listed patents will respectively expire November 16, 2024; October 19, 2029; and April 29, 2036 in view of the CSP.

Canada also employs a data exclusivity regime for innovative drugs that provides an eight-year period of data protection from the date of market approval by Health Canada. An additional six months of data exclusivity is provided for drugs studied in clinical trials relating to use in pediatric populations. Drug submissions seeking approval based on a comparison to an innovative drug cannot be filed during the first six years of the data exclusivity period. Generic or biosimilar drug submissions remain on hold until expiry of the innovator's data protection term, unless the innovative product is a patented drug subject to further protection under the PM(NOC) Regulations. Canada has no distinct drug submission process for biosimilar or orphan drug products.

Tradipitant

Lilly owns the NCE patent as well as patent applications directed to polymorphic forms of, and methods of making tradipitant. This patent protection was sought in the U.S. and in other countries worldwide. These patents and patent applications have been licensed to us. The NCE patent covering tradipitant expired in April 2023, except in the U.S., where it expires normally in June 2024, subject to any extension that may be received under the Hatch-Waxman Act. We have filed additional patent applications based on discoveries made during recent studies with tradipitant.

VTR-297

VTR-297 is a small molecule HDAC inhibitor with potential use as a treatment for several oncology indications. We have pending patent applications covering the use of VTR-297 and plan on filing additional applications based on discoveries made throughout the development plan of this molecule.

Portfolio of CFTR activators and inhibitors

Our portfolio of CFTR activators and inhibitors may have broad applicability in addressing a number of high unmet medical needs, including chronic dry eye, constipation, polycystic kidney disease, cholestasis and secretory diarrheas. We plan on filing applications based on discoveries made throughout the development plan of these product candidates.

VQW-765

Novartis owns the NCE patent as well as patent applications directed to methods of using VQW-765, VQW-765 formulations, and combinations of VQW-765 with other active pharmaceutical ingredients. In connection with the settlement agreement with Novartis relating to Fanapt®, we received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize VQW-765, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist. The NCE patent expired normally in 2023 in the U.S., Europe, and other markets.

Other patents

Aside from the NCE patents and other in-licensed patents discussed above, we have obtained or filed numerous patents and patent applications, most of which have been filed in key markets including the U.S., relating to our products and product candidates. In addition, we have filed numerous other patent applications relating to drugs not presently in clinical studies. The claims in these various patents and patent applications are directed to compositions of matter, including claims covering other products, pharmaceutical compositions and methods of use.

Proprietary know-how

For proprietary know-how that is not appropriate for patent protection, processes for which patents are difficult to enforce and any other elements of our discovery process that involve proprietary know-how and technology that are not covered by patent applications, we generally rely on trade secret protection and confidentiality agreements to protect our interests. We require all of our employees, relevant consultants and advisors to enter into confidentiality agreements. Where it is necessary to share our proprietary information or data with outside parties, our policy is to make available only that information and data required to accomplish the desired purpose and only pursuant to a duty of confidentiality on the part of those parties.

Marketing and Sales

HETLIOZ® capsules were approved in the U.S. for the treatment of Non-24 in January 2014 and HETLIOZ® capsules and oral suspension were approved for the treatment of nighttime sleep disturbances in SMS in December 2020. We commercially launched HETLIOZ® capsules in the U.S. in April 2014 and the oral suspension in March 2021. Additionally, HETLIOZ® capsules were approved in the E.U. for the treatment of Non-24 in totally blind adults in July 2015 and, in August 2016, we commercially launched HETLIOZ® in Germany. Given the range of potential indications for HETLIOZ®, we may pursue one or more partnerships for the development and commercialization of HETLIOZ® worldwide.

Fanapt® oral tablets were approved in the U.S. for the treatment of schizophrenia in May 2009 and commercially launched in the U.S. in January 2010. We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation in other regions.

PONVORY® tablets were approved in the U.S. for the treatment of RMS in adults in March 2021 and commercially launched in the U.S. by Janssen in April 2021. PONVORY® tablets were approved in Canada for the treatment of RMS in adults in April 2021 and commercially launched in Canada by Janssen in November 2021. We acquired the U.S. and Canadian rights to PONVORY® in December 2023 from Janssen. Janssen will continue PONVORY® operations during a transition period, following which, regulatory and supply responsibilities will be transitioned to us.

Major Customers

Our revenues are generated from product sales and are concentrated with two specialty pharmacies and three wholesalers. There were five major customers that each accounted for more than 10% of total revenues for 2023 and, as a group, represented 80% of total revenues for the year ended December 31, 2023.

Competition

The pharmaceutical industry, in particular, is highly competitive and includes a number of established large and mid-sized companies with greater financial, technical and personnel resources than we have and significantly greater commercial infrastructures than we have. Our market segment also includes several smaller emerging companies whose activities are directly focused on our target markets and areas of expertise. Our products, once approved for commercial use, will compete with numerous therapeutic treatments offered by these competitors. While we believe that our products will have certain favorable features, existing and new treatments may also possess advantages. Additionally, the development of other drug technologies and methods of disease prevention are occurring at a rapid pace. These developments may render our products or technologies obsolete or noncompetitive.

We believe the competitors for HETLIOZ®, Fanapt® and PONVORY® are as follows:

- For HETLIOZ® in the treatment of nighttime sleep disturbances in SMS, there are no FDA approved direct competitors. For HETLIOZ® in the treatment of Non-24, Teva has launched at risk, and the FDA has approved the Abbreviated New Drug Applications (ANDA) for Apotex and MSN. In addition, sedative-hypnotic treatments for certain sleep related disorders include, Ambien® (zolpidem) by Sanofi (including Ambien CR®), Lunesta® (eszopiclone) by Woodward Pharma Services., Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, Silenor® (doxepin) by Currax Pharmaceuticals LLC, Belsomra® (suvorexant) by Merck & Co., Inc., Dayvigo® (lemborexant) by Eisai Inc., generic products such as agomelatine, zaleplon, trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®. The class of melatonin agonists includes Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, and the food supplement melatonin. Shift work and excessive sleepiness disorder treatments include Nuvigil® (armodafinil) and Provigil® (modafinil) both by Teva.
- For Fanapt® in the treatment of schizophrenia, the atypical antipsychotics competitors are Risperdal® (risperidone), including the LAI formulation Risperdal Consta® and Invega® (paliperidone), including the LAI formulation Invega® Sustenna®, each by Johnson & Johnson, the LAI formulation Zyprexa® Relprevv™ (olanzapine) by Cheplapharm, Abilify® (aripiprazole) by Otsuka America Pharmaceutical Inc., Abilify Maintena® (the LAI formulation of Abilify®) by Lundbeck/Otsuka America Pharmaceutical Inc., Geodon® (ziprasidone) by Viatris, Inc., Saphris® (asenapine) by Allergan, Latuda® (lurasidone) by Sunovion Pharmaceuticals Inc., Rexulti® (brexpiprazole) by Lundbeck/Otsuka America Pharmaceutical, Inc., Aristada® (aripiprazole lauroxil) extended-release injectable suspension by Alkermes, plc, Vraylar® (cariprazine) by AbbVie Inc., Perseris® (risperidone) extended-release injectable suspension by Indivior plc, Caplyta® (lumapteperone) by Intra-Cellular Therapies, Inc., Lybalvi® (olanzapine and samidorphan) by Alkermes, plc, and generic clozapine and quetiapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic).
- For PONVORY® in the treatment of RMS, the competitors include Avonex® (interferon beta-1a), Tysabri® (natalizumab) and Plegridy® (peginterferon beta-1a), all by Biogen Inc., Vumerity® (diroximel fumerate) by Biogen Inc./Alkermes, plc, Betaseron® (interferon beta-1b) by Bayer Healthcare Pharmaceuticals Inc., Rebif® (interferon beta-1a) and Mavenclad® (cladribine), both by Merck KGaA, Extavia® (interferon beta-1b) and Mayzent® (siponimod), both by Novartis AG, Lemtrada® (alemtuzumab) by Sanofi, Ocrevus® (ocrelizumab) by Roche Holding AG/Biogen Inc., Zeposia® (ozanimod) by BMS, Briumvi® (ubiltuximab) by TG Therapeutics, Inc., Kesimpta® (ofatumumab) by Novartis, Tyruko® (natalizumab) by Sandoz Group AG and generic dimethyl fumarate, fingolimod, glatiramer acetate and teriflunomide.

Our ability to compete successfully will depend in part on our ability to utilize our pharmacogenetics and pharmacogenomics and drug development expertise to identify, develop, secure rights to and obtain regulatory approvals for promising pharmaceutical products before others are able to develop competitive products. Our ability to compete successfully will also depend on our ability to attract and retain skilled and experienced personnel. Additionally, our ability to compete may be affected because insurers and other third-party payors in some cases seek to encourage the use of cheaper, generic products, which could make our products less attractive.

Manufacturing

We currently utilize a virtual supply manufacturing and distribution chain, meaning that we do not have our own facilities to manufacture commercial or clinical trial supplies of drugs, and we do not have our own distribution facilities. Instead, we contract with third parties to source critical raw materials and for the manufacture, warehousing, order management, billing and collection and distribution of our products and product candidates.

We expect to continue to rely solely on third-party manufacturers to manufacture drug substance and final drug products for both clinical development and commercial sale. However, there are numerous factors that could cause interruptions in the supply of our products, including regulatory reviews, changes in our sources for manufacturing, disputes with a

manufacturer, or financial instability of manufacturers, all of which could negatively impact our operation and our financial results.

We have agreements in place with Patheon Pharmaceuticals Inc. and Patheon Inc. (collectively, Patheon), subsidiaries of Thermo Fisher Scientific, for the manufacture of HETLIOZ® capsules and Fanapt® oral tablets.

In January 2014, we entered into a manufacturing agreement with Patheon for the manufacture of commercial supplies of HETLIOZ® 20 mg capsules at Patheon's Cincinnati, Ohio manufacturing site. Under the HETLIOZ® manufacturing agreement, we are responsible for supplying the active pharmaceutical ingredient (tasimelteon) for HETLIOZ® to Patheon and have agreed to order from Patheon at least 80% of the total expected yearly production of new units of HETLIOZ® capsules. Patheon is responsible for manufacturing the HETLIOZ® 20 mg capsules, conducting quality control and stability testing, and packaging the HETLIOZ® capsules. The HETLIOZ® manufacturing agreement had an initial term of five years and automatically renews after the initial term for successive terms of one year each, unless either party gives notice of its intention to terminate the agreement at least 12 months prior to the end of the then current term. Either party may terminate the HETLIOZ® manufacturing agreement under certain circumstances upon specified written notice to the other party.

As part of a settlement agreement in 2014, we assumed Novartis' manufacturing agreement with Patheon for the manufacture of commercial supplies of Fanapt®. In May 2016, we entered into a new manufacturing agreement with Patheon for the manufacture of commercial supplies of Fanapt® 1, 2, 4, 6, 8, 10 and 12 mg tablets at Patheon's Mississauga, Ontario, Canada manufacturing site. Under the Fanapt® manufacturing agreement, we are responsible for sourcing the supply of the active pharmaceutical ingredient (iloperidone), and have agreed to order from Patheon at least 70% of the total expected yearly production of new units of Fanapt® tablets for the U.S. and other specified countries each year for the term of the agreement. Patheon is responsible for manufacturing the Fanapt® 1, 2, 4, 6, 8, 10 and 12 mg tablets, conducting quality control and stability testing, and packaging the Fanapt® tablets. The Fanapt® manufacturing agreement had an initial term of five years and automatically renews after the initial term for successive terms of one year each, unless either party gives notice of its intention to terminate the agreement at least 12 months prior to the end of the then current term. Either party may terminate the Fanapt® manufacturing agreement under certain circumstances upon specified written notice to the other party.

In December 2020, we entered into a non-exclusive manufacturing agreement for the manufacture of commercial supplies of both 48 mL and 158 mL HETLIOZ LQ® bottles. The HETLIOZ LQ® manufacturing agreement has an initial term of five years and automatically renews after the initial term for successive terms of one year each, unless either party gives notice of its intention to terminate the agreement at least 12 months prior to the end of the then current term.

PONVORY® is manufactured by third parties and supplied to Jannsen, which is currently distributing PONVORY® pursuant to the terms of a transition agreement. During the transition period, Vanda and Janssen will transition supply responsibility for PONVORY® to us.

Government Regulation

Government authorities in the U.S. at the federal, state and local levels and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, marketing and export and import of pharmaceutical products. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the U.S. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign laws and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market. Any judicial, administrative or other governmental enforcement action could have a material adverse effect on our business.

U.S. government regulation

U.S. drug development and regulation

In the U.S., the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act (FDCA) and related regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning

letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our business.

Once a drug candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND application sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the first phase of clinical trials, the parameters to be used in monitoring the safety of the trial, and the effectiveness criteria to be evaluated should the first phase lend itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with FDA good clinical practice (GCP) requirements, which include a requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and/or effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An Institutional Review Board (IRB) at each institution participating in the clinical trial must review and approve each protocol before a clinical trial may commence at the institution and must also approve the information regarding the trial as well as the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with all applicable IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined in certain cases:

- Phase I: The compound is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness. In most cases, initial Phase I clinical trials are conducted with healthy volunteers. However, where the compound being evaluated is for the treatment of severe or life-threatening diseases, such as cancer, and especially when the product may be too toxic to ethically administer to healthy volunteers, the initial human testing may be conducted on patients with the target disease or condition. Sponsors sometimes subdivide their Phase I clinical trials into Phase Ia and Phase Ib clinical trials. Phase Ib clinical trials are typically aimed at confirming dosage, pharmacokinetics and safety in a larger number of patients. Some Phase Ib studies evaluate biomarkers or surrogate markers that may be associated with efficacy in patients with specific types of diseases or conditions.
- Phase II: This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to confirm dosage tolerance and appropriate dosage.
- Phase III: Phase III clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population, generally at geographically dispersed clinical study sites. These clinical trials, often referred to as “pivotal” clinical trials, are intended to establish the overall risk-benefit ratio of the compound and provide, if appropriate, an adequate basis for product labeling.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including any finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug has been associated with unexpected, serious harm to study subjects. In addition, clinical trials may be overseen by a DSMB, an independent group of qualified experts organized by the sponsor. Depending on its charter, the DSMB may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

Post-approval trials may also be conducted after a drug receives initial marketing approval. These trials, often referred to as “Phase IV” trials, are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of such clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given several opportunities to meet with the FDA. These meetings can provide an opportunity for the sponsor to share information about the progress of the application or clinical trials, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. These meetings may occur prior to the submission of an IND, at the end of Phase II clinical trials, or before an NDA is ultimately submitted. Sponsors typically use the meetings at the end of the Phase II trials to discuss Phase II clinical results and present plans for the pivotal Phase III clinical trials that they believe will support approval of the new drug. Meetings at other times may be made upon request.

Concurrent with clinical trials, companies typically complete additional, animal or other non-clinical studies, develop additional information about the chemistry and physical characteristics of the drug, and finalize a process for manufacturing the product in commercial quantities in accordance with the FDA's current Good Manufacturing Practices (cGMP) requirements. The manufacturing process must consistently produce quality batches of the drug and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life.

While the IND is active, progress reports summarizing the results of ongoing clinical trials and nonclinical studies performed since the last progress report must be submitted on at least an annual basis to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important, increased incidence of a serious adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the submission of certain clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial registration and results information, which is made publicly available at www.clinicaltrials.gov. Failure to properly report clinical trial results can result in civil monetary penalties. Disclosure of clinical trial results can often be delayed until the new product or new indication being studied has been approved.

U.S. review and approval process

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of which may be obtained under certain limited circumstances.

The FDA reviews NDAs to determine, among other things, whether the product is safe and effective for its intended use and whether it is manufactured in a cGMP-compliant manner, which will assure and preserve the product's identity, strength, quality and purity. Under Prescription Drug User Fee Act Amendments of 2022, the FDA has a goal of 10 months from the date of "filing" of a standard, completed NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to the FDA because the FDA has 60 days to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may refer an application for a new drug to an advisory committee within the FDA. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether and under what conditions the application should be approved. The FDA is not bound by the recommendations of such an advisory committee, but it considers advisory committee recommendations carefully when making decisions.

Before approving an NDA, the FDA will also inspect the facility where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Before approving an NDA, the FDA may also inspect one or more clinical trial sites to assure compliance with GCP requirements.

After the FDA evaluates an NDA, it will issue an approval letter or a CRL. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase III trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications.

The Pediatric Research Equity Act (PREA) requires IND sponsors to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under the PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or the FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

If a drug receives FDA approval, the approval may be limited to specific diseases and dosages, which could restrict the commercial value of the product. In addition, the FDA may require testing and surveillance programs to monitor the safety of approved products that have been commercialized, and may require a sponsor to conduct post-marketing clinical trials, which are designed to further assess a drug's safety and effectiveness after NDA approval. The FDA may also place other conditions on approval, including a requirement for a risk evaluation and mitigation strategy (REMS) to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescribing or dispensing of products. Marketing approval may be withdrawn for non-compliance with REMS or other regulatory requirements, or if problems occur following initial marketing.

Post-approval requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. After approval, some types of changes to the approved drug, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations.

Our approved products are, and any additional product manufactured or distributed by us following FDA approval will be, subject to continuing regulation by the FDA, including, among other things, recordkeeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information regarding approved drugs that are placed on the market, and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product for a certain indication or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable governmental requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds on post-marketing clinical trials, enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or

communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties, any of which could have a material adverse effect on our business.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, generally a disease or condition that affects fewer than 200,000 individuals in the U.S or, if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that sales of the drug will be sufficient to offset the cost of developing and making the drug available in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and development expenses and a waiver of the NDA application user fee.

Expedited development and review programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

A product is eligible for priority review if it is intended to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to currently marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date, as compared to 10 months for review of NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drugs intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Drugs receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing trials or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, Congress is considering various proposals to potentially make changes to the accelerated approval pathway, including proposals to increase the likelihood of withdrawal of approval in such circumstances.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as “breakthrough therapies” that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA

designation of a compound as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as a breakthrough therapy, the FDA will work to expedite the development and review of such drug.
Fast track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. However, even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Marketing exclusivity

The FDA provides periods of regulatory exclusivity, which provide the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. Five years of exclusivity are available to NCEs. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound), or clathrate (i.e., a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if it includes a certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid. If a product is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA, including a 505(b)(2) NDA, for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence trials, was essential to the approval of the application and was conducted or sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Pediatric exclusivity is another type of marketing exclusivity available in the U.S. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug designation, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Orange Book listing, the Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Orange Book. Drugs listed in the Orange Book can, in turn be cited by potential competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved drug in the Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new drug. A certification that the new drug will not infringe the already approved drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If the

applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced drug have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of an NCE, listed in the Orange Book for the referenced drug has expired. The U.S. Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act," provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original drug approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which FDA cannot grant effective approval of an ANDA based on that listed drug.

Fraud and abuse laws and other U.S. regulatory matters

Pharmaceutical companies are subject to broadly applicable fraud and abuse and other healthcare laws and regulations, in addition to the FDCA, that may constrain the business or financial arrangements and relationships through which these companies market, sell and distribute the products for which they obtain marketing approval. Some of the laws and regulations that may affect the ability of pharmaceutical companies to operate are described below.

Anti-kickback laws

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease, or order of any health care item or service reimbursable under federal healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, patients, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. Violations of the Anti-Kickback Statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs, such as Medicare and Medicaid. A number of states also have anti-kickback laws that establish similar prohibitions that may apply to items or services reimbursed by government programs, as well as any third-party payors, including commercial payors, known as "all-payor" laws.

Prescription Drug Marketing Act

As part of the sales and marketing process, pharmaceutical companies frequently provide healthcare providers with samples of approved drugs. The Prescription Drug Marketing Act (PDMA) imposes requirements and limitations upon the distribution of drugs and drug samples, and prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage and handling, as well as recordkeeping and other requirements. Violations of the PDMA may result in criminal and civil penalties. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act or ACA), discussed in more detail in *Pharmaceutical Coverage, Pricing and Reimbursement and Healthcare Reform* below, imposes annual reporting requirements related to sample distribution.

False Claims Act

The False Claims Act prohibits, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds and knowingly making, or causing to be made or used, a false record or statement to get a false claim paid. Certain marketing practices may implicate the False Claims Act, including promotion of pharmaceutical products for unapproved uses, providing free product to customers with the expectation that customers would bill federal programs for the product, or inflating prices reported to private price publication services used to set drug reimbursement rates under federal healthcare programs. In addition, the ACA amended the Social Security Act to provide that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false claim for purposes of the False Claims Act. Actions under the False Claims Act may be brought by the government or as a qui tam action by private individuals who may receive financial awards if their claims are successful. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and monetary penalties of $5,500 to $11,000 per false claim or statement, adjusted for inflation as applicable, with respect to violations occurring after November 2, 2015. Violations of the False Claims Act are also punishable by exclusion from participation in federal healthcare programs, such as Medicare and Medicaid. Pharmaceutical and other life sciences companies often resolve allegations without admissions of liability for significant and sometimes material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation. These companies may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance.

Health Insurance Portability and Accountability Act of 1996

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), includes federal criminal statutory provisions that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and 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 healthcare benefits, items or services.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, impose certain requirements and restrictions on certain types of entities relating to the privacy and security of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable not only to covered entities (e.g., health care providers and health plans), but also to business associates (i.e., independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity). HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Physician Payment Sunshine Act

The Physician Payment Sunshine Act requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually (with certain exceptions) to Centers for Medicare & Medicaid Services (CMS) information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other *"*transfers of value*"* to such physician or teaching hospitals. Failure to report relevant data may result in civil fines and/or penalties.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (FCPA), prohibits U.S. corporations and their representatives and intermediaries from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Violation of the FCPA could result in substantial civil and criminal penalties and remedies, including fines, disgorgement, and/or imprisonment.

Analogous state laws

Analogous state fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to the business practices of pharmaceutical companies, including but not limited to research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors and are generally broad and are enforced by many different federal and state agencies as well as through private actions. In addition to requiring reporting transfers of value, some states have imposed price reporting requirements. These state laws apply to items

and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, a number of states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states restrict when pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities or require pharmaceutical companies to implement compliance programs or marketing codes of conduct, and file periodic reports or disclosures with states. Compliance with these laws requires significant resources and companies that do not comply may face civil penalties or other consequences.

Many state laws govern the privacy and security of personal information in specified circumstances. For example, the California Consumer Privacy Act (CCPA), which became effective on January 1, 2020, established a new legal framework governing covered businesses' collection and use of personal information of California residents by, among other things, creating an expanded definition of covered personal information, establishing new privacy rights for California residents, imposing an opt-in standard for certain disclosures of personal information about minors, and creating a new and potentially severe statutory damages framework for businesses subject to certain data breaches resulting from the failure to implement and maintain reasonable security procedures and practices. While properly collected clinical trial data and all protected health information governed by HIPAA are exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope.

Foreign regulation

Foreign drug development, review and approval processes

Regardless of whether a sponsor obtains FDA approval for a product, it must obtain approval 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 to country, 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 vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the U.S. typically are administered with the three-Phase sequential process that is discussed above under *U.S. drug development and regulation*. However, the foreign equivalent of an IND is not a prerequisite to performing pilot studies or Phase I clinical trials.

Under E.U. regulatory systems, a sponsor may submit Marketing Authorization Applications either under a centralized or decentralized procedure. The centralized procedure, which is available for drugs produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all E.U. member states. This authorization is a marketing authorization approval. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure. In addition, regulatory approval of prices is required in most countries other than the U.S. Companies face the risk that the resulting prices would be insufficient to generate an acceptable return.

Foreign fraud and abuse laws and other regulatory matters

Outside the U.S., companies are subject to similar regulations in those countries where we market and sell products, including with respect to transparency, bribery and other laws mentioned above. In some foreign countries, including major markets in the E.U. and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies, which can be costly and time-consuming.

The collection and processing of personal data in the E.U. is governed by the General Data Protection Regulation (GDPR), which became applicable in May 2018. The GDPR applies to personal data processing carried out by a controller or processor (i) located within the E.U. or (ii) targeting E.U. individuals regardless of controller or processor's location. The GDPR implements stringent operational requirements for controllers and processors of personal data, including, for example, transparent information for the data subjects regarding the processing of their personal data, appropriate legal basis for processing personal data that may require to obtain the valid consent of the data subjects where applicable, expanded individual data subject rights, limitations on retention of personal data, increased requirements pertaining to data security and confidentiality, shortened mandatory data breach notification with the competent supervisory authority and higher standards for controllers and processors to demonstrate their compliance with the GDPR by documenting it. The GDPR provides that E.U.

Member States may supplement the GDPR with their own additional laws and regulations in relation to the personal data processing, in particular regarding sensitive personal data (e.g., genetic, biometric or health data), which could result in differences between E.U. Member States, limit our ability to collect, use and share such personal data or cause our costs to increase, and harm our reputation, business and financial condition. Further, the U.K.'s exit from the E.U., often referred to as Brexit, has created uncertainty with regard to applicable data protection regulation in the U.K. While the transition period has now concluded, decisions are still to be made on how to adapt the U.K. data protection provisions further to Brexit. We are also subject to evolving and strict rules on the transfer of personal data out of the E.U., in particular to the U.S. Failure to comply with the GDPR results in fines of up to the higher of €20,000,000 or 4% of total worldwide annual revenue of the preceding financial year, and other administrative penalties.

Pharmaceutical Coverage, Pricing and Reimbursement and Healthcare Reform

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the U.S. such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a drug product does not imply that the reimbursement rate ultimately paid will be adequate. Third party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last several years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the U.S. By way of example, the ACA was passed in 2010 and made significant changes to the coverage and payment for products under government health care programs. Among the provisions of the ACA of importance to pharmaceutical companies are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program (MDRP) by increasing the minimum rebate for both branded and generic drugs and extending rebate liability to prescriptions for individuals enrolled in Medicaid managed care plans;
- introduced a new methodology for the reporting of average manufacturer price by manufacturers under the MDRP for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- added a requirement to annually report product samples that manufacturers and distributors provide to physicians;

- expanded healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, and enhanced penalties for noncompliance; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. In June 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, included aggregate reductions of Medicare payments to providers that started in 2013 and will stay in effect through 2031 unless additional congressional action is taken. More recently, in March 2021, President Biden signed into law the American Rescue Plan Act of 2021, which eliminated the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Additionally, in December 2020, CMS issued a final rule that materially modifies current MDRP regulations by, among other things, broadening the definitions of what constitutes a "line extension." A "line extension" drug may be subject to a higher Medicaid rebate, and broadening this definition is likely to subject a greater number of drugs to the higher rebate. These new definitions became effective on January 1, 2022.

Most significantly, in August 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (beginning October 1, 2022); and replaces the Medicare Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On March 15, 2023 and June 30, 2023, HHS issued guidance regarding implementation of the Medicare drug price negotiation program in initial price applicability year 2026. HHS stated it would provide additional information in the future related to implementation for initial price applicability years 2027 and beyond. Several manufacturers and industry groups have challenged the drug price negotiation program for Medicare Parts B and D in federal court. These lawsuits are ongoing, and additional lawsuits may be filed in the future related to provisions of the IRA. It is unknown whether such litigation or other litigation, if brought, will be successful. For these and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

The cost of prescription pharmaceuticals in the U.S. is likely to remain the subject of considerable discussion. There have been several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. The likelihood of implementation of these and other reform initiatives is uncertain. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures. Some measures encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. The IRA, as well as other federal, state and foreign healthcare reform measures that have been and may be adopted in the future, could have a material adverse effect on our business.

These healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies

and additional downward pressure on the price for any approved product and/or the level of reimbursement physicians receive for administering any approved product. Reductions in reimbursement levels may negatively impact the prices we can charge or the frequency with which products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Similarly, pricing and reimbursement and the containment of healthcare costs has become a priority in a number of foreign jurisdictions. In the E.U., pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies, or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the E.U. provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. E.U. member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not provide favorable reimbursement and pricing arrangements.

See the risk factor entitled "*If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects*" in Part I, Item 1A of this Annual Report for additional information regarding our participation in federal healthcare programs and related compliance obligations.

Human Capital

We had 203 full-time employees as of December 31, 2023, compared with 290 employees as of December 31, 2022. None of our employees are represented by a labor union. We have not experienced any work stoppages and consider our employee relations to be good. Our human capital objectives include attracting, training and retaining employees in a manner that supports innovation across our business.

Corporate Information

We were incorporated in Delaware in 2002. Our principal executive offices are located at 2200 Pennsylvania Avenue NW, Suite 300E, Washington, D.C. 20037, and our telephone number is (202) 734-3400. Our website address is www.vandapharma.com, and the information contained in, or that can be accessed through, our website is not incorporated by reference in this Annual Report and should not be considered a part of this Annual Report.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission (SEC) under the Securities Exchange Act of 1934 (Exchange Act). The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC.

We also make available free of charge on our Internet website at www.vandapharma.com our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Our code of business conduct and ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee and Nominating/Corporate Governance Committee are available at our corporate website at www.vandapharma.com. To access these documents from the main page of our website, click on "Investor" at the top of the page, then click on "Learn More" under "Corporate Governance" and then click on the desired document. We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding amendments to, or waivers from, provisions of our code of business conduct and ethics by posting such information on the website address and location specified above.

None of the information contained on our website or www.sec.gov is incorporated by reference into this Annual Report or any other report or document filed with the SEC unless expressly stated otherwise therein.

ITEM 1A. RISK FACTORS

Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding any statement in this annual report on Form 10-K (Annual Report) or elsewhere. The following information should be read in conjunction with the consolidated financial statements and related notes in Part II, Item 8, Financial Statements and Supplementary Data and Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations.

Because of the following risk factors, as well as other risk factors affecting our financial condition and operating results, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

Risks Related to our Business and Industry

We are dependent on the commercial success of HETLIOZ®, Fanapt® and PONVORY®. In the U.S., HETLIOZ® competes with generic versions of HETLIOZ® and we could experience increased generic competition in the near term.

We are substantially dependent upon the commercial success of HETLIOZ® capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), HETLIOZ® capsules and oral suspension (HETLIOZ LQ®) for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS), Fanapt® oral tablets for the treatment of schizophrenia and PONVORY® oral tablets for the treatment of relapsing forms of multiple sclerosis (RMS) in adults.

In January 2014, the U.S. Food and Drug Administration (FDA) approved our New Drug Application (NDA) for HETLIOZ® for the treatment of Non-24 and in April 2014, we commenced the U.S. commercial launch of HETLIOZ®. In July 2015, the European Commission (EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults, and in August 2016 we commenced the commercial launch of HETLIOZ® in Germany. This authorization, which was renewed in July 2020 for an unlimited duration, is valid in the 27 countries that are members of the European Union (E.U.), as well as European Economic Area members Iceland, Liechtenstein and Norway. In December 2020, the FDA approved our NDA and supplemental New Drug Application (sNDA) for HETLIOZ® for the treatment of nighttime sleep disturbances in SMS in adults and children, respectively. HETLIOZ® capsules, for adults with SMS, were immediately available after approval and the HETLIOZ LQ® liquid formulation, for children with SMS, became available in March 2021.

In December 2022, the U.S. District Court for the District of Delaware (Delaware District Court) ruled in favor of certain generic drug companies in our patent litigation alleging that the companies' generic versions of HETLIOZ® capsules, for which they were seeking FDA approval, infringed our patents covering HETLIOZ®. We appealed the decision to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). In May 2023, a three-judge panel of the Federal Circuit affirmed the Delaware District Court's ruling. In August 2023, the Federal Circuit denied our request for a rehearing. In January 2024, we filed a petition for a writ of certiorari with the U.S Supreme Court to review the Federal Circuit's decision. The FDA has approved Abbreviated New Drug Applications (ANDA) for generic versions of HETLIOZ® for Teva Pharmaceuticals USA, Inc. (Teva), Apotex Inc. (Apotex) and MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN). Teva and Apotex have launched their generic versions of HETLIOZ® at risk in the U.S., and MSN has launched its generic version as well. HETLIOZ® could face even more competition from other generic companies in the U.S. in the near term in light of the patent litigation rulings against us. Sales of generic versions of HETLIOZ® have resulted in and could continue to result in a reduction in the demand for HETLIOZ® and/or the price at which we can sell it and/or create volatility in net product sales in future periods, which would have a material and adverse impact on our revenues and results of operations. Unless and until we are able to successfully enforce our legal rights to exclusivity, we may reduce the amount we spend with the intention of retaining the capability to ramp-up promptly. Our expansion and development of HETLIOZ® outside the U.S. is generally not subject to the adverse patent ruling in the U.S.

In the fourth quarter of 2014, we acquired the U.S. commercial rights to Fanapt®, and began selling, marketing and distributing Fanapt® in the U.S. In December 2023, we acquired the U.S. and Canadian rights to PONVORY® from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company. Janssen is responsible for the continued marketing and sale of PONVORY® during a transition period until the regulatory and supply responsibilities for PONVORY® are transitioned to us.

Our ability to generate significant product revenue from sales of HETLIOZ®, Fanapt® and PONVORY® both in the U.S. and abroad, in the near term will depend on, among other things, our ability to:

- defend our patents and intellectual property from generic competition;
- properly price and obtain adequate coverage and reimbursement of these products by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- gain broad acceptance of our products from physicians, health care payors, patients, pharmacists and the medical community;
- minimize the impact of disruptions caused by public health crises;
- maintain commercial manufacturing arrangements with third-party manufacturers;
- produce, through a validated process, sufficiently large quantities of inventory of our products to meet demand;
- continue to maintain and grow a wide variety of internal sales, distribution and marketing capabilities sufficient to sustain sales trajectories of our products;
- maintain compliance with ongoing labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements;
- obtain regulatory approval to expand the labeling of our approved products for additional indications;
- obtain regulatory approval for HETLIOZ® or Fanapt® in additional countries;
- maintain our existing regulatory approval for HETLIOZ® in Europe and PONVORY® in Canada;
- adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe their rights; and
- adequately protect against and effectively respond to any unanticipated adverse effects or unfavorable publicity that develops in respect to our products, as well as the emergence of new or existing competitive products, which may be proven to be more clinically effective and cost-effective.

We expect to continue to incur significant expenses and to utilize a substantial portion of our cash resources as we continue the commercialization of HETLIOZ® and Fanapt® and commence commercial operations for PONVORY®, evaluate foreign market opportunities for HETLIOZ® and Fanapt® and continue to grow our operational capabilities, both domestically and abroad. This activity represents a significant investment in the commercial success of HETLIOZ®, Fanapt® and PONVORY®, which is uncertain.

If our continued commercial efforts are not successful with respect to HETLIOZ®, Fanapt® and PONVORY® in the U.S., Europe, Canada or other jurisdictions in which these products may be approved for sale, our ability to generate increased product sales revenue may be adversely affected.

The cost of growing and maintaining a sales, marketing and distribution organization may exceed its cost effectiveness. If we fail to continue to develop sales, marketing and distribution capabilities, if sales efforts are not effective or if costs of developing sales, marketing and distribution capabilities exceed their cost effectiveness, our business, results of operations and financial condition could be materially adversely affected.

As a result of the decision in favor of generic drug companies in connection with our HETLIOZ® patent litigation, we have faced generic competition in the near term and our revenues and results of operations could be further affected by the launch of additional generic versions of HETLIOZ® in the U.S.

Between April 2018 and March 2021, we filed numerous Hatch-Waxman lawsuits in the Delaware District Court against Teva, MSN and Apotex asserting that our patents would be infringed by their generic versions of HETLIOZ®. In January 2022, we entered into a license agreement with MSN and Impax Laboratories LLC (Impax), resolving the lawsuits against MSN. A trial was held in March 2022 in the Delaware District Court to resolve the consolidated lawsuits against the remaining companies (the Defendants).

In December 2022, following conclusion of the trial, the Delaware District Court issued its ruling in favor of the Defendants, finding that the Defendants' use of a generic HETLIOZ®, for which they were seeking FDA approval, did not infringe one of our HETLIOZ® patents and the asserted claims of certain of our other HETLIOZ® patents were invalid. We appealed the decision to the Federal Circuit and in May 2023, a three-judge panel of the Federal Circuit affirmed the Delaware District Court's ruling. In August 2023, the Federal Circuit denied our request for a rehearing. In January 2024, we filed a petition for a writ of certiorari with the U.S. Supreme Court to review the Federal Circuit's decision. Teva and Apotex have since launched their generic versions at risk and MSN has launched its generic version as well. The commercial launch of the generic versions, and potential increased competition from additional generic entrants in the near term, have resulted in and could continue to have a material and adverse impact on our revenues and our results of operations.

Further, although we are pursuing additional remedies in other courts, including seeking injunctions against Apotex and Teva, we may not be successful in any such efforts, which will be costly and time-consuming to pursue. Such efforts will also require considerable attention of management and could, even if ultimately successful, negatively impact our results of operations. See Note 17, *Legal Matters,* to the consolidated financial statements in Part II, Item 8 of this Annual Report and the risk factor entitled "*We are, have been, and may continue to be, involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful*," each of which is incorporated herein by reference, for additional information.

In addition, while we believe that HETLIOZ® is difficult to manufacture and that building capacity to manufacture HETLIOZ® is time-consuming and expensive, which may limit the amount of tasimelteon supply available to generic companies, we do not have direct visibility into the supply levels of any of the generic companies and we rely on our own experience together with information from third parties, which information may not be reliable. The generic companies could potentially find or develop sources of qualified HETLIOZ® supply that are not known to us and that are more efficient or inexpensive than our sources. Furthermore, generic companies could potentially convince our suppliers or third-party manufacturers to prioritize supply to the generic companies ahead of any applicable contractual commitments to supply us. Such circumstances could have a material and adverse impact on our revenues and results of operations directly in the U.S. and potentially outside of the U.S. as well if supply costs and availability are affected.

Future performance of HETLIOZ®, Fanapt® and PONVORY® may be impacted by a number of factors including competing products or unanticipated safety issues. If HETLIOZ®, Fanapt® or PONVORY® is not successful in gaining broad commercial acceptance, our business would be harmed.

Future performance of HETLIOZ®, Fanapt® and PONVORY® sales will be dependent on several factors, including our ability to educate physicians and to increase physician awareness of the benefits of our products relative to competing products. The degree of further market acceptance of any of our products, including with respect to new indications, or market acceptance of approved product candidates among physicians, patients, health care payors and the medical community will depend on a number of factors, including but not limited to:

- the impact and outcome of our pending patent litigation and appeals efforts;
- the commercialization and pricing of any generic version of HETLIOZ® on the market;
- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- market awareness of the condition to be treated; and
- pricing and cost effectiveness.

In addition, HETLIOZ®, Fanapt® and PONVORY® are subject to continual review by the FDA, and we cannot assure that newly discovered or reported safety issues will not arise. With the use of any newly marketed drug by a wider patient population, serious adverse events may occur from time to time that initially do not appear to relate to the drug itself. Any safety issues could cause us to suspend or cease marketing of our approved products, cause us to modify how we market our approved products, subject us to substantial liabilities and adversely affect our revenues and financial condition. In the event of a withdrawal of HETLIOZ®, Fanapt® or PONVORY® from the market, our revenues would decline significantly and our business would be seriously harmed.

With the launch of generic versions of HETLIOZ® and further generic versions possible, it may not be viable for us to invest in market education to grow the U.S. market and our ability to maintain current promotional efforts and attract favorable commercial terms in several aspects of our business will likely be adversely affected as we face increased generic competition.

We are subject to uncertainty relating to pricing and reimbursement policies in the U.S., including recent and future health reform measures, which, if not favorable for our products, could hinder or prevent our products' commercial success.

Our ability to commercialize our products successfully depends in part on the coverage and reimbursement levels with governmental authorities, private health insurers and other third-party payors. In determining whether to reimburse our products and at what level, third-party payors consider factors that include the efficacy, cost effectiveness and safety of our products, as well as the availability of other treatments including generic prescription drugs and over-the-counter alternatives. We expect to continue to face pressure to make unfavorable pricing modifications, such as discounts or rebates. Negotiating favorable reimbursement can be a time consuming and expensive process, and there is no guarantee that we will be able to reach pricing terms with third-party payors at levels that are profitable to us. Certain third-party payors also have reimbursement or coverage processes that we believe are difficult to navigate and require prior authorization for, or even refuse to provide, reimbursement for our products, and others may do so in the future. Our business may be materially adversely affected if our patients are not able to receive approval for reimbursement of our products from third-party payors on a broad, timely or satisfactory basis; if reimbursement is subject to difficult reimbursement or coverage processes or prior authorization requirements; or if reimbursement is not maintained at satisfactory levels. In addition, our business could be adversely affected if third-party payors limit or reduce the indications for, or conditions under which, or the patient populations for whom, our products may be reimbursed. Moreover, as discussed further below and above in Part I, Item 1 under the heading *Pharmaceutical Coverage, Pricing and Reimbursement and Healthcare Reform*, changes in insurance coverage or reimbursement levels by third-party payors, or in the type of such coverage held by patients may materially harm our business and commercialization efforts.

We expect to experience pricing pressures in connection with the sale of our current and future products due to the healthcare reforms discussed below and above in Part I, Item 1 under the heading *Pharmaceutical Coverage, Pricing and Reimbursement and Healthcare Reform*, as well as the trend toward initiatives aimed at reducing healthcare costs, the increasing influence of managed care, the scrutiny of pharmaceutical pricing, the ongoing debates on reducing government spending and additional legislative proposals. There has been significant scrutiny of pharmaceutical pricing and the resulting costs of pharmaceutical products that could cause significant operational and reimbursement changes for the pharmaceutical industry. There have been a number of federal and state efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices, price increases or other related costs.

Most significantly, in August 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (beginning October 1, 2022); and replaces the Medicare Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On March 15, 2023 and June 30, 2023, HHS issued guidance regarding implementation of the Medicare drug price negotiation program in initial price applicability year 2026. HHS stated it would provide additional information in the future related to implementation for initial price applicability years 2027 and beyond. Several manufacturers and industry groups have challenged the drug price negotiation program for Medicare Parts B and D in federal court. These lawsuits are ongoing, and additional lawsuits may be filed in the future related to provisions of the IRA. It is unknown whether such litigation or other litigation, if brought, will be successful. For these and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Healthcare reform efforts or any future legislation or regulatory actions aimed at controlling and reducing healthcare costs, including through measures designed to limit reimbursement, restrict access or impose unfavorable pricing modifications

on pharmaceutical products, could impact our ability to obtain or maintain reimbursement for our products at satisfactory levels, or at all, which could materially harm our business and financial results.

We have encountered third-party payors that refuse to cover or reimburse prescriptions written for HETLIOZ® and patients who are unable to navigate the coverage or reimbursement processes established by these third-party payors. If this trend continues, the commercial success of HETLIOZ® may be limited, and our business and results of operations may be materially harmed.

We have encountered third-party payors that refuse to cover or reimburse prescriptions written for HETLIOZ®. This rate may increase further as a result of the recent entry into the market of generic versions of HETLIOZ®. Additionally, we are aware of patients who are experiencing difficulties navigating coverage processes established by third-party payors, making it difficult for them to fill a prescription for HETLIOZ®. The revenue that we receive from HETLIOZ® is significantly less than it would be if third-party payors were to remove or lessen these reimbursement challenges and hurdles and approve a greater percentage of the prescriptions written for HETLIOZ®. Our business may be materially adversely affected if this trend continues and large numbers of patients cannot fill their HETLIOZ® prescriptions due to coverage or reimbursement challenges.

If the FDA does not approve our tradipitant NDA filing for the use of tradipitant for patients with gastroparesis or accept our sNDA filing for the use of tradipitant for patients with motion sickness; or if the FDA determines that our clinical trial results for tradipitant for the treatment of gastroparesis or for the treatment of motion sickness do not demonstrate adequate safety and substantial evidence of efficacy, continued development of tradipitant will be significantly delayed or terminated, our business will be significantly harmed, and the market price of our stock could decline.

In February 2022, we announced results from our Phase III clinical study, VP-VLY-686-3301, evaluating the efficacy and safety of tradipitant in treating the symptoms of gastroparesis. The study did not meet its prespecified primary endpoint, which was the difference between drug and placebo on the change of the severity of nausea from baseline at week 12 of treatment. Both treatment arms showed significant improvements from baseline on nausea as well as the other core symptoms of gastroparesis. When restricting the analysis in the group of patients that used no rescue medications at baseline and adjusting for poor compliance, we identified strong evidence of a drug effect across a number of symptoms and across the duration of the study, including a significant and meaningful effect at the prespecified primary endpoint of nausea change at week 12. The FDA may not view this data as constituting substantial evidence of efficacy for tradipitant in any indication for the treatment of gastroparesis or its symptoms, for any length of treatment. In May 2023, we announced positive results from the first Phase III study of tradipitant in motion sickness, confirming the previously reported results demonstrating that tradipitant is effective in the prevention of vomiting associated with motion sickness. Our second Phase III study of tradipitant in motion sickness is ongoing. We have also initiated a Phase III clinical study of tradipitant for the treatment of motion sickness. Any adverse developments or results or perceived adverse developments or results with respect to our regulatory submission or the tradipitant clinical programs in any or all indications will significantly harm our business and could cause the market price of our stock to decline. Examples of such adverse developments include, but are not limited to:

- the FDA determining that they believe additional clinical studies are required with respect to tradipitant for the treatment of gastroparesis or for the treatment of motion sickness;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs; or
- the FDA determining that the tradipitant clinical trial programs raise safety concerns or do not demonstrate substantial evidence of efficacy.

We believe that tradipitant has a well-established safety profile, as demonstrated by the results of extensive testing in animals and humans. Despite these results, however, the FDA informed us in December 2018 that in order to treat patients beyond 12 weeks, we would have to conduct a nine-month non-rodent chronic toxicity study. This currently limits our ability to collect safety data in humans for more than 12 weeks. The non-rodent study required by the FDA necessitates the sacrifice of dozens of animals and we have disputed the necessity of a nine-month non-rodent chronic toxicity study. In February 2019, we filed a lawsuit in the U.S. District Court for the District of Columbia (DC District Court) challenging the FDA's position, but we ultimately did not prevail. Despite our disagreement with the FDA, the preclinical package has allowed us to continue to conduct all of the efficacy studies necessary for NDA filing. Moreover, in July 2020, the FDA authorized tradipitant through an expanded access program (EAP) for a single patient. An EAP allows a patient to request the use of tradipitant, prior to NDA approval, for up to six months with an option to request renewal. Since then, certain patients who experienced a benefit in tradipitant studies have requested and received expanded access, while others have been denied treatment under the EAP. The EAP is ongoing and a number of patients have initiated treatment. Although this EAP is not intended for data collection, we collect safety data from this cohort of expanded access patients and included this data in the NDA that we submitted for tradipitant for patients with gastroparesis. In December 2023, the FDA accepted our NDA for tradipitant in gastroparesis for

filing and set a PDUFA target action date of September 18, 2024. If approved, tradipitant will be the first novel drug to be approved by the FDA for the treatment of gastroparesis in over 40 years and tradipitant is the first novel drug to be accepted for review by the FDA for gastroparesis in over 30 years. The FDA may disregard such safety data when reviewing the NDA. The lack of long-term (i.e., more than 12 weeks in humans) safety data would likely impact the FDA's willingness to approve tradipitant for a chronic indication. However, because long-term safety data is not normally a requirement for short-term indications, and with a preclinical profile that has not precluded clinical development, we believe the package was complete for any NDA filing to treat patients for 12 weeks or less. For example, the FDA has communicated to us that it is considering an indication for the short-term relief of nausea in gastroparesis. While this short-term indication is not preferred, we would consider accepting this limited indication while continuing to pursue a chronic indication. However, the FDA may not deem the safety information sufficient even for a short-term indication. Moreover, FDA authorization of an EAP is not a guarantee of or a step in obtaining full FDA approval of an NDA. Our business will be materially adversely impacted if we are not able to agree with the FDA on a regulatory path to approval for tradipitant or the FDA delays or denies approval of NDA or sNDA filings for the treatment of gastroparesis or motion sickness.

Global economic conditions may have an adverse effect on our business.

Financial instability or a general decline in economic conditions in the U.S. and other countries caused by political instability and conflict and economic challenges caused by general health crises such as the COVID-19 pandemic have led to market disruptions, including significant volatility in commodity prices, credit and capital market instability and supply chain interruptions, which have caused record inflation globally and could adversely affect our operations. Increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control and may make any necessary debt or equity financing more difficult, costly and dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, an economic downturn or significant increase in our expenses could require 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 stock price and could require us to delay or abandon clinical development plans.

As discussed in the risk factor entitled "*We are subject to uncertainty relating to pricing and reimbursement policies in the U.S., including recent and future health reform measures, which, if not favorable for our products, could hinder or prevent our products' commercial success*", sales of our products are dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. In the event of economic decline, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may further reduce Medicare and Medicaid reimbursements, and private insurers may further increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue.

In addition, we rely on third parties for several important aspects of our business. For example, we use third parties for sales, distribution, medical affairs and clinical research, and we rely upon several single source providers of raw materials and contract manufacturers for the manufacture of our products. During challenging and uncertain economic times and in tight credit markets, there may be a disruption or delay in the performance of our third-party contractors, suppliers or partners. If such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected.

Global health crises and pandemics may adversely impact our business.

Global health crises and pandemics, such as the COVID-19, could lead to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures that may negatively impact productivity and disrupt our business. Additionally, the COVID-19 pandemic caused global supply chain disruptions that may have lasting impacts and consequences that are difficult to predict.

The COVID-19 pandemic impacted clinical research globally, including delays in our development programs. While our clinical trials have since resumed patient enrollment, we may experience future disruptions as a result of the lasting effects of the COVID-19 pandemic or other health crises that could adversely impact our sales activities, supply chain, our ongoing and planned clinical trials, and other regulatory activities, including:

- curtailment of our sales force or patient access to healthcare providers, which may reduce the number of prescription refills or new patient starts, thereby adversely affecting our revenues;
- interruption of, or delays in receiving, supplies of the active pharmaceutical ingredients that our contract manufacturing organizations use to manufacture our products and any related interruption of, or delays in receiving, supplies of our products from these organizations, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as procedures that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- limitations on our employee resources or those of third-party clinical research organizations towards the development of our products, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays in the operations of regulatory agencies, which may impact review and approval timelines.

If the FDA does not approve our sNDAs for HETLIOZ® for the treatment of jet lag disorder or insomnia, continued development of tasimelteon for the treatment of jet lag disorder and insomnia will be significantly delayed or terminated, our business will be significantly harmed, and the market price of our stock could decline.

In December 2018, we announced that the FDA had accepted the HETLIOZ® sNDA for the treatment of jet lag disorder. We received a complete response letter (CRL) in August 2019 in which the FDA asserted that the measures of the study were of unclear clinical significance and declined to approve our sNDA. We met with the FDA to discuss the CRL in a Post Action meeting and in 2022 we requested the opportunity for a hearing with the FDA on the approvability of the jet lag disorder sNDA. We filed a lawsuit against the FDA in September 2022 demanding that the FDA immediately publish in the Federal Register a notice of opportunity for a hearing on the jet lag disorder sNDA. The FDA then published the notice in the Federal Register in October 2022. We have asked the U.S. District Court for the District of Columbia (DC District Court) to, among other things, compel the FDA to comply with its obligations and declare that its lack of compliance violates the FDCA and the FDA regulations. In January 2024, the DC District Court held an oral argument on dispositive cross-motions, following which the DC District Court granted our motion for summary judgment. The DC District Court ruled that the FDA violated the statute and ordered the FDA to either finally resolve our application or commence a hearing on or before March 5, 2024. Our lawsuit remains pending. We have asked the DC District Court to, among other things, compel the FDA to comply with its obligations and declare that its lack of compliance violates the FDCA and the FDA regulations. In January 2024, the DC District Court held an oral argument on dispositive cross-motions, following which the DC District Court granted our motion for summary judgment. The DC District Court ruled that the FDA violated the statute and ordered the FDA to either finally resolve our application or commence a hearing on or before March 5, 2024. Our lawsuit remains pending.

In July 2023, the FDA accepted our sNDA for HETLIOZ® in insomnia for filing and set a Prescription Drug User Fee Act (PDUFA) target action date of March 4, 2024 for its decision.

Any additional adverse developments or results or perceived adverse developments or results with respect to our regulatory submissions for jet lag disorder or insomnia will significantly harm our business and could cause the market price of our stock to decline. Examples of such adverse developments include, but are not limited to:

- the FDA determining that additional clinical studies are required with respect to the jet lag disorder or insomnia programs;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in the jet lag disorder or insomnia programs, or the manufacturing processes or facilities used for the jet lag disorder program; or
- the FDA determining that the jet lag disorder or insomnia programs raise safety concerns or do not demonstrate substantial evidence of efficacy.

If the FDA does not approve our sNDA for Fanapt® for the treatment of bipolar I disorder, our business will be significantly harmed, and the market price of our stock could decline.

In December 2022, we announced Fanapt® was effective in the treatment of acute manic and mixed episodes associated with bipolar I disorder in adults in a randomized double-blind placebo controlled Phase III study. In August 2023, the FDA accepted our sNDA for Fanapt® in bipolar I disorder in adults for filing and set a PDUFA target action date of April 2, 2024 for its decision.

Any additional adverse developments or results or perceived adverse developments or results with respect to our regulatory submission for bipolar I disorder will significantly harm our business and could cause the market price of our stock to decline. Examples of such adverse developments include, but are not limited to:

- the FDA determining that additional clinical studies are required with respect to the bipolar I disorder program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in the bipolar I disorder program, or the manufacturing processes or facilities used for the bipolar I disorder program; or
- the FDA determining that the bipolar I disorder program raises safety concerns or does not demonstrate substantial evidence of efficacy.

We may enter into third-party collaborations from time to time in order to develop and commercialize our products. If we are unable to identify or enter into an agreement with any material third-party collaborator, if our collaborations with any such third party are not commercially successful or if our agreement with any such third party is terminated or allowed to expire, we could be adversely affected financially or our business reputation could be harmed.

Our business strategy includes entering into collaborations with corporate collaborators for the commercialization of HETLIOZ®, Fanapt® and our other products. While we are not currently party to any material commercial collaborative arrangements, areas in which we may potentially enter into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing in certain E.U. countries and elsewhere outside of the U.S., and future product development arrangements. If we are unable to identify or enter into an agreement with any material third-party collaborator, our business, results of operations or financial condition could be adversely affected. The launch of generic versions of HETLIOZ® and further generic competition may make it more difficult for us to identify or attract third-party collaborators and obtain favorable commercial terms in any such agreement or arrangement. Any arrangements we do enter into may not be scientifically or commercially successful. The termination of any of these arrangements might adversely affect our ability to develop, commercialize and market our products.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations. We expect that the risks we face in connection with these future collaborations will include the following:

- our collaboration agreements are expected to be for fixed terms and subject to termination under various circumstances, including, in many cases, on short notice without cause;
- our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with our products that are the subject of their collaboration with us; and
- our collaborators may change the focus of their commercialization efforts.

In recent years there have been a significant number of mergers and consolidations in the pharmaceutical and biotechnology industries, some of which have resulted in the participant companies reevaluating and shifting the focus of their business following the completion of these transactions. The ability of our products to reach their potential could be limited if any of our future collaborators decreases or fails to increase spending relating to such products.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration with respect to our future collaborations could adversely affect us financially as well as harm our business reputation.

Even after we obtain regulatory approvals of a product, acceptance of the product in the marketplace is uncertain and failure to achieve commercial acceptance will prevent or delay our ability to generate significant revenue from such product.

Even after obtaining regulatory approvals for the sale of our products, the commercial success of these products will depend, among other things, on their acceptance by physicians, patients, third-party payors and other members of the medical

community as therapeutic and cost-effective alternatives to competing products and treatments. The degree of market acceptance of any product will depend on a number of factors, including the demonstration of its safety and efficacy, its cost-effectiveness, its potential advantages over other therapies, the reimbursement policies of government and third-party payors with respect to such product, our ability to attract and maintain corporate partners, including pharmaceutical companies, to assist in commercializing our products, receipt of regulatory clearance of marketing claims for the uses that we are developing and the effectiveness of our marketing and distribution capabilities. If our approved products fail to gain market acceptance or do not become widely accepted by physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable on a sustained basis or achieve significant revenues. Generic competition may also adversely affect our ability to grow our markets and obtain acceptance of our products in the marketplace.

We have just recently completed the acquisition of PONVORY® and our ability to commercialize PONVORY® in the U.S. and Canada and transition regulatory and supply responsibility to us is uncertain, and we may not realize all of the anticipated benefits of the acquisition, those benefits make take longer to realize than expected or we may encounter significant integration difficulties.

We acquired the U.S. and Canadian rights to PONVORY® in December 2023. Our ability to realize the anticipated benefits of the acquisition will depend, to a large extent, on our ability to integrate PONVORY® into our business and realize anticipated growth opportunities and synergies. We will be required to devote significant management attention and resources to integrating this product into our business. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of the acquisition could adversely affect our business, financial condition and results of operations.

Our ability to realize the anticipated benefits of the transaction will require us to overcome a number of difficulties, including, among others:

- the diversion of management attention to integration matters;
- difficulties in achieving anticipated business opportunities and growth prospects from the acquisition;
- challenges related to public and market perception of PONVORY® and/or our acquisition of the product;
- delays or other difficulties with the transition of regulatory and supply responsibilities for PONVORY® to us from Janssen; and
- potential unknown liabilities, adverse consequences, unforeseen increased expenses or other unanticipated problems associated with the acquisition.

Many of these factors are outside of our control, and any one of them could result in increased costs, decreased expected revenues and further diversion of management time and energy, which could materially harm our business, financial condition and results of operations.

In addition, we have no Canadian operations and no history of commercializing products in Canada. As a result, we will have to either build our own Canadian sales force or enter into an agreement with one or more third-party collaborators for the sale and distribution of PONVORY® in Canada. There is no guarantee that we will be successful in building our own Canadian sales force or that we will be able to identify or enter into an agreement with any such third-party collaborator on favorable terms, or at all.

All of these factors could decrease or delay the expected accretive effect of the acquisition and negatively impact our stock price and harm our business. As a result, it cannot be assured that the acquisition of PONVORY® will result in the full realization of the benefits anticipated from the transaction within the anticipated time frames or at all.

We rely on, and will continue to rely on, outsourcing arrangements for many of our activities, including preclinical and clinical development and supply of HETLIOZ®, HETLIOZ LQ®, Fanapt®, PONVORY® and our other products.

We rely on outsourcing arrangements for a significant portion of our activities, including distribution, preclinical and clinical research and development, data collection and analysis and manufacturing. We have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

Disruptions to our HETLIOZ®, HETLIOZ LQ® Fanapt® or PONVORY® supply chains could materially affect our level of success in commercializing these products, thereby reducing our future earnings and prospects.

A loss or disruption with any one of our manufacturers or suppliers could disrupt the supply of HETLIOZ®, HETLIOZ LQ®, Fanapt® or PONVORY®, possibly for a significant time period, and we may not have sufficient inventories to maintain supply before the manufacturer or supplier could be replaced or the disruption is resolved. In addition, marketed drugs and their contract manufacturing organizations are subject to continual review, including review and approval by regulatory authorities of their manufacturing facilities and the manufacturing processes, which can result in delays in the regulatory approval process and/or commercialization. Introducing a replacement or backup manufacturer or supplier for HETLIOZ®, HETLIOZ LQ®, Fanapt® or PONVORY® requires a lengthy regulatory and commercial process, including FDA approval of chemistry, manufacturing and controls (CMC) changes, and there can be no guarantee that we could obtain necessary regulatory approvals in a timely fashion or at all. In addition, it is difficult to identify and select qualified suppliers and manufacturers with the necessary technical capabilities, and establishing new supply and manufacturing sources involves a lengthy and technical engineering process.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In U.S. markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, should we choose to do so, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the U.S., governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. We therefore participate in, and have drug price reporting, payment, and other compliance obligations under, these programs.

We participate in the Medicaid Drug Rebate Program (MDRP). Under the MDRP, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having our drugs eligible for coverage under Medicaid and Medicare Part B. Those rebates are based on pricing data that are reported by us on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services (CMS). If we become aware that our MDRP submissions for a prior period were incorrect or have changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the MDRP and the 340B program discussed below. Pursuant to the IRA, certain figures we report under the MDRP will also be used to compute rebates under Medicare Part D triggered by price increases that outpace inflation. If we fail to provide information timely or are found to have knowingly submitted false information to CMS, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service Act's 340B drug pricing discount program (340B program), in order for the manufacturer's drugs to be eligible for coverage under Medicaid and Medicare Part B. The 340B program is administered by the Health Resources and Services Administration (HRSA) and requires us to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered drugs when used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as certain small rural hospitals and hospitals that serve a disproportionate share of low-income patients. The ACA expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts drugs designated under section 526 of the Federal Food, Drug and Cosmetic Act as "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula, which is based on pricing data we report under the MDRP and the rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities and state Medicaid programs. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges. A recent court decision in the District Court of South Carolina, *Genesis Health Care, Inc. v. Becerra*, found that HRSA's definition of "patient" as applied to the 340B Program was too broad and may result in covered entities expanding the number of individuals considered eligible to receive drugs purchased through the 340B Program, resulting in higher volumes of drugs purchased at the discounted 340B ceiling price. In addition, legislation may be introduced that, if passed, would further expand the 340B program, such as adding further covered entities or requiring participating manufacturers to agree to provide 340B discounted pricing on drugs when used in an inpatient setting.

In order for products to be eligible for coverage under the Medicaid and Medicare Part B programs and to be purchased by certain federal agencies and grantees, we must also participate in the Department of Veterans Affairs Federal Supply Schedule (FSS), pricing program. As a participant, we must list our covered (innovator and authorized generic) drugs on an FSS contract and charge no more than Federal Ceiling Price (FCP), to the Department of Veterans Affairs, Department of Defense, Public Health Service, and Coast Guard when those agencies purchase from the FSS contract or a depot contract. FCP is calculated based on non-federal average manufacturer price data, which we are required to submit quarterly and annually. In addition, because our products are available in the retail and specialty pharmacy setting, we are required to provide rebates to the Department of Defense for prescriptions dispensed to Tricare beneficiaries from Tricare retail network pharmacies under the Tricare Retail Refund Program. If a manufacturer participating in the FSS program fails to provide timely information or is found to have knowingly submitted false information, the manufacturer may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations vary among products and programs. The calculations are complex and will often be subject to interpretation by us, governmental or regulatory agencies and the courts. We may be liable for errors associated with our submission of pricing data. If we are found to have knowingly submitted false pricing data to the Medicaid program or the FSS pricing program, or fail to submit pricing data on a timely basis, we may be subject to significant civil monetary penalties. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, which is the agreement under which we would participate in the MDRP. In the event that CMS terminates our rebate agreement, our products may no longer be eligible for coverage under Medicaid or Medicare Part B. There can be no assurance that our submissions will not be found to be incomplete or incorrect.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to 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. In addition, the requirements and penalties described above may affect our ability to profitably sell any product for which we obtain marketing approval.

We are subject to ongoing regulatory obligations and oversight of our products, and any failure by us to maintain compliance with applicable regulations may result in adverse consequences including the suspension of the manufacturing, marketing and sale of our respective products, the incurrence of significant additional expense and other limitations on our ability to commercialize our respective products.

We are subject to ongoing regulatory requirements and review, including periodic audits pertaining to the development, manufacture, labeling, packaging, adverse event reporting, distribution, storage, marketing, promotion, recordkeeping and export of our products. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with the manufacture, distributions and storage of our products, or our third-party contract manufacturing facilities or processes by which we manufacture our products may result in restrictions on our ability to develop, manufacture, market, distribute or sell our products, including potential withdrawal of our products from the market. Any such restriction could slow or stop production development or result in decreased sales, damage to our reputation or the initiation of lawsuits against us or our third-party contract manufacturers. We may also be subject to additional sanctions, including, but not limited, to the following:

- Warning letters, public warnings and untitled letters;
- Court-ordered seizures or injunctions;

- Civil or criminal penalties, or criminal prosecutions;
- Variation, suspension or withdrawal of regulatory approvals for our products;
- Changes to the package insert of our products, such as additional warnings regarding potential side effects or potential limitations on the current dosage or administration;
- Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving our products;
- Implementation of risk mitigation programs and post-approval obligations;
- Restrictions on our continued manufacturing, marketing, distribution or sale of our products;
- Temporary or permanent closing of the facilities of our third-party contract manufacturers;
- Interruption or suspension of clinical trials; and
- Refusal by regulators to consider or approve applications for additional indications.

Any of the above sanctions could have a material adverse impact on our revenues or our reputation, and cause us to incur significant additional expenses.

In addition, if our products face any safety or efficacy issues, including drug interaction problems, under the federal Food, Drug, and Cosmetic Act (FDCA), the FDA has broad authority to force us to take any number of actions, including, but not limited to, the following:

- Requiring us to conduct post-approval clinical studies to assess product efficacy or known risks or new signals of serious risks, or to evaluate unexpected serious risks;
- Mandating changes to a product's label;
- Requiring us to implement a risk evaluation and mitigation strategy (REMS) where necessary to assure safe use of the drug; or
- Removing an already approved product from the market.

Further, our partners, including our licensors, are subject to similar requirements and obligations as well as the attendant risks and uncertainties. If our partners, including our licensors, suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material adverse effect on our business.

If our products are marketed or distributed in a manner that violates federal or state healthcare fraud and abuse laws, marketing disclosure laws or other federal or state laws and regulations, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, our general operations, and the research, development, manufacture, sale and marketing of our products, are subject to extensive additional federal and state healthcare regulation, including the federal Anti-Kickback Statute, the Prescription Drug Marketing Act, and the federal False Claims Act (FCA), the federal Health Insurance Portability and Accountability Act of 1996, the federal Physician Payment Sunshine Act and the Foreign Corrupt Practices Act (and their state analogues), as discussed above in Part I, Item 1 under the heading *Government Regulation - Fraud and abuse laws and other U.S. regulatory matters*. If we or our partners, such as licensors, fail to comply with any federal and state laws or regulations governing our industry, we could be subject to administrative, criminal and civil penalties and a range of regulatory actions that could adversely affect our ability to commercialize our products, harm or prevent sales of our products, or substantially increase the costs and expenses of commercializing and marketing our products, all of which could have a material adverse effect on our business, financial condition and results of operations. In recent years, CMS has been actively proposing and implementing changes to the list of business practices that are protected by safe harbors. There is inherent risk and uncertainty in any changing regulatory environment as companies work to transition business practices to conform with new regulations.

Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws, and private individuals have been active in bringing so-called "whistleblower" lawsuits on behalf of the government (as Relators) under the FCA and similar regulations in other countries. In addition, incentives exist under applicable U.S. law that encourage employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives have led to, and could continue to lead to, FCA lawsuits, which attempt to recoup moneys paid by government agencies and extract penalties from manufacturers. For example, federal enforcement agencies have recently pursued

enforcement actions against pharmaceutical companies' product and patient assistance programs, including relationships with specialty pharmacies, and support for charitable foundations providing patients with co-pay assistance. In addition, Relators have filed lawsuits involving manufacturer reimbursement support services as well as promotion of pharmaceutical products beyond labeled claims. Some FCA lawsuits have resulted in government enforcement authorities obtaining significant civil and criminal settlements. Such lawsuits, whether with or without merit, are typically time-consuming and costly to defend. Such suits may also result in related shareholder lawsuits, which are also time-consuming and costly to defend. See Note 17, *Legal Matters*, to the consolidated financial statements in Part II, Item 8 of this Annual Report, which is incorporated herein by reference, for information regarding ongoing litigation related to similar matters.

Further, the FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. A product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA also regulates the content of promotional material, including, among other things, the presentation of efficacy information, the types of comparative claims that can be made to distinguish products from those with similar indications, and the balance of risk information provided. For drug products that are approved by the FDA under the FDA's accelerated approval regulations, unless otherwise informed by the FDA, the sponsor must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the promotional materials, which delays and may negatively impact a company's ability to implement changes to its marketing materials, thereby negatively impacting revenues. For other products, the FDA does not review promotional materials prior to dissemination but does issue "Untitled Letters" or "Warning Letters" if it objects to content that has been used promotionally. The FDA may also withdraw approval of drug products under certain conditions. In particular, the FDA may withdraw approval of a drug if, among other things, the promotional materials are false or misleading, or other evidence demonstrates that the drug is not shown to be safe or effective under its conditions of use.

In recent years, in addition to federal legislation related to transparency reporting of transfers of value to healthcare providers and healthcare organizations, several states have enacted legislation requiring pharmaceutical companies to file periodic reports. Several states have adopted legislation to require pharmaceutical companies to establish marketing and promotional compliance programs or codes of conduct or to file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Several states have also adopted laws that prohibit certain marketing-related activities, including the provision of gifts, meals or other items to certain healthcare providers.

We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry; however, relevant compliance laws are broad in scope and there may not be regulations, guidance or court decisions that definitively interpret these laws in the context of particular industry practices. We cannot guarantee that we, our employees, our partners, our consultants or our contractors are or will be in compliance with all federal and state regulations. If we, our partners, or our representatives fail to comply with any of these laws or regulations, a range of fines, penalties or other sanctions and regulatory actions could be imposed on us, including, but not limited to, restrictions on how we market and sell our products, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. Even if it is not determined that we have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have a material adverse effect on our business, financial condition and results of operations. Such investigations or suits have resulted in, and may continue to result in, related shareholder lawsuits, which can also have a material adverse effect on our business.

Our partners, including our licensors, are subject to similar requirements and obligations as well as the attendant risks and uncertainties. If our partners, including our licensors, suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material adverse effect on our business.

We rely on a limited number of specialty pharmacies for distribution of HETLIOZ® in the U.S., and the loss of one or more of these specialty pharmacies or their failure to distribute HETLIOZ® effectively would materially harm our business.

HETLIOZ® is available for distribution through a limited number of specialty pharmacies in the U.S. A specialty pharmacy is a pharmacy that specializes in the dispensing of medications for complex or chronic conditions that often require a high level of patient education and ongoing management. The use of specialty pharmacies involves certain risks, including, but not limited to, risks that these specialty pharmacies will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using HETLIOZ® or complaints about HETLIOZ®;

- reduce their efforts or discontinue to sell or support or otherwise not effectively sell or support HETLIOZ®, particularly in light of the recent entry into the market of generic versions of HETLIOZ®;
- not devote the resources necessary to sell HETLIOZ® in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

In addition, if one or more of our specialty pharmacies do not fulfill their contractual obligations to us, or refuse or fail to adequately serve patients, or their agreements are terminated without adequate notice, shipments of HETLIOZ®, and associated revenues, would be adversely affected. We expect that it would take a significant amount of time if we were required to replace one or more of our specialty pharmacies.

Our revenues from Fanapt® are substantially dependent on sales through a limited number of wholesalers, and such revenues may fluctuate from quarter to quarter.

We sell Fanapt® primarily through a limited number of pharmaceutical wholesalers in the U.S. The use of pharmaceutical wholesalers involves certain risks, including, but not limited to, risks that these pharmaceutical wholesalers will:

- not provide us accurate or timely information regarding their inventories, demand from wholesaler customers buying Fanapt® or complaints about Fanapt®;
- reduce their efforts or discontinue to sell or support or otherwise not effectively sell or support Fanapt®;
- not devote the resources necessary to sell Fanapt® in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

Additionally, our reliance on a small number of wholesalers could cause revenues to fluctuate from quarter to quarter based on the buying patterns of these wholesalers. In addition, if any of these wholesalers fails to pay on a timely basis or at all, our business, financial condition and results of operations could be materially adversely affected.

We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.

Our future success will depend on our ability to demonstrate and maintain a competitive advantage with respect to our products and our ability to identify and develop additional products. Large, fully integrated pharmaceutical companies, either alone or together with collaborative partners, have substantially greater financial resources and have significantly greater experience than we do in:

- developing products;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of products; and
- manufacturing, marketing and selling products.

These companies may invest heavily and quickly to discover and develop novel products that could make our products obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or foreign regulatory approval or commercializing superior products or other competing products before we do. Technological developments or the approval by the FDA or foreign regulators of new therapeutic indications for existing products may make our products obsolete or may make them more difficult to market successfully, any of which could have a material adverse effect on our business, results of operations and financial condition.

Our products, if successfully developed and approved for commercial sale, will compete with a number of drugs and therapies currently manufactured and marketed by other biotechnology companies, including major pharmaceutical companies. Our products may also compete with new products currently under development by others or with products that may cost less than our products. Physicians, patients, third-party payors and the medical community may not accept or utilize any of our products that may be approved. If HETLIOZ®, Fanapt®, PONVORY® and our other products, if and when approved, do not achieve significant market acceptance, our business, results of operations and financial condition would be materially adversely

affected. See Part I, Item 1, *Competition,* for a discussion of the primary competitors for HETLIOZ®, Fanapt® and PONVORY®.

In addition, we may face competition from newly developed generic products. Under the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act seeks to stimulate competition by providing incentives to generic pharmaceutical manufacturers to introduce non-infringing forms of patented pharmaceutical products and to challenge patents on branded pharmaceutical products. If we are unsuccessful at challenging an ANDA filed pursuant to the Hatch-Waxman Act, cheaper generic versions of our products, which may be favored by insurers and third-party payors, may be launched commercially, which would significantly harm our business. In December 2022, the Delaware District Court ruled in favor of the Defendants in our patent litigation relating to the Defendants' filing of ANDAs for generic versions of HETLIOZ® in the U.S. We appealed the decision to the Federal Circuit, and in May 2023, a three-judge panel of the Federal Circuit affirmed the Delaware District Court's ruling. In August 2023, the Federal Circuit denied our request for a rehearing. In January 2024, we filed a petition for a writ of certiorari with the U.S Supreme Court to review the Federal Circuit's decision. The FDA has approved ANDAs for Teva, Apotex and MSN, and Teva and Apotex have launched their generic versions of HETLIOZ® at risk in the U.S., and MSN has launched its generic version as well. In addition, other potential competitors may be successful in obtaining ANDA approval and launching their own generic versions.

To obtain an ANDA approval for a generic drug, the generic company needs to show, among other things, that its version of the product is bioequivalent to the Reference Listed Drug (RLD). This usually requires the generic company to conduct bioequivalence studies comparing its product to the RLD, and to retain sufficient samples of the RLD used in testing after a study is complete. In recent years, U.S. federal lawmakers and the FDA have considered proposals and enacted legislation to facilitate the generic drug company's access to samples and foster the generic competition. For example, the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act) allows a biosimilar or generic product developer to bring a civil action against a brand drug manufacturer for failing to provide samples of the brand product for comparative testing "on commercially reasonable, market-based terms." The developer could receive injunctive relief and a monetary award "sufficient to deter the license holder from failing to provide other eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms" in certain cases. While the full impact of the CREATES Act is unclear at this time, its provisions do have the potential to facilitate the development and future approval of generic versions of our products, introducing generic competition that could have a material adverse effect on our business, results of operations and financial condition.

Certain states have also taken similar actions. For example, in 2018, Maine passed a new law that requires brand drug manufacturers to make samples of drugs distributed in the state available for sale in Maine at a price no greater than wholesale acquisition cost and without any restriction that would block or delay a biosimilar and generic drug application in a manner inconsistent with federal law. The state may seek injunctive relief and attorney's fees from a drug manufacturer who fails to comply with this requirement.

FDA and foreign regulatory approval of our products is uncertain.

The research, testing, manufacturing and marketing of products such as those that we have developed or that we are developing are subject to extensive regulation by federal, state and local government authorities, including the FDA, as well as foreign regulatory authorities in jurisdictions in which we seek approval. To obtain regulatory approval of such products, we must demonstrate to the satisfaction of the applicable regulatory agency that, among other things, the product is safe and effective for its intended use. In addition, we must show that the manufacturing facilities used to produce such products are in compliance with current good manufacturing practices (cGMPs).

The process of obtaining FDA and other required regulatory approvals and clearances can take many years and will require us to expend substantial time and capital. Despite the time and expense expended, regulatory approval is never guaranteed. The number of preclinical and clinical trials that will be required for FDA or foreign regulatory approval varies depending on the product, the disease or condition that the product is in development for, and the requirements applicable to that particular product. The FDA or applicable foreign regulatory agency can delay, limit or deny approval of a product for many reasons, including that:

- a product may not be shown to be safe or effective;
- the FDA or foreign agency may interpret data from preclinical and clinical trials in different ways than we do;
- the FDA or foreign agency may not approve our or our partners' manufacturing processes or facilities;
- a product may not be approved for all the indications we request;

- the FDA or foreign agency may change its approval policies or adopt new regulations;
- the FDA or foreign agency may not meet, or may extend, the PDUFA date or its foreign equivalent with respect to a particular NDA or foreign application; and
- the FDA or foreign agency may not agree with our regulatory approval strategies or components of the regulatory filings, such as clinical trial designs.

For example, if certain of our methods for analyzing trial data are not accepted by the FDA or the applicable foreign agency, we may fail to obtain regulatory approval for our products.

Additionally, the approval procedure varies among countries and jurisdictions and can involve additional trials, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

Any delay or failure to obtain regulatory approvals for our products will result in increased costs, could diminish competitive advantages that we may attain and would adversely affect the marketing and sale of our products. Other than HETLIOZ® and HETLIOZ LQ® in the U.S. and HETLIOZ® in the countries in Europe covered by the centralized marketing authorization by the EC, and Fanapt® in the U.S., Mexico and Israel, we have not received, and may never receive, regulatory approval to market any of our products in any jurisdiction. In December 2023, we acquired U.S. and Canadian rights to PONVORY®, which had already been approved by the FDA and Health Canada, for the treatment of adults with RMS.

Even following regulatory approval of our products, the FDA or the applicable foreign agency may impose limitations on the indicated uses for which such products may be marketed, subsequently withdraw approval or take other actions against us, or such products that are adverse to our business. The FDA and foreign agencies generally approve drugs for use in specific indications. An approval for a more limited indication reduces the size of the potential market for the product. Product approvals, once granted, may be withdrawn or modified if problems occur after initial marketing.

We and our partners also are subject to numerous federal, state, local and foreign laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the environment and the use and disposal of hazardous substances used in connection with discovery, research and development work. In addition, we cannot predict the extent to which new governmental regulations might significantly impede the discovery, development, production and marketing of our products. We or our partners may be required to incur significant costs to comply with current or future laws or regulations, and we may be adversely affected by the cost of such compliance or the inability to comply with such laws or regulations.

Our products may cause undesirable side effects or have other properties that could delay, prevent or result in the revocation of their regulatory approval or limit their marketability.

Undesirable side effects caused by our products could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing or continuing the commercialization of such products and generating revenues from their sale. We will continue to assess the side effect profile of our products in ongoing clinical development programs. However, we cannot predict whether the commercial use of our approved products (or our products in development, if and when they are approved for commercial use) will produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such products to date. For example, despite the positive results of the completed trials for HETLIOZ®, Fanapt® and PONVORY®, as well as the FDA's approval of the NDA for HETLIOZ® for the treatment of Non-24 in January 2014, the NDA for Fanapt® for the treatment of schizophrenia in May 2009, the EC's grant of the centralized marketing authorization for HETLIOZ® for the treatment of Non-24 in totally blind adults in July 2015, the FDA's approval of the sNDA and NDA for HETLIOZ® capsule and liquid formulation for the treatment of adults and children, respectively, with nighttime sleep disturbances in SMS in December 2020, and the NDA for PONVORY® for the treatment of RMS in adults in March 2021 and Health Canada's approval of PONVORY® for the treatment of adults with RMS in April 2021, we are uncertain whether either of these products will ultimately prove to be effective and safe in humans long term and in all uses. Frequently, products that have shown promising results in clinical trials have suffered significant setbacks in later clinical trials or even long after they are approved for commercial sale. Additionally, incidents of product misuse may occur. These events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls, any of which could have a material adverse effect on our business, results of operations and financial condition.

In addition, if after receiving marketing approval of a product, we or others identify undesirable side effects caused by such product, we could face one or more of the following:

- regulatory authorities may require us to implement a REMS, such as the addition of labeling statements (e.g., "black box" warning or a contraindication);
- regulatory authorities may withdraw their approval of the product;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and
- our or the product's reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from its sale.

Clinical trials for our products are expensive and their outcomes are uncertain. Any failure or delay in completing clinical trials for our products could severely harm our business.

Preclinical studies and clinical trials required to demonstrate the safety and efficacy of our products are time-consuming and expensive and together take several years to complete. Before obtaining regulatory approvals for the commercial sale of any of our products, we must demonstrate through preclinical testing and clinical trials that such product is safe and effective for use in humans. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, preclinical testing and clinical trials.

Historically, the results from preclinical testing and early clinical trials often have not predicted results of later clinical trials. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Clinical trials conducted by us or by third parties on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our products. Regulatory authorities may not permit us to undertake any additional clinical trials for our products, may force us to stop any ongoing clinical trials and it may be difficult to design efficacy studies for our products in new indications.

Clinical development efforts performed by us may not be successfully completed or completed in a timely manner. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the products and the size of the prospective patient population. Our ability to enroll patients in, and the commencement and rate of completion of, clinical trials for our products may be affected by many factors, including:

- the size and nature of the patient population;
- the design of the trial protocol for our clinical trials;
- the eligibility and exclusion criteria for the trial in question;
- the availability of competing therapies and competing clinical trials, and physician and patient perception of our product candidates and our other product candidates being studied in relation to these other potential options;
- the availability of raw materials and the possibility of raw materials expiring prior to their use;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of our products during clinical trials;
- unforeseen safety issues or side effects;
- the number and location of clinical sites in our clinical trials;
- the proximity and availability of clinical trial sites for prospective patients;
- the availability of time and resources at the institutions where clinical trials are and will be conducted;
- the availability of adequate financing to fund ongoing clinical trial expenses;
- the study endpoints that rely on subjective patient reported outcomes;
- the impact of global health crises; and

- governmental or regulatory delays and changes in regulatory requirements and guidelines.

If we fail to complete successfully, or have difficulty enrolling a sufficient number of patients for, our clinical trials, we or they may not receive the regulatory approvals needed to market that product. Any such failure or difficulty could have a material adverse effect on our business.

We may not be able to achieve sustained profitability.

We have been engaged in identifying and developing drug products since March 2003, which has required, and will continue to require, significant research and development expenditures. The continued commercialization of HETLIOZ®, Fanapt® and PONVORY® will also require substantial additional expenditures.

As of December 31, 2023, we had an accumulated deficit of $155.4 million and we cannot estimate with precision the extent of our future income or loss. We may not succeed in maintaining or gaining additional market acceptance of HETLIOZ®, Fanapt® and PONVORY® in the U.S. and we may not succeed in commercializing HETLIOZ® or Fanapt® outside of the U.S or PONVORY® in Canada. We may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive revenue from our products in the timeframes we project, if at all, and our inability to do so would materially and adversely impact the market price of our common stock and our ability to raise capital and continue operations.

There can be no assurance that we will achieve sustained profitability, which depends on many factors, including but not limited to, our ability to obtain regulatory approval for our products and achieve success in commercializing them in the U.S., Europe, Canada and our other target jurisdictions, as well as other factors described in this Annual Report.

In addition, the amount we spend on developing, obtaining and maintaining regulatory approval for and commercializing our products, among other expenditures described in this Annual Report, will impact our profitability.

Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income is dependent on generating future taxable income and may be limited, including as a result of transactions involving our common stock.

We have recorded deferred tax assets based on our assessment that we will be able to realize the benefits of our net operating losses and other favorable tax attributes. Realization of deferred tax assets involves significant judgments and estimates, which are subject to change and ultimately depends on generating sufficient taxable income of the appropriate character during the appropriate periods. Changes in circumstances may affect the likelihood of such realization, which in turn may trigger the need for additional valuation allowance against our deferred tax assets and adversely affect our net income and financial condition. In addition, we are potentially subject to ongoing and periodic tax examinations and audits in various jurisdictions, including with respect to the amount of our net operating losses and any limitation thereon. An adjustment to such net operating loss carryforwards, including an adjustment from a taxing authority, could result in higher tax costs, penalties and interest, thereby adversely impacting our financial condition.

Certain of our tax attributes, including net operating losses (NOLs) and credit carryforwards, would be subject to limitation under Section 382 and 383 should an ownership change as defined under Section 382 of the Internal Revenue Code of 1986, as amended (IRC), occur. The limitation resulting from a “change in ownership” could affect our ability to utilize NOLs and credit carryforwards (tax attributes) to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders’ lowest percentage ownership during the testing period (generally three years). Transactions involving our common stock, even those outside our control, such as purchases or sales by investors, within the testing period could result in an ownership change. A limitation on our ability to utilize some or all of our NOLs or credit carryforwards could have a material adverse effect on our results of operations and cash flows. An ownership change occurred in the year ended December 31, 2014. We believe that the ownership change in 2014 will not impact our ability to utilize NOL and credit carryforwards; however, future ownership changes may cause our existing tax attributes to have additional limitations.

If we fail to adequately fund our research and development activities and commercialization efforts, we may be unable to continue operations or we may be forced to share our rights to commercialize our products with third parties on terms that may not be attractive to us.

Our activities will necessitate significant uses of working capital throughout 2024 and beyond. It is uncertain whether cash provided by our operating activities, together with our existing funds, will be sufficient to meet our long-term operating

needs. As of December 31, 2023, our total cash and cash equivalents and marketable securities were $388.3 million. Our long-term capital requirements are expected to depend on many factors, including, among others:

- our level of success in commercializing HETLIOZ®, Fanapt® and PONVORY®, as well as other products that may be approved, globally;
- outcomes of ongoing and potential patent litigation;
- costs of developing and maintaining sales, marketing and distribution channels and our ability to sell our products;
- market acceptance of our products;
- costs involved in establishing and maintaining manufacturing capabilities for commercial quantities of our products;
- the number of potential formulations and products in development;
- progress with preclinical studies and clinical trials;
- time and costs involved in obtaining regulatory (including FDA) approval;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims;
- cost of evaluating and acquiring new products from third parties;
- competing technological and market developments;
- costs for recruiting and retaining employees and consultants;
- costs for training physicians; and
- legal, accounting, insurance and other professional and business-related costs.

As a result, we may need to raise additional capital to fund our anticipated operating expenses and execute on our business plans. In our capital-raising efforts, we may seek to sell debt securities or additional equity securities, obtain a bank credit facility, or enter into partnerships or other collaboration agreements. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders and may also result in a lower price for our common stock. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that could restrict our operations, including potentially limiting our ability to license product rights or enter into product development collaborations. However, we may not be able to raise additional funds on acceptable terms, or at all. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies or products, take advantage of business opportunities or respond to competitive market pressures, any of which would materially harm our business, financial condition and results of operations.

If our contract research organizations (CROs) do not successfully carry out their duties or if we lose our relationships with CROs, our drug development efforts could be delayed.

Our arrangements with CROs are critical to our success in bringing our products to the market. We are generally dependent on CROs, third-party vendors and investigators for preclinical testing and clinical trials related to our drug discovery and development efforts and we will likely continue to depend on them to assist in our future discovery and development efforts. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. As such, they may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the development, approval and commercialization of our products. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

Our CROs could merge with or be acquired by other companies or experience financial or other setbacks unrelated to our collaboration that could, nevertheless, materially adversely affect our business, results of operations and financial condition.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In

addition, any provider that we retain will be subject to current Good Laboratory Practices as set forth in 21 Code of Federal Regulations (C.F.R.) Part 58 and Good Clinical Practices as set forth in 21 C.F.R. Part 50, 54, and 312, and similar international standards and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our products could be delayed.

We rely on a limited number of third-party manufacturers to formulate and manufacture our products, and our business will be seriously harmed if these manufacturers are not able to satisfy our demand and alternative sources are not available.

We do not have an in-house manufacturing capability and depend completely on a small number of third-party manufacturers and active pharmaceutical ingredient formulators for the manufacture of our products. Therefore, we are dependent on third parties for our formulation development and manufacturing of our products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to successfully launch and maintain the marketing of our products. Furthermore, these third-party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or other unforeseeable events that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes would have a material adverse effect on our ability to develop and commercialize our products. In addition, if we are not able to continue to operate our business relationships in a manner that is sufficiently profitable for us and our suppliers, certain members of our supply chain could compete with us through supply to competitors, such as generic drug companies, through breach of our agreements or otherwise.

We have agreements in place with Patheon Pharmaceuticals Inc. and Patheon Inc. (collectively, Patheon), subsidiaries of Thermo Fisher Scientific, for the manufacture of HETLIOZ® and Fanapt®. In January 2014, we entered into a manufacturing agreement with Patheon for the manufacture of commercial supplies of HETLIOZ® 20 mg capsules at Patheon's Cincinnati, Ohio manufacturing site. In May 2016, we entered into a manufacturing agreement with Patheon for the manufacture of commercial supplies of Fanapt® tablets at Patheon's Mississauga, Ontario, Canada manufacturing site. Additionally, in December 2020, we entered into a non-exclusive third-party manufacturing agreement for the manufacture of commercial supplies of HETLIOZ LQ®. We do not have exclusive long-term agreements with any other third-party manufacturers of our products. If our current manufacturers, or any other third-party manufacturer, is unable or unwilling to perform its obligations under our manufacturing agreements for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our products in a timely manner from these third parties could adversely affect sales of our products, delay clinical trials and prevent us from developing our products in a cost-effective manner or on a timely basis. In addition, manufacturers of our products are subject to cGMP and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our products could be interrupted, resulting in delays and additional costs. Moreover, if the facilities of such manufacturers do not pass a pre-approval or post-approval plant inspection, the FDA will not grant approval for our products and may institute restrictions on the marketing or sale of our products. Similarly, if we change contract manufacturers, the FDA must approve these contract manufacturers or any other CMC changes before our products can be manufactured.

PONVORY® is manufactured by third parties and supplied to Janssen, which is currently distributing PONVORY® pursuant to the terms of a transition agreement. During the transition period, Vanda and Janssen will transition supply responsibility for PONVORY® to us. If we, or Janssen during the transition period, are unable to acquire sufficient quantities of PONVORY®, our sales of PONVORY® would suffer adverse effects.

Our manufacturing strategy presents the following additional risks:

- because most of our third-party manufacturers and formulators are located outside of the U.S., there may be difficulties in importing our products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging; and
- because of the complex nature of our products, our manufacturers may not be able to successfully manufacture our products in a cost-effective and/or timely manner.

Materials necessary to manufacture our products may not be available on commercially reasonable terms, or at all, which may delay the development, regulatory approval and commercialization of our products.

We rely on manufacturers to purchase from third-party suppliers the materials necessary to produce our products for clinical trials and commercialization. Suppliers may not sell these materials to such manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by these manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. If the manufacturers are unable to obtain these materials for our clinical trials, including due to supply chain issues caused by global health crises, product testing, potential regulatory approval of our products and commercial scale manufacturing could be delayed, significantly affecting our ability to further develop and commercialize our products. If we or our manufacturers are unable to purchase these materials for our products, there would be a shortage in supply or the commercial launch of such products would be delayed, which would materially and adversely affect our ability to generate revenues from the sale of such products.

If we cannot identify, or enter into licensing arrangements for, new products, our ability to develop a diverse product portfolio will be limited.

A component of our business strategy is acquiring rights to develop and commercialize products discovered or developed by other pharmaceutical and biotechnology companies for which we may find effective uses and markets through our unique pharmacogenetics and pharmacogenomics expertise. Competition for the acquisition of these products is intense. If we are not able to identify opportunities to acquire rights to commercialize additional products, we may not be able to develop a diverse portfolio of products. Additionally, it may take substantial human and financial resources to secure commercial rights to promising products. Moreover, if other firms develop pharmacogenetics and pharmacogenomics capabilities, we may face increased competition in identifying and acquiring additional products.

If we lose key scientists or management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify, develop, and commercialize new products will be impaired.

We are highly dependent on principal members of our management team and scientific staff, including our Chief Executive Officer, Mihael H. Polymeropoulos, M.D. These executives each have significant pharmaceutical industry experience. The loss of any such executives, including Dr. Polymeropoulos, or any other principal member of our management team or scientific staff, would impair our ability to identify, develop and market new products. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, we depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs.

Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

The risk that we may be sued on product liability claims is inherent in the development and sale of pharmaceutical products. For example, we face a risk of product liability exposure related to the testing of our products in clinical trials and will face even greater risks upon commercialization of our products. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because certain of our products are intended to treat central nervous system disorders, among others, and it is possible that we may be held liable for the behavior and actions of patients who use our products. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and we may be forced to limit or forego further commercialization of one or more of our products. Although we maintain product liability insurance, our aggregate coverage limit under this insurance is $30.0 million, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover potential liabilities. As our development activities and commercialization efforts progress and we sell our products, this coverage may be inadequate, we may be unable to obtain adequate coverage at an acceptable cost or we may be unable to get adequate coverage at all or our insurer may disclaim coverage as to a future claim. This could prevent the commercialization or limit the commercial potential of our

products. Even if we are able to maintain insurance that we believe is adequate, our results of operations and financial condition may be materially adversely affected by a product liability claim. Uncertainties resulting from the initiation and continuation of products liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability litigation and other related proceedings may also require significant management time.

E.U. Member States tend to impose strict price controls, which may delay or prevent the further commercial launch or impede the commercial success of HETLIOZ® in Europe and adversely affect our future results of operations.

In the E.U., prescription drug pricing and reimbursement are subject to governmental control and reimbursement mechanisms used by private and public health insurers in the E.U. vary by Member State. For the public systems, reimbursement is determined by law and/or by guidelines established by the responsible national authority. As elsewhere, inclusion in reimbursement catalogues focuses on the medical usefulness, need, quality and economic benefits to patients and the health care system. Acceptance for reimbursement comes with cost, use and often volume restrictions, which can vary by Member State. Although we have received marketing authorization for HETLIOZ® capsules from the EC, pricing negotiations with governmental authorities may take a considerable amount of time in those Member States that impose price controls. For example, we launched HETLIOZ® commercially in Germany in August 2016, and concluded our pricing negotiations with German authorities in October 2017. In addition, to obtain reimbursement or pricing approval for HETLIOZ® in some Member States, we may be required to conduct an additional clinical trial that compares the cost-effectiveness of HETLIOZ® to other available therapies.

Some Member States require approval of the sale price of a drug before it can be marketed. In others, the pricing review period begins after marketing or product licensing approval is granted. In some Member States, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may be subject to lengthy price regulations that delay or prevent the commercial launch of HETLIOZ® in a particular Member State and negatively impact the revenues that are generated from the sale of HETLIOZ® in that country. If reimbursement of HETLIOZ® is unavailable or limited in scope or amount, or if pricing for HETLIOZ® is set at unsatisfactory levels or takes too long to establish, or if there is competition from lower priced cross-border sales, our results of operations will be negatively affected.

We may not be able to effectively market and sell our future products, if approved, in the U.S.

We plan to continue to build our sales and marketing capabilities in the U.S. to commercialize future products, if approved. Our current sales and marketing capabilities in the U.S. may not be adequate to support the commercialization of future products and we would expect to build such capabilities by investing significant amounts of financial and management resources. Furthermore, the cost of establishing and maintaining marketing and sales capabilities may not be justifiable in light of the revenues generated by any future products.

If we are unable to establish and maintain adequate sales and marketing capabilities for future products or are unable to do so in a timely manner, we may not be able to generate product revenues from these products, which may prevent us from reaching or maintaining profitability.

Healthcare legislative reform measures or developments arising from changes in the political climate may have a material adverse effect on our business and results of operations.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. Most significantly, in August 2022, President Biden signed the IRA into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (beginning October 1, 2022); and replaces the Medicare Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On March 15, 2023 and June 30, 2023, HHS issued guidance regarding implementation of the Medicare drug price negotiation program in initial price applicability year 2026. HHS stated it would provide additional information in the future related to implementation for initial price applicability years 2027 and beyond. Several manufacturers and industry groups have challenged the drug price negotiation program for Medicare Parts B and D in federal court. These lawsuits are ongoing, and additional lawsuits may be filed in the future related to provisions of the IRA. It is unknown whether such litigation or other litigation, if brought, will be successful. For these and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Healthcare reforms are discussed above in Part I, Item 1 under the heading *Pharmaceutical Coverage, Pricing and Reimbursement and Healthcare Reform* and in the risk factor entitled "*We are subject to uncertainty relating to pricing and reimbursement policies in the U.S., including recent and future health reform measures, which, if not favorable for our products, could hinder or prevent our products' commercial success.*"

These healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price for any approved product and/or the level of reimbursement physicians receive for administering any approved product which could affect our business strategy or commercial prospects. Reductions in reimbursement levels may negatively impact the prices we can charge or the frequency with which products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade, manufacturing, development and investment, and any negative sentiments towards the U.S. as a result of such changes, could also adversely affect our business.

We are subject to stringent laws, rules, regulations, policies, industry standards and contractual obligations regarding data privacy and security in foreign jurisdictions and may be subject to additional related laws, rules, regulations, policies, industry standards and contractual obligations in other jurisdictions into which we expand. Many of these provisions are subject to change and reinterpretation depending on the jurisdiction and could result in claims, changes to our business practices, monetary penalties, increased cost of operations or other harm to our business activities.

The regulatory framework for privacy and personal information security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Various foreign government bodies and agencies have adopted or are considering adopting laws, rules, regulations and standards limiting, or laws, rules, regulations and standards regarding, the collection, distribution, use, disclosure, storage, security and other processing of personal information.

Outside of the U.S., legal requirements relating to the collection, storage, processing and transfer of personal data continue to evolve. For example, the collection and use of health data and other personal data is governed in the E.U. by the General Data Protection Regulation (GDPR), which became applicable in May 2018. The GDPR applies to personal data processing carried out by a controller or processor (i) located within the E.U. or (ii) targeting E.U. individuals regardless of controller or processor's location. The GDPR implements stringent operational requirements for controllers and processors of personal data, including, for example, transparent information for the data subjects regarding the processing of their personal data, appropriate legal basis for processing personal data that may require to obtain the valid consent of the data subjects where applicable, expanded individual data subject rights, limitations on retention of personal data, increased requirements pertaining to data security and confidentiality, mandatory data breach notification with the competent supervisory authority and higher standards for controllers and processors to demonstrate their compliance with the GDPR by documenting it. The GDPR provides that E.U. Member States may supplement the GDPR with their own additional laws and regulations in relation to the personal data processing, in particular regarding sensitive personal data, (e.g., genetic, biometric or health data), which could result in differences between E.U. Member States, limit our ability to collect, use and share such personal data or cause our costs to increase, and harm our reputation, business and financial condition. Failure to comply with the GDPR may result in fines up to the higher of €20,000,000 or 4% of the total worldwide annual revenue of the preceding financial year and other administrative penalties. The GDPR may increase our responsibility and liability in relation to health data and other personal data that we may collect and process, and we may be required to implement additional measures in an effort to comply with the GDPR and with other laws, rules, regulations and standards in the E.U., including those of E.U. Member States, relating to privacy and data protection. This may be onerous and if our efforts to comply with GDPR or other applicable E.U. laws, rules, regulations and standards are not successful, or are perceived to be unsuccessful, it could adversely affect our business. In July 2020, the European Court of Justice (ECJ) invalidated the E.U.-U.S. Privacy Shield, which had enabled the transfer of personal data from the E.U. to the U.S. for companies that had self-certified to the Privacy Shield. While we do not rely on the Privacy Shield, the ECJ decision also raised questions about the continued validity of the EC's Standard Contractual Clauses, on which we rely. E.U. regulators have issued additional guidance regarding considerations and requirements that we and other companies must consider and undertake when using the Standard Contractual Clauses.

The EC has presented a new set of Standard Contractual Clauses, to be included in agreements involving personal data transfers outside the E.U. In addition, in July 2023, the European Commission adopted its adequacy decision for the E.U.-U.S. Data Privacy Framework (DPF). U.S. companies with the DPF certification can lawfully transfer personal data from the E.U. to the U.S. without additional transfer mechanisms. However, the validity of such mechanism is currently challenged by NYOB, an Austrian non-profit organization seeking to enforce digital rights (particularly privacy, and data protection rights) in the E.U.

This uncertainty regarding the validity of the existing transfer mechanisms could restrict our activities in those jurisdictions, limit our ability to provide our products and services in those jurisdictions, require us to modify our policies and practices, and to engage in additional contractual negotiations, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data from the E.U. to the U.S. for conducting our business activities.

Risks related to intellectual property and other legal matters

Our rights to develop and commercialize our products are subject in part to the terms and conditions of licenses or sublicenses granted to us by other pharmaceutical companies.

Our rights to our product portfolio are based in part on patents and other intellectual property licensed from third parties. These third parties may generally terminate the license agreements under certain circumstances, including a material breach of the agreement by the other. In the event we terminate our license, or if the third party terminates our license due to our breach, rights to the intellectual property revert back to the licensor. Any termination or reversion of our rights to develop or commercialize our products would have a material adverse effect on our business.

If our efforts to protect the proprietary nature of the intellectual property related to our products are not adequate, we may not be able to compete effectively in our markets.

Method of treatment patents protect the use of a product for the method specified in the patent claims. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for a use that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our patented methods, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of treatment patents, such infringement may be difficult to prevent.

Our patents and patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. In addition, we generally rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug development processes that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable and/or not infringed. In December 2022, the Delaware District Court ruled in favor of the Defendants in our patent litigation relating to the Defendants' filing of ANDAs for generic versions of HETLIOZ® in the U.S. We appealed the decision to the Federal Circuit, and in May 2023, a three-judge panel of the Federal Circuit affirmed the Delaware District Court's ruling. In August 2023, the Federal Circuit denied our request for a rehearing. In January 2024, we filed a petition for a writ of certiorari with the U.S Supreme Court to review the Federal Circuit's decision. Please see Note 17, *Legal Matters*, to the consolidated financial statements in Part II, Item 8 of this Annual Report, which is incorporated herein by reference, for additional information.

Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part,

which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

We are, have been, and may continue to be, involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful.

Even where laws provide protection or we are able to obtain patents, costly and time-consuming litigation may be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property rights against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than we have. To counter infringement or unauthorized use of any patents we may obtain, we may be required to file infringement claims, which can be expensive and time-consuming to litigate. In addition, if we or one of our future collaborators were to initiate legal proceedings against a third party to enforce a patent covering one of our products, current product candidates, or one of our future products, the defendant could counterclaim that the patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace and challenges to validity of patents in certain foreign jurisdictions are common as well. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the U.S. Patent and Trademark Office, or made a materially misleading statement, during prosecution. We may assert the patents in Hatch-Waxman litigation against the party filing the ANDA to keep the competing product off of the market until the patents expire but there is a risk that we will not succeed. The party filing the ANDA may also counterclaim in the litigation that our patents are not valid or unenforceable, and the court may find one or more claims of our patents invalid or unenforceable. If this occurs, a competing generic product could be marketed prior to expiration of our patents listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book," which would harm our business.

We have been and continue to be involved in number of lawsuits with a variety of generic drug manufacturers who have filed ANDAs relating to certain of our patents. In December 2022, the Delaware District Court ruled in favor of the Defendants in our patent litigation relating to the Defendants' filing of ANDAs for generic versions of HETLIOZ® in the U.S. We appealed the decision to the Federal Circuit, and in May 2023, a three-judge panel of the Federal Circuit affirmed the Delaware District Court's ruling. In August 2023, the Federal Circuit denied our request for a rehearing. In January 2024, we filed a petition for a writ of certiorari with the U.S Supreme Court to review the Federal Circuit's decision. Please see Note 17, *Legal Matters,* to the consolidated financial statements in Part II, Item 8 of this Annual Report, which is incorporated herein by reference, for additional information.

If we do not obtain protection under the Hatch-Waxman Act and similar foreign legislation to extend our patents and to obtain market exclusivity for our products, our business will be harmed.

The Hatch-Waxman Act provides for an extension of patent term for drugs for a period of up to five years to compensate for time spent in development. The HETLIOZ® U.S. new chemical entity (NCE) patent (the primary patent covering the product as a new composition of matter) received the full five-year patent term extension under the Hatch-Waxman Act and so, assuming that we continue to have rights under our license agreement with respect to this product, this patent in the U.S. expired in December 2022. We also own HETLIOZ® U.S. method of treatment patents (directed to the approved method of treatment as described in the HETLIOZ® label approved by the FDA), which expire normally between 2033 and 2041, and four drug substance patents that expire in 2035. Additionally, the U.S. Patent and Trademark Office has issued a drug formulation patent for HETLIOZ LQ® that will expire in 2040. The Fanapt® U.S. NCE patent received the full five-year patent term extension under the Hatch-Waxman Act and so this patent in the U.S. expired in November 2016. In November 2013, a patent directed to a method of treating patients with Fanapt® based on genotype was issued to us by the U.S. Patent and Trademark Office. This patent, which was listed in the Orange Book in January 2015, is set to expire in 2027. Eight additional U.S. patents directed to methods of treating patients with Fanapt®, which are set to expire between 2025 and 2031, were issued to us in 2015. With respect to PONVORY®, an application for term extension of the NCE patent pursuant to the Hatch-Waxman Act is pending. Based on correspondence between FDA and the U.S. Patent and Trademark Office, we expect that the NCE patent's term should be extended for the maximum amount of time, five years, which would extend the term of this patent until November 2029. The U.S. Patent and Trademark Office has granted additional patents, including a further patent directed to a crystalline form of the active ingredient in PONVORY®, which will expire in May 2032 in view of awarded patent term adjustment. The U.S. Patent and Trademark Office has also issued three method of treatment patents for

PONVORY®, which will expire between November 2024 and December 2035. Furthermore, on January 24, 2024, the U.S. Patent and Trademark Office issued a Notice of Allowance in the case of U.S. Pat. Appl. No. 17/962,968, which covers other methods of treatment using the active ingredient in PONVORY®. Once issued, this patent would be expected to expire on October 10, 2042. Also, a number of patent applications covering further methods of treatment remain pending at the U.S. Patent and Trademark Office.

In December 2022, the Delaware District Court ruled in favor of the Defendants in our patent litigation relating to the Defendants' filing of ANDAs for generic versions of HETLIOZ® in the U.S. See Note 17, *Legal Matters,* to the consolidated financial statements in Part II, Item 8 of this Annual Report and the risk factor entitled "*We are, have been, and may continue to be, involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful*," each of which is incorporated herein by reference, for additional information.

The E.U. provides that companies that receive regulatory approval for a new medicinal product will have a 10-year period of regulatory data protection and market protection for that product (with the possibility of a further one-year extension under certain conditions), beginning on the date of such European regulatory approval, regardless of when the European NCE patent covering such product expires. A generic version of the approved drug that refers to the approved drug's regulatory data may not be marketed or sold in Europe during such market protection period. This legislation is of material importance with respect to Fanapt®, since the European NCE patent for Fanapt® has expired.

Assuming we gain a five-year patent term restoration for tradipitant, and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to tradipitant's U.S. NCE patent until 2029. Assuming we gain a five-year patent term restoration for VQW-765, and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to VQW-765's U.S. NCE patent until 2028.

However, there is no assurance that we will receive the extensions of our patents or other exclusive rights available under the Hatch-Waxman Act or similar foreign legislation. Such extensions may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or any other failure to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we fail to receive such extensions or exclusive rights, our ability to prevent competitors from manufacturing, marketing and selling generic versions of our products will be materially impaired.

Generic company competitors have received FDA approval of generic versions of HETLIOZ® in the U.S. We are pursuing U.S. Supreme Court review of the May 2023 decision of the Federal Circuit affirming the December 2022 Delaware District Court decision that declared as invalid claims of a group of patents that protect our exclusivity in the U.S.

The FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, permits the FDA to approve ANDAs for generic versions of brand name drugs like HETLIOZ®. We refer to the process of generic drug applications as the "ANDA process." The ANDA process permits competitor companies to obtain marketing approval for a drug product with the same active ingredient, dosage form, strength, route of administration, and labeling as the approved brand name drug, but without having to conduct and submit clinical studies to establish the safety and efficacy of the proposed generic product. In place of such clinical studies, an ANDA applicant needs to submit data demonstrating that its product is bioequivalent to the brand name product, usually based on pharmacokinetic studies.

As an alternate path to FDA approval for modifications of products previously approved by the FDA, an applicant may submit an NDA, under Section 505(b)(2) of the FDCA (enacted as part of the Hatch-Waxman Amendments). This statutory provision permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the owner of the data. The Hatch-Waxman Amendments permit the applicant to rely upon the FDA findings of safety and effectiveness of a drug that has obtained FDA approval based on preclinical or clinical studies conducted by others. In addition to relying on FDA prior findings of safety and effectiveness for a referenced drug product, the FDA may require companies to perform additional preclinical or clinical studies to support approval of the modification to the referenced product.

If an application for a generic version of a branded product or a Section 505(b)(2) application relies on a prior FDA finding of safety and effectiveness of a previously-approved product including an alternative strength thereof, the applicant is required to certify to the FDA concerning any patents listed for the referenced product in the Orange Book. Specifically, the applicant must certify in the application that:

I. there is no patent information listed for the reference drug;

II. the listed patent has expired for the reference drug;

III. the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration; or

IV. the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the ANDA or 505(b)(2) NDA is submitted.

The Hatch-Waxman Amendments require an applicant for a drug product that relies, in whole or in part, on the FDA's prior approval of HETLIOZ®, to notify us of its application, a "paragraph IV" notice, if the applicant is seeking to market its product prior to the expiration of the patents that both claim HETLIOZ® and are listed in the Orange Book. A bona fide paragraph IV notice may not be given under the Hatch-Waxman Amendments until after the generic company receives from the FDA an acknowledgement letter stating that its ANDA is sufficiently complete to permit a substantive review.

The paragraph IV notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe our patents, that the relevant patents are invalid, or both. After receipt of a valid notice, the branded product manufacturer has the option of bringing a patent infringement suit in federal district court against any generic company seeking approval for its product within 45 days from the date of receipt of each notice. If such a suit is commenced within this 45-day period, the Hatch-Waxman Amendments provide for a 30-month stay on FDA's ability to give final approval to the proposed generic product, which period begins on the date the paragraph IV notice is received. Generally, during a period of time in which generic applications may be submitted for a branded product based on a product's regulatory exclusivity status, if no patents are listed in the Orange Book before the date on which a complete ANDA application for a product (excluding an amendment or supplement to the application) is submitted, an ANDA application could be approved by FDA without regard to a stay. For products entitled to five-year exclusivity status, the Hatch-Waxman Amendments provide that an ANDA application may be submitted after four years following FDA approval of the branded product if it contains a certification of patent invalidity or non-infringement to a patent listed in the Orange Book. In such a case, the 30-month stay runs from the end of the five-year exclusivity period. Statutory stays may be shortened or lengthened if either party fails to cooperate in the litigation and it may be terminated if the court decides the case in less than 30 months. If the litigation is resolved in favor of the ANDA applicant before the expiration of the 30-month period, the stay will be immediately lifted and the FDA's review of the application may be completed. Such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents.

Between April 2018 and March 2021, we filed numerous Hatch-Waxman lawsuits in the Delaware District Court against Teva, MSN and Apotex asserting that U.S. Patent Nos. RE46,604 ('604 Patent) , 9,060,995, 9,539,234, 9,549,913, 9,730,910 ('910 Patent), 9,844,241, 10,071,977, 10,149,829 ('829 Patent), 10,376,487 ('487 Patent), 10,449,176, 10,610,510, 10,610,511, 10,829,465, and 10,611,744 would be infringed by their generic versions of HETLIOZ®, for which they were seeking FDA approval. In January 2022, we entered into a license agreement with MSN and Impax resolving the lawsuits against MSN. The license agreement grants MSN and Impax a non-exclusive license to manufacture and commercialize MSN's version of HETLIOZ® in the U.S. effective as of March 13, 2035, unless prior to that date we obtain pediatric exclusivity for HETLIOZ®, in which case the license will be effective as of July 27, 2035. MSN and Impax may enter the market earlier under certain limited circumstances. In January 2023, MSN and its commercial partner, Amneal Pharmaceuticals, Inc., informed us of their belief that such circumstances have occurred and have since launched their generic. We disagree with this position and continue to aggressively defend our legal rights to exclusivity for HETLIOZ®. There is no guarantee, however, that we will be successful in our efforts. The consolidated lawsuits against the remaining Defendants went to trial in March 2022.

In December 2022, the Delaware District Court ruled that Teva and Apotex did not infringe the '604 Patent, and that the asserted claims of the '604 Patent, '910 Patent, '829 Patent and '487 Patent were invalid. We appealed the decision to the Federal Circuit and in May 2023, a three-judge panel of the Federal Circuit affirmed the Delaware District Court's ruling. In August 2023, the Federal Circuit denied our request for a rehearing. In January 2024, we filed a petition for a writ of certiorari with the U.S. Supreme Court to review the Federal Circuit's decision. While we are pursuing additional remedies, we cannot be certain of the success, timing or efforts involved in connection with these efforts. If any of the generic manufacturers has adequate supply available and is successful, such generic competition in the short term could have a material and adverse impact on our revenues and our stock price.

We may also face challenges to the validity of our patents through a procedure known as inter partes review. Inter partes review is a trial proceeding conducted through the Patent Trial and Appeal Board, of the U.S. Patent and Trademark Office. Such a proceeding could be introduced against us within the statutory one-year window triggered by service of a

complaint for infringement related to an ANDA filing or at any time by an entity not served with a complaint. Such proceedings may review the patentability of one or more claims in a patent on specified substantive grounds such as allegations that a claim is obvious on the basis of certain prior art.

We intend to continue to vigorously enforce our intellectual property rights relating to HETLIOZ®, but we cannot predict the outcome of the pending lawsuits, our appeal, or any subsequently filed lawsuits or inter partes review. See Note 17, *Legal Matters,* to the consolidated financial statements in Part II, Item 8 of this Annual Report and the risk factor entitled "*We are, have been, and may continue to be, involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful,*" each of which is incorporated herein by reference, for additional information.

Any significant degree of generic market entry would limit our U.S. sales, which would have a significant adverse impact on our business and results of operations. In addition, even if a competitor's effort to introduce a generic product is ultimately unsuccessful, the perception that such development is in progress and/or news related to such progress could materially affect the perceived value of our company and our stock price. For example, our stock price suffered a significant decline following our announcement of the Delaware District Court's ruling in favor of the Defendants.

We may not be successful in the development of products for our own account.

In addition to our business strategy of acquiring rights to develop and commercialize products, we may develop products for our own account by applying our technologies to off-patent drugs as well as developing our own proprietary molecules. Because we will be funding the development of such programs, there is a risk that we may not be able to continue to fund all such programs to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals or market any approved products. We expect the development of products for our own account to consume substantial resources. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those associated with our programs with collaborative partners.

Litigation or third-party claims of intellectual property infringement could require us to divert resources and may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize one or more of our products. Defense of these claims, regardless of their merit, would divert substantial financial and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain additional licenses from third parties to advance our research or allow commercialization of our products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to develop and commercialize further one or more of our products.

In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others could divert substantial financial and employee resources from our business. If we fail to enforce our proprietary rights against others, our business will be harmed.

As described elsewhere in these risk factors and in Note 17, *Legal Matters*, to the consolidated financial statements in Part II, Item 8 of this Annual Report, incorporated herein by reference, we have initiated lawsuits to enforce our patent rights against certain generic pharmaceutical companies.

General Risk Factors

Our stock price has been highly volatile and may be volatile in the future, and purchasers of our common stock could incur substantial losses.

The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. Between January 1, 2023 and December 31, 2023, the high and low sale prices of our common stock as reported on The Nasdaq Global Market varied between $3.30 and $8.15. Additionally,

market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons that were unrelated to the operating performance of any one company.

The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

- our level of success in commercializing our products;
- our level of success in executing our commercialization strategies;
- publicity regarding actual or potential litigation involving us and the outcome of any such litigation;
- publicity regarding actual or potential testing or trial results relating to products under development by us or our competitors;
- the outcome of regulatory review relating to products under development by us or our competitors;
- regulatory developments in the U.S. and foreign countries;
- newly enacted healthcare legislation or changes to existing legislation;
- developments concerning any collaboration or other strategic transaction we may undertake;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- safety issues with our products or those of our competitors;
- announcements of technological innovations or new therapeutic products or methods by us or others;
- actual or anticipated variations in our quarterly operating results;
- changes in estimates of our financial results or recommendations by securities analysts or failure to meet such financial expectations;
- changes in government regulations or policies;
- changes in patent legislation or patent decisions or adverse changes to patent law;
- additions or departures of key personnel or members of our board of directors;
- the publication of negative research or articles about our company, our business or our products by industry analysts or others;
- market rumors or press reports;
- publicity regarding actual or potential transactions involving us; and
- economic, political and other external factors beyond our control.

We have been and may in the future be subject to litigation, which could harm our stock price, business, results of operations and financial condition.

We have been the subject of litigation in the past and may be subject to litigation in the future. In the past, following periods of volatility in the market price of their stock, many companies, including us, have been the subjects of securities class action litigation. Any such litigation can result in substantial costs and diversion of management's attention and resources and could harm our stock price, business results of operations and financial condition. For example, our stock price suffered a significant decline following our announcement of the Delaware District Court's ruling in favor of the Defendants. As a result of these factors, holders of our common stock might be unable to sell their shares at or above the price they paid for such shares.

If there are substantial sales of our common stock, our stock price could decline.

A small number of institutional investors and private equity funds hold a significant number of shares of our common stock. Sales by these stockholders of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

In addition to our outstanding common stock, as of December 31, 2023, there were a total of 6,697,816 shares of our common stock that we have registered and are obligated to issue upon the exercise of currently outstanding options and settlement of restricted stock unit awards granted under our 2006 and 2016 Equity Incentive Plans. Upon the exercise of these options or settlement of the shares underlying these restricted stock units, as the case may be, in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms, if at all.

If securities or industry analysts do not publish research or reports or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have research coverage by one securities and industry analyst. If the analyst who covers us downgrades our stock, our stock price would likely decline. If this analyst ceases coverage of our company or fails to regularly publish reports on us, interest in the purchase of our stock could decrease, which could cause our stock price or trading volume to decline.

Our common stock may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in previous offerings. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in previous offerings, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors.

Our business could be negatively affected as a result of the actions of activist stockholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry, including us, over the last several years. If faced with a proxy contest or other type of shareholder activism, we may not be able to respond successfully to the contest or dispute, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest or shareholder dispute involving us for several reasons, including, among others:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

These actions could cause our stock price to experience periods of volatility.

Anti-takeover provisions in our charter and bylaws and under Delaware law, and the adoption of a rights plan, could prevent or delay a change in control of our company.

We are a Delaware corporation and the anti-takeover provisions of Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and bylaws:

- authorize the issuance of “blank check” preferred stock that could be issued by our board of directors to thwart a takeover attempt;
- do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors;

- establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election;
- require that directors only be removed from office for cause;
- provide that vacancies on the board of directors, including newly created directorships, may be filled only by a majority vote of directors then in office;
- limit who may call special meetings of stockholders;
- prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders; and
- establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

Our board of directors previously adopted a rights agreement, the provisions of which could have had the effect of discouraging, delaying or preventing a change in management or control over us. While there is no plan to do so at this time, our board of directors may choose to adopt a new rights plan in the future.

Changes to tax regulations to which we are subject could adversely affect us.

We are subject to tax laws, treaties and regulations in the countries in which we operate, and these laws and treaties are subject to interpretation. New legislation or regulation that could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. We have taken, and will continue to take, tax positions based on our interpretation of such tax laws. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions may cause our actual financial results to deviate from previous estimates.

Future transactions may harm our business or the market price of our stock.

We regularly review potential transactions related to technologies, products or product rights and businesses complementary to our business. These transactions could include:

- mergers;
- acquisitions;
- asset purchases;
- strategic alliances;
- licensing agreements; and
- co-promotion and similar agreements.

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations in the market price of our stock. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also materially adversely affect our results of operations and could harm the market price of our stock. It is too early to tell whether our December 2023 acquisition of PONVORY® from Janssen will yield the results that we expect. If we experience difficulties integrating PONVORY® into our portfolio of approved products, or we are unable to achieve market acceptance of PONVORY®, our business and results of operations may be materially harmed.

We may undertake strategic acquisitions in the future, and difficulties integrating such acquisitions could damage our ability to achieve or sustain profitability.

Although we have no experience in acquiring businesses, we may acquire businesses or assets that complement or augment our existing business. If we acquire businesses with promising products or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to move one or more products through preclinical and/or clinical development to regulatory approval and commercialization. Integrating any newly acquired businesses or technologies could be expensive and time-consuming, resulting in the diversion of resources from our current business. We may not be able to integrate any acquired business successfully. We cannot assure that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or

private debt or equity financing to acquire any businesses, which would result in dilution for stockholders or the incurrence of indebtedness and may not be available on terms which would otherwise be acceptable to us. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

Our operating results may fluctuate significantly due to a number of factors which make our future results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our operating results will continue to be subject to fluctuations and are affected by numerous factors, including:

- product sales;
- cost of product sales;
- the rate at which third-party payors approve coverage for our products;
- marketing and other expenses;
- manufacturing or supply issues;
- the timing and amount of royalties or milestone payments;
- our addition or termination of development programs;
- variations in the level of expenses related to our products or future development programs;
- regulatory developments affecting our products or those of our competitors;
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- any intellectual property infringement or other lawsuit in which we may become involved; and
- the timing and recognition of stock-based compensation expense.

If our operating results fall below the expectations of investors or securities analysts or below any guidance we may provide, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

We are increasingly dependent on information technology systems, infrastructure and data. Cybersecurity breaches could expose us to liability, damage our reputation, compromise our confidential information or otherwise adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data. Our computer systems may be vulnerable to service interruption or destruction, malicious intrusion and random attack. Security breaches pose a risk that sensitive data, including intellectual property, trade secrets or personal information may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our key business partners face similar risks, and a security breach of their systems could adversely affect our security posture. While we continue to invest in data protection and information technology, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm.

Our internal computer systems, or those of our collaborators, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our collaborators, CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Information security risks have significantly increased in recent years in part due to the proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign state actors. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security breaches.

While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our independent drug development programs. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Our information security systems are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information or personal health information, we could incur substantial liability, our reputation would be damaged, and the further development of our product candidates could be delayed.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include, among other things, operational risks; intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy or security laws and other litigation and legal risk; and reputational risks. We have implemented several cybersecurity processes, technologies, and controls to aid in our efforts to assess, identify, and manage such material risks.

Our process for identifying and assessing material risks from cybersecurity threats operates alongside our broader overall risk assessment process, covering all company risks. As part of this process, appropriate personnel will collaborate with subject matter specialists, as necessary, to gather insights for identifying and assessing material cybersecurity threat risks, their severity and potential mitigations.

We also have a cybersecurity specific risk assessment process, which helps identify our cybersecurity threat risks. As part of this process, and our processes to provide for the availability of critical data and systems, maintain regulatory compliance, identify and manage our risks from cybersecurity threats and to protect against, detect and respond to cybersecurity incidents, as such term is defined in Item 106(a) of Regulation S-K, we undertake the below listed activities, among others:

- comparing our processes to benchmark standards, such as those set by the National Institute of Standards and Technology (NIST);
- closely monitor emerging data protection laws and implement changes to our processes designed to comply;
- conduct annual customer data handling and use requirements training for employees;
- conduct annual cybersecurity management and incident training for employees involved in our systems and processes that handle sensitive data;
- through policy, practice and contract (as applicable) require employees, as well as third-parties who provide services on our behalf, to treat customer information and data with care;
- run tabletop exercises to simulate a response to a cybersecurity incident and use the findings to improve our processes and technologies;
- conduct regular network and endpoint monitoring, vulnerability assessments, and penetration testing to improve our information systems, as such term is defined in Item 106(a) of Regulation S-K;
- leverage the NIST incident handling framework to help us identify, protect, detect, respond, and recover when there is an actual or potential cybersecurity incident; and
- carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate brand and reputational damage.

As part of the above processes, we may engage with assessors, consultants, auditors, and other third-parties, including by having a third-party review our cybersecurity program to help identify areas for continued focus, improvement and/or compliance.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including those in our supply chain, our CROs or those who have access to our customer and employee data or our systems. Third-party risks are included within our broader overall risk assessment process, as well as our cybersecurity-specific risk identification program, both of which are discussed above. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. We perform diligence on third-parties that have access to our systems, data or facilities that house such systems or data, and continually monitor cybersecurity threat risks identified through such diligence.

We describe whether and how risks from identified cybersecurity threats have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the risk factors entitled "*We are increasingly dependent on information technology systems, infrastructure and data. Cybersecurity breaches could expose us to liability, damage our reputation, compromise our confidential information or otherwise adversely affect our business*," and "*Our internal computer systems, or those of our collaborators, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates*," in Part I, Item 1A of this Annual Report on Form 10-K, each of which is incorporated herein by reference.

Cybersecurity Governance

Cybersecurity is an important part of our risk management processes and an area of increasing focus for our Board and management.

Our Audit Committee is responsible for the oversight of risks from cybersecurity threats. At least quarterly, the Audit Committee receives an overview from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. Members of the Audit Committee are also encouraged to regularly engage in ad hoc conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. Material cybersecurity threat risks are also considered during separate Board meeting discussions of important matters like risk management, business continuity planning, brand management, and other relevant matters.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by a team of senior level management, including our President, Chief Executive Officer and Chairman of the Board, Senior Vice President, Chief Financial Officer and Treasurer, Senior Vice President, General Counsel and Secretary, and VP of Information Technology. Such individuals collectively have significant prior work experience in various roles involving managing information security, developing cybersecurity strategy and implementing effective information and cybersecurity programs.

These members of management are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan.

As discussed above, these members of management report to the Audit Committee about cybersecurity threat risks, among other cybersecurity related matters.

ITEM 2. PROPERTIES

Our headquarters office consists of a total of 43,462 square feet of office space located at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. under operating leases and subleases that expire between 2026 and 2028 and certain of these leases are subject to renewal options. In addition, we have 2,880 square feet of office space in London, England under an operating lease that has a lease term ending in 2026, and other short-term leases. We believe that these facilities are suitable and adequate

to meet our anticipated near-term needs. We anticipate that following the expiration of the leases, additional or alternative space will be available at commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

Information with respect to this item may be found in Note 17, *Legal Matters,* to the consolidated financial statements in Part II, Item 8 of this annual report on Form 10-K, which is incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

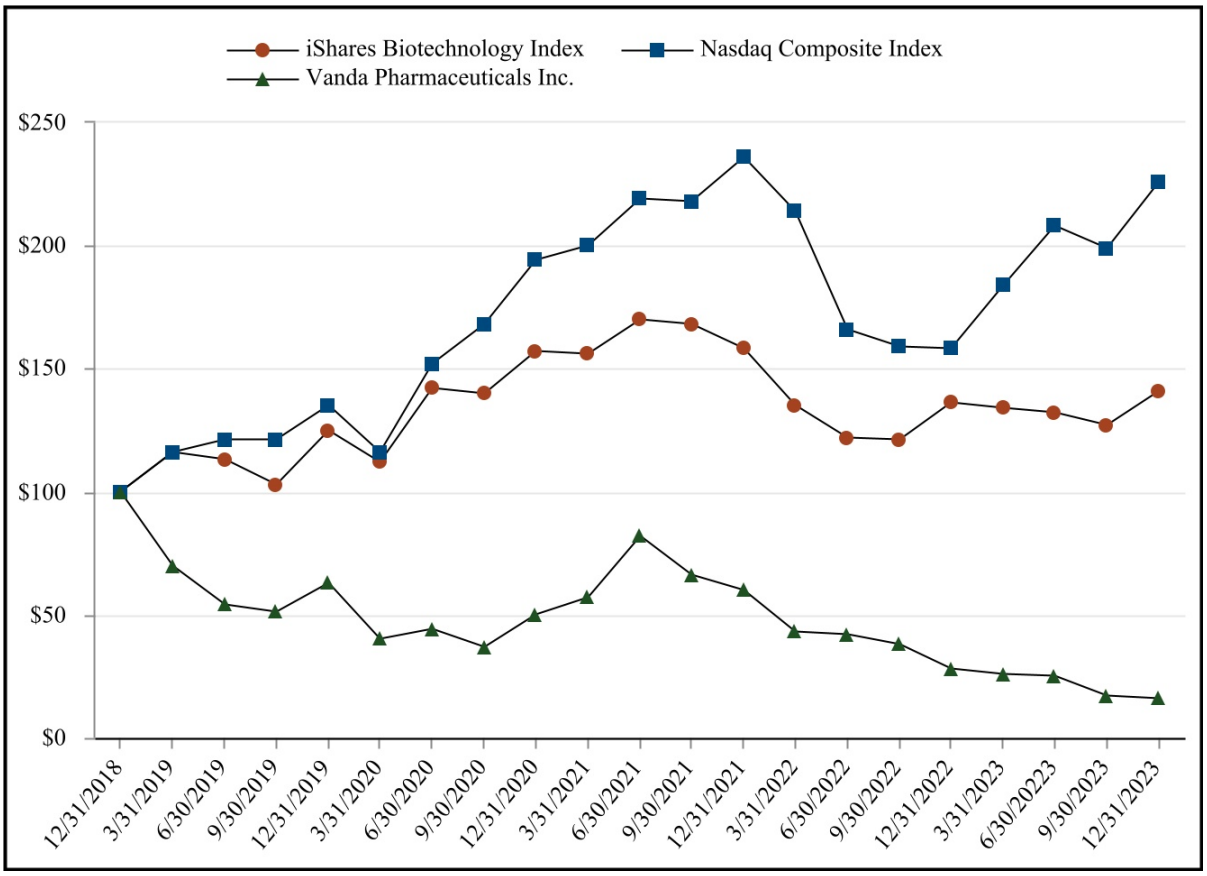
PART II

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

Our common stock is quoted on The Nasdaq Global Market under the symbol "VNDA." As of February 1, 2024, there were nine holders of record of our common stock. The number of holders of record of our common stock does not reflect the number of beneficial holders whose shares are held by depositors, brokers or other nominees.

Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters

The following graph shows the cumulative five-year total return on our common stock relative to the cumulative total returns of the Nasdaq Composite Index and the iShares Biotechnology Index. An investment of $100 (with reinvestment of dividends) is assumed to have been made in our common stock and in each of the indexes on December 31, 2018 and its relative performance is tracked through December 31, 2023. The comparisons in the table are required by the Securities and Exchange Commission (SEC) and are not intended to forecast or be indicative of possible future performance of our common stock. We have never paid cash dividends to our stockholders and do not plan to pay dividends in the foreseeable future. The following graph and related information is being furnished solely to accompany this annual report on Form 10-K pursuant to Item 201(e) of Regulation S-K and shall not be deemed "soliciting materials" or to be "filed" with the SEC (other than as provided in Item 201), nor shall such information be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, and irrespective of any general incorporation language in any such filing.



ITEM 6. RESERVED

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing in this annual report on Form 10-K (Annual Report). This discussion and analysis generally addresses 2023 and 2022 items and year-to-year comparisons between 2023 and 2022. Discussions of 2021 items and year-to-year comparisons between 2022 and 2021 that are not included in this Annual Report can be found in Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report include historical information and other information with respect to our plans and strategy for our business and contain forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under Part I, Item 1A, Risk Factors, and elsewhere in this Annual Report.

Overview

Vanda Pharmaceuticals Inc. (we, our or Vanda) is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients.

We strive to advance novel approaches to bring important new medicines to market through responsible innovation. We are committed to the use of technologies that support sound science, including genetics and genomics, in drug discovery, clinical trials and the commercial positioning of our products.

Our commercial portfolio is currently comprised of three products, HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS), Fanapt® for the treatment of schizophrenia and PONVORY®, which we acquired the U.S. and Canadian rights to on December 7, 2023, for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease, in adults. HETLIOZ® is the first product approved by the U.S. Food and Drug Administration (FDA) for patients with Non-24 and for patients with SMS. In addition, we have a number of drugs in development, including:

- HETLIOZ® (tasimelteon) for the treatment of jet lag disorder, insomnia, delayed sleep phase disorder (DSPD) and pediatric Non-24;
- Fanapt® (iloperidone) for the treatment of bipolar I disorder and a long acting injectable (LAI) formulation for the treatment of schizophrenia;
- PONVORY (ponesimod) for the treatment of inflammatory/autoimmune disorders, including but not limited to ulcerative colitis, psoriasis, Crohn's disease, atopic dermatitis, eosinophilic esophagitis and alopecia areata;
- Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness and atopic dermatitis;
- VHX-896, the active metabolite of iloperidone;
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors, including VSJ-110 for the treatment of dry eye and ocular inflammation and VPO-227 for the treatment of secretory diarrhea disorders, including cholera;
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of onychomycosis, hematologic malignancies and with potential use as a treatment for several oncology indications;
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, for the treatment of social/performance anxiety and psychiatric disorders; and
- Antisense oligonucleotide (ASO) molecules, including VCA-894A for the treatment of Charcot-Marie-Tooth Disease, Type 2S (CMT2S), caused by cryptic slice site variants within IGHMBP2.

Operational Highlights

HETLIOZ®

- The supplemental New Drug Application (sNDA) for HETLIOZ® in the treatment of insomnia is under review by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of March 4, 2024. We announced that on February 4, 2024, we received a notification from the FDA stating that the FDA had identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. No deficiencies were disclosed by the FDA in the notification, and the FDA stated that the notification does not reflect a final decision on the information under review. On February 6, 2024, we filed suit in the U.S. District Court for the District of Columbia (D.C. District Court) challenging the FDA's conduct in reviewing the insomnia sNDA. We are asking the D.C. District Court to compel the FDA to adhere to the legally mandated 180-day review period for sNDAs and to declare as unlawful and void the regulations the FDA relies upon to issue complete response letters.
- We are also continuing to pursue FDA approval for HETLIOZ® in the treatment of jet lag disorder. We announced in January 2024 that the D.C. District Court granted our motion for summary judgment on our claim against the FDA for unlawfully delaying a hearing on the approvability of our sNDA for HETLIOZ® in the treatment of jet lag disorder. The D.C. District Court ordered the FDA to either finally resolve our jet lag sNDA or commence a hearing on the sNDA on or before March 5, 2024.
- In January 2024, we filed a petition for a writ of certiorari with the U.S. Supreme Court to review the decision of the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) in our HETLIOZ® Abbreviated New Drug Application (ANDA) litigation against Teva Pharmaceuticals USA, Inc. (Teva), Apotex Inc. and Apotex Corp. (collectively, Apotex). Teva and Apotex have waived their opportunity to respond to our petition, which is now ripe for decision by the U.S. Supreme Court.

Fanapt®

- The article "Efficacy and Safety of Iloperidone in Bipolar Mania: A Double-Blind, Placebo-Controlled Study" was published in January 2024 in the Journal of Clinical Psychiatry. The findings of this pivotal study have been submitted to the FDA as part of our sNDA for Fanapt® in the treatment of bipolar I disorder in adults.
- The sNDA for Fanapt® in the treatment of bipolar I disorder in adults is under review by the FDA with a PDUFA target action date of April 2, 2024.

PONVORY®

- We completed the acquisition of the U.S. and Canadian rights to PONVORY® from Janssen for $100.0 million in December 2023 and the transition is ongoing. PONVORY® is a once-daily oral selective sphingosine-1-phosphate receptor 1 modulator, approved by the FDA and Health Canada to treat adults with relapsing forms of multiple sclerosis, and is a potential therapeutic candidate for the treatment of a diverse group of inflammatory/autoimmune disorders ranging from psoriasis to ulcerative colitis.
- We announced in January 2024 that the U.S. Patent and Trademark Office (USPTO) had issued a notice of allowance for its PONVORY® patent application, 17/962,968, covering methods for reducing clinical management events before or during the treatment of multiple sclerosis and methods for reinstating treatment after missed doses. When issued, the patent is anticipated to expire on October 10, 2042. Upon issuance, we intend to list this patent in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

Tradipitant

- The article "The Efficacy of Tradipitant in Patients with Diabetic and Idiopathic Gastroparesis in Phase III Randomized Placebo-Controlled Clinical Trial" was published in January 2024 in the *Clinical Gastroenterology and Hepatology Journal*. The findings of this pivotal study as well as a previously reported positive placebo-controlled study in diabetic and idiopathic gastroparesis have been submitted to the FDA as part of our New Drug Application (NDA) for tradipitant in the treatment of symptoms of gastroparesis in adults.
- In December 2023, we announced that the NDA for tradipitant for the treatment of symptoms of gastroparesis was accepted for filing and is under review by the FDA with a PDUFA target action date of September 18, 2024.
- The second Phase III study of tradipitant in the treatment of motion sickness is over 50% enrolled. In May 2023, we previously announced positive results from its first Phase III study of tradipitant in the treatment of motion sickness. We plan to pursue FDA approval upon completion of the clinical development program.

Early-Stage Programs

- In January 2024, we announced that the FDA had approved the Investigational New Drug (IND) application to evaluate VCA-894A for the treatment of a patient with Charcot-Marie-Tooth disease, axonal, type 2S (CMT2S), an inherited peripheral neuropathy for which there is no available treatment.
- In January 2024, we announced that the FDA had also approved the IND to evaluate VTR-297 for the treatment of onychomycosis, a fungal infection of the nail.

Since we began operations, we have devoted substantially all of our resources to the in-licensing, clinical development and commercialization of our products. Our ability to generate meaningful product sales and achieve profitability largely depends on our level of success in commercializing HETLIOZ® and Fanapt® in the U.S. and Europe and PONVORY® in the U.S and Canada, on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and to manufacture, market and sell our products. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks that are detailed in Part I, Item 1A, *Risk Factors,* of this Annual Report.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements for the year ended December 31, 2023 included in this Annual Report. However, we believe that the following accounting policies are important to understanding and evaluating our reported financial results as they involve the most significant judgments and estimates used in the preparation of our consolidated financial statements, and we have accordingly included them in this discussion.

Revenue from net product sales. We account for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. We recognize revenue when control of the product is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those product sales, which is typically once the product physically arrives at the customer.

HETLIOZ® is available in the U.S. for distribution through a limited number of specialty pharmacies and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. PONVORY® is available in the U.S. for distribution primarily through specialty pharmacies. We invoice and record revenue when customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse, which is the point at which control is transferred to the customer. Revenues and accounts receivable are concentrated with these customers. Outside the U.S., we sell HETLIOZ® in Germany and have a distribution agreement for the commercialization of Fanapt® in Israel. Receivables are carried at transaction price net of allowance for credit losses. Allowance for credit losses is measured using historical loss rates based on the aging of receivables and incorporating current conditions and forward-looking estimates.

The transaction price is determined based upon the consideration to which we will be entitled in exchange for transferring product to the customer. Our product sales are recorded net of applicable product revenue allowances for which reserves are established and include discounts, rebates, chargebacks, service fees, co-pay assistance and product returns that are applicable for various government and commercial payors. Where appropriate, our estimates of variable consideration included in the transaction price consider a range of possible outcomes. Allowances for rebates, chargebacks and co-pay assistance are based upon the insurance benefits of the end customer, which are estimated using historical activity and, where available, actual and pending prescriptions for which we have validated the insurance benefits. Variable consideration may be constrained and is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts. If actual results in the future vary from our estimates, we adjust our estimate in the period identified, which would affect net product sales in the period such variances become known. During the year ended December 31, 2023, we constrained the variable consideration for HETLIOZ® net product sales. The constrained revenue relates to the uncertainties of payor utilization, patient demand and chargeback and rebate amounts,

including Medicaid, and other reserves related to transactions that resulted in elevated levels of inventory at specialty pharmacy customers during 2023.

Reserves for variable consideration are classified as product revenue allowances on the Consolidated Balance Sheets, with the exception of prompt-pay discounts, which are classified as reductions of accounts receivable. The reserve for product returns for which the product may not be returned for a period of greater than one year from the balance sheet date is included as a component of other non-current liabilities in the Consolidated Balance Sheets. Uncertainties related to variable consideration are generally resolved in the quarter subsequent to period end, with the exception of Medicaid rebates, which are dependent upon the timing of when states submit reimbursement claims, Medicare inflationary rebates, and product returns that are resolved during the product expiry period specified in the customer contract. Due to transactions that resulted in increased inventory stocking at specialty pharmacy customers of HETLIOZ® in 2023, the time it takes to resolve these uncertainties is expected to be longer than we have historically experienced. We currently record sales allowances for the following:

- *Prompt-pay:* Specialty pharmacies and wholesalers are generally offered discounts for prompt payment. We expect that the specialty pharmacies and wholesalers will earn prompt payment discounts and, therefore, deduct the full amount of these discounts from total product sales when revenues are recognized.
- *Rebates:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors, including the new Medicare Part D inflationary rebate effective October 1, 2022. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid and Medicare. The allowances for rebates are based on statutory or contracted discount rates and estimated patient utilization.
- *Chargebacks:* Chargebacks are discounts that occur when contracted indirect customers purchase directly from specialty pharmacies and wholesalers. Contracted indirect customers, which currently consist primarily of Public Health Service institutions and federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or wholesaler, in turn, charges back the difference between the price initially paid by the specialty pharmacy or wholesaler and the discounted price paid to the specialty pharmacy or wholesaler by the contracted customer.
- *Medicare Part D coverage gap:* The Medicare Part D prescription drug benefit requires manufacturers to fund approximately 70% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients for applicable drugs. We account for the Medicare Part D coverage gap using a point of sale model. Estimates for expected Medicare Part D coverage gap are based in part on historical activity and, where available, actual and pending prescriptions when we have validated the insurance benefits. Beginning January 1, 2025, the Medicare Part D coverage gap discount program will be replaced with a new discounting program under the Inflation Reduction Act.
- *Service fees:* We receive sales order management, data and distribution services from certain customers, for which we are assessed fees. These fees are based on contracted terms and are known amounts. We accrue service fees at the time of revenue recognition, resulting in a reduction of product sales and the recognition of an accrued liability, unless it is a payment for a distinct good or service from the customer in which case the fair value of those distinct goods or services are recorded as selling, general and administrative expense.
- *Co-pay assistance:* Patients who have commercial insurance and meet certain eligibility requirements may receive co-pay assistance. Co-pay assistance utilization is based on information provided by our third-party administrator.
- *Product returns:* We generally offer direct customers a limited right to return as contractually defined with our customers. We consider several factors in the estimation process, including expiration dates of product shipped to customers, inventory levels within the distribution channel, product shelf life, historical return activity, including activity for product sold for which the return period has past, prescription trends and other relevant factors. We do not expect returned goods to be resalable. There was no right of return asset as of December 31, 2023 or 2022.

The following table summarizes sales discounts and allowance activity as of and for the years ended December 31, 2023, 2022 and 2021:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balances at December 31, 2020	26,870	8,873	35,743
Provision related to current period sales	83,965	31,176	115,141
Adjustments for prior period sales	(853)	193	(660)
Credits/payments made	(78,128)	(30,641)	(108,769)
Balances at December 31, 2021	31,854	9,601	41,455
Provision related to current period sales	92,109	30,636	122,745
Adjustments for prior period sales	(2,647)	1,396	(1,251)
Credits/payments made	(83,857)	(31,609)	(115,466)
Balances at December 31, 2022	37,459	10,024	47,483
Provision related to current period sales	85,916	28,488	114,404
Adjustments for prior period sales	(267)	276	9
Credits/payments made	(82,957)	(28,361)	(111,318)
Balances at December 31, 2023	$ 40,151	$ 10,427	$ 50,578

The provision for rebates and chargebacks of $85.9 million and $92.1 million for the years ended December 31, 2023 and 2022, respectively, and their ending balances at December 31, 2023 and 2022, primarily represent Medicaid rebates applicable to sales of Fanapt® and, to a lesser extent, Medicaid rebates applicable to sales of HETLIOZ®. The provision for discounts, returns and other of $28.5 million and $30.6 million for the years ended December 31, 2023 and 2022, represents wholesaler distribution fees applicable to sales of Fanapt® and estimated product returns of Fanapt®, and co-pay assistance costs and prompt pay discounts applicable to the sales of both HETLIOZ® and Fanapt®. The ending balances of discounts, returns and other as of December 31, 2023 and 2022 primarily represent estimated product returns of Fanapt® and wholesaler distribution fees applicable to sales of Fanapt®.

Stock-based compensation. Compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the period during which the employee or director is required to perform service in exchange for the award. We use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility rates are based on the historical volatility of our publicly traded common stock and other factors. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have never paid cash dividends to our stockholders and do not plan to pay dividends in the foreseeable future. As stock-based compensation expense recognized in the Consolidated Statements of Operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Research and development expenses. Research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services for clinical trial use, milestone payments made under licensing agreements prior to regulatory approval, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop products, related facilities costs, and salaries, other employee-related costs and stock-based compensation for research and development personnel. We expense research and development costs as they are incurred for products in the development stage, including manufacturing costs and milestone payments made under license agreements prior to FDA approval. Upon and subsequent to FDA approval, manufacturing and milestone payments made under license agreements are capitalized. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved. Costs related to the acquisition of intellectual property are expensed as incurred if the underlying technology is developed in connection with our research and development efforts and has no alternative future use.

Clinical trials are inherently complex, often involve multiple service providers, and can include payments made to investigator physicians at study sites. Because billing for services often lags delivery of service by a substantial amount of time, we often are required to estimate a significant portion of our accrued clinical expenses. Our assessments include, but are not limited to: (i) an evaluation by the project manager of the work that has been completed during the period, (ii) measurement of progress prepared internally and/or provided by the third-party service provider, (iii) analyses of data that justify the progress, and (iv) management's judgment. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high.

Intangible assets and impairment of long-lived assets. Our intangible assets consist of capitalized license costs for products approved by the FDA or costs to acquire already commercialized products. We amortize our intangible assets on a straight-line basis over the estimated useful economic life of the related product patents. We assess the impairment of intangible assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important that could trigger an impairment review include significant underperformance relative to expected historical or projected future operating results, a significant adverse change in legal or regulatory factors that could affect the value or patent life including our ability to defend and enforce patent claims and other intellectual property rights and significant negative industry or economic trends. When we determine that the carrying value of our intangible assets may not be recoverable based upon the existence of one or more of the indicators of impairment, we measure any impairment based on the amount that carrying value exceeds fair value.

As a result of the unfavorable events and subsequent developments in the fourth quarter of 2022 and second quarter of 2023 related to the HETLIOZ® patent litigation (see Note 17, *Legal Matters*, to the consolidated financial statements included in Part II, Item 8 of this Annual Report) we performed impairment reviews for our HETLIOZ® asset group and determined, based upon our review of undiscounted cash flows, that the carrying value of our HETLIOZ® asset group, inclusive of the intangible asset, is recoverable. Accordingly, we did not record an intangible asset impairment charge during the years ended December 31, 2023 and 2022. The litigation and subsequent developments do not affect the sale of HETLIOZ® in the E.U. and there is no generic litigation pending outside of the U.S. with respect to HETLIOZ®. Furthermore, the litigation and subsequent events do not relate to the HETLIOZ LQ® oral suspension formulation. Our expected cash flows continue to support our estimated useful economic life of the intangible asset through 2035.

Income taxes. We assess the need for a valuation allowance against our deferred tax asset each quarter through the review of all available positive and negative evidence. Deferred tax assets are reduced by a tax valuation allowance when, in the opinion of management, it is more likely than not that some portion of the deferred tax assets will not be realized. The analysis is highly dependent upon historical and projected taxable income. Projected taxable income includes significant assumptions related to revenue, commercial expenses and research and development activities, which could be affected by the HETLIOZ® generic competition and our ability to obtain regulatory approval from the FDA for products or new indications in development, among other factors. Tax benefits are recognized from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement.

Recent Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies,* to the consolidated financial statements included in Part II, Item 8 of this Annual Report for information on recent accounting pronouncements.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including our and our partners' ability to continue to successfully commercialize our products, including activities related to recently acquired PONVORY®, any possible payments made or received pursuant to license agreements, progress of our research and development efforts, the timing and outcome of clinical trials and related possible regulatory approvals and the status of existing and future potential litigation involving our products and intellectual property. In December 2022, the U.S. District Court for the District of Delaware (Delaware District Court) ruled in favor of Teva and Apotex in our patent litigation relating to their filing of ANDAs for generic versions of HETLIOZ® in the U.S., and in May 2023, a three-judge panel of the Federal Circuit affirmed this ruling. In August 2023, the Federal Circuit denied our request for a rehearing. In January 2024, we filed a petition for a writ of certiorari with the U.S Supreme Court to review the Federal Circuit's decision. See Note 17, *Legal Matters*, to the consolidated financial statements in Part II, Item 8 of this Annual Report. The FDA has approved ANDAs for Teva and Apotex, both of which have since launched their generic versions of HETLIOZ® at risk in the U.S. The FDA has also

approved the ANDA for MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (MSN), and HETLIOZ® could face even more competition from other generic companies in the U.S. in the near term in light of the patent litigation rulings against us. The license agreement that we entered into when we settled our litigation with MSN (MSN/Impax License Agreement) grants MSN and Impax Laboratories LLC (Impax) a non-exclusive license to manufacture and commercialize MSN's generic version of HETLIOZ® in the U.S. effective as of March 13, 2035, unless prior to that date we obtain pediatric exclusivity for HETLIOZ®, in which case the license will be effective as of July 27, 2035. The MSN/Impax License Agreement also provides that MSN and Impax may launch a generic version of HETLIOZ® earlier under certain limited circumstances. In January 2023, MSN and its commercial partner, Amneal Pharmaceuticals, Inc., informed us of their belief that such circumstances had occurred and have since launched their generic version. We disagree with this position and intend to aggressively defend our legal rights to exclusivity for HETLIOZ®. There is no guarantee, however, that we will be successful in our efforts. Sales of generic versions of HETLIOZ® have resulted in and could continue to result in a reduction in the demand for HETLIOZ® and/or the price at which we can sell it and/or create volatility in net product sales in future periods, which could have a material impact on our revenues and results of operations.

Year ended December 31, 2023 compared to year ended December 31, 2022

Revenues. Total revenues decreased by $61.7 million, or 24%, to $192.6 million for the year ended December 31, 2023 compared to $254.4 million for the year ended December 31, 2022. Revenue from net product sales were as follows:

	Year Ended December 31,			
(in thousands)	**2023**	**2022**	**Net Change**	**Percent**
HETLIOZ® net product sales	$ 100,167	$ 159,655	$ (59,488)	(37)%
Fanapt® net product sales	90,873	94,727	(3,854)	(4)%
PONVORY® net product sales	1,600	—	1,600	N/A
Total net product sales	$ 192,640	$ 254,382	$ (61,742)	(24)%

HETLIOZ® net product sales decreased by $59.5 million, or 37%, to $100.2 million for the year ended December 31, 2023 compared to $159.7 million for the year ended December 31, 2022. The decrease to net product sales was attributable to a decrease in price net of deductions and a decrease in volume. Our HETLIOZ® net product sales as reported for the three months ended March 31, 2023 reflected transactions that resulted in higher unit sales as compared to recent prior periods and a significant increase of inventory stocking at specialty pharmacy customers during 2023 and at December 31, 2023. HETLIOZ® net product sales during 2023 reflect lower unit sales as a result of generic competition. HETLIOZ® net product sales may continue to reflect lower unit sales as a result of continued reduction of the elevated inventory levels at specialty pharmacy customers. Further, HETLIOZ® net product sales will likely decline in future periods, potentially significantly, related to continued generic competition in the U.S. Additionally, we constrained HETLIOZ® net product sales for the year ended December 31, 2023 to an amount not probable of significant revenue reversal. HETLIOZ® net product sales could experience variability in future periods as the remaining uncertainties associated with variable consideration related to transactions in the early part of 2023 are resolved.

Fanapt® net product sales decreased by $3.9 million to $90.9 million for the year ended December 31, 2023 compared to $94.7 million for the year ended December 31, 2022. The decrease to net product sales was attributable to a decrease in volume.

In December 2023, we purchased the right to market and sell PONVORY® in the U.S. and Canadian markets from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company. PONVORY® net product sales were $1.6 million for the year ended December 31, 2023, which reflects sales during the post-acquisition period.

Cost of goods sold. Cost of goods sold decreased by $9.5 million, or 39%, to $14.8 million for the year ended December 31, 2023 compared to $24.3 million for the year ended December 31, 2022. Cost of goods sold includes third-party manufacturing costs of product sold, third-party royalty costs and distribution and other costs. Third-party royalty costs were 5% of HETLIOZ® net product sales in Germany and 6% of Fanapt® net product sales. Third-party royalty costs on HETLIOZ® net product sales in the U.S. decreased from 10% to 5% in December 2022 and are expected to end in the second quarter of 2024. We evaluate the risk of excess inventory and product expiry by evaluating current and future product demand relative to product shelf life and build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance, patient usage, and generic competition. Our inventory balance consisted of $7.2 million and $8.0 million of HETLIOZ® product and $3.0 million and $3.4 million of Fanapt® product as of December 31, 2023 and 2022, respectively.

Research and development expenses. Research and development expenses decreased by $8.9 million, or 10%, to $76.8 million for the year ended December 31, 2023 compared to $85.8 million for the year ended December 31, 2022. The decrease was primarily due to a decrease in clinical trial expenses associated with our Fanapt® development program, partially offset by an increase in our tradipitant and VHX-896 development programs. Expenses for our other development programs, which include expenses incurred on product discovery such as ASO, included a $3.0 million upfront fee expensed in the third quarter of 2022 in consideration for entering into a research and development agreement.

The following table summarizes the costs of our product development initiatives for the years ended December 31, 2023 and 2022.

	Year Ended December 31,	
(in thousands)	**2023**	**2022**
Direct project costs (1)		
HETLIOZ®	$ 8,978	$ 12,084
Fanapt®	11,306	26,931
Tradipitant	32,781	25,232
VTR-297	1,595	1,814
CFTR	1,490	1,168
VQW-765	988	3,570
VHX-896	6,186	2,148
Other	5,683	5,082
Total direct project costs	69,007	78,029
Indirect project costs (1)		
Stock-based compensation	3,323	3,964
Other indirect overhead	4,493	3,777
Total indirect project costs	7,816	7,741
Total research and development expense	$ 76,823	$ 85,770

(1) We record direct costs, including personnel costs and related benefits, on a project-by-project basis. Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record indirect costs that support a number of our research and development activities in the aggregate, including stock-based compensation.

We expect to incur significant research and development expenses as we continue to develop our products. In addition, we expect to incur licensing costs in the future that could be substantial, as we continue our efforts to expand our product pipeline.

Selling, general and administrative expenses. Selling, general and administrative expenses decreased by $23.6 million, or 17%, to $112.9 million for the year ended December 31, 2023 compared to $136.5 million for the year ended December 31, 2022. The decrease in selling, general and administrative expenses was primarily the result of a decrease in spending on marketing, sales and commercial support activities for our commercial products.

Intangible asset amortization. Intangible asset amortization was $2.1 million for the year ended December 31, 2023 compared to $1.5 million for the year ended December 31, 2022. Amortization expense increased in 2023 due to amortization on the intangible asset from the recently acquired rights to PONVORY® in the U.S. and Canada.

Other income. Other income was $20.3 million for the year ended December 31, 2023 compared to $5.0 million for the year ended December 31, 2022. Other income primarily consists of investment income on our marketable securities, which increased in 2023 as a result of higher yields on our marketable securities.

Provision for income taxes. A provision for income taxes of $3.8 million and $5.0 million was recorded for the years ended December 31, 2023 and 2022, respectively. Our income tax expense or benefit is determined by applying the statutory tax rates in jurisdictions where we operate to each period's income before income taxes. Adjustments are made for permanent differences in taxability or deductibility of pretax items as well as for other items, such as tax credits that are generated on our research and development activities. See Note 15, *Income Taxes,* to the consolidated financial statements in Part II, Item 8 of this Annual Report for additional information.

Liquidity and Capital Resources

As of December 31, 2023, our total cash and cash equivalents and marketable securities were $388.3 million compared to $466.9 million at December 31, 2022. Cash decreased in 2023 primarily due to our acquisition of the U.S. and Canadian rights for PONVORY® in December 2023. Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original maturity of 90 days or less at date of purchase and consist of investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored and corporate enterprises and commercial paper.

Our liquidity resources as of December 31, 2023 and 2022 are summarized as follows:

(in thousands)	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 135,821	$ 135,029
Marketable securities:		
U.S. Treasury and government agencies	185,115	177,170
Corporate debt	67,328	154,660
Total marketable securities	252,443	331,830
Total cash, cash equivalents and marketable securities	$ 388,264	$ 466,859

As of December 31, 2023, we maintained all of our cash, cash equivalents and marketable securities in two financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits, but we do not anticipate any losses with respect to such deposits.

In the normal course of our business, we regularly enter into agreements with third-party vendors under fee service arrangements which generally may be terminated on 90 days' notice without incurring additional charges, other than charges for work completed or materials procured but not paid for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination. Our non-cancellable purchase commitments for agreements longer than one year are not material. Various other long-term agreements entered into for services with other third-party vendors, such as inventory purchase arrangements, are cancellable in nature or contain variable commitment terms within the agreement that are within our control.

We also have long-term contractual obligations related to our operating leases and license agreements. See Note 8, *Leases*, and Note 11, *Commitments and Contingencies*, respectively, to the consolidated financial statements in Part II, Item 8 of this Annual Report for more information about these commitments.

We do not have any off-balance sheet arrangements.

Based on our current operating plans, which include costs and expenses in connection with our continued clinical development of tradipitant and our other products, pursuit of regulatory approval of tradipitant, U.S. commercial activities for HETLIOZ®, Fanapt® and PONVORY®, pursuit of regulatory approval of HETLIOZ® and Fanapt® in other regions and in other indications, and payments due upon achievement of milestones under our license agreements, we believe that our cash, cash equivalents and marketable securities and cash received from product sales will be sufficient for at least the next 12 months. Our future cash requirements and the adequacy of our available funds will depend on many factors, primarily including our ability to generate revenue, the scope and costs of our commercial, manufacturing and process development activities, the magnitude of our discovery, preclinical and clinical development programs, and potential costs to acquire or license the rights to additional products.

We may need or desire to obtain additional capital to finance our operations through debt, equity or alternative financing arrangements. We may also seek capital through collaborations or partnerships with other companies. The issuance of debt could require us to grant liens on certain of our assets that may limit our flexibility and debt securities may be convertible into common stock. If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of our existing stockholders. If we are unable to obtain additional financing, we may be required to reduce the scope of our future activities, which could harm our business, financial condition and operating results. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

Cash Flow

The following table summarizes our net cash flows from operating, investing and financing activities for the years ended December 31, 2023 and 2022:

(in thousands)	Year Ended December 31, 2023	2022	Net Change
Net cash provided by (used in):			
Operating activities:			
Net income	$ 2,509	$ 6,275	$ (3,766)
Non-cash charges	11,039	19,635	(8,596)
Net change in operating assets and liabilities	(747)	6,074	(6,821)
Operating activities	12,801	31,984	(19,183)
Investing activities:			
Asset acquisition	(100,665)	—	(100,665)
Purchases of property and equipment	(383)	(679)	296
Net purchases, sales and maturities of marketable securities	88,992	50,604	38,388
Investing activities	(12,056)	49,925	(61,981)
Financing activities:			
Proceeds from the exercise of stock options	—	734	(734)
Financing activities	—	734	(734)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	47	265	(218)
Net change in cash, cash equivalents and restricted cash	$ 792	$ 82,908	$ (82,116)

Operating Activities. Cash flows provided by operating activities during the year ended December 31, 2023 were $12.8 million, a decrease of $19.2 million compared to $32.0 million during the year ended December 31, 2022. The decrease reflects a decrease of $3.8 million in net income, a decrease of $8.6 million in non-cash charges primarily due to additional amortization of discounts on our marketable securities, and a decrease of $6.8 million from the net change in operating assets and liabilities.

Investing Activities. Cash flows used in investing activities during the year ended December 31, 2023 were $12.1 million, a decrease in cash of $62.0 million compared to cash provided by investing activities of $49.9 million during the year ended December 31, 2022. The change in investing activities reflects the timing of net reinvestment of available cash and cash equivalents in our portfolio of marketable securities and the acquisition of the U.S. and Canadian rights to PONVORY® in 2023.

Financing Activities. Financing activities include proceeds from exercises of stock options. Cash flows provided by financing activities during the year ended December 31, 2022 were $0.7 million. There were no exercises of stock options during the year ended December 31, 2023.

ITEM 7A. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities and restricted cash. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes.

We deposit our cash with financial institutions that we consider to be of high credit quality and purchase marketable securities that are generally investment grade, liquid, short-term fixed income securities and money-market instruments denominated in U.S. dollars. Our marketable securities consist of commercial paper, corporate notes and U.S. government agency notes and have maturities of less than two years. We do not believe that an increase in market rates would have any significant impact on the realized value of our cash equivalents and marketable securities.

We are also exposed to risks related to changes in foreign currency exchange rates relating to our foreign operations. The functional currency of our international subsidiaries is the local currency. We are exposed to foreign currency risk to the extent that we enter into transactions denominated in currencies other than our subsidiaries' respective functional currencies. We are also exposed to unfavorable fluctuations of the U.S. dollar, which is our reporting currency, against the currencies of

our operating subsidiaries when their respective financial statements are translated into U.S. dollars for inclusion in our consolidated financial statements. We do not currently hedge our foreign currency exchange rate risk. Foreign currency has not had, nor do we believe that a decrease or increase in any foreign currency exchange rates would have, a material impact on our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and related financial statement schedules required to be filed are listed in the Index to Consolidated Financial Statements and are incorporated in Part IV, Item 15 of this annual report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (Exchange Act)) as of December 31, 2023. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of December 31, 2023, the end of the period covered by this annual report on Form 10-K (Annual Report), to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). Management conducted an assessment of our internal control over financial reporting based on the original framework established in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control — Integrated Framework.* Based on the assessment, management concluded that, as of December 31, 2023, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report included in this Annual Report.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter of 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

During the fiscal quarter ended December 31, 2023, none of our directors or officers informed us of the adoption, modification or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408. Furthermore, during the fiscal quarter ended December 31, 2023, we did not adopt or terminate a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required under this item will be contained in our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information required under this item will be contained in our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 and is incorporated herein by reference, except that information required by Item 407(e)(5) of Regulation S-K will be deemed furnished in this Form 10-K and will not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate it by reference into such filing.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required under this item will be contained in our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 and is incorporated herein by reference.

Securities Authorized for Issuance under Equity Incentive Plans

Information regarding securities authorized for issuance under equity incentive plans will be contained in our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required under this item will be contained in our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required under this item will be contained in our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The consolidated financial statements filed as part of this annual report on Form 10-K are listed in the Index to Consolidated Financial Statements. Certain schedules are omitted because they are not applicable, or not required, or because the required information is included in the consolidated financial statements or notes thereto. The Exhibits are listed in the Exhibit Index.

ITEM 16. Form 10-K Summary

None.

Signatures

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

Vanda Pharmaceuticals Inc.

February 8, 2024

By: /s/ Mihael H. Polymeropoulos, M.D.
Mihael H. Polymeropoulos, M.D.
President, Chief Executive Officer and Chairman of the Board of Directors

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.

Name	Title	Date
/s/ Mihael H. Polymeropoulos, M.D. Mihael H. Polymeropoulos, M.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	February 8, 2024
/s/ Kevin Moran Kevin Moran	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 8, 2024
/s/ Richard W. Dugan Richard W. Dugan	Lead Independent Director	February 8, 2024
/s/ Anne Sempowski Ward Anne Sempowski Ward	Director	February 8, 2024
/s/ Phaedra Chrousos Phaedra Chrousos	Director	February 8, 2024
/s/ Stephen Ray Mitchell Stephen Ray Mitchell	Director	February 8, 2024
/s/ Tage Honoré Tage Honoré	Director	February 8, 2024

Vanda Pharmaceuticals Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Vanda Pharmaceuticals Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Vanda Pharmaceuticals Inc. and its subsidiaries (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations, of comprehensive income, of changes in stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2023, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2023, 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated 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.

Medicaid Rebates for Fanapt®

As described in Note 2 to the consolidated financial statements, the allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contracted discount rates and estimated patient utilization. The Company has recorded product revenue allowances of $49.2 million as of December 31, 2023, of which a significant amount relates to allowances for Medicaid Rebates for Fanapt®.

The principal considerations for our determination that performing procedures relating to the Medicaid Rebates for Fanapt® is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing the allowances, as these allowances are based on assumptions developed for estimated patient utilization, primarily payor mix and invoice lag; this in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating audit evidence related to the estimated patient utilization assumption.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the allowances for Medicaid Rebates for Fanapt®, including controls over the assumptions used to estimate these rebates. These procedures also included, among others, (i) developing an independent estimate of the Medicaid Rebates for Fanapt® by utilizing third-party information related to patient utilization, as well as the historical trends of the invoice lag; and (ii) comparing the independent estimate to management's estimate. Developing the independent estimate involved (i) testing the completeness and accuracy of the patient utilization data from third-party reports, and (ii) testing rebate claims processed by the Company, including evaluating those claims for consistency with the contractual and mandated terms of the Medicaid Drug Rebate Program.

/s/ PricewaterhouseCoopers LLP

Washington, District of Columbia
February 8, 2024

We have served as the Company's auditor since 2003.

VANDA PHARMACEUTICALS INC.
CONSOLIDATED BALANCE SHEETS

(in thousands, except for share and per share amounts)	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 135,821	$ 135,029
Marketable securities	252,443	331,830
Accounts receivable, net	34,155	33,512
Inventory	1,357	1,194
Prepaid expenses and other current assets	9,170	17,727
Total current assets	432,946	519,292
Property and equipment, net	2,037	2,573
Operating lease right-of-use assets	7,103	8,400
Intangible assets, net	121,369	18,565
Deferred tax assets	75,000	74,039
Non-current inventory and other	9,985	11,378
Total assets	$ 648,440	$ 634,247
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 38,460	$ 45,551
Product revenue allowances	49,237	45,885
Total current liabilities	87,697	91,436
Operating lease non-current liabilities	7,006	8,813
Other non-current liabilities	8,827	6,800
Total liabilities	103,530	107,049
Commitments and contingencies (Notes 11 and 17)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding at December 31, 2023 and 2022, respectively	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 57,534,499 and 56,783,764 shares issued and outstanding at December 31, 2023 and 2022, respectively	58	57
Additional paid-in capital	700,274	686,235
Accumulated other comprehensive loss	(30)	(1,193)
Accumulated deficit	(155,392)	(157,901)
Total stockholders' equity	544,910	527,198
Total liabilities and stockholders' equity	$ 648,440	$ 634,247

The accompanying notes are an integral part of these consolidated financial statements.

VANDA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except for share and per share amounts)	Year Ended December 31, 2023	2022	2021
Revenues:			
Net product sales	$ 192,640	$ 254,382	$ 268,682
Total revenues	192,640	254,382	268,682
Operating expenses:			
Cost of goods sold excluding amortization	14,796	24,282	25,629
Research and development	76,823	85,770	75,363
Selling, general and administrative	112,883	136,485	124,047
Intangible asset amortization	2,090	1,516	1,478
Total operating expenses	206,592	248,053	226,517
Income (loss) from operations	(13,952)	6,329	42,165
Other income	20,291	4,971	199
Income before income taxes	6,339	11,300	42,364
Provision for income taxes	3,830	5,025	9,212
Net income	$ 2,509	$ 6,275	$ 33,152
Net income per share:			
Basic	$ 0.04	$ 0.11	$ 0.60
Diluted	$ 0.04	$ 0.11	$ 0.58
Weighted average shares outstanding:			
Basic	57,380,975	56,461,877	55,548,122
Diluted	57,557,911	56,983,171	56,921,836

The accompanying notes are an integral part of these consolidated financial statements.

VANDA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in thousands)	Year Ended December 31, 2023	2022	2021
Net income	$ 2,509	$ 6,275	$ 33,152
Other comprehensive income (loss):			
Net foreign currency translation gain (loss)	28	(39)	(49)
Change in net unrealized gain (loss) on marketable securities	1,461	(1,271)	(472)
Tax benefit (provision) on other comprehensive income (loss)	(326)	292	107
Other comprehensive income (loss), net of tax	1,163	(1,018)	(414)
Comprehensive income	$ 3,672	$ 5,257	$ 32,738

The accompanying notes are an integral part of these consolidated financial statements.

VANDA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(in thousands, except for share amounts)	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value				
Balances at December 31, 2020	54,865,092	$ 55	$ 650,300	$ 239	$ (197,328)	$ 453,266
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	1,035,763	1	3,549	—	—	3,550
Stock-based compensation expense	—	—	15,374	—	—	15,374
Net income	—	—	—	—	33,152	33,152
Other comprehensive loss, net of tax	—	—	—	(414)	—	(414)
Balances at December 31, 2021	55,900,855	56	669,223	(175)	(164,176)	504,928
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	882,909	1	733	—	—	734
Stock-based compensation expense	—	—	16,279	—	—	16,279
Net income	—	—	—	—	6,275	6,275
Other comprehensive loss, net of tax	—	—	—	(1,018)	—	(1,018)
Balances at December 31, 2022	56,783,764	57	686,235	(1,193)	(157,901)	527,198
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	750,735	1	(1)	—	—	—
Stock-based compensation expense	—	—	14,040	—	—	14,040
Net income	—	—	—	—	2,509	2,509
Other comprehensive income, net of tax	—	—	—	1,163	—	1,163
Balances at December 31, 2023	57,534,499	$ 58	$ 700,274	$ (30)	$ (155,392)	$ 544,910

The accompanying notes are an integral part of these consolidated financial statements.

VANDA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Year Ended December 31, 2023	2022	2021
Cash flows from operating activities			
Net income	$ 2,509	$ 6,275	$ 33,152
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation of property and equipment	920	1,217	1,363
Stock-based compensation	14,040	16,279	15,374
Amortization of premiums and accretion of discounts on marketable securities	(8,799)	(2,963)	1,649
Loss (gain) on sales of marketable securities	655	—	(12)
Intangible asset amortization	2,090	1,516	1,478
Deferred income taxes	(1,286)	1,130	6,745
Other non-cash adjustments, net	3,419	2,456	1,728
Changes in operating assets and liabilities:			
Accounts receivable	(707)	(1,089)	(2,469)
Prepaid expenses and other assets	8,523	(6,136)	(1,247)
Inventory	(771)	(4,479)	(2,233)
Accounts payable and other liabilities	(10,984)	11,793	3,040
Product revenue allowances	3,192	5,985	5,646
Net cash provided by operating activities	12,801	31,984	64,214
Cash flows from investing activities			
Asset acquisition	(100,665)	—	—
Purchases of property and equipment	(383)	(679)	(552)
Purchases of marketable securities	(512,606)	(349,258)	(420,461)
Sales and maturities of marketable securities	601,598	399,862	344,317
Net cash provided by (used in) investing activities	(12,056)	49,925	(76,696)
Cash flows from financing activities			
Proceeds from exercise of stock options	—	734	3,550
Net cash provided by financing activities	—	734	3,550
Effect of exchange rate changes on cash, cash equivalents and restricted cash	47	265	(91)
Net change in cash, cash equivalents and restricted cash	792	82,908	(9,023)
Cash, cash equivalents and restricted cash			
Beginning of year	135,498	52,590	61,613
End of year	$ 136,290	$ 135,498	$ 52,590

The accompanying notes are an integral part of these consolidated financial statements.

VANDA PHARMACEUTICALS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business Organization and Presentation

Business Organization

Vanda Pharmaceuticals Inc. (the Company) is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. The Company commenced its operations in 2003 and operates in one reporting segment.

The Company's commercial portfolio is currently comprised of three products, HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS), Fanapt® for the treatment of schizophrenia and PONVORY®, which the Company acquired the U.S. and Canadian rights to on December 7, 2023, for the treatment of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease, in adults. HETLIOZ® is the first product approved by the United States Food and Drug Administration (FDA) for patients with Non-24 and for patients with SMS. In addition, the Company has a number of drugs in development, including:

- HETLIOZ® (tasimelteon) for the treatment of jet lag disorder, insomnia, delayed sleep phase disorder (DSPD) and pediatric Non-24;
- Fanapt® (iloperidone) for the treatment of bipolar I disorder and a long acting injectable (LAI) formulation for the treatment of schizophrenia;
- PONVORY (ponesimod) for the treatment of inflammatory/autoimmune disorders, including but not limited to ulcerative colitis, psoriasis, Crohn's disease, atopic dermatitis, eosinophilic esophagitis and alopecia areata;
- Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness and atopic dermatitis;
- VHX-896, the active metabolite of iloperidone;
- Portfolio of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) activators and inhibitors, including VSJ-110 for the treatment of dry eye and ocular inflammation and VPO-227 for the treatment of secretory diarrhea disorders, including cholera;
- VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of onychomycosis, hematologic malignancies and with potential use as a treatment for several oncology indications;
- VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, for the treatment of social/performance anxiety and psychiatric disorders; and
- Antisense oligonucleotide (ASO) molecules, including VCA-894A for the treatment of Charcot-Marie-Tooth Disease, Type 2S (CMT2S), caused by cryptic slice site variants within IGHMBP2.

Basis of Presentation

The accompanying consolidated financial statements includes the accounts of Vanda Pharmaceuticals Inc. and its wholly owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). All intercompany accounts and transactions have been eliminated in consolidation.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluation could change. Actual results could differ from those estimates.

Cash, Cash Equivalents and Restricted Cash

For purposes of the Consolidated Balance Sheets and Consolidated Statements of Cash Flows, cash equivalents represent highly-liquid investments with a maturity date of three months or less at the date of purchase. Cash and cash equivalents include investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Restricted cash relates primarily to amounts held as collateral for letters of credit for leases for office space at the Company's Washington, D.C. headquarters.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Consolidated Balance Sheets to the total end of period cash, cash equivalents and restricted cash reported within the Consolidated Statements of Cash Flows:

	December 31,	
(in thousands)	**2023**	**2022**
Cash and cash equivalents	$ 135,821	$ 135,029
Restricted cash included in non-current inventory and other	469	469
Total cash, cash equivalents and restricted cash	$ 136,290	$ 135,498

Marketable Securities

The Company classifies all of its marketable securities as available-for-sale securities. The Company's investment policy requires the selection of high-quality issuers. Available-for-sale securities are carried at fair market value, with unrealized gains and losses reported as a component of stockholders' equity in accumulated other comprehensive income (loss). At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether it intends to sell or if it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value. The Company also reviews its available-for-sale securities in an unrealized loss position to determine whether the unrealized loss is the result of a change in creditworthiness or other factors. If declines in the value of available for-sale securities are determined to be credit-related, a loss is recorded in earnings in the current period. Interest and dividend income is recorded when earned and included in other income. Premiums and discounts on marketable securities are amortized and accreted, respectively, to earliest call date and maturity, respectively, and included in other income. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which would be included in the Consolidated Statements of Operations when generated. All available-for-sale marketable securities are available for use in current operations and are classified as current.

Inventory

Inventory, which is recorded at the lower of cost or net realizable value, includes the cost of third-party manufacturing and other direct and indirect costs and is valued using the first-in, first-out method. The Company evaluates expiry risk by evaluating current and future product demand relative to product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Inventory levels are evaluated for the amount of inventory that would be sold within one year. At certain times, the level of inventory can exceed the forecasted level of cost of goods sold for the next 12 months. The Company classifies the estimate of such inventory as non-current.

Asset Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If determined to be an asset acquisition, the Company accounts for the transaction under Accounting Standards Codification (ASC) 805-50, which requires the recognition of assets acquired and liabilities assumed on a relative fair value basis based on the acquisition cost, which includes transaction costs in addition to consideration given. Any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values.

See Note 3, *PONVORY® Acquisition*, for further discussion of the Company's acquisition of the U.S. and Canadian rights to PONVORY® from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company, which the Company accounted for as an asset acquisition under ASC 805-50.

Intangible Assets

Costs incurred for products not yet approved by the FDA and for which no alternative future use exists are recorded as research and development expense. Obligations for milestone payments to other pharmaceutical companies that may result in a capitalized intangible asset are recognized when it is deemed probable that the milestone event will occur. In the event a product has been approved by the FDA or an alternative future use exists for a product, patent and license costs are capitalized and amortized on a straight-line basis over the estimated useful economic life of the related product patents. For intangible assets related to HETLIOZ®, the estimated useful life is through 2035, which is the estimated economic useful life of the related product patents.

Useful lives for acquired intangible assets accounted for under ASC 805 are generally estimated based on the market participant methodology. For intangible assets related to PONVORY®, the estimated useful life is through 2035, which is the estimated economic useful life of the related acquired product patents. Intangible assets related to Fanapt® have been fully amortized on a straight-line basis to 2016. The Fanapt® transaction represented reacquired rights, and therefore did not reflect the impact of additional Fanapt® patents solely owned by the Company with varying expiration dates, the latest of which is December 2031.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation of most property and equipment is provided on a straight-line basis over the estimated useful lives of the assets. Leasehold improvements are amortized using a straight-line basis over the lesser of the estimated useful lives of the assets or the terms of the related leases. The costs of additions and improvements are capitalized, and repairs and maintenance costs are charged to operations in the period incurred. Upon retirement or disposition of property and equipment, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in the Consolidated Statement of Operations for that period.

Leases

The Company determines if an arrangement contains a lease at inception. Right-of-use (ROU) assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from that lease. For leases with a term greater than 12 months, ROU assets and liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term. The lease term includes the option to extend the lease when it is reasonably certain the Company will exercise that option. When available, the Company uses the rate implicit in the lease to discount lease payments to present value. In the case the implicit rate is not available, the Company uses its incremental borrowing rate based on information available at the lease commencement date, including publicly available data for instruments with similar characteristics, to determine the present value of lease payments. The Company does not combine lease and non-lease elements for office leases. For existing office leases as of the adoption date of ASC 842, *Leases*, on January 1, 2019, executory costs are excluded from lease expense, which is consistent with the Company's accounting under ASC 840, *Leases*. For all office leases entered into after January 1, 2019, executory costs are allocated between lease and non-lease elements based upon their relative stand-alone prices.

Impairment of Long-Lived Assets

The Company evaluates if events and circumstances have occurred that indicate the remaining estimated useful life of its long-lived assets may warrant revision or that the remaining balance of these assets may not be recoverable. In evaluating for recoverability, the Company estimates the future undiscounted cash flows expected to result from the use of the assets and their eventual disposition. In the event that the balance of any asset exceeds the future undiscounted or discounted cash flow estimate, impairment is recognized based on the excess of the carrying amounts of the asset above its estimated fair value. No impairment was recognized for the years ended December 31, 2023, 2022 and 2021.

Accounts Payable and Accrued Liabilities

The Company's management is required to estimate accrued liabilities as part of the process of preparing financial statements. The estimation of accrued liabilities involves identifying services that have been performed on the Company's behalf, and then estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in the financial statements. Accrued liabilities include research and development expenses, such as accrued costs under contracts with clinical monitors, data management organizations and investigators in conjunction with clinical trials, fees to contract manufacturers in conjunction with the production of clinical materials, consulting and professional fees, such as lawyers and fees for marketing and other commercialization activities, accrued compensation and employee benefits, such as accrued bonus, royalties payable under licensing agreements, and other accrued fees. Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes these expenses as the services are provided.

Revenue from Net Product Sales

The Company accounts for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. The Company recognizes revenue when control of the product is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for those product sales, which is typically once the product physically arrives at the customer. Sales taxes, value add taxes, and usage-based taxes are excluded from revenues.

The Company's net product sales consist of sales of HETLIOZ®, Fanapt® and PONVORY®. Net sales by product for the years ended December 31, 2023, 2022 and 2021 were as follows:

	Year Ended December 31,		
(*in thousands*)	2023	2022	2021
HETLIOZ® net product sales	$ 100,167	$ 159,655	$ 173,536
Fanapt® net product sales	90,873	94,727	95,146
PONVORY® net product sales	1,600	—	—
Total net product sales	$ 192,640	$ 254,382	$ 268,682

The Company's HETLIOZ® net product sales as reported for the three months ended March 31, 2023 reflected higher unit sales as compared to recent prior periods. The higher unit sales during the three months ended March 31, 2023 resulted in a significant increase of inventory stocking at specialty pharmacy customers during 2023 and at December 31, 2023. HETLIOZ® net product sales during the year ended December 31, 2023 reflect lower unit sales as a result the impact of generic competition.

HETLIOZ® net product sales may continue to reflect lower unit sales as a result of continued reduction of the elevated inventory levels at specialty pharmacy customers. Further, HETLIOZ® net product sales will likely decline in future periods, potentially significantly, related to generic competition in the U.S. Additionally, the Company constrained HETLIOZ® net product sales for the year ended December 31, 2023 to an amount not probable of significant revenue reversal. HETLIOZ® net product sales could experience variability in future periods as the remaining uncertainties associated with variable consideration related to inventory stocking by specialty pharmacy customers are resolved.

HETLIOZ® is available in the United States (U.S.) for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. PONVORY® is available in the U.S. for distribution primarily through specialty pharmacies. The Company invoices and records revenue when its customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse, which is the point at which control is transferred to the customer. Revenues and accounts receivable are concentrated with these customers. Outside the U.S., the Company sells HETLIOZ® in Germany and has a distribution agreement for the commercialization of Fanapt® in Israel. Receivables are carried at transaction price net of allowance for credit losses. Allowance for credit losses is measured using historical loss rates based on the aging of receivables and incorporating current conditions and forward-looking estimates.

The following table presents each major customer that represented more than 10% of total revenues for the years ended December 31, 2023, 2022 and 2021:

	Year Ended December 31,		
Percent of Net Product Sales	**2023**	**2022**	**2021**
Customer A	20 %	36 %	40 %
Customer B	16 %	13 %	12 %
Customer C	15 %	11 %	11 %
Customer D	15 %	*	*
Customer E	14 %	11 %	10 %
Customer F	*	16 %	18 %
Total net product sales from major customers	80 %	87 %	91 %

*Represents less than 10% of respective balance.

The following table presents each major customer that represented more than 10% of accounts receivable, net, as of December 31, 2023 and 2022:

	December 31,	
Percent of Accounts Receivable, Net	**2023**	**2022**
Customer A	*	18 %
Customer B	19 %	20 %
Customer C	21 %	14 %
Customer D	34 %	*
Customer E	16 %	16 %
Customer F	*	13 %
Total accounts receivable, net from major customers	90 %	81 %

*Represents less than 10% of respective balance.

The transaction price is determined based upon the consideration to which the Company will be entitled in exchange for transferring product to the customer. The Company's product sales are recorded net of applicable product revenue allowances for which reserves are established and include discounts, rebates, chargebacks, service fees, co-pay assistance and product returns that are applicable for various government and commercial payors. Where appropriate, the Company's estimates of variable consideration included in the transaction price consider a range of possible outcomes. Allowances for rebates, chargebacks and co-pay assistance are based upon the insurance benefits of the end customer, which are estimated using historical activity and, where available, actual and pending prescriptions for which the Company has validated the insurance benefits. Variable consideration may be constrained and is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts. If actual results in the future vary from the Company's estimates, it adjusts its estimates in the period identified, which would affect net product sales in the period such variances become known. During the year ended December 31, 2023, the Company constrained the variable consideration for HETLIOZ® net product sales. The constrained revenue relates to the uncertainties of payor utilization, patient demand and chargeback and rebate amounts, including Medicaid, related to the elevated levels of inventory on hand at the specialty pharmacies.

Reserves for variable consideration are classified as product revenue allowances on the Consolidated Balance Sheets, with the exception of prompt-pay discounts that are classified as reductions of accounts receivable. The reserve for product returns for which the product may not be returned for a period of greater than one year from the balance sheet date is included as a component of other non-current liabilities in the Consolidated Balance Sheets. Uncertainties related to variable consideration are generally resolved in the quarter subsequent to period end, with the exception of Medicaid rebates, which are dependent upon the timing of when states submit reimbursement claims, Medicare inflationary rebates, and product returns that are resolved during the product expiry period specified in the customer contract. Due to increased inventory stocking at specialty pharmacy customers of HETLIOZ® in 2023, the time it takes to resolve these uncertainties could be longer than the Company has historically experienced. The Company currently records sales allowances for the following:

- *Prompt-pay:* Specialty pharmacies and wholesalers are generally offered discounts for prompt payment. The Company expects that the specialty pharmacies and wholesalers will earn prompt payment discounts and, therefore, deducts the full amount of these discounts from total product sales when revenues are recognized.
- *Rebates:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors, including the new Medicare Part D inflationary rebate effective October 1, 2022. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid and Medicare. The allowances for rebates are based on statutory or contracted discount rates and estimated patient utilization.
- *Chargebacks:* Chargebacks are discounts that occur when contracted indirect customers purchase directly from specialty pharmacies and wholesalers. Contracted indirect customers, which currently consist primarily of Public Health Service institutions and federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or wholesaler, in turn, charges back the difference between the price initially paid by the specialty pharmacy or wholesaler and the discounted price paid to the specialty pharmacy or wholesaler by the contracted customer.
- *Medicare Part D Coverage Gap:* The Medicare Part D prescription drug benefit requires manufacturers to fund approximately 70% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients for applicable drugs. The Company accounts for the Medicare Part D coverage gap using a point of sale model. Estimates for expected Medicare Part D coverage gap are based in part on historical activity and, where available, actual and pending prescriptions when the Company has validated the insurance benefits. Beginning January 1, 2025, the Medicare Part D coverage gap discount program will be replaced with a new discounting program under the Inflation Reduction Act.
- *Service Fees:* The Company receives sales order management, data and distribution services from certain customers, for which it is assessed fees. These fees are based on contracted terms and are known amounts. The Company accrues service fees at the time of revenue recognition, resulting in a reduction of product sales and the recognition of an accrued liability, unless it is a payment for a distinct good or service from the customer in which case the fair value of those distinct goods or services are recorded as selling, general and administrative expense.
- *Co-pay Assistance:* Patients who have commercial insurance and meet certain eligibility requirements may receive co-pay assistance. Co-pay assistance utilization is based on information provided by the Company's third-party administrator.

- *Product Returns*: The Company generally offers direct customers a limited right to return as contractually defined with its customers. The Company considers several factors in the estimation process, including expiration dates of product shipped to customers, inventory levels within the distribution channel, product shelf life, historical return activity, including activity for product sold for which the return period has past, prescription trends and other relevant factors. The Company does not expect returned goods to be resalable. There was no right of return asset as of December 31, 2023 or 2022. The following table summarizes activity for product returns as of and for the years ended December 31, 2023, 2022 and 2021, all of which relates to sales of Fanapt®:

(in thousands)	Reserve for Product Returns
Balances at December 31, 2020	$ 4,698
Additions	2,870
Credits/payments	(3,017)
Balances at December 31, 2021	4,551
Additions	4,332
Credits/payments	(3,739)
Balances at December 31, 2022	5,144
Additions	3,001
Credits/payments	(2,934)
Balances at December 31, 2023	$ 5,211

Cost of Goods Sold

Cost of goods sold includes royalties payable, the cost of inventory sold, costs to write down inventory to net realizable value, manufacturing and supply chain costs and product shipping and handling costs related to sales of HETLIOZ® and Fanapt® to the Company's distribution partners.

Research and Development Expenses

Research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services, milestone payments, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop products, related facilities costs, and salaries, other employee-related costs and stock-based compensation for research and development personnel. The Company expenses research and development costs as they are incurred for products in the development stage, including manufacturing costs and milestone payments made under license agreements prior to FDA approval. Upon and subsequent to FDA approval, manufacturing and milestone payments related to license agreements are capitalized. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved. Costs related to the acquisition of intellectual property are expensed as incurred if the underlying technology is developed in connection with the Company's research and development efforts and has no alternative future use.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of salaries, other employee-related costs and stock-based compensation, and facilities and third-party expenses. Selling, general and administrative expenses are associated with the activities of the corporate, finance, accounting, information technology, business development, commercial support, trade and distribution, sales, marketing, legal, medical affairs and human resource functions. Additionally, selling, general and administrative expenses included an estimate for the annual Affordable Care Act fee.

Stock-Based Compensation

Compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the period during which the employee or director is required to perform service in exchange for the award. The Company recognizes the expense over the award's vesting period. The fair value of stock options granted and restricted stock units (RSUs) awarded are amortized using the straight-line method. As stock-based compensation expense recognized in the Consolidated Statements of Operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Advertising Expense

The Company expenses the costs of advertising, including branded promotional expenses, as incurred. Branded advertising expenses, recorded in selling, general and administrative expenses, were $0.5 million, $2.6 million and $6.7 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Foreign Currency

The reporting currency of the Company is the U.S. dollar. The functional currency of the Company's international subsidiaries is the local currency. Assets and liabilities denominated in foreign currencies, including intercompany balances for which settlement is anticipated in the foreseeable future, are translated at exchange rates in effect at the balance sheet date. Foreign currency equity balances are translated at historical rates. Revenues and expenses denominated in foreign currencies are translated at average exchange rates for the respective periods. Foreign currency translation adjustments are recorded in accumulated other comprehensive income (loss).

Transactions denominated in currencies other than functional currency are recorded based on exchange rates at the time such transactions arise. Changes in exchange rates with respect to amounts recorded in the Consolidated Balance Sheets related to these items will result in unrealized foreign currency transaction gains and losses based upon period-end exchange rates. The Company also records realized foreign currency transaction gains and losses upon settlement of the transactions. Foreign currency transaction gains and losses are included in other income and were not material for the years ended December 31, 2023, 2022 and 2021, respectively.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under the asset and liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion of the deferred tax assets will not be realized. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss (NOL) carryforwards that can be utilized in the future to offset taxable income. Tax benefits are recognized from an uncertain tax position only if it is more likely than not that the position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement. Interest and penalties related to income taxes are recognized as a component of income tax expense in the Consolidated Statements of Operations, and cumulative accrued interest and penalties are recognized within the related liability line items in the Consolidated Balance Sheets.

Certain Risks and Uncertainties

The Company's products under development require approval from the FDA or other international regulatory agencies prior to commercial sales. There can be no assurance the products will receive the necessary clearance. If the Company is denied clearance or clearance is delayed, it may have a material adverse impact on the Company.

The Company's products are concentrated in rapidly changing, highly competitive markets, which are characterized by rapid technological advances, increasing generic competition, changes in customer requirements and evolving regulatory requirements and industry standards. Any failure by the Company to anticipate or to respond adequately to technological developments in its industry, challenges from new generic market entrants, changes in customer or regulatory requirements or changes in industry standards, or any significant delays in the development or introduction of products or services could have a material adverse effect on the Company's business, operating results and future cash flows.

The Company depends on single source suppliers for critical raw materials for manufacturing, as well as other components required for the administration of its products. The loss of these suppliers could delay the clinical trials or prevent or delay commercialization of the products.

Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable

securities with highly rated financial institutions. At December 31, 2023, the Company maintained all of its cash, cash equivalents and marketable securities in two financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand, and the Company believes there is minimal risk of losses on such balances.

Segment and Geographic Information

The Company operates in one reporting segment and, accordingly, no segment disclosures are presented herein. Foreign sales were not material for each of the years ended December 31, 2023, 2022 and 2021.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which is intended to provide enhanced segment disclosures. The standard will require disclosures about significant segment expenses and other segment items and identifying the Chief Operating Decision Maker and how they use the reported segment profitability measures to assess segment performance and allocate resources. These enhanced disclosures are required for all entities on an interim and annual basis, even if they have only a single reportable segment. The standard is effective for years beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024 and early adoption is permitted. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to provide enhancements to annual income tax disclosures. The standard will require more detailed information in the rate reconciliation table and for income taxes paid, among other enhancements. The standard is effective for years beginning after December 15, 2024 and early adoption is permitted. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

3. PONVORY® Acquisition

On December 7, 2023, the Company entered into an Asset Purchase Agreement (the Purchase Agreement) to acquire the U.S. and Canadian rights to PONVORY®, Janssen, and the closing of the transaction took place simultaneously with signing. PONVORY® is a once-daily oral selective sphingosine-1-phosphate receptor 1 modulator, indicated to treat adults with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. The total consideration for the acquisition was $104.9 million consisting of cash paid to Janssen and acquisition-related transaction costs, of which $4.2 million of the consideration was accrued as of December 31, 2023 and recorded in the accounts payable and accrued liabilities balance of the Consolidated Balance Sheets; the $4.2 million is a non-cash investing item in the Consolidated Statement of Cash Flows. The Purchase Agreement includes customary representations, warranties and covenants, as well as standard mutual indemnities covering losses arising from any material breach of the Purchase Agreement or inaccuracy of representations and warranties. Janssen has agreed to indemnify the Company against losses arising from its activities prior to the closing, and the Company has agreed to indemnify Janssen against losses arising from the Company's activities pertaining to PONVORY® after the closing. Simultaneously and in connection with the Purchase Agreement, the parties have also entered into certain supporting agreements, including a customary transition agreement, pursuant to which, during a transition period, Janssen will continue PONVORY® operations and the Company and Janssen will transition regulatory and supply responsibility for PONVORY® to the Company.

The acquisition of PONVORY® has been accounted for as an asset acquisition in accordance with ASC 805-50 because substantially all of the fair value of the assets acquired is concentrated in a single asset, the PONVORY® product rights. The PONVORY® products rights consist of certain patents and trademarks, regulatory approvals, marketing assets, and other records, and are considered a single asset as they are inextricably linked. The total consideration of $104.9 million was fully allocated to the acquired intangible asset for the U.S. and Canada rights to PONVORY®. The straight-line method is used to amortize the intangible asset, as disclosed in Note 9.

4. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2023, which all have contractual maturities of less than two years:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 185,168	$ 227	$ (280)	$ 185,115
Corporate debt	67,352	2	(26)	67,328
Total marketable securities	$ 252,520	$ 229	$ (306)	$ 252,443

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2022, which all have contractual maturities of less than two years:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 178,351	$ —	$ (1,181)	$ 177,170
Corporate debt	155,017	14	(371)	154,660
Total marketable securities	$ 333,368	$ 14	$ (1,552)	$ 331,830

5. Fair Value Measurements

Authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 — defined as observable inputs such as quoted prices in active markets
- Level 2 — defined as inputs other than quoted prices in active markets that are either directly or indirectly observable
- Level 3 — defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions

The Company's assets classified in Level 1 and Level 2 as of December 31, 2023 and 2022 consist of cash equivalents and available-for-sale marketable securities. The valuation of Level 1 instruments is determined using a market approach and is based upon unadjusted quoted prices for identical assets in active markets. The valuation of Level 2 instruments is also determined using a market approach based upon quoted prices for similar assets in active markets, or other inputs that are observable for substantially the full term of the financial instrument. Level 2 securities include certificates of deposit, commercial paper and corporate notes that use as their basis readily observable market parameters.

The Company held certain assets that are required to be measured at fair value on a recurring basis as of December 31, 2023, as follows:

		Fair Value Measurement as of December 31, 2023 Using		
(in thousands)	Total Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 209,103	$ 209,103	$ —	$ —
Corporate debt	107,108	—	107,108	—
Total assets measured at fair value	$ 316,211	$ 209,103	$ 107,108	$ —

The Company held certain assets that are required to be measured at fair value on a recurring basis as of December 31, 2022, as follows:

		Fair Value Measurement as of December 31, 2022 Using		
(in thousands)	Total Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
U.S. Treasury and government agencies	$ 177,170	$ 177,170	$ —	$ —
Corporate debt	154,660	—	154,660	—
Total assets measured at fair value	$ 331,830	$ 177,170	$ 154,660	$ —

Total assets measured at fair value as of December 31, 2023 include $63.8 million cash equivalents. Total assets measured at fair value as of December 31, 2022 include no cash equivalents.

The Company also has financial assets and liabilities, not required to be measured at fair value on a recurring basis, which primarily consist of cash, accounts receivable, restricted cash, accounts payable and accrued liabilities and product revenue allowances, the carrying values of which materially approximate their fair values.

6. Inventory

Inventory consisted of the following as of December 31, 2023 and 2022:

(in thousands)	December 31, 2023	December 31, 2022
Current assets		
Work-in-process	$ 27	$ 23
Finished goods	1,330	1,171
Total inventory, current	$ 1,357	$ 1,194
Non-Current assets		
Raw materials	$ 934	$ 1,043
Work-in-process	7,177	8,212
Finished goods	737	1,041
Total inventory, non-current	8,848	10,296
Total inventory	$ 10,205	$ 11,490

The Company's inventory balance consisted of $7.2 million and $8.0 million of HETLIOZ® product and $3.0 million and $3.4 million of Fanapt® product as of December 31, 2023 and 2022, respectively.

7. Property and Equipment

The following is a summary of the Company's property and equipment, at cost, as of December 31, 2023 and 2022:

(in thousands)	Estimated Useful Life (Years)	December 31, 2023	December 31, 2022
Computer and other equipment	3	$ 6,284	$ 5,941
Furniture and fixtures	5 - 7	1,496	1,634
Leasehold improvements	5 - 11	5,438	5,417
Total property and equipment, gross		13,218	12,992
Accumulated depreciation and amortization		(11,181)	(10,419)
Total property and equipment, net		$ 2,037	$ 2,573

Depreciation expense was $0.9 million, $1.2 million and $1.4 million for the years ended December 31, 2023, 2022 and 2021, respectively.

8. Leases

The Company's long-term leases primarily include operating leases and subleases for office space in Washington, D.C. and London, England. The Company recognized ROU assets and lease liabilities related to fixed payments for these long-term operating leases in its Consolidated Balance Sheets as of December 31, 2023 and 2022. The Company also has short-term leases, including office space in Berlin, Germany.

In June 2011, the Company entered into an operating lease agreement under which it leases 33,534 square feet of office space for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. Subject to the prior rights of other tenants, the Company has the right to renew the lease for five years following its expiration in July 2028. As of December 31, 2023, the renewal period has not been included in the lease term. The Company has the right to sublease or assign all or a portion of the premises, subject to standard conditions. The lease may be terminated early by the Company or the landlord under certain circumstances.

In June 2016, the Company entered into a sublease agreement under which it subleases an additional 9,928 square feet of office space for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. The sublease term began in

January 2017 and ends in July 2026 but may be terminated earlier by either party under certain circumstances. The Company has the right to sublease or assign all or a portion of the premises, subject to standard conditions.

In May 2016, the Company entered into an operating lease agreement under which it leases 2,880 square feet of office space in London, England. In November 2022, the Company extended the non-cancellable portion of the lease term from 2023 to 2026.

The following is a summary of the Company's ROU assets and operating lease liabilities as of December 31, 2023 and 2022:

(in thousands)	Classification on the Balance Sheet	December 31, 2023	December 31, 2022
Assets			
Operating lease assets	Operating lease right-of-use assets	$ 7,103	$ 8,400
Liabilities			
Operating lease current liabilities	Accounts payable and accrued liabilities	$ 2,398	$ 2,328
Operating lease non-current liabilities	Operating lease non-current liabilities	7,006	8,813
Total lease liabilities		$ 9,404	$ 11,141
Weighted average remaining lease term		4.3	5.2
Weighted average discount rate		8.2 %	8.2 %

The Company recognized operating lease cost of $2.2 million, $2.2 million and $2.3 million and short-term operating lease cost of $0.4 million for each of the years ended December 31, 2023, 2022 and 2021, respectively. The Company also recognized $1.4 million of expense for each of the years ended December 31, 2023, 2022 and 2021, respectively, related to non-lease elements, such as building maintenance services and utilities, and executory costs associated with the operating leases.

Cash paid for amounts included in the measurement of operating lease liabilities is included in operating cash flows and was $2.7 million, $2.6 million and $2.3 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The table below reconciles the Company's future cash obligations to operating lease liabilities recorded on the balance sheet as of December 31, 2023:

(in thousands)	Operating Leases
2024	$ 2,726
2025	2,796
2026	2,410
2027	2,159
2028	1,099
Thereafter	—
Total minimum lease payments	11,190
Less: amount of lease payments representing interest	(1,786)
Present value of future minimum lease payments	9,404
Less: current obligations under leases	(2,398)
Operating lease non-current liabilities	$ 7,006

9. Intangible Assets

HETLIOZ®. In January 2014, the Company announced that the FDA had approved the New Drug Application (NDA) for HETLIOZ®. As a result of this approval, the Company met a milestone under its license agreement with Bristol-Myers Squibb (BMS) that required the Company to make a license payment of $8.0 million to BMS. In April 2018, the Company met its final milestone under its license agreement with BMS when cumulative worldwide sales of HETLIOZ® reached $250.0 million. As a result of the achievement of this milestone, the Company made a payment to BMS of $25.0 million in 2018.

These milestone payments were determined to be additional consideration for the acquisition of HETLIOZ® and capitalized as an intangible asset and are being amortized on a straight-line basis over the estimated economic useful life of the related product patents.

PONVORY®. On December 7, 2023, the Company acquired the U.S. and Canadian rights to PONVORY®, from Janssen. The total purchase price was allocated to the acquired intangible for the U.S. and Canada rights to PONVORY®. The PONVORY® intangible asset is being amortized on a straight-line basis over the estimated economic useful life of the related product rights. See Note 3, *PONVORY® Acquisition*, for additional details about the PONVORY® acquisition.

The following is a summary of the Company's amortizing intangible assets as of December 31, 2023:

		December 31, 2023		
(in thousands)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	2035	$ 33,000	$ 15,937	$ 17,063
PONVORY®	2035	$ 104,894	$ 588	$ 104,306
Total amortizing intangible assets		$ 137,894	$ 16,525	$ 121,369

The following is a summary of the Company's intangible assets as of December 31, 2022:

		December 31, 2022		
(in thousands)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	2035	$ 33,000	$ 14,435	$ 18,565
Total amortizing intangible assets		$ 33,000	$ 14,435	$ 18,565

As of December 31, 2023 and 2022, the Company also had $27.9 million of fully amortized intangible assets related to Fanapt®. Intangible assets are amortized over their estimated useful economic life using the straight-line method. Amortization expense for the years ended December 31, 2023, 2022 and 2021 was as follows:

	Year Ended December 31,		
(in thousands)	2023	2022	2021
HETLIOZ®	$ 1,502	$ 1,516	$ 1,478
PONVORY®	588	—	—
Total amortization expense	$ 2,090	$ 1,516	$ 1,478

The following is a summary of the future intangible asset amortization schedule as of December 31, 2023:

(in thousands)	Total	2024	2025	2026	2027	2028	Thereafter
HETLIOZ®	$ 17,063	$ 1,463	$ 1,463	$ 1,463	$ 1,463	$ 1,463	$ 9,748
PONVORY®	104,306	8,741	8,741	8,741	8,741	8,741	60,601
Total amortization expense	$ 121,369	$ 10,204	$ 10,204	$ 10,204	$ 10,204	$ 10,204	$ 70,349

10. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of December 31, 2023 and 2022:

(in thousands)	December 31, 2023	December 31, 2022
Research and development expenses	$ 15,691	$ 9,474
Compensation and employee benefits	6,413	6,839
Consulting and other professional fees	4,404	9,241
Royalties payable	2,409	4,979
Operating lease liabilities	2,398	2,328
Accounts payable and other accrued liabilities	7,145	12,690
Total accounts payable and accrued liabilities	$ 38,460	$ 45,551

As of December 31, 2022, the prepaid expenses and other current assets and accounts payable and accrued liabilities balances included $11.5 million related to the case *Gordon v. Vanda Pharmaceuticals Inc.* In January 2023, the settlement related to the case was fully and finally approved. As a result, the Company removed the associated prepaid and liability balances.

11. Commitments and Contingencies

Guarantees and Indemnifications

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain conditions.

License Agreements

The Company's rights to develop and commercialize its products are subject to the terms and conditions of licenses granted to the Company by other pharmaceutical companies.

HETLIOZ®. In February 2004, the Company entered into a license agreement with BMS under which it received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize HETLIOZ®. As of December 31, 2023, the Company has paid BMS $37.5 million in upfront fees and milestone obligations, including $33.0 million of regulatory approval and commercial milestones capitalized as intangible assets (see Note 9, *Intangible Assets*). The Company has no remaining milestone obligations to BMS. Additionally, the Company is obligated to make royalty payments on HETLIOZ® net sales to BMS. The royalty period in each territory where the Company commercializes HETLIOZ® is 10 years following the first commercial sale in the territory. In territories outside the U.S., the royalty is 5% on net sales. In the U.S., the royalty on net sales in the U.S. decreased from 10% to 5% in December 2022. This U.S. royalty will end in April 2024. The Company is also obligated under the license agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that it receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. The Company is obligated to use its commercially reasonable efforts to develop and commercialize HETLIOZ®.

Fanapt®. Pursuant to the terms of a settlement agreement with Novartis Pharma AG (Novartis), Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. The Company paid directly to Sanofi S.A. (Sanofi) a fixed royalty of 3% of net sales through December 2019 related to manufacturing know-how. The Company is also obligated to pay Sanofi a fixed royalty on Fanapt® net sales equal to 6% on Sanofi know-how not related to manufacturing under certain conditions for a period of up to 10 years in markets where the new chemical entity (NCE) patent has expired or was not issued. The Company is obligated to pay this 6% royalty on net sales in the U.S. through November 2026.

Tradipitant. In April 2012, the Company entered into a license agreement with Eli Lilly and Company (Lilly) pursuant to which the Company acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1 receptor antagonist, tradipitant, for all human indications. Lilly is eligible to receive future payments based upon achievement of specified development, regulatory approval and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. As of December 31, 2023, the Company has paid Lilly $5.0 million in upfront fees and development milestones. These payments for upfront fees and development milestones include a $2.0 million milestone paid to Lilly during the year ended December 31, 2023 for the filing of the first application for marketing authorization for tradipitant in either the U.S. or European Union (E.U.). As of December 31, 2023, remaining milestone obligations include $10.0 million and $5.0 million milestones for the first approval of an application for marketing authorization for tradipitant in the U.S. and E.U., respectively, and up to $80.0 million for sales milestones. The Company is obligated to use its commercially reasonable efforts to develop and commercialize tradipitant.

Portfolio of CFTR activators and inhibitors. In March 2017, the Company entered into a license agreement with the University of California San Francisco (UCSF), under which the Company acquired an exclusive worldwide license to develop and commercialize a portfolio of CFTR activators and inhibitors. Pursuant to the license agreement, the Company will develop and commercialize the CFTR activators and inhibitors and is responsible for all development costs, including current pre-investigational new drug development work. UCSF is eligible to receive future payments based upon achievement of specified development and commercialization milestones as well as single-digit royalties on net sales. As of December 31, 2023, the Company has paid UCSF $1.6 million in upfront fees and development milestones. As of December 31, 2023, remaining milestone obligations include $11.9 million for development milestones and $33.0 million for future regulatory approval and sales milestones. Included in the $11.9 million of development milestones are $1.1 million of milestone obligations due upon the conclusion of clinical studies for each licensed product but not to exceed $3.2 million in total for the CFTR portfolio.

VQW-765. In connection with a settlement agreement with Novartis relating to Fanapt®, the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize VQW-765, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist. Pursuant to the license agreement, the Company is obligated to use its commercially reasonable efforts to develop and commercialize VQW-765 and is responsible for all development costs. The Company has no milestone obligations; however, Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens.

Other Agreements

In September 2022, the Company entered into an agreement with OliPass Corporation (OliPass) to jointly develop a set of antisense oligonucleotide (ASO) molecules based on OliPass' proprietary modified peptide nucleic acids. As consideration for entering into the arrangement, the Company paid OliPass an upfront fee of $3.0 million, which was recorded as research and development expense during the three months ended September 30, 2022. The Company is funding the research and development activities and has the option to license jointly developed intellectual property upon successful development.

Purchase Commitments

In the course of its business, the Company regularly enters into agreements with third-party vendors under fee service arrangements, which generally may be terminated on 90 days' notice without incurring additional charges, other than charges for work completed or materials procured but not paid for through the effective date of termination and other costs incurred by the Company's contractors in closing out work in progress as of the effective date of termination. The Company's non-cancellable purchase commitments for agreements longer than one year are not material. Various other long-term agreements entered into for services with other third-party vendors, such as inventory purchase commitments, are cancellable in nature or contain variable commitment terms within the agreement.

12. Accumulated Other Comprehensive Loss

The accumulated balances related to each component of other comprehensive loss, net of taxes, were as follows for the years ended December 31, 2023 and 2022:

(in thousands)	December 31, 2023	December 31, 2022
Foreign currency translation	$ 21	$ (7)
Unrealized loss on marketable securities	(51)	(1,186)
Accumulated other comprehensive loss	$ (30)	$ (1,193)

13. Stock-Based Compensation

As of December 31, 2023, there were 6,697,816 shares subject to outstanding options and RSUs under the 2006 Equity Incentive Plan (2006 Plan) and the Amended and Restated 2016 Equity Incentive Plan (2016 Plan, and together with the 2006 Plan, Plans). The 2006 Plan expired by its terms in April 2016, and the Company adopted the 2016 Plan. Outstanding options under the 2006 Plan remain in effect and the terms of the 2006 Plan continue to apply, but no additional awards can be granted under the 2006 Plan. In June 2016, the Company's stockholders approved the 2016 Plan. The 2016 Plan has been amended a number of times since to increase the number of shares reserved for issuance, among other administrative changes. Each of the amendments to the 2016 Plan was approved by the Company's stockholders. There is a total of 13,790,000 shares of common stock authorized for issuance under the 2016 Plan, 4,537,290 shares of which remained available for future grant as of December 31, 2023.

Stock Options

The Company has granted option awards under the Plans with service conditions (service option awards) that are subject to terms and conditions established by the compensation committee of the board of directors. Service option awards have 10-year contractual terms. Service option awards granted to employees and new directors upon their election vest and become exercisable over four years, with the first 25% of the shares subject to service option awards vesting on the first anniversary of the grant date and the remaining 75% of the shares subject to the service option awards in 36 equal monthly installments thereafter. Subsequent annual service option awards granted to directors vest and become exercisable in full on the first anniversary of the grant date. Service option awards granted to executive officers and certain other employees provide for partial acceleration of vesting if the executive officer or employee is subject to an involuntary termination, and full acceleration of vesting if the executive officer or employee is subject to an involuntary termination within 24 months after a change in control of the Company. Service option awards granted to directors provide for accelerated vesting if there is a change in control of the Company or if the director's service terminates as a result of the director's death or total and permanent disability.

As of December 31, 2023, $6.0 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.1 years. No option awards are classified as a liability as of December 31, 2023.

A summary of option activity under the Plans for the year ended December 31, 2023 is as follows:

(in thousands, except for share and per share amounts)	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2022	4,232,210	$ 14.19	5.81	$ —
Granted	944,776	6.92		
Expired	(384,480)	11.86		
Outstanding at December 31, 2023	4,792,506	12.95	6.00	—
Exercisable at December 31, 2023	3,292,951	14.47	4.79	—
Vested and expected to vest at December 31, 2023	4,642,322	13.10	5.90	—

The weighted average grant-date fair value of options granted was $3.53, $5.18 and $8.91 per share for the years ended December 31, 2023, 2022 and 2021, respectively. There were no options exercised for the year ended December 31, 2023. The total intrinsic value of options exercised was $1.6 million and $4.1 million for the years ended December 31, 2022 and 2021, respectively. There were no proceeds from the exercise of stock options for the year ended December 31, 2023. Proceeds from the exercise of stock options amounted to $0.7 million and $3.6 million for the years ended December 31, 2022 and 2021, respectively.

Restricted Stock Units

An RSU is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of each RSU is based on the closing price of the Company's stock on the date of grant. The Company has granted RSUs under the Plans with service conditions (service RSUs) that are subject to terms and conditions established by the compensation committee of the board of directors. Service RSUs granted to employees and new directors upon their election vest in four equal annual installments. Subsequent annual service RSUs granted to directors vest on the first anniversary of the date of grant. Service RSUs granted to executive officers and certain other employees provide for accelerated vesting if the executive officer or employee is subject to an involuntary termination within 24 months after a change in control. Service RSUs granted to directors provide for accelerated vesting if there is a change in control of the Company.

As of December 31, 2023, $13.8 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.5 years. No RSUs are classified as a liability as of December 31, 2023.

A summary of RSU activity for the Plans for the year ended December 31, 2023 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2022	1,915,546	$ 14.41
Granted	868,243	6.96
Forfeited	(127,744)	12.82
Vested	(750,735)	15.04
Unvested at December 31, 2023	1,905,310	10.87

The weighted average grant-date fair value of RSUs granted was $6.96, $11.24 and $19.57 per share for the years ended December 31, 2023, 2022 and 2021, respectively. The total fair value of the RSUs that vested during the years ended December 31, 2023, 2022 and 2021 was $11.3 million, $11.6 million, and $9.1 million, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense recognized for the years ended December 31, 2023, 2022 and 2021 comprised of the following:

	Year Ended December 31,		
(in thousands)	2023	2022	2021
Research and development	$ 3,323	$ 3,964	$ 3,955
Selling, general and administrative	10,717	12,315	11,419
Total stock-based compensation expense	$ 14,040	$ 16,279	$ 15,374

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. Expected volatility rates are based on the historical volatility of the Company's publicly traded common stock and other factors. The expected terms are determined based on a combination of historical exercise data and hypothetical exercise data for unexercised stock options. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has never paid cash dividends to its stockholders and does not plan to pay dividends in the foreseeable future. Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the years ended December 31, 2023, 2022 and 2021 were as follows:

	Year Ended December 31,		
	2023	2022	2021
Expected dividend yield	— %	— %	— %
Weighted average expected volatility	47 %	46 %	46 %
Weighted average expected term (years)	6.16	6.05	5.98
Weighted average risk-free rate	3.89 %	2.03 %	0.75 %

14. Employee Benefit Plan

The Company has a defined contribution plan under IRC Section 401(k). This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Currently, the Company matches fifty percent up to the first six percent of employee contributions. All matching contributions have been paid by the Company. The Company match vests over a 4-year period and amounted to $1.0 million, $1.1 million and $1.0 million for the years ended December 31, 2023, 2022 and 2021, respectively.

15. Income Taxes

The following is a summary of the domestic and foreign components of income before income taxes for the years ended December 31, 2023, 2022 and 2021:

(in thousands)	Year Ended December 31, 2023	2022	2021
Domestic	$ 6,184	$ 11,216	$ 42,221
Foreign	155	84	143
Total income before income taxes	$ 6,339	$ 11,300	$ 42,364

The following is a summary of the provision (benefit) for income taxes for the years ended December 31, 2023, 2022 and 2021:

(in thousands)	Year Ended December 31, 2023	2022	2021
Current			
Federal	$ 2,577	$ —	$ —
State	2,447	3,710	2,200
Foreign	91	185	267
Deferred			
Federal	(2,240)	1,238	6,604
State	970	(111)	119
Foreign	(15)	3	22
Provision for income taxes	$ 3,830	$ 5,025	$ 9,212

The following is reconciliation between the federal statutory tax rate and the Company's effective tax rate for the years ended December 31, 2023, 2022 and 2021:

	Year Ended December 31, 2023	2022	2021
Federal tax at statutory rate	21.0 %	21.0 %	21.0 %
State taxes	5.0 %	4.8 %	2.3 %
Change in valuation allowance	22.6 %	1.0 %	(0.1)%
Research and development credit	(69.3)%	(25.9)%	(6.5)%
Orphan drug credit	(4.5)%	(0.9)%	(0.1)%
Section 162(m) limitation	17.2 %	9.4 %	2.6 %
Other tax rate changes	(23.4)%	1.7 %	(0.2)%
Other changes in state deferred taxes	12.7 %	— %	— %
Uncertain tax positions	41.0 %	24.5 %	4.0 %
Stock-based compensation	30.2 %	5.8 %	(1.8)%
Settlements	2.7 %	2.6 %	— %
Non-deductible items	5.5 %	0.3 %	0.4 %
Other items	(0.3)%	0.2 %	0.1 %
Effective tax rate	60.4 %	44.5 %	21.7 %

The following is a summary of the components of the Company's net deferred tax assets and the related tax valuation allowance as of December 31, 2023 and 2022.

(in thousands)	December 31, 2023	December 31, 2022
Deferred tax assets		
Net operating loss carryforwards	$ 5,897	$ 13,746
Stock-based compensation	4,187	4,930
Accrued expenses	1,453	1,469
Allowance for returns and credit losses	1,748	1,560
Research and development and orphan drug credit carryforwards	38,559	42,402
Capitalized research and development expenses	29,036	16,990
Other	5,037	3,798
Total deferred tax assets	85,917	84,895
Deferred tax liabilities		
Intangible assets	(812)	(1,924)
Other	(1,558)	(1,796)
Total deferred tax liabilities	(2,370)	(3,720)
Deferred tax assets, net	83,547	81,175
Less: Valuation allowance	8,547	7,136
Net deferred tax assets	$ 75,000	$ 74,039

The following is a summary of changes in the Company's tax valuation allowance for the years ended December 31, 2023, 2022 and 2021:

(in thousands)	Balance at Beginning of Year	Additions	Reductions	Balance at End of Year
Year Ended				
December 31, 2023	$ 7,136	$ 1,411	$ —	$ 8,547
December 31, 2022	7,025	111	—	7,136
December 31, 2021	7,051	—	(26)	7,025

The Company has NOL and other tax credit carryforwards in several jurisdictions. As of December 31, 2023, the Company has utilized all of its U.S. federal NOL carryforwards. The Company has deferred tax assets of $16.1 million and $22.5 million related to U.S. federal research and development credits and orphan drug credits, respectively. These tax attributes will begin to expire in 2031 and 2030, respectively. In addition, the Company has $5.9 million of deferred tax assets relating to other U.S. NOL carryforwards, which primarily relate to the District of Columbia. NOLs for the District of Columbia will begin to expire in 2032 and state NOLs will begin to expire in 2034.

Cash paid for income taxes was $3.6 million for the year ended December 31, 2023. Cash paid for income taxes for the years ended December 31, 2022 and 2021 were not material. Cash taxes in 2023 include federal tax payments as a result of utilizing the Company's remaining federal net operating loss carryover. For U.S. tax purposes, utilization of the Company's tax credits is limited to 75 percent of federal income tax each year.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	Year Ended December 31,		
(in thousands)	2023	2022	2021
Unrecognized tax benefits at the beginning of the year	$ 15,485	$ 12,935	$ 11,233
Increases (decreases) related to prior year tax positions	919	(75)	122
Increases related to current year tax positions	2,003	2,895	1,580
Settlements	—	(270)	—
Statute lapses	$ (95)	$ —	$ —
Unrecognized tax benefits at the end of the year	$ 18,312	$ 15,485	$ 12,935

The amount of uncertain tax benefits that, if recognized, would impact the effective tax rate is $18.3 million. Unrecognized tax benefits are not expected to change materially over the next 12 months. Generally, the tax years 2020 through

2022 remain open to examination by the major taxing jurisdiction to which the Company is subject. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, or state or foreign tax authorities, to the extent utilized in a future period.

Certain tax attributes of the Company, including NOLs and credit carryforwards, would be subject to limitation under Section 382 and 383 should an ownership change as defined under Section 382 of the Internal Revenue Code of 1986, as amended (IRC) occur. The limitation resulting from a change in ownership could affect the Company's ability to utilize its NOLs and credit carryforwards (tax attributes) to offset future taxable income. An ownership change occurred in the year ended December 31, 2014. The Company believes that the ownership change in 2014 will not impact its ability to utilize NOL and credit carryforwards; however, future ownership changes may cause the Company's existing tax attributes to have additional limitations.

16. Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the net income by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net income by the weighted average number of shares of common stock outstanding, plus potential outstanding common stock for the period. Potential outstanding common stock includes stock options and shares underlying RSUs, but only to the extent that their inclusion is dilutive, as calculated using the treasury stock method.

The following table presents the calculation of basic and diluted net income per share of common stock for the years ended December 31, 2023, 2022 and 2021:

	Year Ended December 31,		
(in thousands, except for share and per share amounts)	**2023**	**2022**	**2021**
Numerator:			
Net income	$ 2,509	$ 6,275	$ 33,152
Denominator:			
Weighted average shares outstanding, basic	57,380,975	56,461,877	55,548,122
Effect of dilutive securities	176,936	521,294	1,373,714
Weighted average shares outstanding, diluted	57,557,911	56,983,171	56,921,836
Net income per share, basic and diluted:			
Basic	$ 0.04	$ 0.11	$ 0.60
Diluted	$ 0.04	$ 0.11	$ 0.58
Antidilutive securities excluded from calculations of diluted net income per share	6,464,057	4,786,891	2,176,944

17. Legal Matters

HETLIOZ®. Between April 2018 and March 2021, the Company filed numerous Hatch-Waxman lawsuits in the U.S. District Court for the District of Delaware (Delaware District Court) against Teva Pharmaceuticals USA, Inc. (Teva), MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (MSN) and Apotex Inc. and Apotex Corp. (Apotex, and collectively with Teva and MSN, the HETLIOZ® Defendants) asserting that U.S. Patent Nos. RE46,604 ('604 Patent), 9,060,995, 9,539,234, 9,549,913, 9,730,910 ('910 Patent), 9,844,241, 10,071,977, 10,149,829 ('829 Patent), 10,376,487 ('487 Patent), 10,449,176, 10,610,510, 10,610,511, 10,829,465, and 10,611,744 will be infringed by the HETLIOZ® Defendants' generic versions of HETLIOZ® for which they were seeking FDA approval. As initially disclosed in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 14, 2022, in January 2022, the Company entered into a license agreement with MSN and Impax Laboratories LLC (Impax) resolving the lawsuits against MSN (the MSN/Impax License Agreement). The MSN/Impax License Agreement grants MSN and Impax a non-exclusive license to manufacture and commercialize MSN's generic version of HETLIOZ® in the U.S. effective as of March 13, 2035, unless prior to that date the Company obtains pediatric exclusivity for HETLIOZ®, in which case the license will be effective as of July 27, 2035. The MSN/Impax License Agreement also provides that MSN and Impax may launch a generic version of HETLIOZ® earlier under certain limited circumstances. In January 2023, MSN and its commercial partner, Amneal Pharmaceuticals, Inc., informed the Company of their belief that such circumstances have occurred and have since launched their generic version. The Company disagrees with this position and continues to aggressively defend its legal rights to exclusivity for HETLIOZ®. The consolidated lawsuits against the remaining HETLIOZ® Defendants were tried in March 2022.

In December 2022, the Delaware District Court ruled that Teva and Apotex did not infringe the '604 Patent, and that the asserted claims of the '604, '910, '829 and '487 Patents were invalid. In December 2022, the Company appealed the Delaware District Court's decision to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) and an oral argument for the appeal was held in March 2023. In May 2023, a three-judge panel of the Federal Circuit affirmed the Delaware District Court's ruling, and in June 2023, the Company requested a rehearing or rehearing en banc from the Federal Circuit. In August 2023, the Federal Circuit denied the Company's petition for a rehearing. In January 2024, the Company filed a petition for a writ of certiorari with the U.S. Supreme Court to review the Federal Circuit's decision.

In December 2022, the Company filed patent infringement lawsuits, including Hatch-Waxman Act claims, against each of Teva and Apotex in the U.S. District Court for the District of New Jersey (NJ District Court) asserting that U.S. Patent No. 11,285,129, a method of administration patent that was not litigated in the Delaware District Court cases ('129 Patent), will be infringed by Teva's and Apotex' generic versions of HETLIOZ®, each of which was approved by the FDA. The Company asked the NJ District Court to, among other things, order that the effective date of the FDA's approval of Teva's and Apotex' generic versions of HETLIOZ® be a date that is no earlier than the expiration of the '129 Patent, or such later date that the NJ District Court may determine, and enjoin each of Teva and Apotex from the commercial manufacture, use, import, offer for sale and/or sale of their generic versions of HETLIOZ® until the expiration of the '129 Patent, or such later date that the NJ District Court may determine. In February 2023, the case was transferred to the Delaware District Court, where the Company's lawsuit remains pending.

In January 2023, the Company filed a lawsuit in the NJ District Court against Teva challenging Teva's advertising and marketing practices related to its at risk launch of its generic version of HETLIOZ® for the single indication of Non-24. The Company believes that Teva's advertising and marketing practices related to its generic version of HETLIOZ® promote its product for uses beyond the limited labeling that Teva sought, and the FDA approved. The Company seeks to, among other things, enjoin Teva from engaging in false and misleading advertising and recover monetary damages. In December 2023, the case was transferred to the Delaware District Court.

In January 2023, the Company filed a lawsuit in the U.S. District Court for the District of Columbia (DC District Court) against the FDA challenging the FDA's approval of Teva's Abbreviated New Drug Application (ANDA) for its generic version of HETLIOZ® capsules under the Administrative Procedure Act, the Food, Drug, and Cosmetic Act (FDCA), and FDA regulations. Under the FDCA, every ANDA must contain information to show that the labeling proposed for the generic drug is the same as the labeling approved for the listed drug. The labeling and packaging for HETLIOZ® includes Braille, but Teva's generic version does not. On this basis, the Company believes that Teva's approved labeling does not comply with applicable requirements. The Company has asked the DC District Court to, among other things, vacate the FDA's approval of Teva's ANDA, declare that the approval of the ANDA was unlawful, arbitrary, and capricious and compel the FDA to order Teva to recall its generic HETLIOZ® product. In February 2023, Teva intervened in the lawsuit as a defendant. In September 2023, the Company amended its lawsuit to request that the DC District Court set aside the FDA's July 2023 denial of the Company's citizen petition, originally filed with the FDA in January 2023. The Company's lawsuit remains pending.

In September 2023, the Company filed a lawsuit in the DC District Court against the FDA challenging the FDA's approval of MSN's ANDA for its generic version of HETLIOZ® capsules under the APA, the FDCA, and FDA regulations. The Company believes that MSN's underlying approval data, particularly its bioequivalence studies, are faulty. On this basis, the Company has asked the DC District Court to, among other things, vacate the FDA's approval of MSN's ANDA, declare that the approval of the ANDA was unlawful, arbitrary, and capricious and compel the FDA to order MSN to recall its generic HETLIOZ® product. In December 2023, the Company filed a motion for summary judgment. In January 2024, the FDA opposed the Company's motion and moved to waive the administrative record, following which the court held an oral argument on the cross-motions. The DC District Court has issued an order compelling the FDA to serve the administrative record and setting deadlines for further proceedings. The Company's lawsuit remains pending.

Other Matters. From April 2022 to February 2024, the Company filed fourteen lawsuits in the DC District Court against the FDA to compel the FDA to produce records under the Freedom of Information Act (FOIA) regarding, among other matters: the FDA's denial of the Company's supplemental New Drug Application (sNDA) for HETLIOZ® in the treatment of jet lag disorder; cases in which the FDA waived its putative requirement of a 9-month non-rodent toxicity study before drugs can be tested on human patients for extended durations; communications external to and within the FDA relating to tradipitant, HETLIOZ® and Fanapt®; a warning letter that the FDA sent to the Company concerning its webpages for HETLIOZ® and Fanapt®; the FDA's removal of a clinical trials design presentation from its website; discipline reviews relating to the FDA's evaluations of the Company's sNDA for HETLIOZ® and a third-party sNDA for jet lag; internal standard operating procedures or guidance relating to the FDA's processing of incoming FOIA requests; and bioequivalence and other study reports submitted relating to the FDA's consideration of tasimelteon ANDAs. Three of these lawsuits were resolved in the Company's favor in June 2023, August 2023, and January 2024, respectively, one is pending resolution and the other ten remain outstanding. The

FDA has failed to respond and provide the requested documents within the statutory timeframe with respect to each of these ten outstanding requests. The Company has asked the DC District Court to, among other things, compel the FDA to comply with its obligations and declare that its lack of compliance violates FOIA.

In April 2022, the Company filed a lawsuit in the U.S. District Court for the District of Maryland (MD District Court) against the Centers for Medicare & Medicaid Services (CMS) and the Administrator of CMS challenging CMS' rule broadly interpreting the defined terms "line extension" and "new formulation" under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA), which went into effect in January 2022 (the Rule). The Company believes that the Rule is unlawful and contrary to the intent of Congress when it passed the ACA. Under the Rule, certain of the Company's products would be treated as line extensions and new formulations subject to enhanced rebates, despite the statutory text and CMS' own long-standing practice, under which such products would not constitute line extensions or new formulations. In March 2023, the MD District Court ruled that CMS' interpretation of the terms was reasonable and consistent with Congress' intent. In April 2023, the Company appealed the ruling to the U.S. Court of Appeals for the Fourth Circuit (Fourth Circuit). In January 2024, the Fourth Circuit held an oral argument. The Company's lawsuit remains pending.

In May 2022, the Company filed a lawsuit in the DC District Court against the FDA challenging the FDA's denial of Fast Track designation for tradipitant. In October 2021, the Company submitted to the FDA a request for Fast Track designation for tradipitant under the Food and Drug Administration Modernization Act of 1997 (FDAMA). The FDAMA provides for expedited development and review of drugs that receive Fast Track designation from the FDA. Under the FDAMA, the FDA must designate a drug as a Fast Track product if it both (1) is intended to treat a serious or life-threatening disease or condition and (2) demonstrates the potential to address unmet medical needs for such disease or condition. Although Fast Track designation is non-discretionary when the criteria are satisfied, the FDA denied the Company's request for Fast Track designation. The Company does not believe that the FDA based its decision on the relevant criteria. Therefore, among other reasons, the Company maintains that the FDA's denial is unlawful. The Company has asked the DC District Court to, among other things, set aside and vacate the FDA's denial. An oral argument was held in January 2023. In August 2023, the DC District Court ruled against the Company. In September 2023, the Company appealed the ruling to the U.S. Court of Appeals for the District of Columbia Circuit, where the Company's lawsuit remains pending.

In September 2022, the Company filed a lawsuit in the DC District Court against the FDA to compel the FDA to comply with two separate non-discretionary obligations under the FDCA and its implementing regulations: an obligation to publish a notice of an opportunity for a hearing on the Company's sNDA for HETLIOZ® in the treatment of jet lag disorder in the Federal Register within 180 days of the filing of the sNDA, and a separate obligation to publish the same notice within 60 days of the request for a hearing. The FDA published the notice of an opportunity for a hearing on October 11, 2022. The Company has asked the DC District Court to, among other things, compel the FDA to comply with its obligations and declare that its lack of compliance violates the FDCA and the FDA regulations. In January 2024, the DC District Court held an oral argument on dispositive cross-motions, following which the DC District Court granted the Company's motion for summary judgment. The DC District Court ruled that the FDA violated the statute and ordered the FDA to either finally resolve the Company's application or commence a hearing on or before March 5, 2024. The Company's lawsuit remains pending.

In May 2023, the Company filed a lawsuit in the U.S. Court of Federal Claims (Federal Claims Court) against the federal government for the uncompensated taking and misuse of the Company's trade secrets and confidential information. The Company believes that the FDA violated the Fifth Amendment's due process clause by improperly providing confidential details from the Company's drug master files for HETLIOZ® and Fanapt® to generic drug manufacturers during the FDA's review of the manufacturers' ANDAs. The Company has asked the Federal Claims Court to, among other things, declare that the FDA's disclosure of the Company's confidential commercial information constitutes a taking for purposes of the Fifth Amendment and award just compensation. The federal government filed a motion to dismiss the complaint, which the Company opposed. In January 2024, the Federal Claims Court held an oral argument on the motion to dismiss, following which the Federal Claims Court issued a decision denying in part the government's motion, allowing the Company's takings claim to proceed. The Company's lawsuit remains pending.

In February 2024, the Company filed a lawsuit in the DC District Court against the FDA to compel the FDA to comply with its statutory obligations under the FDCA and its implementing regulations, and to challenge the FDA's complete response letter and 60-day filing regulations, which the Company believes do not absolve the FDA of its statutory responsibilities. Under the FDCA, the FDA has an obligation to either approve the Company's sNDA for HETLIOZ® in the treatment of insomnia characterized by difficulties with sleep initiation within 180 days of the filing of the sNDA or give the Company a notice of an opportunity for a hearing. The Company submitted the sNDA on May 4, 2023. The Company has asked the DC District Court to, among other things, compel the FDA to comply with its obligations, declare that its lack of compliance violates the FDCA and the FDA regulations and declare the FDA's complete response letter and 60-day filing regulations unlawful.

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant's registration statement on Form S-1 (File No. 333-130759) on March 17, 2006 and incorporated herein by reference).
3.2	Amended and Restated Bylaws of the registrant, as amended and restated on December 13, 2023 (filed as Exhibit 3.1 to the registrant's current report on Form 8-K (File No. 001-34186) on December 15, 2023 and incorporated herein by reference).
4.1	Specimen certificate representing the common stock of the registrant (filed as Exhibit 4.4 to Amendment No. 2 to the registrant's registration statement on Form S-1 (File No. 333-130759) on March 17, 2006, and incorporated herein by reference).
4.2	Description of Securities of the registrant (filed as Exhibit 4.2 to the registrant's Annual Report on Form 10-K (File No. 001-34186) on February 24, 2022 and incorporated herein by reference).
10.1	Amended and Restated License, Development and Commercialization Agreement, dated July 24, 2005, by and between Bristol-Myers Squibb Company and the registrant (relating to HETLIOZ®) (filed as Exhibit 10.3 to Amendment No. 1 to the registrant's registration Statement on Form S-1 (File No. 333-130759) on February 16, 2006 and incorporated herein by reference).
10.2†	Form of Indemnification Agreement entered into by directors and executive officers (filed as Exhibit 10.11 to the registrant's registration statement on Form S-1 (File No. 333-130759) on December 29, 2005 and incorporated herein by reference).
10.3†	2006 Equity Incentive Plan, as amended (filed as Exhibit 10.17 to Amendment No. 2 to the registrant's Registration Statement on Form S-1 (File No. 333-130759), as filed on March 17, 2006, and incorporated herein by reference).
10.4†	Amended and Restated Employment Agreement, dated December 16, 2008, by and between Mihael H. Polymeropoulos and the registrant (filed as Exhibit 10.34 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on August 10, 2009 and incorporated herein by reference).
10.5†	Amendment to Amended and Restated Employment Agreement, dated December 16, 2010, by and between Mihael H. Polymeropoulos and the registrant (filed as Exhibit 10.39 to the registrant's annual report on Form 10-K (File No. 001-34186) on March 10, 2011 and incorporated herein by reference).
10.6†	Amended and Restated Tax Indemnity Agreement, dated December 16, 2010, by and between Mihael H. Polymeropoulos and the registrant (filed as Exhibit 10.41 to the registrant's annual report on Form 10-K (File No. 001-34186) on March 10, 2011 and incorporated herein by reference).
10.7	Lease, effective as of July 25, 2011, by and between Square 54 Office Owner LLC and the registrant (filed as Exhibit 10.42 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 7, 2011 and incorporated herein by reference).
10.8	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of April 15, 2010, by and between Bristol-Myers Squibb Company and the registrant (filed as Exhibit 10.38 to the registrant's current report on Form 8-K (File No. 001-34186) on April 19, 2010 and incorporated herein by reference).
10.9	Ninth Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of May 24, 2012, by and between Bristol-Myers Squibb Company and the registrant (filed as Exhibit 10.46 to the registrant's current report on Form 8-K (File No. 001-34186) on May 30, 2012 and incorporated herein by reference).
10.10	License, Development and Commercialization Agreement, dated as of April 12, 2012, by and between Eli Lilly and Company and the registrant (filed as Exhibit 10.48 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on August 3, 2012 and incorporated herein by reference).
10.11	Tenth Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of April 25, 2013, by and between Bristol-Myers Squibb Company and the registrant (filed as Exhibit 10.50 to the registrant's current report on Form 8-K (File No. 001-34186) on April 29, 2013 and incorporated herein by reference).

Exhibit Number	Description
10.12‡	Manufacturing Agreement, dated January 24, 2014, by and between Patheon Pharmaceuticals Inc. and the registrant (relating to HETLIOZ®) (filed as Exhibit 10.12 to the registrants annual report on Form 10-K (File No. 001-34186) on February 24, 2022 and incorporated herein by reference).
10.13	First Amendment to Lease Agreement, dated March 18, 2014, by and between Square 54 Office Owner LLC and the registrant (filed as Exhibit 10.54 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on May 8, 2014 and incorporated herein by reference).
10.14	Settlement Agreement and Mutual General Release, dated December 22, 2014, by and among Novartis Pharma AG and the registrant (filed as Exhibit 10.55 to the registrant's annual report on Form 10-K (File No. 001-34186) on March 13, 2015 and incorporated herein by reference).
10.15	Asset Transfer Agreement, dated December 22, 2014, by and among Novartis Pharma AG, Novartis AG and the registrant (relating to Fanapt®) (filed as Exhibit 10.56 to the registrant's annual report on Form 10-K/A (File No. 001-34186) on June 10, 2015 and incorporated herein by reference).
10.16	Sublicense Agreement, dated November 20, 1997, by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG (filed as Exhibit 10.30 to Titan Pharmaceutical Inc.'s registration statement on Form S-3 (File No. 333-42367) on December 16, 1997 and incorporated herein by reference).
10.17	Amendment No. 1 to Sublicense Agreement by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG, dated November 30, 1998 (filed as Exhibit 10.58 to the registrant's annual report on Form 10-K (File No. 001-34186) on March 13, 2015 and incorporated herein by reference).
10.18	Amendment No. 2 to Sublicense Agreement, dated April 10, 2001, by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG (filed as Exhibit 10.59 to the registrant's annual report on Form 10-K/A (File No. 001-34186) on June 10, 2015 and incorporated herein by reference).
10.19	Amendment No. 3 to Sublicense Agreement, dated June 4, 2004, by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG (filed as Exhibit 10.60 to the registrant's annual report on Form 10-K (File No. 001-34186) on March 13, 2015 and incorporated herein by reference).
10.20	Stock Purchase Agreement, dated December 22, 2014, by and between Novartis AG and the registrant (filed as Exhibit 10.61 to the registrant's annual report on Form 10-K (File No. 001-34186) on March 13, 2015 and incorporated herein by reference).
10.21	License Agreement, dated December 22, 2014, by and between Novartis Pharma AG and the registrant (relating to AQW051) (filed as Exhibit 10.62 to the registrant's annual report on Form 10-K (File No. 001-34186) on March 13, 2015 and incorporated herein by reference).
10.22	Agreement, dated February 2, 2016, by and among Titan Pharmaceuticals, Inc., Aventisub LLC, the successor-in-interest to Aventisub II Inc. Sanofi-Aventis and the registrant (filed as Exhibit 10.1 to the registrant's current report on Form 8-K (File No. 001-34186) on February 4, 2016 and incorporated herein by reference).
10.23†	Vanda Pharmaceuticals Inc. Amended and Restated 2016 Equity Incentive Plan, as amended effective as of June 8, 2023 (filed as Exhibit 10.1 to the registrant's registration statement on Form S-8 (File No. 333-272522) on June 8, 2023 and incorporated herein by reference).
10.24†	UK Sub Plan under the Amended and Restated 2016 Equity Incentive Plan (filed as Exhibit 10.4 to the registrant's registration statement on Form S-8 (File No. 333-218774) on June 15, 2017 and incorporated herein by reference).
10.25‡	Manufacturing Agreement, dated May 6, 2016, by and between Patheon Pharmaceuticals Inc. and the registrant (relating to Fanapt®) (filed as Exhibit 10.29 to the registrant's annual report on Form 10-K (File No. 001-34186) on February 24, 2022 and incorporated herein by reference).
10.26	Second Amendment to Lease Agreement, dated June 20, 2016, by and between Square 54 Office Owner LLC and the registrant (filed as Exhibit 10.43 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on July 28, 2016 and incorporated herein by reference).
10.27	Sublease Agreement, dated June 22, 2016, by and between Hunton & Williams LLP and the registrant (filed as Exhibit 10.44 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on July 28, 2016 and incorporated herein by reference).
10.28	License Agreement, dated October 24, 2016, by and among Taro Pharmaceuticals USA, Inc., Taro Pharmaceuticals Industries Ltd. and the registrant (filed as Exhibit 10.45 to the registrant's annual report on Form 10-K (File No. 001-34186) on February 17, 2017 and incorporated herein by reference).

Exhibit Number	Description
10.29	License Agreement, dated December 7, 2016, by and between Apotex, Inc. and the registrant (filed as Exhibit 10.46 to the registrant's annual report on Form 10-K (File No. 001-34186) on February 17, 2017 and incorporated herein by reference).
10.30	Third Amendment to Lease Agreement, dated March 28, 2018, by and between Square 54 Office Owner LLC and the registrant (filed as Exhibit 10.38 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on May 2, 2018 and incorporated herein by reference).
10.31	Fourth Amendment to Lease Agreement, dated March 29, 2018, by and between Square 54 Office Owner LLC and the registrant (filed as Exhibit 10.39 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on May 2, 2018 and incorporated herein by reference).
10.32†	Amended and Restated Employment Agreement, dated April 30, 2018, by and between Gunther Birznieks and the registrant (filed as Exhibit 10.40 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on May 2, 2018 and incorporated herein by reference).
10.33†	Employment Agreement, dated August 13, 2018, by and between Timothy Williams and the registrant (filed as Exhibit 10.41 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 7, 2018 and incorporated herein by reference).
10.34†	Employment Agreement, dated August 5, 2019, by and between Joakim Wijkstrom and the registrant (filed as Exhibit 10.41 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 7, 2019 and incorporated herein by reference).
10.35†	Amended and Restated Employment Agreement, dated July 27, 2020, by and between Kevin Moran and the registrant (filed as Exhibit 10.1 to the registrant's current report on Form 8-K (File No. 001-34186) on July 29, 2020 and incorporated herein by reference).
10.36	Fifth Amendment to Lease Agreement, dated April 11, 2019, by and between Square 54 Office Owner LLC and the registrant (filed as Exhibit 10.40 to the registrant's annual report on Form 10-K (File No. 001-34186) on February 10, 2021 and incorporated herein by reference).
10.37	Sixth Amendment to Lease Agreement, dated May 7, 2020, by and between Square 54 Office Owner LLC and the registrant (filed as Exhibit 10.41 to the registrant's annual report on Form 10-K (File No. 001-34186) on February 10, 2021 and incorporated herein by reference).
10.38	License Agreement, dated January 13, 2022, by and among MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, Impax Laboratories LLC and the registrant (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on May 6, 2022 and incorporated herein by reference).
10.39†	Form of Restricted Stock Unit Award Agreement for U.S. Employees under the Amended and Restated 2016 Equity Incentive Plan (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 9, 2023 and incorporated herein by reference).
10.40†	Form of Restricted Stock Unit Award Agreement for Senior Management under the Amended and Restated 2016 Equity Incentive Plan (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 9, 2023 and incorporated herein by reference).
10.41†	Form of Restricted Stock Unit Award Agreement for Outside Directors under Amended and Restated 2016 Equity Incentive Plan, as amended (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 9, 2023 and incorporated herein by reference).
10.42†	Form of Restricted Stock Unit Award Agreement for UK Employees under the UK Sub Plan under Amended and Restated 2016 Equity Incentive Plan, as amended (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 9, 2023 and incorporated herein by reference).
10.43†	Form of Notice of Stock Option Grant and Stock Option Agreement for U.S. Employees under Amended and Restated 2016 Equity Incentive Plan, as amended (filed as Exhibit 10.5 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 9, 2023 and incorporated herein by reference).
10.44†	Form of Notice of Stock Option Grant and Stock Option Agreement for Senior Management under Amended and Restated 2016 Equity Incentive Plan, as amended (filed as Exhibit 10.6 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 9, 2023 and incorporated herein by reference).
10.45†	Form of Notice of Stock Option Grant and Stock Option Agreement for Outside Directors under Amended and Restated 2016 Equity Incentive Plan, as amended (filed as Exhibit 10.7 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 9, 2023 and incorporated herein by reference).

Exhibit Number	Description
10.46†	Form of Notice of Stock Option Grant and Stock Option Agreement for UK Employees under the UK Sub Plan under Amended and Restated 2016 Equity Incentive Plan, as amended (filed as Exhibit 10.8 to the registrant's quarterly report on Form 10-Q (File No. 001-34186) on November 9, 2023 and incorporated herein by reference).
10.47*‡	Asset Purchase Agreement, dated December 7, 2023, by and between Actelion Pharmaceuticals Ltd. and the registrant.
21.1	List of Subsidiaries (filed as Exhibit 21.1 to the registrant's annual report on Form 10-K (File No. 001-34186) on February 10, 2021 and incorporated herein by reference).
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Chief Executive Officer and Chief Financial Officer as required by Section 906 of the Sarbanes-Oxley Act of 2002.
97*	Policy Relating to Recovery of Erroneously Awarded Compensation
101*	The following financial information from this annual report on Form 10-K for the fiscal year ended December 31, 2023, formatted in Inline Extensible Business Reporting Language (iXBRL) and furnished electronically herewith: (i) Consolidated Balance Sheets as of December 31, 2023 and 2022; (ii) Consolidated Statements of Operations for the years ended December 31, 2023, 2022 and 2021; (iii) Consolidated Statements of Comprehensive Income for the years ended December 31, 2023, 2022 and 2021; (iv) Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2023, 2022 and 2021; (v) Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022 and 2021; and (vi) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

† Indicates management contract or compensatory plan or arrangement.

‡ Portions of this exhibit have been omitted under rules of the Securities and Exchange Commission permitting the confidential treatment of select information.

* Filed herewith.

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE THAT THE REGISTRANT NORMALLY TREATS AS PRIVATE AND CONFIDENTIAL. SUCH EXCLUDED INFORMATION HAS BEEN MARKED "[***]".

ASSET PURCHASE AGREEMENT

by and between

ACTELION PHARMACEUTICALS LTD.

and

VANDA PHARMACEUTICALS INC.

DATED AS OF

DECEMBER 7, 2023

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ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement, dated as of December 7, 2023, is made by and between Actelion Pharmaceuticals Ltd., a limited liability company organized under the laws of Switzerland ("Seller"), and Vanda Pharmaceuticals Inc., a Delaware corporation ("Purchaser").

W I T N E S S E T H:

WHEREAS, Seller, directly and indirectly through certain of its Affiliates (as defined below), is in the business of researching, developing, manufacturing or having made, marketing, distributing and selling, as the case may be, products (including pharmaceutical drugs) for use in health care;

WHEREAS, Seller desires to sell (or to cause to be sold), and Purchaser desires to purchase, certain rights and assets related to the products set forth on Schedule 1.01(a) (the "Products"), and Purchaser is willing to assume certain liabilities related to the Products, to allow Purchaser to market and sell the Products, in each case upon the terms set forth herein and in the Transitional Business License Agreement; and

WHEREAS, in connection with the foregoing purchase and sale of certain assets and rights and assumption of certain liabilities, Seller and Purchaser each desire Seller or its Affiliates to continue to distribute and sell the Products on a transitional basis, pursuant to the terms set forth in the Transitional Business License Agreement.

NOW, THEREFORE, in consideration of the foregoing and the representations, warranties, covenants and agreements contained herein, the Parties hereby agree as follows:

ARTICLE I.
DEFINITIONS AND TERMS

Section 1.01 Definitions. As used in this Agreement, the following terms shall have the meanings set forth or as referenced below:

"2-4mg Tablets" means [***].

"5-20mg Tablets" means [***].

"Accounts Payable" means all invoices, bills, accounts payable or other trade payables due and owed to any third party arising on or prior to the Closing Date out of or in connection with developing, commercializing, manufacturing (or having manufactured), packaging, importing, marketing, distributing and/or selling the Products by Seller and the Divesting Entities and any of their respective Affiliates on or prior to the Closing Date.

"Accounts Receivable" means all accounts receivable, notes receivable and other indebtedness due and owed by any third party to Seller or any of its Affiliates arising or held in connection with the sale of the Products on or prior to the Closing Date.

"Action" means any litigation, arbitration, investigation, proceeding, claim, suit or similar action by or before a Governmental Authority.

"Affiliate" means, with respect to any Person, any other Person directly or indirectly controlling, controlled by, or under common control with, such Person at any time during the period for which the determination of affiliation is being made. For purposes of this definition, "control" of a Person means the power, direct or indirect, to direct or cause the

direction of the management and policies of such Person whether by contract or otherwise and, in any event and, without limitation of the previous sentence, any Person owning more than fifty percent (50%) or more of the voting securities of another Person shall be deemed to control such Person.

"Agreement" means this Asset Purchase Agreement, including all Schedules and Exhibits attached hereto, as the same may be amended, modified or supplemented from time to time in accordance with the terms hereof.

"Ancillary Agreements" means, collectively, the Transitional Business License Agreement, the Bill of Sale and Assignment and Assumption Agreement, the Trademark Assignments, the Patent Assignments, the Pharmacovigilance Agreement, the Supply Agreement (as applicable), the Quality Agreement (as applicable), the Seller Supply Agreement (as applicable), the Seller Quality Agreement (as applicable), the Letter Agreement, and each other agreement, certificate or instrument being executed and delivered (either at the Closing or at a later date pursuant to the terms herein) pursuant to the terms of this Agreement.

"Assignment and Assumption Agreement" means the assignment and assumption agreement in substantially the form attached hereto as Exhibit G.

"Anticorruption Laws" has the meaning set forth in Section 4.13.

"Assumed Liabilities" has the meaning set forth in Section 2.04.

"Bankruptcy and Equity Exceptions" has the meaning set forth in Section 4.02(b).

"Bill of Sale and Assignment and Assumption Agreement" means that certain bill of sale and assignment and assumption agreement delivered by the Parties at the Closing.

"Business" means [***].

"Business Books and Records" has the meaning set forth in Section 2.01(c).

"Business Day" means any day other than a Saturday, a Sunday or a day on which banks in New York City, New York are authorized or obligated by law or executive order to close or any other day that Seller or any of the Divesting Entities are closed consistent with the Johnson & Johnson Universal Calendar (for illustrative purposes, a copy of the Johnson & Johnson Universal Calendar for the year 2023 is attached hereto as Exhibit C).

"Carve-Out Financial Statements" has the meaning set forth in Section 6.16.

"cGMP" has the meaning set forth in Section 4.08(a).

"Claim" has the meaning set forth in Section 7.03.

"Closing" means the consummation of the Transactions pursuant to the terms of this Agreement.

"Closing Date" has the meaning set forth in Section 3.01(a).

"CMO Contracts" means (i) [***] and (ii) [***].

"Confidentiality Agreement" means that certain letter agreement dated [***], between Vanda Pharmaceuticals Inc. and Janssen Global Services, LLC.

"Contract" means any legally binding contract, agreement or commitment.

"Control" means ownership or possession (including through control of an Affiliate or through an agreement with an Affiliate or third party) of the right or ability to grant a license or sublicense of specified intellectual property rights (such as know-how) without violating the terms of any agreement or other arrangement with any third party.

"Copyrights" means all copyrights and mask works (in the United States, as defined in 17 U.S.C. §901), whether registered or unregistered, and pending applications to register the same in the United States and Canada and copyrightable works of authorship in any media now known or hereafter created and whether or not completed, published, or used, including: (i) all rights of authorship, use, publication, reproduction, display, distribution, performance, preparation of derivative works and transformation of such copyrightable works, including all moral rights, mask works, drafts, writings, plans, sketches, layouts, designs, artwork, printed or graphic matter, video, films, photographs, illustrations, slides, audio and video recordings and other audiovisual works, software development documentation and programming tools, literary and artistic works; (ii) all copies, compilations and derivative works of such copyrightable works, including translations, adaptations, or combinations of any of the foregoing; (iii) all rights of ownership of copyrightable works, whether or not registered; and (iv) all rights to register and obtain renewals and extensions of copyright registrations.

"Data Room" means the electronic data room [***].

"De Minimis Amount" has the meaning set forth in Section 7.06.

"Divesting Entities" means , collectively, Seller and all Affiliates of Seller that have any right, title or interest in, to or under the Purchased Assets.

"DSCSA" has the meaning set forth in Section 4.08(a).

"Excluded Assets" has the meaning set forth in Section 2.03.

"FDA" means the U.S. Food and Drug Administration.

"FDA Laws and Regulations" means the FDCA and all other applicable laws and regulations of the relevant Governmental Authority in the countries in which Seller distributes or markets the Products.

"FDCA" means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. § 301 et seq.), and the regulations promulgated thereunder.

"Fiscal Year" means a year based on the Johnson & Johnson Universal Calendar [***].

"Forward-Looking Statements" has the meaning set forth in Section 6.01(d).

"Fraud" means actual and intentional fraud.

"Fundamental Representations" means [***].

"GAAP" means accounting principles and practices generally accepted in the United States, as in effect during the relevant time period, consistently applied.

"GCP" has the meaning set forth in Section 4.08(a).

"GLP" has the meaning set forth in Section 4.08(a).

"Governmental Authority" means any domestic or foreign supranational, national, multinational, federal, provincial, state, county or local judicial (including any arbitration panel), legislative, executive, administrative, regulatory or enforcement authority, agency, commission, body, board, bureau or instrumentality with competent jurisdiction, including regulatory agencies, or quasi-governmental, self-regulatory organization, commission, body, authority or agency (or any department, agency, or political subdivision thereof).

"Governmental Authorizations" means all marketing authorizations, licenses, clearances, permits and other authorizations, consents, registrations, grants, exemptions, orders and approvals required to market or sell the Products under the applicable Laws of any Governmental Authority.

"Governmental Order" means any order, writ, judgment, injunction, decree, stipulation, determination, award or similar order entered by or with any Governmental Authority.

"Healthcare Laws" means all applicable Laws with respect to healthcare matters.

"Implementation Plan" means the implementation plan which sets out an estimated timeline for the transfer of Governmental Authorizations for each jurisdiction in the Relevant Jurisdictions attached to the Transitional Business License Agreement as Exhibit B.

"IND(s)" means all investigational new drug applications in effect, filed with the FDA pursuant to 21 C.F.R. Part 312, or any comparable filing made with any Governmental Authority, and all supplements and amendments that may be filed with respect to the foregoing.

"Indemnified Party" has the meaning set forth in Section 7.03.

"Indemnifying Party" has the meaning set forth in Section 7.03.

"Intellectual Property" means Patent Rights, Trademarks, Copyrights, and any other intellectual property rights.

"Inventories" means all finished Products held for sale or use in the Relevant Jurisdictions by Seller or any of its Affiliates.

"Judgment" means any judgment, order, writ, injunction, legally binding agreement, stipulation or decree from a Governmental Authority.

"Knowledge" or "Knowledge of Seller" means the actual knowledge of any of the individuals listed on Schedule 1.01(b), in each case, after reasonable inquiry of such Person's direct reports.

"Laws" means any federal, state, provincial, foreign or local law, common law, statute, ordinance, rule, regulation, code, Judgment, Governmental Order promulgated or enforced by any Governmental Authority.

"Letter Agreement" means the letter agreement delivered by the Parties at the Closing.

"Liabilities" means [***].

"Lien" means, with respect to any property or asset, any lien, security interest, mortgage, pledge, assessment, restriction, adverse claim, levy, charge, encumbrance or other claim of any kind, character or description, whether of record or not, or any contract to give any of the foregoing, in respect of such property or asset.

"Limited License Period" has the meaning set forth in Section 6.05(a).

"Losses" means losses, liabilities, damages, deficiencies, costs, expenses, penalties, assessments, fines, fees, suits, actions, causes of action, judgments, Taxes and awards directly incurred or suffered (and, if applicable, reasonable attorneys' fees associated therewith).

"Material Adverse Effect" means, with respect to Seller and any Divesting Entity, any effect, change or event that has had or would reasonably be expected to have a materially adverse effect on the value of the Purchased Assets, taken as a whole provided that none of the following changes, effects, events, circumstances, occurrences or states of facts shall be deemed, either alone or in combination, to constitute a Material Adverse Effect, or be taken into account in determining whether there has been or would reasonably be expected to be a Material Adverse Effect: (i) Seller's or its Affiliate's compliance with the terms of this Agreement; (ii) changes or effects in the general business, economic, social, legal, tax, regulatory or political conditions or the securities, syndicated loan, credit or financial markets; (iii) changes or proposed changes in applicable Law or GAAP (or any applicable accounting standards in any jurisdiction outside the United States) or in the interpretation or the enforcement thereof; (iv) changes or proposed changes to Law that generally affect the industries in which the Business operates, or any change in governmental or private third party payor reimbursement rules or policies; (v) changes or effects that arise out of or are attributable to the commencement, occurrence, continuation or intensification of any war, sabotage, armed hostilities or acts of terrorism including any cyber- terrorism or cyber-attack, or any changes in political conditions; (vi) earthquakes, hurricanes, pandemics (including COVID-19), epidemics, natural disasters, or any other force majeure event, whether or not caused by any Person, or any national or international calamity or crisis; (vii) declining sales of the Product due to competition or failure to meet projections, estimates, plans or forecasts; (viii) changes or effects that arise out of or are attributable to the negotiation, execution, announcement or pendency of the Transactions or the performance of and compliance with the terms of this Agreement, including any Action, any reduction in revenues or income, any loss of employees or customers, any cancellation of or delay in customer orders, any disruption in supplier, distributor or similar relationships; (ix) changes in the number or type of competing products in the market(s) in which the Products are sold; (x) any decline in the Business that results therefrom; (xi) any labor strikes, labor stoppages or loss of employees; (xii) currency or interest rate fluctuations; (xiii) changes or effects that arise out of or are attributable to actions or omissions of Purchaser or any of its Affiliates or actions or omissions of Seller or any of its Affiliates and consented to, in advance, in writing by Purchaser or any of its Affiliates; and (xiv) any action or inaction (a) Seller is required to take or refrain from taking under this Agreement or (b) Seller takes at the request or with the consent of Purchaser, except in the case of clauses (ii) – (vi), (xi) and (xii), to the extent that the Purchased Assets or the Business, taken as a whole, are materially disproportionally affected thereby as compared to other companies or businesses participating in the industries in which the Business operates.

"NDA(s)" means all new drug applications and supplemental new drug applications, as defined in the FDCA, and other comparable registrations and approvals required by any Governmental Authority associated with the commercialization and marketing of pharmaceutical products.

"Net Sales" has the meaning [***].

"Non-assigned Asset" has the meaning set forth in Section 2.02(a).

"Party" means Seller or Purchaser individually, as the context so requires, and the term "Parties" means, collectively, Seller and Purchaser.

"Patent Assignments" means [***].

"Patent Rights" means [***].

"Permitted Liens" means (a) all Liens approved in writing by Purchaser as Permitted Liens, including Liens securing indebtedness for borrowed money; (b) statutory Liens arising out of operation of Law with respect to a Liability incurred in the ordinary course of business and which is not delinquent; (c)Liens, other than Liens securing indebtedness for borrowed money, that, individually and in the aggregate, do not and would not reasonably be expected to materially detract from the value or impair the use of the property subject thereto or make such property unmarketable; (d) Liens for Taxes not yet due, payable, delinquent or subject to penalties for nonpayment, or which are being contested in good faith; (e) mechanics', materialmens', carriers', workmens', warehousemens', repairmens', landlords' or other like Liens and security obligations that are incurred in the ordinary course of business which are not delinquent; and (f) all laws, and all restrictions, covenants, conditions, limitations, agreements, reservations and easements now or hereafter recorded in the public records, which may include, without limitation, zoning restrictions, property use limitations and obligations, easements (rights-of-way) and agreements relating to telephone lines, water and sewer lines and other utilities that do not have a Material Adverse Effect on, and otherwise do not materially and adversely impact the current use of the property subject thereto.

"Person" means an individual, a Governmental Authority, a limited liability company, a joint venture, a corporation, a partnership, an association, a trust, a division or an operating group of any of the foregoing or any other entity or organization.

"Pharmacovigilance Agreement" has the meaning set forth in Section 6.18(a).

"Post-Closing Tax Period" means any taxable period (or portion thereof) that begins after the Closing Date.

"Pre-Closing Tax Period" means any taxable period (or portion thereof) that ends on or before the Closing Date.

"Products" has the meaning set forth in the Recitals to this Agreement.

"Purchase Price" means an amount equal to $100,000,000.

"Purchased Assets" has the meaning set forth in Section 2.01.

"Purchaser" has the meaning set forth in the Preamble of this Agreement.

"Purchaser FDA Letter" has the meaning set forth in Section 6.04(a).

"Purchaser Indemnitees" has the meaning set forth in Section 7.01(a).

"Purchaser IP Rights" means all Intellectual Property under Purchaser's Control as of and at any time following the Closing Date.

"Purchaser Material Adverse Effect" means any change, effect, event, circumstance, occurrence or state of facts that has or would reasonably be expected to have a material and adverse effect on the ability of Purchaser to consummate the Transactions.

"Quality Agreement" has the meaning set forth in Section 6.20.

"Regulatory Information" means [***].

"Relevant Jurisdictions" means the jurisdictions set forth on Schedule A.

"Representatives" means, with respect to either Party, such Party's Affiliates and their respective parents, directors, officers, employees, attorneys, accountants, representatives, financial advisors, lenders, consultants, advisors and other agents.

"Retained Liabilities" has the meaning set forth in Section 2.05.

"ROW Products" means [***].

"ROW Purchaser" means [***].

"ROW Transaction" means [***].

"S1P1 Patents" means [***].

"SEC" has the meaning set forth in Section 6.02.

"Seller" has the meaning set forth in the Preamble of this Agreement.

"Seller FDA Letter" has the meaning set forth in Section 6.04(a).

"Seller Indemnitees" has the meaning set forth in Section 7.02(a).

"Seller Mark Products" means the Products bearing any Seller Marks.

"Seller Marks" means the (i) Seller Names and (ii) Seller Symbols.

"Seller Names" means the names and logos of Seller, the Divesting Entities and all of its and their Affiliates, in each case as set forth in Schedule 1.01(c)(i).

"Seller Quality Agreement" has the meaning set forth in Section 6.20.

"Seller Supply Agreement" has the meaning set forth in Section 6.20.

"Seller Symbols" means [***].

"Straddle Period" means any taxable period that begins on or prior to the Closing Date and ends after the Closing Date.

"Supply Agreement" means the supply agreement by and between Seller and ROW Purchaser, in substantially the form attached hereto as Exhibit D.

"Tax Return" means any return, report, declaration, election, notice, form, claim for refund, information return, statement or other document filed or required to be filed with any Taxing Authority in connection with the determination, assessment or collection of any Tax or the administration of any Laws relating to any Tax, including any schedule or attachment thereto, and including any amendment thereof.

"Taxes" means all taxes, charges, duties, fees, levies or other assessments, including income, gross revenue, excise, property, sales or use, value added, GST/HST, profits, license, withholding (with respect to compensation or otherwise), payroll, employment, net worth, capital gains, transfer, stamp, social security, occupation and franchise taxes, severance, stamp, occupation, alternative or add-on minimum, in each case imposed by any Taxing Authority and in the nature of a tax, of any kind whatsoever, and including any interest, penalties and additions attributable thereto, whether disputed or not.

"Taxing Authority" means any Governmental Authority, exercising any authority to impose, regulate or administer the imposition of Taxes.

"Third Party Claim" has the meaning set forth in Section 7.03.

"Third Party Claim Notice" has the meaning set forth in Section 7.03.

"Trademark Assignments" means the trademark assignments delivered by the Parties at the Closing (with assignments in recordable form to be delivered as promptly as practicable after the Closing).

"Trademarks" means any registered or unregistered United States, Canadian, or state trademark, service mark, trade name, designs, slogans, logos, trade dress, 800-numbers, URLs, or other designation of origin or source identifiers, together with the goodwill pertaining to the foregoing, and all registrations, applications, and renewals therefor.

"Transaction Documents" means this Agreement and the Ancillary Agreements.

"Transactions" means, collectively, the transactions contemplated by this Agreement and the Ancillary Agreements, including the purchase and sale of the Purchased Assets and the assumption of the Assumed Liabilities.

"Transfer Taxes" means any federal, state, county, local, foreign and other sales, use, transfer, value added, conveyance, documentary transfer, stamp duty, sales, use, registration, value-added, goods and services, recording or other similar Tax, fee or charge imposed in connection with the Transactions or the recording of any sale, transfer or assignment of property (including any expenses attributable thereto, penalties and interest) effected pursuant to this Agreement.

"Transferred Contracts" has the meaning set forth in Section 2.01(g).

"Transferred Copyrights" means all Copyrights exclusively related to the Products.

"Transferred Governmental Authorizations" has the meaning set forth in Section 2.01(b).

"Transferred IP Rights" means the Transferred Patent Rights, Transferred Copyrights, and Transferred Trademarks.

"Transferred Patent Rights" means the Patent Rights set forth on Schedule 1.01(e).

"Transferred Trademarks" means the Trademarks set forth on Schedule 1.01(d), together with all goodwill associated with the foregoing.

"Transitional Business License Agreement" means the transitional business license agreement for the Relevant Jurisdictions delivered by the Parties at the Closing.

Section 1.02 Other Definitional Provisions.

(a) The words "hereof", "herein", "hereto" and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement.

(b) The terms defined in the singular have a comparable meaning when used in the plural, and vice versa.

(c) The terms "U.S. Dollars" and "$" mean lawful currency of the United States and the terms "Euros" and "€" mean lawful currency of the European Union.

(d) The terms "include," "includes" and "including" means "including, without limitation."

(e) When a reference is made in this Agreement to an Article, a Section, an Exhibit or a Schedule, such reference shall be to an Article or a Section of, or an Exhibit or a Schedule to, this Agreement unless otherwise indicated.

(f) Time periods based on a number of days within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period commences and including the day on which the period ends and, if applicable, by extending the period to the next Business Day following if the last day of the period is not a Business Day.

(g) The term "United States" shall refer to the United States of America and its territories, including Puerto Rico, and the term "Canada" shall refer to Canada, including all of its provinces and territories.

(h) Whenever the phrase "made available", "delivered" "provided to" or similar phrases are used in this Agreement, it shall mean the subject documents were either delivered to Purchaser or its Representatives or made available for view by Purchaser or its Representatives in the "Project Kicker" electronic data room hosted by Intralinks no later than 5:00 P.M. Boston, MA time at least [***] prior to the date hereof and that such documents remains available for viewing as of the Closing.

ARTICLE II.
PURCHASE AND SALE

Section 2.01 Purchase and Sale of Assets. Upon the terms set forth herein, at the Closing, Seller shall, and shall cause the Divesting Entities to, sell, convey, assign and transfer to Purchaser, and Purchaser shall purchase, acquire and accept from Seller and the Divesting Entities, free and clear of all Liens (other than Permitted Liens), all of Seller's and the Divesting Entities' rights, titles and interests in, to or under the assets, properties and rights set forth below (collectively, the "Purchased Assets"):

(a) the Transferred IP Rights;

(b) the Governmental Authorizations set forth on Schedule 2.01(b) to the extent transferrable (collectively, the "Transferred Governmental Authorizations");

(c) subject to Section 6.03 and Section 6.04 (and other than the items set forth in Section 2.03(h)), [***] (the foregoing records and documents, collectively the "Business Books and Records"); provided, however, that Seller may retain copies of the Business Books and Records; provided, further, that with respect to the preceding clauses (i) through (v) such records shall be produced solely for such records created or acquired during [***].

(d) the Regulatory Information;

(e) all claims, counterclaims, defenses, causes of action, rights under express or implied warranties, rights of recovery, rights of set-off, rights of subrogation and all other rights of any kind against any third party, to the extent solely relating to the Business, the Products, any Assumed Liabilities or Purchased Assets;

(f) all commercial marketing materials, including [***] relating to the Business or Purchased Assets in the Relevant Jurisdictions and in the possession or Control of Seller or any of its Affiliates;

(g) the Contracts and other instruments set forth on Schedule 2.01(g) (the "Transferred Contracts"); and

(h) all goodwill relating to the Purchased Assets.

Section 2.02 Matters Related to Purchased Assets and Commingled Assets.

(a) Notwithstanding anything in this Agreement to the contrary, this Agreement shall not constitute an agreement to assign or transfer any Purchased Asset to the extent that such Purchased Asset is not assignable or transferable without the consent of any Person, other than Seller, Purchaser or any of their respective Affiliates, to the extent that such consent shall not have been given prior to the Closing (each, a "Non-assigned Asset"); provided, however, that, subject to Section 6.07, Seller shall use, [***] after the Closing, commercially reasonable efforts to obtain, and Purchaser shall use its commercially reasonable efforts to assist and cooperate with Seller in connection therewith, all necessary consents to the assignment and transfer of each Non-assigned Asset; provided, further, that, subject to Section 6.07, none of Seller, Purchaser or any of their respective Affiliates shall be required to pay money to any third party, commence any litigation or offer or grant any accommodation (financial or otherwise) to any third party in connection with such efforts. With respect to any Non-assigned Asset, for a period beginning on the Closing Date and ending on the earlier of (i) the time such requisite consent is obtained and such Non-assigned Asset is transferred and assigned to Purchaser and (ii) [***], Seller shall, and shall cause the Divesting Entities to, use commercially reasonable efforts to provide to Purchaser substantially the benefits thereof and shall enforce, at the request of and for the benefit of Purchaser, and at the expense of Purchaser, any rights of Seller or the Divesting Entities arising thereunder against any Person, including the right to seek any available remedies or to elect to terminate in accordance with the terms thereof upon the advice of Purchaser. As a condition to Seller providing Purchaser with benefits of any Non-assigned Asset, Purchaser shall perform, at the direction of Seller or the applicable Divesting Entity, the obligations of Seller or the Divesting Entity thereunder. Upon receipt following the Closing of the consents required to transfer any Non-assigned Asset to Purchaser, Seller shall, or shall cause the applicable Divesting Entity to, transfer and convey such Non- assigned Asset to Purchaser without payment of any additional consideration by Purchaser.

(b) Seller provides no assurances to Purchaser that any consent, authorization, approval or waiver of a third party contemplated by this Section 2.02 will be granted. Subject to compliance by Seller with the provisions of this Section 2.02 and the accuracy of the representations and warranties of Seller contained in ARTICLE IV, the Parties acknowledge and agree that neither Seller nor its Affiliates shall be obligated to obtain any such authorization, approval, consent or waiver hereunder and neither (i) the failure to so actually obtain any such authorization, approval, consent or waiver in connection with the consummation of the Transactions in and of itself nor (ii) any default or termination or any lawsuit, action, claim, proceeding or investigation commenced or threatened by or on behalf of any Person to the extent arising out of any such failure to so actually obtain any such authorization, approval, consent or waiver in connection with the consummation of the Transactions in and of itself shall be deemed (A) a breach of any representation, warranty or covenant of Seller contained in this Agreement or (B) to cause any condition to Purchaser's obligations to close the Transactions to be deemed not satisfied, except to the extent such authorization, approval, consent or waiver is a condition to Purchaser's obligations to close. Subject to Seller's compliance with the terms of this Section 2.02, if such consent is not obtained, Seller will be deemed to have fulfilled its obligations under this Section 2.02 and under no circumstances shall the Purchase Price be reduced or Seller or its Affiliates be subject to any liability on account of the failure to obtain such authorization, approval, consent or waiver in accordance with the terms of this Section 2.02.

Section 2.03 Excluded Assets. Purchaser shall not acquire any right, title or interest in, to or under any of the following assets (collectively, the "Excluded Assets"):

(a) [***];

(b) any component of working capital;

(c) any cash, checks, money orders, marketable securities, short-term instruments and other cash equivalents, funds in time and demand deposits or similar accounts, and any evidence of indebtedness issued or guaranteed by any Governmental Authority;

(d) any Accounts Receivable;

(e) any Contracts of Seller or the Divesting Entities, or rights therein or thereunder except for the Transferred Contracts set forth on Schedule 2.01(g);

(f) any licenses, permits, registrations, certificates or other authorizations, consents, clearances or approvals of Seller and its Affiliates, other than the Transferred Governmental Authorizations set forth on Schedule 2.01(b);

(g) any losses, loss carryforwards, credits, credit carryforwards and other Tax attributes of Seller and its Affiliates, all deposits or advance payments with respect to Taxes, and any claims, rights, and interest of Seller or its Affiliates in and to any refund, credit or reduction of Taxes;

(h) (i) the corporate books and records of Seller and its Affiliates that are not Business Books and Records, (ii) all personnel records, (iii) any attorney-client work product, attorney client communications and other items protected by attorney client or similar privilege to the extent directly relating to or in connection with this Agreement or any of the Transactions, (iv) Tax Returns, Tax information, and Tax records related to Seller or its Affiliates, and (iv) any documents that were received from third parties in

connection with their proposed acquisition of the Purchased Assets or the Products or that were prepared by Seller or any of its Affiliates in connection therewith;

(i) any current and prior insurance policies of Seller and its Affiliates and all rights of any nature with respect thereto, including all insurance recoveries thereunder and rights to assert claims with respect to any such insurance recoveries;

(j) any Intellectual Property of Seller or its Affiliates, other than the Transferred IP Rights;

(k) any real estate owned or leased by Seller or any of its Affiliates;

(l) any rights, claims and credits of Seller or any of its Affiliates to the extent relating to any Excluded Asset or any Retained Liability, including any guarantees, warranties, indemnities and similar rights in favor of Seller or any of its Affiliates relating to any Excluded Asset or any Retained Liability;

(m) [***];

(n) all purchase orders for Products that are outstanding as of the Closing;

(o) all employees of Seller, any Divesting Entity or any of their Affiliates;

(p) any rights that could be construed to interfere with, hinder or compromise Seller's ability to institute or maintain any claim, action, suit or proceeding against a third party for infringement of patents owned or licensed by Seller or its Affiliates, including patents being licensed or sub-licensed to Purchaser by Seller; and

(q) any other assets, properties or rights (including Intellectual Property) of Seller or any of its Affiliates other than the Purchased Assets.

Section 2.04 Assumption of Certain Obligations. Purchaser hereby assumes and agrees to timely satisfy and discharge the Liabilities of Seller and its Affiliates set forth on Schedule B, in each case other than the Retained Liabilities (all of such Liabilities being collectively referred to hereinafter as the "Assumed Liabilities").

Section 2.05 Retained Liabilities. Seller and its Affiliates hereby retain and agree to be responsible for the Liabilities set forth on Schedule C (the "Retained Liabilities"), except to the extent any such Liabilities constitute Assumed Liabilities.

Section 2.06 Purchase Price. In consideration of the sale and transfer of the Purchased Assets, Purchaser agrees to pay to Seller at the Closing, on behalf of Seller and each Divesting Entity, the Purchase Price, exclusive of any Transfer Taxes, and to assume, satisfy and discharge when due all Assumed Liabilities. The Purchase Price shall be paid in immediately available funds by wire transfer on the Closing Date, in accordance with written instructions given by Seller to Purchaser [***], in cash in U.S. Dollars. The Purchase Price shall be allocated as described in Section 2.07.

Section 2.07 Allocation of Purchase Price. Purchaser and Seller agree that 100% of the Purchase Price (including any Assumed Liabilities and any other relevant items) to the extent treated as consideration for Tax purposes [***]. [***].

Section 2.08 Transfer Taxes. All Transfer Taxes payable in connection with the transfer of the Purchased Assets to Purchaser under this Agreement shall be borne and paid [***]

by Purchaser and [***] by Seller when due in compliance with applicable Transfer Tax Laws. The Party responsible under applicable Law will timely file all necessary Tax Returns and other documentation with respect to all such Transfer Taxes. Each Party agrees to cooperate with the other Party's reasonable requests in the filing of any Tax Returns with respect to Transfer Taxes, including promptly supplying any information in its possession that is reasonably necessary to complete such returns. The Parties shall cooperate and use commercially reasonable efforts to take, reduce, or eliminate any such Transfer Taxes to the extent permitted by applicable Law.

Section 2.09 Tax Withholding. Purchaser shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to Seller such amounts as Purchaser is required to deduct and withhold under applicable Tax law with respect to the making of such payment. Purchaser and Seller shall use commercially reasonable efforts to cooperate to reduce the amount of withholding Taxes imposed on amounts payable hereunder, including by executing and filing any forms or certificates reasonably required to claim an available reduced rate of, or exemption from, withholding Taxes. To the extent that amounts are so withheld and paid over to the applicable Taxing Authority, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to Seller. On the date of execution of this Agreement, Seller will deliver to Purchaser an accurate and complete IRS Form W-8 certifying that Seller is entitled to the applicable benefits under the Convention Between the United States of America and the Swiss Confederation for the Avoidance of Double Taxation with Respect to Taxes on Income.

Section 2.10 Risk of Loss; Casualty and Condemnation. Subject to the terms and conditions of this Agreement and not in limitation of any representation, warranty, covenant or condition set forth herein, prior to the Closing, any loss or damage to the Purchased Assets from fire, casualty or otherwise shall be the sole responsibility of Seller and, after the Closing, any such loss or damage shall be the sole responsibility of Purchaser.

Section 2.11 Certain Costs. All costs and fees associated with (a) removing and moving any Purchased Asset to a location designated in writing by Purchaser and (b) transferring to Purchaser or one of its Affiliates the Transferred IP Rights and the Transferred Governmental Authorizations for the Products conveyed to Purchaser hereunder shall be borne and paid solely by Purchaser when due; provided, however, that if any such amount shall be incurred by Seller, Purchaser shall, subject to receipt of satisfactory evidence of Seller's payment thereof, promptly reimburse Seller for the amount of such costs and expense. For the avoidance of doubt, any amounts constituting Transfer Taxes shall be governed by Section 2.08 and not this Section 2.11.

ARTICLE III.
CLOSING

Section 3.01 Closing.

(a) The Closing shall take place by email exchange of electronic (.pdf format or DocuSign) counterpart signature pages on the date hereof (the "Closing Date") at the offices of Ropes & Gray LLP, Prudential Tower, 800 Boylston Street, Boston, MA (including any Persons connected by remote access to the Closing). Unless otherwise provided for in this Agreement, all proceedings to be taken and all documents to be executed and delivered at the Closing will be deemed to have been taken and executed simultaneously and no proceedings will be deemed to have been taken nor documents executed or delivered until all have been taken, executed and delivered.

(b) Seller hereby delivers, or causes to be delivered, to Purchaser the instruments and documents set forth on Exhibit A.

(c) Purchaser hereby delivers, or causes to be delivered, to Seller (i) the Purchase Price, by wire transfer in accordance with Section 2.06, and (ii) the instruments and documents set forth on Exhibit B.

ARTICLE IV.
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller hereby represents and warrants to Purchaser as follows:

Section 4.01 Organization. Seller is a limited liability company duly organized, validly existing and in good standing under the Laws of Switzerland. Each Divesting Entity is duly organized, validly existing and, where applicable, in good standing under the Laws of the jurisdiction of its organization. Seller and each Divesting Entity is authorized to do business and is in good standing under the Laws of all jurisdictions in which it is required to be so authorized except as would not, individually or in the aggregate, be material to the Business.

Section 4.02 Authority; Binding Effect.

(a) Seller and each Divesting Entity has all requisite corporate, limited liability company or other similar organizational power and authority to own and operate its properties and assets and to carry on the Business as it is now being conducted and as it is related to the Purchased Assets. Seller and each Divesting Entity has all requisite corporate, limited liability company or other similar organizational power and authority to execute and deliver each Transaction Document to which it is a party, and to carry out, or to cause to be carried out, the Transactions. The execution and delivery by Seller and each Divesting Entity of each Transaction Document to which it is a party, and the performance by Seller and each Divesting Entity of its obligations hereunder and thereunder, have been duly authorized by all requisite corporate, limited liability company or other similar organizational power and action on the part of Seller and such Divesting Entity.

(b) This Agreement has been duly and validly authorized, executed and delivered by Seller and, assuming the valid execution and delivery by Purchaser, constitutes a legal, valid and binding obligation of Seller, enforceable against Seller in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, fraudulent conveyance, moratorium or similar Laws affecting creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a proceeding in equity or law) (collectively, the "Bankruptcy and Equity Exceptions").

(c) Each of the Ancillary Agreements has been (or will be) duly authorized by all necessary action on the part of Seller and each Divesting Entity party thereto and has been (or will be when executed) duly and validly executed and delivered by Seller and each Divesting Entity party thereto and, assuming the valid execution and delivery by Purchaser, constitutes (or will constitute when executed) a legal, valid and binding obligation of Seller and each Divesting Entity party thereto, enforceable against Seller and each Divesting Entity party thereto in accordance with its terms, except as such enforceability may be limited by the Bankruptcy and Equity Exceptions.

Section 4.03 Non-Contravention. The execution, delivery and performance of this Agreement and the other Transaction Documents by Seller and each Divesting Entity party thereto, as applicable, and the consummation of the Transactions, do not and will not: (a) conflict with, violate or result in any breach of any provision of the certificate of incorporation or bylaws of Seller and the comparable organizational documents of any Divesting Entity; (b) subject to

obtaining the consents referred to in Schedule 4.03 and before giving effect to Section 2.02, materially conflict with, or result in a material breach of, constitute a material violation or default under or result in the termination, cancellation or acceleration (whether after the giving of notice or the lapse of time or both) or give rise to any right of termination, cancellation or acceleration of any material obligation under, or a loss of any material benefit to which any of Seller or any Divesting Entity is entitled under (whether after the giving of notice or the lapse of time or both) of any material right or obligation of Seller or any Divesting Entity, or require the consent of any Person under, any Contract; (c) assuming compliance with the matters set forth in Section 4.04 and Section 5.04, violate or result in a breach of, in any material respect, or constitute a material default under any Law or Judgment applicable to, binding upon, or enforceable against Seller or any of its Affiliates; or (d) result in the creation of any Lien (other than Permitted Liens) upon any of the Purchased Assets.

Section 4.04 Governmental Authorization. Except as set forth on Schedule 4.04 and before giving effect to Section 2.02, the execution, delivery and performance of this Agreement and the other Transaction Documents by Seller and each Divesting Entity, and the consummation of the Transactions, do not require any consent, waiver, authorization, license or approval of, or any notice to or filing, qualification, recording or other action or filing with, any Governmental Authority or any other Person, except for consents, approvals, notices and filings the failure of which to obtain would not, individually or in the aggregate, reasonably be expected to be material to the Business or the value of the Purchased Assets.

Section 4.05 No Litigation. Except as set forth on Schedule 4.05, no Action by or before any Governmental Authority, in each case arising out of or relating to or involving the Purchased Assets, the Products or the Business, is, [***], threatened in writing against Seller or any of its Affiliates, other than Actions which, if adversely determined, would not reasonably be expected to result in the imposition of damages in an amount in excess of [***] individually or [***] in the aggregate, or result in the imposition of any equitable relief. As of the date of this Agreement, none of Seller or the Divesting Entities in respect of the Business, the Products or the Purchased Assets is or has during [***] been subject to any outstanding Judgment. This Section 4.05 does not relate to Intellectual Property, which is the subject of Section 4.09. During [***], neither Seller nor any Divesting Entity has entered into any settlement related to or involving the Purchased Assets, the Products or the Business that resulted in a loss or payment in excess of $[***] (excluding payments by insurance) or involved any material restrictions, limitations, obligations or prohibitions relating to the Purchased Assets, the Products or the Business.

Section 4.06 Compliance with Laws. Except as to matters set forth in Schedule 4.06 Seller and each Divesting Entity:

(a) [***], is, and in the past [***] has been, in material compliance with all Laws and material Governmental Authorizations applicable to the ownership, conduct, use or operation of the Purchased Assets and the conduct of the Business;

(b) has not received any written notice (or, [***], verbal notice) alleging, or, [***], been subject to any investigation or audit by a Governmental Authority concerning, any such violation or conducted any investigation in connection with which outside legal counsel was retained for the purpose of conducting or assisting with such investigation with respect to any actual, potential or alleged violation of the type described in the foregoing clause (a); and

(c) is not a party to any corporate integrity agreements, monitoring agreements, deferred prosecution agreements, consent decrees, settlement orders or similar agreements with or imposed by any Governmental Authority related to the

ownership, conduct, use or operation of the Purchased Assets or the conduct of the Business and, [***], no such action is currently contemplated, proposed or pending.

Section 4.07 Regulatory Matters.

(a) Schedule 4.07(a) sets forth, as of the date of this Agreement, a list of material Governmental Authorizations granted to Seller or any Divesting Entity by, or pending with, any Governmental Authority necessary to (i) market or sell the Products in the Relevant Jurisdictions or (ii) operate the Business. All Transferred Governmental Authorizations are owned by Seller or any Divesting Entity and registered in the name of Seller or any Divesting Entity and, to Knowledge of Seller are in full force and effect. All FDA user fees and similar fees in Canada have been paid and are up to date for current fiscal year in each Relevant Jurisdiction.

(b) All Products sold under the Governmental Authorizations in the Relevant Jurisdictions are and have been manufactured, marketed and sold, in all material respects, in accordance and in compliance with applicable Laws, and the specifications and standards contained in such Governmental Authorizations, and [***], have not been adulterated or misbranded.

(c) Except as set forth on Schedule 4.07(c), since [***], there has not been, nor, [***], is there currently under consideration by Seller or any Governmental Authority, any withdrawal, recall, or suspension of research, manufacturing, distribution, or commercialization in respect of any of the Products in the Relevant Jurisdictions, except for such instances which would not have a Material Adverse Effect.

(d) Except for ordinary course inquiries or as set forth on Schedule 4.07(d), since [***], Seller has not received, with respect to the Products marketed and sold in the Relevant Jurisdictions, any written notice or communications from any applicable Governmental Authority in the Relevant Jurisdictions alleging noncompliance with any applicable Laws and Seller is not subject to any enforcement proceedings by Governmental Authority in the Relevant Jurisdictions related to the Products and, [***], no such proceedings have been threatened.

(e) [***], neither Seller nor any Divesting Entity has received any written notice of any alleged violation of any Healthcare Law from either a Governmental Authority or a customer, and no Governmental Authority or customer has imposed a penalty, corrective action plan, or taken any other enforcement action against Seller or any Divesting Entity during the past [***]. Neither Seller nor any Divesting Entity has received any written, nor [***], other notice of any pending or threatened audit, investigation, or inquiry in any way relating to compliance with Healthcare Laws and, [***], neither Seller nor any Divesting Entity is currently the subject of any such audit, investigation, or inquiry.

Section 4.08 FDA Matters.

(a) Seller and each Divesting Entity is, and at all times since January 1, 2021 has been, in compliance Seller and each Divesting Entity is, and at all times since January 1, 2021 has been, in compliance with all FDA Laws and Regulations, in all material respects including but not limited to (i) the requirement for and the terms of all necessary Governmental Authorizations, including, without limitation, approvals, clearances, exemptions, licenses and other authorizations, (ii) current Good Manufacturing Practices ("cGMP"), (iii) establishment registration and product listing, (iv) labeling, promotion, and advertising, (v) Good Clinical Practices ("GCP") and Good Laboratory Practices

("GLP"), (vi) the Drug Supply Chain Security Act ("DSCSA"), (vii) payment of all application, product and establishment fees, and (viii) recordkeeping and reporting requirements other than those applicable to cGMP, GCP, GLP and DSCSA.

(b) Neither Seller nor any Divesting Entity (with respect to the Purchased Assets, the Products or the Business in the Relevant Jurisdictions) has received any written notice or written communication from any Governmental Authority of any actual or threatened investigation, inquiry, or administrative or regulatory action, hearing, or enforcement proceeding against Seller or any Divesting Entity regarding any material violation of FDA Laws and Regulations. [***], neither Seller nor any Divesting Entity (with respect to the Purchased Assets, the Products or the Business in the Relevant Jurisdictions) is subject to any material obligation arising under an investigation, inquiry, or administrative, regulatory or judicial action, hearing, or enforcement proceeding by or on behalf of the FDA, warning letter, untitled letter, FDA Form 483, notice of violation letter, consent decree, request for information or other notice, response, or commitment made to or with any Governmental Authority with respect to FDA Laws and Regulations, and no such material obligation has been threatened in writing.

(c) [***], there is no product liability, civil, or criminal action, suit, proceeding, demand, claim, complaint, hearing, investigation, demand letter, warning letter, proceeding or request for information pending against or relating to Seller or any Divesting Entity or to any of their employees (with respect to the Purchased Assets, the Products or the Business) that involves or arises from a material violation of FDA Laws or Regulations, and neither Seller nor any Divesting Entity (with respect to the Purchased Assets, the Products or the Business) has any known material liability for failure to comply with any FDA Laws and Regulations. [***], there is no act, omission, event, or circumstance that would reasonably be expected to give rise to or lead to any such action, suit, demand, claim, complaint, hearing, investigation, notice, demand letter, warning letter, proceeding or request for information or any such material liability.

Section 4.09 Intellectual Property.

(a) Except as set forth on Schedule 4.09(a):

(i) (A) all registrations, issuances and applications for the Transferred Trademarks have been duly filed or registered (as applicable) with the applicable Governmental Authority, have been properly maintained, and are in good standing in all material respects; (B) the Transferred Trademarks are enforceable, valid and subsisting; and (C) none of the Transferred Trademarks have lapsed or expired, have been abandoned, cancelled, revoked or adjudicated invalid or are subject to any outstanding order, judgment or decree restricting its use or that would affect Purchaser's rights therein and there is no Action being asserted by any Person, or, [***], threats thereof, with respect to the ownership, scope, enforceability, subsistence or validity of any the Transferred Trademarks;

(ii) (A) all patent and patent applications in the Transferred Patent Rights have been duly filed or registered (as applicable) with the applicable Governmental Authority, have been properly maintained, and are in good standing in all material respects; (B) [***], the Transferred Patent Rights are enforceable, valid and subsisting; and (C) [***], none of the Transferred Patent Rights have lapsed or expired, or have been cancelled, revoked or adjudicated invalid or are subject to any outstanding order, judgment or decree, and, there is no Action being asserted by any Person, or, [***], threats thereof, with respect to

the ownership, scope, enforceability, subsistence or validity of any the Transferred Patent Rights;

(iii) neither Seller nor any Divesting Entity has granted any rights to any Person which would conflict with the rights granted in the Transferred IP Rights to Purchaser hereunder;

(iv) Seller or one or more of the Divesting Entities is the legal and beneficial owner of the Transferred IP Rights; and

(v) [***], there are no Actions pending or threatened by Seller against any Person, nor has Seller sent any written notice to any Person, regarding actual or potential infringement, misappropriation or other unauthorized use of the Transferred IP Rights.

(b) [***], the manufacture, packaging, marketing, distributing, sale, and other commercialization of the Products and the conduct of the Business do not infringe or violate or constitute a misappropriation of any Intellectual Property of any third party. Except as set forth on Schedule 4.09(a)(v) there are no, during [***] there have been no, Actions pending against Seller by any Person in any court, arbitration or proceeding by or before any Governmental Authority.

(c) [***], there is no pending, or threatened, Action, including any interference, opposition or demand of any third party, challenging the ownership, validity, enforceability, scope, registration or use of any Transferred IP Rights, and Seller has not been served with or provided written notice that any Transferred IP Rights are the subject of any Action, order, judgment or decree, and Seller is not subject to any order, judgment or decree, barring or limiting Seller's use of any Transferred IP Rights.

(d) Seller has required each employee, independent contractor, consultant and any other Person employed or engaged by Seller or any Divesting Entity who contributed to the discovery or development of any Transferred Patent Rights for or on behalf of Seller or such Divesting Entity to assign in favor of Seller or such Divesting Entity as assignee that assigns to Seller or such Divesting Entity exclusive ownership of all such Transferred Patent Rights.

(e) [***], the Transferred IP Rights constitute all Intellectual Property used or held for use by Seller exclusively in the conduct of the Business in the Relevant Jurisdictions and under which the Business operates as of the date hereof, or necessary for the conduct of the Business and under which the Business operates as of the date hereof, including as relating to the manufacturing, marketing, sale, distribution or other commercialization of the Products. Schedules 1.01(d), and 1.01(e) completely and accurately identify the Trademarks and Patent Rights controlled, used or held for use by Seller to conduct the Business.

(f) Seller has good and valid title to all Transferred IP Rights, free and clear of all Liens, other than Permitted Liens.

(g) Section 4.09(g) contains a list and description of all Contracts that are material to the Products or the Business in the Relevant Jurisdictions and relate to: (i) any Transferred IP Rights and (ii) any Intellectual Property in connection with the Product or the Business, including any Contracts by which Seller has licensed, sublicensed, or otherwise authorized a third party to use any such Transferred IP Rights, including license agreements, settlement agreements and covenants not to sue.

(h) Seller is not a party to any Contract pursuant to which Seller has licensed any Transferred IP Rights from a third party in the Relevant Jurisdictions. Seller has the sole and exclusive right to bring actions for infringement, misappropriation, dilution, violation or unauthorized use of the Transferred IP Rights in the Relevant Jurisdictions.

(i) The representations and warranties set forth in this Section 4.09 constitute the only representations and warranties given by Seller with respect to matters related to Intellectual Property.

Section 4.10 Brokers. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee, commission or similar compensation in connection with the Transactions based upon arrangements made by or on behalf of Seller or any of the Divesting Entities.

Section 4.11 Purchased Assets. Except as set forth on Schedule 4.11 Seller and the Divesting Entities (i) own, lease or have the legal right to use all of the Purchased Assets and (ii) have good and valid title to, and the right to transfer (or cause to be transferred) in accordance with the terms of this Agreement, all the Purchased Assets free and clear of all Liens, except for Permitted Liens. This Section 4.11 does not relate to Intellectual Property, which is the subject of Section 4.09.

Section 4.12 Financial Information. The Net Sales for the Products, which are unaudited and were prepared using consistent presentation from the books and records of Seller and the Divesting Entities, for the Fiscal Years ended December 30, 2021 and December 29, 2022 are [***], respectively in U.S. Dollars.

Section 4.13 Certain Business Practices. Neither Seller nor any of its Affiliates nor any of their respective directors, officers or employees, nor, [***], any distributor, agent, Representative, sales intermediary or other third party acting on behalf of Seller or any of its Affiliates, in any way relating to the Business, the Products or the Purchased Assets: (i) has taken any action in violation of any applicable anticorruption Law, including the U.S. Foreign Corrupt Practices Act of 1977 (15 U.S.C. § 78 dd-1 et seq.) (all such Laws, "Anticorruption Laws") in any jurisdiction in which Products are manufactured or sold by or on behalf of Seller, (ii) has received any notice alleging any potential or alleged violation of any Anticorruption Laws in any jurisdiction in which Products are manufactured or sold by or on behalf of Seller, or (iii) has corruptly, offered, paid, given, promised to pay or give or authorized the payment or gift of anything of value, directly or indirectly, to any "Public Official," as defined in this Section 4.13 in any jurisdiction in which Products are manufactured or sold by or on behalf of Seller, for purposes of (A) influencing any act or decision of any Public Official in his official capacity; (B) inducing such Public Official to do or omit to do any act in violation of his lawful duty; (C) securing any improper advantage; or (D) inducing such Public Official to use his or her influence with a government, Governmental Authority, or commercial enterprise owned or controlled by any Governmental Authority (including state-owned or controlled medical facilities), in order to assist any Person in obtaining or retaining business or directing any business to any Person. For purposes of this Section 4.13, "Public Official" means: (i) any officer, employee or representative of any Governmental Authority; (ii) any officer, employee or representative of any commercial enterprise that is owned or controlled by a Governmental Authority, including any state-owned or controlled medical facility; (iii) any officer, employee or representative of any public international organization; (iv) any person acting in an official capacity for any Governmental Authority; and (v) any political party, party official or candidate for political office. During [***], none of Seller or any of its Affiliates, nor, [***], any of their respective officers or directors, has, in connection with the conduct of the Business, engaged in any transaction with any Person that (i) appears on the Specially Designated Nationals and Blocked Persons List of the Office of Foreign Assets Control of the United States Department of the

Treasury; (ii) is otherwise a party with whom, or has its principal place of business or the majority of its business operations (measured by revenues) located in a country in which, transactions are prohibited by (A) United States Executive Order 13224, Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism; (B) the United States Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001; (C) the United States Trading with the Enemy Act of 1917, as amended; (D) the United States International Emergency Economic Powers Act of 1977, as amended; or (E) the foreign asset control regulations of the United States Department of the Treasury; or (iii) [***], has been convicted of or charged with a felony relating to money laundering or is under investigation by any Governmental Authority for money laundering.

Section 4.14 Absence of Certain Developments. Except as set forth on Schedule 4.14, since [***], (a) except as expressly contemplated by this Agreement, Seller and the Divesting Entities have conducted the Business in the ordinary course consistent with past practice, (b) there has not been any change or event that has had or could reasonably be anticipated to result in a Material Adverse Effect.

Section 4.15 Contracts. Seller has made available to Purchaser true and complete copies of all Transferred Contracts. Except as disclosed in Schedule 4.15, as of the date hereof (i) each Contract is valid and binding on Seller or the Divesting Entity that is a party thereto and, [***], the other party thereto, and is in full force and effect in accordance with its terms, subject to the Bankruptcy and Equity Exceptions, and (ii) neither Seller nor any Divesting Entity nor, [***], any other party thereto is in material breach of, or material default under, any Transferred Contract, and no event has occurred that, with the giving of notice or lapse of time or both, would constitute a material breach or material default thereunder. Neither Seller nor any Divesting Entity has received written notice of termination, cancellation or non-renewal with respect to any Transferred Contract.

Section 4.16 Exclusivity of Representations. The representations and warranties made by Seller in this Agreement are the exclusive representations and warranties made by Seller with respect to Seller and the Divesting Entities, including the Products and the Purchased Assets. Seller hereby disclaims any other express or implied representations or warranties with respect to itself or any of the Divesting Entities, including the Products and the Purchased Assets. It is understood that any materials made available to Purchaser or its Affiliates do not, directly or indirectly, and shall not be deemed to, directly or indirectly, contain representations or warranties of Seller, the Divesting Entities or their respective Affiliates, except as expressly provided in this Agreement.

ARTICLE V.
REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser hereby represents and warrants to Seller as follows:

Section 5.01 Organization. Purchaser is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware. Purchaser is authorized to do business and in good standing under the Laws of all jurisdictions in which it is required to be so authorized, except as would not, individually or in the aggregate, be material to the business of Purchaser.

Section 5.02 Authority; Binding Effect.

(a) Purchaser has all requisite power and authority to own and operate its properties and assets, to carry on its business as it is now being conducted and to execute and deliver this Agreement and the Ancillary Agreements, and to carry out or cause to be carried out, the Transactions. The execution and delivery by Purchaser of this Agreement and the Ancillary Agreements, and the performance by Purchaser of its obligations hereunder and thereunder, have been duly authorized by all requisite corporate power and action on the part of Purchaser.

(b) This Agreement has been duly and validly authorized, executed and delivered by Purchaser and, assuming the valid execution and delivery by Seller, constitutes a legal, valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with its terms, except as enforcement may be limited by the Bankruptcy and Equity Exceptions.

(c) Each of the Ancillary Agreements has been (or will be) duly authorized by all necessary action on the part of Purchaser and has been (or will be when executed) duly and validly executed and delivered by Purchaser and, assuming the valid execution and delivery by Seller, constitutes (or will constitute when executed) a legal, valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with its terms, except as such enforceability may be limited by the Bankruptcy and Equity Exceptions.

Section 5.03 Non-Contravention. The execution, delivery and performance by Purchaser of this Agreement and the other Transaction Documents, and the consummation of the Transactions, do not and will not (a) conflict with, violate or result in any breach of any provision of the certificate of incorporation, bylaws or other organizational documents of Purchaser; (b) materially conflict with, or result in a material breach of, constitute a material violation or default under or result in the termination, cancellation or acceleration (whether after the giving of notice or the lapse of time or both) or give rise to any right of termination, cancellation or acceleration of any material obligation under or a loss of any material benefit to which any of Purchaser or its Affiliates is entitled under (whether after the giving of notice or the lapse of time or both) of any right or obligation of Purchaser or any of its Affiliates under, or to a loss of any material benefit to which Purchaser or any of its Affiliates is entitled under, any agreement, lease of real estate or license of Intellectual Property to which Purchaser or any of its Affiliates is a party or to which its properties or assets are subject; or (c) assuming compliance with the matters set forth in Section 4.04 and Section 5.04, violate or result in a breach of or constitute a default under any Law or Judgment applicable to, binding upon, or enforceable against Purchaser or any of its Affiliates is subject.

Section 5.04 Governmental Authorization. Except as set forth on Schedule 5.04, the execution, delivery and performance of this Agreement and the other Transaction Documents by Purchaser, and the consummation of the Transactions, do not require any consent, waiver, authorization, license or approval of, or any notice to or other filing, qualification, recording or other action or filing with, any Governmental Authority in the Relevant Jurisdictions, except for consents, approvals, notices and filings the failure of which to obtain would not, individually or in the aggregate, reasonably be expected to be material to the Business or the value of the Purchased Assets.

Section 5.05 Knowledge of Misrepresentations or Omissions. Purchaser does not have any knowledge that any of the representations or warranties of Seller made in this Agreement are not true and correct. Purchaser does not have any knowledge of any material errors in, or material omissions from, this Agreement.

Section 5.06 Brokers. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee, commission or similar compensation in connection with the Transactions based upon arrangements made by or on behalf of Purchaser or any of its Affiliates.

Section 5.07 Solvency; Financial Ability to Perform.

(a) As of the Closing Date, after giving effect to all of the Transactions, including without limitation the payment of the Purchase Price, Purchaser shall be Solvent. For the purposes of this Section 5.07, the term "Solvent" when used with respect to any Person, means that, as of any date of determination, (a) the "fair saleable value" of the assets of such Person will, as of such date, exceed (i) the value of all "liabilities of such Person, including contingent and other liabilities," as of such date, as such quoted terms are generally determined in accordance with applicable federal laws governing determinations of the insolvency of debtors, and (ii) the amount that will be required to pay the probable liabilities of such Person on its existing debts (including contingent liabilities) as such debts become absolute and matured, (b) such Person will not have, as of such date, unreasonably small capital for the operation of the businesses in which it is engaged or proposed to be engaged following such date and (c) such Person will be able to pay its liabilities, including contingent and other liabilities, as they mature.

(b) Purchaser currently has or will have cash and cash equivalents sufficient as and when needed to enable it to consummate the Transactions, including payment of the Purchase Price in connection with the Transactions.

ARTICLE VI.
COVENANTS

Section 6.01 Condition of the Purchased Assets.

(a) Purchaser and its Representatives have made all inspections and investigations relating to the Products and the Purchased Assets deemed necessary or desirable by Purchaser. Purchaser acknowledges and agrees that (a) it is purchasing the Purchased Assets based on the results of its own inspections and investigations, and the representations and warranties set forth herein and in any Ancillary Agreement, and not on any representation or warranty of Seller or any of its Affiliates not expressly set forth in this Agreement or any Ancillary Agreement and (b) subject to the representations and warranties set forth herein and in any Ancillary Agreement, the Purchased Assets are sold "as is, where is" and Purchaser accepts the Purchased Assets in the condition they are in and at the place where they are located on the Closing Date. In light of such inspections and investigations, and the representations and warranties expressly made to Purchaser by Seller in this Agreement and the certificates and other documents delivered pursuant hereto, **PURCHASER AGREES THAT PURCHASER IS ACQUIRING THE PURCHASED ASSETS ON AN "AS IS, WHERE IS" BASIS AND THAT THE REPRESENTATIONS AND WARRANTIES GIVEN HEREIN AND IN ANY ANCILLARY AGREEMENT BY SELLER ARE IN LIEU OF, AND PURCHASER HEREBY EXPRESSLY WAIVES ALL RIGHTS TO, ANY IMPLIED WARRANTIES THAT MAY OTHERWISE BE APPLICABLE BECAUSE OF THE PROVISIONS OF THE UNIFORM COMMERCIAL CODE OR ANY OTHER LAWS, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE**.

(b) Any claims Purchaser may have for breach of representation or warranty will be based solely on the representations and warranties of Seller or the Divesting

Entities expressly set forth in this Agreement and the certificates and other documents delivered pursuant hereto or thereto.

(c) Purchaser further acknowledges and agrees that neither Seller, its Affiliates, nor any other Person, has made any representation, warranty or statement, express or implied, regarding Seller, any of the Divesting Entities, the making, selling and offering for sale of the Products, the Purchased Assets or the Assumed Liabilities not expressly set forth in this Agreement or the certificates or other documents delivered pursuant hereto or thereto upon which Purchaser has relied, and, except in the case of Fraud, neither Seller nor any of its Affiliates or any other Person will have, or be subject to, any liability to Purchaser or any other Person resulting from the distribution to Purchaser or its Representatives, or Purchaser's use of, any such information, including confidential memoranda distributed by or on behalf of Seller or any Divesting Entity relating to the Products, the Purchased Assets or the Assumed Liabilities or any other publication, document or information provided in the Data Room or otherwise provided to Purchaser prior to the Closing Date.

(d) Without limiting the foregoing or any representation or warranty set forth herein or any Ancillary Agreement, Purchaser acknowledges and agrees that (i) it may have received from Seller various forward-looking statements (including estimates, assumptions, projections, forecasts and plans) regarding the Products (collectively, the "Forward-Looking Statements") in connection with Purchaser's investigation of the Purchased Assets; (ii) there are uncertainties inherent in attempting to make such Forward-Looking Statements; (iii) Purchaser is familiar with such uncertainties; (iv) Purchaser is taking full responsibility for making its own investigation, examination and valuation of the Purchased Assets, and has employed outside professionals to assist with such investigation, examination and valuation; (v) Purchaser is taking full responsibility for making its own evaluation of the adequacy and accuracy of all Forward-Looking Statements; (vi) Purchaser is not relying on any Forward-Looking Statement in any manner whatsoever; and (vii) except in the case of Fraud, Purchaser has no claim against Seller or any of its Affiliates with respect to the foregoing. Purchaser further acknowledges and agrees that Seller makes no representation or warranty hereunder with respect to (A) the reasonableness of the assumptions underlying any Forward-Looking Statement; or (B) any Forward-Looking Statement made in any materials in the Data Room, any supplemental due diligence information provided or made available to Purchaser, any of Purchaser's discussions with management regarding the Products, any negotiations leading to this Agreement and the other Transaction Documents, or any other circumstance.

Section 6.02 Publicity. No Party to this Agreement shall originate any publicity, news release or other public announcement, written or oral, whether relating to this Agreement or any of the other Transaction Documents or the existence of any arrangement between the Parties, without the prior written consent of the other Party (whether such other Party is named in such publicity, news release or other public announcement or not), except where such publicity, news release or other public announcement is required by Law or any listing or trading agreement concerning its publicly traded securities; provided that, in such event, the Party issuing the same shall still be required to consult with the other Party (whether such other Party is named in such publicity, news release or public announcement or not) at a reasonable time prior to its release to allow the other Party to comment thereon and, after its release, shall provide the other Party with a copy thereof; provided, further, that Purchaser and its Affiliates shall be entitled to disclose such information to their respective employees, investors, lenders and professional advisors, in each case, who agree, or are otherwise already bound by Contract or other legal obligation, to keep such information confidential. If either Party, based on the advice of its counsel, determines that this Agreement, or any of the other Transaction

Documents, must be filed with the United States Securities and Exchange Commission ("SEC") or any other similar Governmental Authority within the Relevant Jurisdictions, then such Party, prior to making any such filing, shall provide the other Party and its counsel a reasonable opportunity to review a redacted version of this Agreement (and any other Transaction Document) which it intends to file and any draft correspondence with the SEC (or such other Governmental Authority within the Relevant Jurisdictions, as applicable) requesting the confidential treatment by the SEC (or such other Governmental Authority within the Relevant Jurisdictions, as applicable) of those redacted sections of the Agreement, and will incorporate any reasonable comments provided by such other Party or its counsel to further redact this Agreement or other Transaction Documents and to the extent permitted by applicable Law, ensure the confidential treatment by the SEC (or such other Governmental Authority within the Relevant Jurisdictions, as applicable) of those sections specified by such other Party or its counsel.

Section 6.03 Books and Records; Regulatory Information. Seller shall use commercially reasonable efforts to transfer to Purchaser at the Closing (or as soon as reasonably practicable after the Closing) the Business Books and Records and Regulatory Information. To the extent that Seller was unable to transfer any of the Business Books and Records or Regulatory Information to Purchaser at the Closing, Seller shall use commercially reasonable efforts to deliver such Business Books and Records and Regulatory Information to Purchaser (i) with respect to any such Business Books and Records and Regulatory Information that are in hard copy format, as soon as practicable and in any event within [***] following the effectiveness of the transfer of a Transferred Governmental Authorization, Seller shall deliver the corresponding Business Books and Records and Regulatory Information pertaining to such Transferred Governmental Authorization and (ii) with respect to any such Business Books and Records and/or Regulatory Information that are in an electronic format, as soon as practicable and in any event within [***] following the date on which Purchaser has established systems that are compatible with the relevant electronic format to facilitate such delivery; provided, however, that Seller's obligations under this Section 6.03 shall expire on [***] the completion of the transfers of all Transferred Governmental Authorizations. Should Seller be required under the applicable Law of a Relevant Jurisdiction to maintain a copy of Business Books and Records and Regulatory Information, Purchaser shall pay for any costs or expenses associated with reproducing the applicable Business Books and Records or Regulatory Information. Seller may transfer copies or originals of the Business Books and Records and Regulatory Information at its election; provided that Seller will not, and will cause its Affiliates not to, disclose any such Business Books and Records and Regulatory Information or any non- public information contained therein or related to the Products, the Purchased Assets or the Business to any Person, except as required by applicable Law.

Section 6.04 Regulatory Matters.

(a) Transfer of Governmental Authorizations. Each of Seller and Purchaser shall reasonably cooperate and use its commercially reasonable efforts to ensure compliance with all Laws, including FDA regulation 21 C.F.R. 314.72, that may be or become applicable to the performance of its and the other Party's obligations pursuant to this Agreement. As soon as reasonably practicable after the Closing, each Party shall execute and deliver to the appropriate Governmental Authorities all necessary documentation to enable the transfer, assignment, and reissuance (as applicable) of the Transferred Governmental Authorizations, including all such documents and instruments of conveyance as necessary and sufficient to effectuate the transfer of each Transferred Governmental Authorization to Purchaser under applicable Law. In furtherance of the foregoing, (i) Seller shall, as soon as reasonably practicable after the Closing, execute and deliver to both the FDA contact described therein and Purchaser a letter from Seller to FDA notifying FDA of the transfer to Purchaser of the rights to the applicable

Transferred Governmental Authorizations issued by FDA, in the form of letter attached hereto as Exhibit E (the "Seller FDA Letter") and (ii) simultaneously with Seller's execution and delivery of the Seller FDA Letter, Purchaser shall execute and deliver to both the FDA contact described therein and Seller a letter from Purchaser to FDA of Purchaser assuming responsibility for the applicable Transferred Governmental Authorizations issued by the FDA, in the form attached hereto as Exhibit F (the "Purchaser FDA Letter"). Further, each of Purchaser and Seller shall work together in good faith to make all other filings with and give all other notices to all Governmental Authorities, including FDA, required in connection with the transfer of the Products and the Transferred Governmental Authorizations.

(b) Notification of Customers. On a schedule mutually agreed upon by the Parties and in alignment with the Implementation Plan, the Parties shall jointly issue a letter reasonably satisfactory to both Parties to each customer within the trade (wholesalers and distributors) and to each commercial chargeback customer notifying such customers (i) that Purchaser has acquired the rights to market and sell the Products, (ii) that all future Product orders are to be placed with Purchaser, (iii) that all returns of finished goods are to be delivered to Purchaser, (iv) of the Seller's and Purchaser's responsibilities in connection with applicable Transferred Contracts providing for payment of chargebacks, rebates, and other charges and administrative fees and (v) providing the appropriate contact information for Purchaser's personnel. After the issuance of such letters, the Parties shall at all times reasonably cooperate in (A) notifying and continuing to notify such customers that all future Product orders are to be placed with Purchaser and that all returns of finished goods are to be delivered to Purchaser and (B) taking such other actions as are reasonably necessary to effect the foregoing, including forwarding to Purchaser any orders placed prior to the effectiveness of the transfer of a Transferred Governmental Authorization for the purchase of Products by customers that are unfulfilled following the effectiveness of the transfer of such Transferred Governmental Authorization.

(c) Governmental Authority Contacts. Purchaser and Seller shall promptly give written notice to the other upon becoming aware of any action by, or notification or other information which it receives (directly or indirectly) from, any Governmental Authority in the Relevant Jurisdictions (together with copies of correspondence related thereto), which (i) raises any material concerns regarding the safety or efficacy of the Products, (ii) indicates or suggests a potential material liability for either Party to third parties arising from or in connection with the Products, or (iii) indicates a potential for a need to initiate a recall, market withdrawal or similar action, in each case with respect to the Products sold by Seller prior to Closing or Products sold by Seller for the benefit of Purchaser pursuant to the Transitional Business License Agreement.

(d) Product Complaints. From and after the transfer of any Transferred Governmental Authorizations to Purchaser, Purchaser shall be responsible for responding to any complaint regarding any Products sold under such Transferred Governmental Authorization that is received by either Purchaser or Seller (or each Party's respective Affiliates) after such transfer from any source for investigating and analyzing such complaint or reaction, as required by applicable Law, and making required reports to the relevant Governmental Authorities in the Relevant Jurisdictions as applicable, regardless of whether the Products involved were sold by Seller or Purchaser (or either Party's respective Affiliates).

(e) Transfer Materials. Within [***], Seller to provide Purchaser with access to the applicable artwork files for the Products.

Section 6.05 Purchaser Use of Seller Marks.

(a) Notwithstanding anything to the contrary, Purchaser hereby acknowledges that Seller or its Affiliates or its or their licensors own all right, title and interest worldwide in and to the Seller Marks, together with all variations, translations, derivatives, transliterations and acronyms thereof and all company names, Trademarks, domain names, social media handles and all other identifiers and other identifiers of source or goodwill containing, incorporating or associated with any of the foregoing (other than the Transferred Trademarks). Purchaser further acknowledges that it has no rights, title, interest or license in or to any of the Seller Marks, and that it is not acquiring any rights, title, interest or license, directly or indirectly, in and to any of the Seller Marks, including any rights to use the Seller Marks in any manner, except as expressly provided in this Section 6.05.

(b) During the period commencing on the Closing Date and ending on the earlier of (i) [***] after the date on which the Transferred Governmental Authorizations have transferred from Seller to Purchaser in the Relevant Jurisdictions or (ii) the time period mandated by the applicable Laws of the relevant Governmental Authority (the "Limited License Period"), Seller grants, and shall cause its Affiliates to grant, to Purchaser and its Affiliates a limited, non-exclusive, fully-paid, royalty-free, and irrevocable right and license to use the Seller Marks and any universal product codes solely for the purpose of utilizing the labels and packaging, and advertising, marketing, sales and promotional materials, for the Seller Mark Products in the Relevant Jurisdictions as they exist on the Closing Date; provided that Purchaser shall use commercially reasonable efforts to stop using the Seller Marks [***].

(c) [***], Purchaser shall, and shall cause its Affiliates to, destroy and dispose of all labels and packaging, and all advertising, marketing, sales and promotional materials, in each case in its possession or subject to its control, bearing any Seller Names.

(d) Seller, on behalf of itself and its Affiliates, hereby grants to Purchaser and its Affiliates a limited, non-exclusive, non-transferable, fully-paid, royalty-free and irrevocable right and license, on a Product-by-Product basis for the 2-4mg Tablets and the 5-20mg Tablets, for the period ending upon the earlier of (i) [***] or (ii) when Purchaser and its Affiliates complete the sale or disposal of all inventory of tablets (including inventory re-ordered by Seller pursuant to its obligations to supply under the Transitional Business License Agreement) of the applicable Product held for sale in the Relevant Jurisdictions that have the applicable Seller Symbol engraved on such tablets, solely to use (i) on the 5-20mg Tablets, the Seller Symbol of the letter "A" as engraved on 5-20mg Tablets as shown on Schedule 1.01(c)(ii) and (ii) on the 2-4mg Tablets and the 5-20mg Tablets, the Seller Symbol of the "arch" as engraved on the 2-4mg Tablets and the 5-20mg Tablets as shown on Schedule 1.01(c)(ii). The foregoing license shall be subject to the terms and conditions of this Section 6.05 and is granted solely to the extent necessary for Purchaser to manufacture, package, market, distribute and sell the 2-4mg Tablets and the 5-20mg Tablets as applicable, in the Relevant Jurisdictions; provided that, on a Product-by-Product basis for the 2-4mg Tablets and the 5-20mg Tablets, following the receipt of approval by the applicable Governmental Authority in such Relevant Jurisdiction of the regulatory variations to the Transferred Governmental Authorizations for the removal of the applicable Seller Symbol engraved on such Product such that Purchaser can distribute and sell such Product without any Seller Symbol engraved on such tablets, the foregoing right and license with respect to such Product shall thereafter be limited solely to the extent necessary for Purchaser to distribute and sell Purchaser's remaining inventory of such Product held for sale in the applicable

Relevant Jurisdiction that have the applicable Seller Symbol engraved on such tablets as of the date of Purchaser's receipt of such approval for such Product. Purchaser shall have the right to grant sublicenses of the foregoing license to its Affiliates and third parties solely for the foregoing purposes; provided that Purchaser shall cause such Affiliates and third parties to comply with this Section 6.05 and Purchaser shall be liable for any breach of this Section 6.05 by such Affiliates or third parties. Purchaser shall cease using any Seller Symbols as permitted under the foregoing license immediately following the termination or expiration of the foregoing license.

(e) In no event shall Purchaser or any of its Affiliates (i) use any Seller Marks in any manner or for any purpose different from the use of such Seller Names by Seller and its Affiliates immediately prior to the Closing Date to market, distribute, sell or otherwise commercialize the Products in the Relevant Jurisdictions or (ii) manufacture or produce, or cause or permit any third party to manufacture or produce, any new labels, packaging or advertising, marketing, sales and promotional materials using or otherwise incorporating any Seller Marks in any manner (subject to this Section 6.05 or as contemplated pursuant to the Transitional Business License Agreement or Supply Agreement).

(f) Purchaser hereby agrees to indemnify Seller and the other Seller Indemnitees from and against any and all Losses incurred or suffered in connection with, or resulting from, use of any Seller Names by Purchaser or any of its Affiliates (or any third party acting on behalf of Purchaser or any of its Affiliates) permitted under this Section 6.05.

(g) Notwithstanding the transfer of any labels or packaging, or any advertising, marketing, sales and promotional materials, Purchaser acknowledges that this Agreement does not, and shall not, convey, transfer or assign any right, title, license or interest in any Trademarks of Seller or any of its Affiliates other than the Transferred Trademarks.

(h) Notwithstanding the foregoing, the Parties acknowledge that this Agreement does not, and shall not, convey, transfer or assign any right, title, license or interest in any Trademarks of any third party.

Section 6.06 Seller Use of Transferred IP Rights. Purchaser hereby grants to Seller and its Affiliates a non-exclusive, transferable, paid-up, royalty-free right and license, with the right to grant sublicenses through multiple tiers, to practice, until the expiration or termination of the Transitional Business License Agreement pursuant to which Seller is obligated to provide services, the Purchaser IP Rights, including the Transferred IP Rights, solely for the purpose of enabling Seller and its Affiliates to provide the services described in the Transitional Business License Agreement, and to perform their obligations thereunder in the Relevant Jurisdictions.

Section 6.07 Further Assurances. From time to time after the Closing, and for no further consideration (other than reimbursement for expenses incurred in packing or shipping any Purchased Asset), each of the Parties shall, and shall cause its Affiliates to, execute, acknowledge and deliver such assignments, transfers, consents, assumptions and other documents and instruments and take such other commercially reasonable actions as may reasonably be requested to more effectively assign, convey or transfer to or vest in: (a) Purchaser and its designated Affiliates, all rights, title and interests in, to and under the Purchased Assets and the Assumed Liabilities contemplated by this Agreement to be transferred or assumed at the Closing and (b) Seller, any rights, title or interests in, to or under any Excluded Asset that may have been transferred to Purchaser at Closing. Purchaser agrees that, following the Closing, it

shall prepare any such additional instruments or documents necessary to assign, convey or transfer the Transferred IP Rights and the Transferred Governmental Authorizations at its own expense.

Section 6.08 Bulk Transfer Laws. Purchaser acknowledges that Seller and its Affiliates have not taken, and do not intend to take, any action required to comply with any applicable bulk sale or bulk transfer Laws or similar Laws and hereby waives compliance therewith.

Section 6.09 Right of Reference. Effective as of the Closing, Purchaser hereby grants to Seller and its Affiliates a right of reference to [***]. Purchaser shall provide a signed statement to this effect, if requested by Seller, in accordance with 21 C.F.R. § 314.50(g)(3) or otherwise provide appropriate notification of such right of Seller to the applicable Governmental Authority. Effective as of the Closing, Seller hereby grants to Purchaser and its Affiliates a right of reference to any data related to the Products that was in existence as of the Closing Date. Seller shall provide a signed statement to this effect, if requested by Purchaser, in accordance with 21 C.F.R. § 314.50(g)(3) or otherwise provide appropriate notification of such right of Purchaser to the applicable Governmental Authority.

Section 6.10 Competition. Purchaser acknowledges and agrees that (i) Seller and its Affiliates shall be entitled to manufacture, develop, distribute, market, use, sell or otherwise deal with any products or technologies that such Person owns or has a license or right to, at or prior to the Closing; and (ii) Seller and its Affiliates may manufacture, develop, distribute, market, use, sell or otherwise deal with any products that Seller or its Affiliates acquires, licenses, or obtains rights to at any time after the Closing, which products or technologies, in the case of both clauses (i) and (ii) of this Section 6.10, may compete, directly or indirectly, with any of the Products.

Section 6.11 Insurance. Following the Closing, the coverage under all insurance policies of Seller and its Affiliates shall continue in force only for the benefit of Seller and its Affiliates, and not for the benefit of Purchaser or any of its Representatives. Following the Closing, Purchaser agrees to arrange for its own insurance policies with respect to the Purchased Assets covering all periods and agrees not to seek, through any means, to benefit from any of Seller's or its Affiliates' insurance policies which may provide coverage for claims relating in any way to the Purchased Assets.

Section 6.12 Support; Access. Subject to the provisions of ARTICLE VII, following the Closing, Purchaser and its Affiliates, on the one hand, and Seller and the Divesting Entities, on the other hand, shall use commercially reasonable efforts to cooperate with each other in conducting recalls and/or in the defense or settlement of any Liabilities or lawsuits involving the Purchased Assets or the Products, in each case for which the other Party has responsibility under this Agreement or the Transitional Business License Agreement, by providing the other Party and such other Party's legal counsel reasonable access to employees, records, documents, data, equipment, facilities, products, parts, prototypes and other information relating primarily to the Purchased Assets or the Products, as such other Party may reasonably request, to the extent maintained or under the possession or control of the requested Party; provided, however, that such access shall not unreasonably interfere with the business of Purchaser or Seller, or any of their respective Affiliates; provided, further, that either Party may restrict the foregoing access to the extent that (a) such restriction is required by applicable Law, (b) such access or provision of information would reasonably be expected to result in a violation of confidentiality obligations to a third party or (c) disclosure of any such information would result in the loss or waiver of the attorney-client privilege, except that Purchaser may have reasonable access to the records described in Section 2.03(h)(iii) if (i) the records can be redacted to the reasonable satisfaction of Seller to avoid a loss or waiver of any attorney-client privilege

belonging to Seller; or (ii) if the records cannot be redacted to the reasonable satisfaction of Seller to avoid a loss or waiver of any attorney-client privilege, Purchaser enters into a joint defense agreement with respect to such records in a form reasonably acceptable to Seller and Purchaser for the purpose of maintaining any attorney-client privilege that may apply to the records. Each Party shall reimburse the other Party for reasonable out-of-pocket expenses paid by such Party to third parties in performing its obligations under this Section 6.12. Following Closing, upon the written request of Purchaser, Seller will provide to Purchaser access to and copies of the Business Books and Records and Regulatory Information described in Section 2.03(h)(iii), and, at the request of Seller, Purchaser and Seller will enter into a joint defense agreement with respect to such records in a form reasonably acceptable to Seller and Purchaser.

Section 6.13 Payments from Third Parties. In the event that, on or after the Closing Date, either Party receives any payments or other funds due to the other Party pursuant to the terms of this Agreement or any of the other Transaction Documents, then the Party receiving such funds shall promptly forward such funds to the proper Party. The Parties acknowledge and agree that there is no right of offset regarding such payments and a Party may not withhold funds received from third parties for the account of the other Party in the event there is a dispute regarding any other issue under any of the Transaction Documents.

Section 6.14 Returned Goods. Purchaser agrees to adhere to the returned goods policy set forth on Schedule 6.14 attached hereto with respect to all Products received from customers, whether sold by Purchaser or Seller, to the extent any such returned Product has the name or any Trademarks of Seller or an Affiliate on it.

Section 6.15 Cooperation. From and after the Closing, upon the reasonable request of Purchaser, Seller will, and will cause its Affiliates to, use commercially reasonable efforts to, at Purchaser's expense, execute and deliver any and all further materials, documents and instruments of conveyance, transfer or assignment as may reasonably be requested by Purchaser to effect, record or verify the transfer to, and vesting in, Purchaser of the Seller's or a Divesting Entities' right, title and interest in and to the Purchased Assets in accordance with the terms of this Agreement. After the expiration or termination of the Transitional Business License Agreement, Seller and its Affiliates shall have no obligation to maintain or renew any Transferred IP Rights.

Section 6.16 Financial Statement Assistance. Within [***] following the Closing Date and continuing until such time as Purchaser files the Carve-Out Financial Statements (as defined below) with the SEC, Seller shall cause its auditors to provide to Purchaser the [***] financial statements for the Business as set forth on Schedule 6.16(a), solely for the purpose of satisfying the Purchaser's requirements under Article 11 and Rule 3-05 of Regulation S-X (the "Carve-Out Financial Statements"), and, [***]. The Carve-Out Financial Statements will comply as to form in all material respects with clause (e) of Rule 3-05 of Regulations S-X. Prior to Purchaser filing the Carve-Out Financial Statements with the SEC, Purchaser shall provide Seller and its counsel a reasonable opportunity to review the filing that contains the Carve- Out Financial Statements and Purchaser agrees to give due consideration to any comments provided by Seller, its Affiliates, its counsel or auditors. Notwithstanding anything to the contrary in this agreement, Seller shall not (i) be required to deliver any representation letter, certificate or other information to Purchaser with respect to any use of such financial statements by Purchaser or its Affiliates subsequent to the Closing or (ii) be responsible for any misstatement or omission in any of Purchaser's or its Affiliates' securities filings or in respect of any of Purchaser's or its Affiliates' financings caused by or resulting from the use by Purchaser or its Affiliates of such financial statements. Purchaser will reimburse Seller, within [***] after demand in writing therefor, for any reasonable costs and expenses incurred by Seller and its Affiliates in complying with the provisions of this Section 6.16. A good faith estimate of the approximate amount of such reasonable costs and expenses that may be incurred by Seller

and its Affiliates in complying with the provisions of this Section 6.16 is set forth for informational purposes only on Schedule 6.16(b).

Section 6.17 Return of Excluded Assets and Purchased Assets. If, for any reason after the Closing, any asset transferred to Purchaser or an Affiliate is ultimately determined to be an Excluded Asset or Purchaser is found to be in possession of any Excluded Asset, (a) Purchaser will promptly notify Seller and return or transfer and convey (without further consideration) to Seller, and Seller will accept, such asset; (b) Seller will assume and agree to pay, perform, fulfill and discharge (without further consideration) any Retained Liabilities associated with such asset as contemplated in this Agreement; and (c) Purchaser and Seller will promptly execute such documents or instruments of conveyance or assumption and take such further actions which are reasonably necessary or desirable to effect the transfer of such asset back to Seller and, until such time, to the extent necessary and applicable, Purchaser hereby grants to Seller an irrevocable, perpetual, global, non-exclusive, royalty-free license to use such right or asset until such transfer is effective. If, for any reason after the Closing, any asset retained by Seller or its Affiliate is ultimately determined to be a Purchased Asset or Seller or its Affiliate is found to be in possession of any Purchased Asset, (i) Seller or such Affiliate will promptly notify Purchaser and transfer and convey (without further consideration) to Purchaser, and Purchaser will accept, such asset; (ii) Purchaser will assume and agree to pay, perform, fulfill and discharge (without further consideration) any Assumed Liabilities associated with such asset as contemplated in this Agreement; and (iii) Purchaser and Seller will promptly execute such documents or instruments of conveyance or assumption and take such further actions which are reasonably necessary or desirable to effect the transfer of such asset to Purchaser and, until such time, to the extent necessary and applicable, Seller hereby grants to Purchaser an irrevocable, perpetual, global, non- exclusive, royalty-free license to use such right or asset until such transfer is effective.

Section 6.18 Pharmacovigilance.

(a) In order to ensure compliance with safety reporting requirements in the Relevant Jurisdictions the Parties shall negotiate in good faith to enter into a Pharmacovigilance Agreement with respect to the Products (the "Pharmacovigilance Agreement") to document the sharing of adverse event information and other safety information. Within [***] of the Closing Date, each Party shall assign a safety representative to begin discussions to ensure that the Pharmacovigilance Agreement is entered into [***].

(b) Pending entry into the Pharmacovigilance Agreement, and if necessary, the Parties shall implement an interim procedure to clarify the parties' respective pharmacovigilance obligations and the process and procedure for exchanging any and all safety information and regulatory reporting of safety information related to the use of the Products with Applicable Governmental Authorities, regardless of source to ensure each Party's compliance with legal and regulatory requirements in the Relevant Jurisdictions.

(c) [***].

Section 6.19 Supply Chain. Without limitation of the foregoing, [***] Purchaser shall apply for the applicable Governmental Authority's approval of any known regulatory variation to the Transferred Governmental Authorizations for (i) the removal of the [***] and (ii) the removal of the [***]. Without limitation of the foregoing, Purchaser shall use commercially reasonable efforts to apply for and obtain such approvals as soon as reasonably practicable following the Closing.

Section 6.20 Quality Agreement. Prior to the effectiveness of the transfer of the Transferred Governmental Authorizations in the United States, Purchaser shall enter into a quality agreement with the ROW Purchaser (the "Quality Agreement"), with respect to the secondary packaging of the Products pursuant to the Supply Agreement; provided, that if the ROW Transaction has not closed by the effectiveness of the transfer of the Transferred Governmental Authorizations in the United States, then Seller shall enter into a quality agreement with Purchaser (the "Seller Quality Agreement"), with respect to the secondary packaging of the Products pursuant to the Seller Supply Agreement (as defined below).

Section 6.21 Supply Agreement. Upon the effectiveness of the transfer of the Transferred Governmental Authorizations in the United States, (i) Seller shall assign all of Seller's rights and obligations under the Supply Agreement to Purchaser and (ii) Purchaser shall assume in a written document that is enforceable by the ROW Purchaser, all of Seller's rights and obligations under the Supply Agreement; provided, that if the ROW Transaction has not closed by the effectiveness of the transfer of the Transferred Governmental Authorizations in the United States, then Seller shall enter into a supply agreement with Purchaser on substantially the same terms except solely to the extent necessary to reflect the change in circumstance resulting from Seller being the counterparty to such supply agreement, as the form of supply agreement attached hereto as Exhibit D (as applicable and in such context, the "Seller Supply Agreement"). [***].

Section 6.22 Certain Tax Matters.

(a) Tax Cooperation. Purchaser and Seller will cooperate, as and to the extent reasonably requested by the other Party, in connection with the filing and preparation of any Tax Return or the conduct of any audit or other examination by any Taxing Authority relating to liability for Taxes in connection with the Purchased Assets. Such cooperation will include the retention and (upon the other Party's reasonable request) the provision of records and information that are reasonably relevant to any such Tax Return, audit or other examination and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. Purchaser and Seller will retain all books and records with respect to Tax matters pertinent to the Business and the Purchased Assets relating to any Tax period beginning before the Closing Date until [***] after the expiration of the statute or period of limitations of the respective Tax periods.

(b) Allocation of Taxes. For the purposes of this Agreement, all *ad valorem* Taxes (*e.g.*, property Taxes) with respect to the Purchased Assets for a Straddle Period shall be allocated between the Pre-Closing Tax Period and the Post-Closing Tax Period based on the relative number of days of such taxable period before and including the Closing Date and after the Closing Date, respectively. For the purposes of this Agreement, all other Taxes with respect to the Purchased Assets for a Straddle Period shall be allocated between the Pre-Closing Tax Period and the Post-Closing Tax Period as if such taxable period ended as of the close of business on the Closing Date; provided, however, that all permitted allowances, exemptions and deductions that are normally computed on the basis of an entire year or period (such as depreciation) will be allocated between the pre-Closing portion of the Straddle Period and the post-Closing portion of the Straddle Period pro rata according to the number of calendar days in each period.

Section 6.23 Covenant Not to Sue. Commencing on the Closing Date, with respect to the Products and any other products containing ponesimod, Seller and its Affiliates hereby covenant not to sue, or support or encourage any third party to sue, Purchaser or its Affiliates, sublicensees, manufacturers, importers, suppliers, distributors, resellers, purchasers, marketing partners and customers, for infringement of any of the S1P1 Patents, now or in the

future purporting to cover any of the Products or any other product containing ponesimod, based on Purchaser's or any of its Affiliate's making, having made, using, importing, selling, or offering for sale the Products or any other products containing ponesimod in or for the Relevant Jurisdictions. In the event any of the S1P1 Patents are assigned by Seller to a third party, including ROW Purchaser, Seller covenants that the foregoing covenant not to sue with respect to such S1P1 Patent(s) shall become an obligation of such third party upon the assignment of such S1P1 Patent(s) to such third party.

Section 6.24 Letter Agreement and Assignment and Assumption Agreement. Concurrent with the Closing, Purchaser and Seller shall execute the Letter Agreement. At or promptly following the closing of the ROW Transaction, Purchaser, ROW Purchaser, and Seller shall execute the Assignment and Assumption Agreement in substantially the form attached hereto as Exhibit G, through which (i) Seller will assign all of Seller's rights and obligations under the Letter Agreement to ROW Purchaser and (ii) ROW Purchaser shall assume, all of Seller's rights and obligations under the Letter Agreement.

Section 6.25 Assignment of CMO Contracts. Seller may, in its sole discretion, and may cause the Divesting Entities to, convey, assign and transfer to Purchaser, and Purchaser shall acquire and accept from Seller and the Divesting Entities, free and clear of all Liens (other than Permitted Liens), all of Seller's and the Divesting Entities' rights, titles and interests in, to or under the CMO Contracts. Subject to the terms of this Section 6.25, each of the Parties shall, and shall cause its Affiliates to, execute, acknowledge and deliver such assignments, transfers, consents, assumptions and other documents and instruments and take such other commercially reasonable actions as may reasonably be requested to more effectively assign, convey or transfer such CMO Contracts. The assignment of the CMO Contracts shall not be subject to any negotiations or modification to the terms of the CMO Contracts. [***].

ARTICLE VII.
INDEMNIFICATION

Section 7.01 Indemnification by Seller.

(a) Subject to the provisions of this ARTICLE VII, Seller agrees, from and after the Closing, to defend, indemnify and hold harmless Purchaser and its Affiliates and, if applicable, their respective directors, officers, agents, employees, successors and assigns (collectively, the "Purchaser Indemnitees"), from and against any and all Losses to the extent arising from or relating to (i) any Retained Liability or Excluded Asset; (ii) any breach by Seller or any Divesting Entity of any of its covenants or agreements contained in this Agreement; or (iii) any inaccuracy or breach of any warranty or representation of Seller or any Divesting Entity contained in this Agreement or any Ancillary Agreement.

(b) Purchaser shall take, and shall cause the other Purchaser Indemnitees to take, commercially reasonable steps, including making claims under any applicable insurance policies to mitigate any Loss upon becoming aware of any event that would reasonably be expected to, or does, give rise thereto, provided that the foregoing shall not be deemed to limit the ability of Purchaser and the other Purchaser Indemnitees to incur reasonable costs and expenses in connection therewith.

Section 7.02 Indemnification by Purchaser.

(a) In addition to the indemnification set forth in Section 6.05(f), subject to the provisions of this ARTICLE VII, Purchaser agrees, from and after the Closing, to defend, indemnify and hold harmless Seller and its Affiliates and, if applicable, their respective directors, officers, agents, employees, successors and assigns (collectively, the "Seller Indemnitees"), from and against any and all Losses to the extent arising from or relating to (i) any Assumed Liability; (ii) any breach by Purchaser of any of its covenants or agreements contained in this Agreement; or (iii) any inaccuracy or breach of any warranty or representation of Purchaser contained in this Agreement or any Ancillary Agreement.

(b) Seller shall take, and cause the other Seller Indemnitees to take, commercially reasonable steps, including making claims under any applicable insurance policies to mitigate any Loss upon becoming aware of any event that would reasonably be expected to, or does, give rise thereto, provided that the foregoing shall not be deemed to limit the ability of Seller and the other Seller Indemnitees to incur reasonable costs and expenses in connection therewith.

Section 7.03 Notice of Claims. Any Purchaser Indemnitee or Seller Indemnitee claiming that it has suffered or incurred any Loss for which it may be entitled to indemnification under Section 6.05(f) or this ARTICLE VII (the "Indemnified Party") shall give prompt written notice to the Party from whom indemnification is sought (the "Indemnifying Party") of the matter, action, cause of action, claim, demand, fact or other circumstances upon which a claim for indemnification under Section 6.05(f) or this ARTICLE VII (each, a "Claim") may be based. Such notice shall contain, with respect to each Claim, such facts, supporting documents and information as are then reasonably available with respect to such Claim, including, to the extent known, a description in reasonable detail of the Losses suffered or incurred by the Indemnified Party, the amount or estimated amount of such Losses (if known or reasonably capable of estimation) and the method of computation of such Losses, and a reference to the provisions of this Agreement or any other agreement, instrument or certificate delivered pursuant hereto in respect of which such Loss shall have occurred. If any Claim is based on any action, claim, suit or proceeding (in equity or at law) instituted by an unaffiliated third party with respect to which the Indemnified Party intends to claim any Loss under this ARTICLE VII (a "Third Party Claim"), the Indemnified Party shall promptly [***] notify (the "Third Party Claim Notice") the Indemnifying Party of such Third Party Claim and offer to tender to the Indemnifying Party the defense of such Third Party Claim. A failure by the Indemnified Party to give written notice of any Claim or to offer to tender the defense of any Third Party Claim in a timely manner pursuant to this Section 7.03 shall not limit the obligation of the Indemnifying Party under this ARTICLE VII, except (a) to the extent such Indemnifying Party is actually prejudiced thereby (in which case the Indemnifying Party shall not be liable for such increase) or (b) as provided in Section 7.05.

Section 7.04 Third Party Claims. The Indemnifying Party shall have the right, but not the obligation, exercisable by written notice to the Indemnified Party within [***] of receipt of a Third Party Claim Notice from the Indemnified Party with respect to a Third Party Claim, to assume the conduct and control, at the expense of the Indemnifying Party and through counsel of its choosing that is reasonably acceptable to the Indemnified Party, of such Third Party Claim, and the Indemnifying Party may compromise or settle the same; provided, however, that the Indemnifying Party shall give the Indemnified Party advance written notice of any proposed compromise or settlement and shall not, without the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed), consent to or enter into any compromise or settlement with respect to such Third Party Claim that commits the Indemnified Party to take, or to forbear to take, any action or does not provide for a full and complete written release by the applicable third party of the Indemnified Party. During such [***] period (and thereafter for so long as the Indemnifying Party has assumed and

is conducting the defense of such Third Party Claim), the Indemnified Party may not compromise or settle such Third Party Claim for which it is seeking indemnification hereunder without the prior written consent of the Indemnifying Party. No Indemnifying Party may consent to the entry of any judgment that does not relate solely to monetary damages arising from any such Third Party Claim without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld, conditioned or delayed. The Indemnifying Party shall permit the Indemnified Party to participate in, but not control, the defense of any such Third Party Claim through counsel chosen by the Indemnified Party, provided that the fees and expenses of such counsel shall be borne solely by the Indemnified Party. If the Indemnifying Party elects not to control or conduct the defense of a Third Party Claim, the Indemnifying Party nevertheless shall have the right to participate in the defense of any Third Party Claim and, at its own expense, to employ counsel of its own choosing for such purpose. The Parties shall reasonably cooperate in the defense of any Third Party Claim, with such cooperation to include (i) the retention and the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim and (ii) reasonable access to employees on a mutually convenient basis for providing additional information and explanation of any material provided hereunder.

Section 7.05 Expiration. All covenants, agreements, warranties and representations made herein or in any certificate or other document delivered pursuant hereto shall survive the Closing. Notwithstanding the foregoing, all representations, warranties, covenants and agreements made herein or in any certificate or other document delivered pursuant hereto, and all indemnification obligations under Section 7.01(a)(ii), Section 7.01(a)(iii), Section 7.02(a)(ii) and Section 7.02(a)(iii) with respect to any such representations, warranties, covenants and agreements, shall (a) (i) in the case of any such representations or warranties (other than Fundamental Representations), terminate and expire on, and no action or proceeding seeking damages or other relief for breach of or for any misrepresentation or inaccuracy with respect thereto, shall be commenced [***] after the Closing Date, unless prior to such date a claim for indemnification with respect thereto shall have been made, with reasonable specificity, by written notice given in accordance with Section 7.03; and (ii) in the case of any such Fundamental Representation, terminate and expire on, and no action or proceeding seeking damages or other relief for breach of or for any misrepresentation or inaccuracy with respect thereto, shall be commenced [***] after the Closing Date, unless prior to such date a claim for indemnification with respect thereto shall have been made, with reasonable specificity, by written notice given in accordance with Section 7.03; and (b) (i) in the case of any such covenants or agreements to be performed prior to the Closing Date, terminate and expire on, and no action or proceeding seeking damages or other relief for breach thereof shall be commenced after, [***] after the Closing Date, unless prior to such date a claim for indemnification with respect thereto shall have been made, with reasonable specificity, by written notice given in accordance with Section 7.03, and (ii) in the case of any such covenants or agreements to be performed on or after the Closing Date, terminate and expire on, and no action or proceeding seeking damages or other relief for breach of any thereof shall be commenced [***] after the last date on which such covenant or agreement is to be performed, unless prior to such date a claim for indemnification with respect thereto shall have been made, with reasonable specificity, by written notice given in accordance with Section 7.03.

Section 7.06 Certain Limitations. Notwithstanding the other provisions of this ARTICLE VII, Seller shall not have any indemnification obligations for Losses under Section 7.01(a)(iii), other than in respect of Fraud, or any inaccuracy or breach of any Fundamental Representation (a) for any individual item or series of related items where the Loss relating thereto is [***] (the "De Minimis Amount") and (b) in respect of each individual item or series of related items where the Loss relating thereto is [***]. [***]

Section 7.07 Losses Net of Insurance, Etc. The amount of any Loss for which indemnification is provided under Section 7.01 or Section 7.02 shall be net of (a) any amounts actually recovered by the Indemnified Party pursuant to any indemnification by or indemnification agreement with any non-affiliated third party and (b) any insurance proceeds actually received as an offset against such Loss, in each case, net of any costs of recovery. The Indemnified Party shall use commercially reasonable efforts to recover any such indemnification or insurance proceeds if and to the extent available. If the amount to be netted hereunder from any payment required under Section 7.01 or Section 7.02 is determined after payment by the Indemnifying Party of any amount otherwise required to be paid to an Indemnified Party pursuant to this ARTICLE VII, the Indemnified Party shall repay to the Indemnifying Party, promptly after such determination, any amount that the Indemnifying Party would not have had to pay pursuant to this ARTICLE VII had such determination been made at the time of such payment. The Indemnifying Party may require, as a condition to the provision of any indemnification hereunder, that the Indemnified Party execute an undertaking consistent with its obligations set forth in this Section 7.07.

Section 7.08 Sole Remedy/Waiver. Except in the case of Fraud, this ARTICLE VII provides the exclusive means by which a Party may assert and remedy Claims after the Closing. Except as set forth in Section 8.09(c) and this ARTICLE VII, effective as of the Closing, each Party hereby waives and releases any other remedies or claims that it may have against the other Party (or any of its Affiliates) with respect to the matters arising out of or in connection with this Agreement or relating to the Products or the Purchased Assets, except that nothing herein shall limit the liability of any Party hereto for Fraud or intentional misrepresentation. With respect to any Losses arising under this Agreement, Purchaser agrees that Purchaser shall only seek such Losses from Seller, and Purchaser hereby waives the right to seek Losses from or equitable remedies, such as injunctive relief, against any Affiliate of Seller or any director, officer or employee of Seller (or any of its Affiliates).

Section 7.09 Indemnity Payments. In the event that either Party agrees to, or is determined to have an obligation to, reimburse the other Party for Losses as provided in this ARTICLE VII, the Indemnifying Party shall promptly pay such amount to the Indemnified Party in U.S. Dollars via wire transfer of immediately available funds to the accounts specified in writing by the Indemnified Party.

Section 7.10 Tax Treatment of Indemnity Payments. Any indemnity payment under this Agreement shall be treated as an adjustment to the Purchase Price for Tax purposes unless otherwise required by applicable Law.

Section 7.11 No Consequential Damages. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED HEREIN, WITH THE EXCEPTION OF RELIEF MANDATED BY STATUTE, (I) NO PARTY TO THIS AGREEMENT SHALL BE LIABLE TO OR OTHERWISE RESPONSIBLE TO THE OTHER PARTY OR ANY AFFILIATE OF THE OTHER PARTY FOR LOST REVENUES OR PROFITS OR DAMAGES OR INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR MULTIPLIED DAMAGES THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF OR ANY LIABILITY RETAINED OR ASSUMED HEREUNDER AND (II) NO PARTY TO THIS AGREEMENT SHALL BE LIABLE TO OR OTHERWISE RESPONSIBLE TO THE OTHER PARTY OR ANY AFFILIATE OF THE OTHER PARTY FOR PUNITIVE OR EXEMPLARY DAMAGES; PROVIDED, HOWEVER, THAT THE FOREGOING SHALL NOT BE CONSTRUED TO PRECLUDE RECOVERY IN RESPECT OF ANY LOSS DIRECTLY INCURRED OR SUFFERED FROM THIRD PARTY CLAIMS.

ARTICLE VIII.
MISCELLANEOUS

Section 8.01 Notices. All notices or other communications hereunder shall be deemed to have been duly given and made if in writing and if served by personal delivery upon the Party for whom it is intended, delivered by registered or certified mail, return receipt requested, or by a national overnight courier service, sent by facsimile (provided that notice by facsimile is promptly confirmed by telephone confirmation thereof and receipt is confirmed by the sending facsimile machine) or sent by email (provided confirmation of delivery is obtained), to the Person at the address set forth below, or such other address as may be designated in writing hereafter, in the same manner, by such Person:

to Seller and any Divesting Entity:

Actelion Pharmaceuticals Ltd.
c/o Johnson & Johnson
[***]
Attn: Assistant General Counsel, Corporate Legal Department

with copies to:

Johnson & Johnson
Office of General Counsel
[***]
Attn: General Counsel

and:

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
Telephone: [***]
Facsimile: [***]
Attn: [***]
Email: [***]

to Purchaser:

Vanda Pharmaceuticals Inc.
2200 Pennsylvania Ave. NW Suite 300-E
Washington, DC 20037
Telephone: [***]
Attn: General Counsel
Email: [***]

with a copy to:

McDermott Will & Emery
444 West Lake Street
Chicago, IL 60606
Telephone: [***]
Attn: [***]
Email: [***]

All notices and other communications under this Agreement shall be deemed to have been received (a) when delivered by hand, if personally delivered; (b) one (1) Business Day after being sent, if delivered to a national overnight courier service; or (c) one (1) Business Day after being sent, if sent by facsimile, with a telephonic acknowledgment of sending and confirmation of receipt by the sending facsimile machine.

Section 8.02 Amendment; Waiver. Any provision of this Agreement may be amended or waived if, and only if, such amendment or waiver is in writing and signed (a) in the case of an amendment, by Purchaser and Seller and (b) in the case of a waiver, by the Party against whom the waiver is to be effective. No failure or delay by either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

Section 8.03 Assignment. Neither Party to this Agreement may assign any of its rights or obligations under this Agreement, including by sale of stock, operation of Law in connection with a merger or sale of substantially all of the assets, without the prior written consent of the other Party, except that (a) Seller may, without such consent, assign its rights or obligations to an Affiliate, (b) Purchaser may, without such consent, (i) assign its rights to acquire the Purchased Assets hereunder, in whole or in part, to one or more of its Affiliates and (ii) collaterally assign this Agreement to any Person providing debt financing to Purchaser or its Affiliates, and (b) Purchaser may, without such consent, assign all of its rights under this Agreement to one or more Person acquiring all or a material portion of the business or assets of Purchaser, including by sale of stock, operation of Law in connection with a merger or sale of substantially all of the assets; provided, however, (i) no such assignment by a Party shall relieve such Party of any of its obligations hereunder, (ii) the permitted assignee shall also assume all obligations of the assigning Party in a written document that is enforceable by the non-assigning Party, and (iii) any permitted assignee must, to the satisfaction of the non-assigning Party, be an entity no less creditworthy than the assigning Party, with assets and experience sufficient, in the reasonable discretion of the non-assigning Party, to satisfy all of the assigning Party's obligations under this Agreement. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 8.03 shall be null and void.

Section 8.04 Entire Agreement. This Agreement, together with the Exhibits and Schedules expressly contemplated hereby and attached hereto (which are hereby incorporated by reference), and the other agreements and certificates delivered in connection herewith (including the Transaction Documents and the Confidentiality Agreement), contains the entire agreement between the Parties with respect to the Transactions and supersedes all prior agreements or understandings between the Parties. Before signing this Agreement, the Parties have had numerous conversations, including preliminary discussions, formal negotiations and informal conversations at meals and social occasions, and have generated correspondence and other writings, in which the Parties discussed the Transactions and their aspirations for success. In such conversations and writings, individuals representing the Parties may have expressed their judgments and beliefs concerning the intentions, capabilities and practices of the Parties, and may have forecasted future events. The Parties recognize that such conversations and writings often involve an effort by both sides to be positive and optimistic about the prospects for the transaction. However, it is also recognized that all business transactions contain an element of risk, as do the Transactions, and that it is normal business practice to limit the legal obligations of contracting Parties to only those promises and representations which are essential to their transaction so as to provide certainty as to their respective future rights and remedies. Accordingly, other than the Confidentiality Agreement entered into between the Parties, the Transaction Documents are intended to define the full extent of the legally enforceable undertakings and representations of the Parties, and no promise or representation, written or oral,

which is not set forth explicitly in such agreements is intended by either Party to be legally binding. Each of the Parties acknowledges that, in deciding to enter into this Agreement and the other Transaction Documents and to consummate the Transactions, none of them has relied upon any statements or representations, written or oral, other than those explicitly set forth herein or therein.

Section 8.05 Fulfillment of Obligations. Any obligation of a Party to the other Party under this Agreement, which obligation is performed, satisfied or fulfilled by an Affiliate of such Party, shall be deemed to have been performed, satisfied or fulfilled by such Party.

Section 8.06 Parties in Interest. This Agreement shall inure to the benefit of and be binding upon the Parties and their respective successors and permitted assigns. Nothing in this Agreement, express or implied, is intended to confer upon any Person other than Purchaser, Seller and the Divesting Entities, or their successors or permitted assigns, any rights or remedies under or by reason of this Agreement.

Section 8.07 Expenses. Except as otherwise expressly provided in this Agreement or the Letter Agreement, all costs and expenses incurred in connection with this Agreement and the Transactions shall be borne solely by the Party incurring such expenses; provided, however that Purchaser shall bear all ongoing costs associated with (i) [***], (ii) [***], and (iii) [***].

Section 8.08 Schedules. The disclosure of any matter in any Schedule to this Agreement shall be deemed to be a disclosure for the purposes of the Section or subsection of this Agreement to which it corresponds in number and each other Section and subsection of this Agreement to the extent such disclosure is reasonably apparent on the face thereof to be relevant to such other Section or subsection. The disclosure of any matter in any Schedule to this Agreement shall expressly not be deemed to constitute an admission by any Party, or to otherwise imply, that any such matter is material for the purposes of this Agreement, could reasonably be expected to have a Material Adverse Effect or a Purchaser Material Adverse Effect, as applicable, or is required to be disclosed under this Agreement.

Section 8.09 Governing Law; Jurisdiction; No Jury Trial; Specific Performance.

(a) This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law, principles or rules of such state, to the extent such principles or rules are not mandatorily applicable by statute and would permit or require the application of the laws of another jurisdiction.

(b) The Parties consent to the exclusive jurisdiction of the Federal and State courts located in the State of New York for the resolution of all disputes or controversies between the Parties. Each of the Parties (i) consents to the exclusive jurisdiction of each such court in any suit, action or proceeding relating to or arising out of this Agreement or the Transactions; (ii) waives any objection that it may have to the laying of venue in any such suit, action or proceeding in any such court; and (iii) agrees that service of any court paper may be made in such manner as may be provided under applicable Laws or court rules governing service of process. THE PARTIES HERETO HEREBY IRREVOCABLY WAIVE, AND AGREE TO CAUSE THEIR RESPECTIVE AFFILIATES TO WAIVE, THE RIGHT TO TRIAL BY JURY IN ANY ACTION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT, ANY RELATED AGREEMENTS OR ANY OF THE TRANSACTIONS.

(c) Each Party acknowledges and agrees that in the event that such Party breaches its obligations under this Agreement, the other Party would be damaged irreparably. Accordingly, each Party agrees that, without posting bond or other undertaking, the other Party hereto shall be entitled to an injunction or injunctions to prevent breaches or violations of this Agreement and to enforce specifically this Agreement and the terms and provisions hereof in any action instituted in any court specified in Section 8.09(b) in addition to any other remedy to which the Parties may be entitled, at law or in equity. Each Party further agrees that, in the event of any action for an injunction or specific performance in respect of any such threatened or actual breach or violation, it shall not assert that a remedy at law would be adequate.

Section 8.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and together shall constitute one and the same agreement and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that both Parties need not sign the same counterpart. This Agreement, following its execution, may be delivered via .pdf or other form of electronic delivery, which shall constitute delivery of an execution original for all purposes.

Section 8.11 Headings. The heading references herein and the table of contents hereto are for convenience purposes only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

Section 8.12 Severability. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof. If any term or other provision of this Agreement, or the application thereof to any Person or any circumstance, is invalid, illegal or unenforceable, (a) a suitable and equitable provision shall be substituted therefore in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid or unenforceable provision and (b) the remainder of this Agreement and the application of such provision to other Persons or circumstances shall not be affected by such invalidity, illegality or unenforceability, nor shall such invalidity, illegality or unenforceability affect the validity or enforceability of such provision, or the application thereof, in any other jurisdiction.

Section 8.13 Non-Recourse.

(a) This Agreement may only be enforced against, and any claim or cause of action based upon, arising out of, or related to this Agreement may only be brought against the entities that are expressly named as Parties hereto (or the Divesting Entities) and then only with respect to the specific obligations set forth herein with respect to such Party. Except to the extent a named Party to this Agreement (and then only to the extent of the specific obligations undertaken by such named Party in this Agreement), no past, present or future director, officer, employee, incorporator, member, partner, stockholder, Affiliate, lender, agent, attorney, or other representative of any Party hereto shall have any liability (whether in contract or in tort, in law or in equity, or based upon any theory that seeks to impose liability of an entity party against its owners or Affiliates) for any obligations or liabilities of any Party hereto under this Agreement or for any claim based on, in respect of, or by reason of, the transactions contemplated hereby or in respect of any oral representations made or alleged to have been made in connection herewith, except for the Divesting Entities to the extent specifically set forth in this Agreement.

(b) The provisions of this Section 8.13 are intended to be for the benefit of, and enforceable by, the directors, officers, employees, incorporators, members, partners,

stockholders, Affiliates, agents, attorneys, and other representatives of the Parties hereto, and each such person shall be a third party beneficiary of this Section 8.13.

[*remainder of page intentionally blank*]

IN WITNESS WHEREOF, the Parties have executed or caused this Agreement to be executed as of the date first written above.

ACTELION PHARMACEUTICLS LTD.

By: /s/ Emmanuelle Quiles
Name: Emmanuelle Quiles
Title: President of the Board of Directors

By: /s/ Emanuele Pozzoni
Name: Emanuele Pozzoni
Title: Member of Administrative Board

IN WITNESS WHEREOF, the Parties have executed or caused this Agreement to be executed as of the date first written above.

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulos, M.D.
Name: Mihael H. Polymeropoulos, MD
Title: Chairman & CEO

EXHIBIT A

SELLER CLOSING DELIVERABLES

[***]

EXHIBIT B

PURCHASER CLOSING DELIVERABLES

[***]

EXHIBIT C

JOHNSON & JOHNSON UNIVERSAL CALENDAR, 2023

[***]

EXHIBIT D

SUPPLY AGREEMENT

[***]

EXHIBIT E

SELLER FDA LETTER

[***]

EXHIBIT F

PURCHASER FDA LETTER

[***]

EXHIBIT G

ASSIGNMENT AND ASSUMPTION AGREEMENT

[***]

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-269654) and Form S-8 (No. 333-133368, No. 333-138070, No. 333-141571, No. 333-148924, No. 333-156995, No. 333-164567, No. 333-171962, No. 333-179265, No. 333-186509, No. 333-193614, No. 333-201754, No. 333-209144, No. 333-212255, No. 333-218774, No. 333-225599, No. 333-239103, No. 333-256994, No. 333-265692, and No. 333-272522) of Vanda Pharmaceuticals Inc. of our report dated February 8, 2024 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Washington, District of Columbia
February 8, 2024

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mihael H. Polymeropoulos, certify that:

1. I have reviewed this annual report on Form 10-K of Vanda 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(s) 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(s) 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.

February 8, 2024

/s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President, Chief Executive Officer and Chairman of the Board of Directors
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin Moran, certify that:

1. I have reviewed this annual report on Form 10-K of Vanda 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(s) 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(s) 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.

February 8, 2024

/s/ Kevin Moran

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Vanda Pharmaceuticals Inc., (the "Company"), does hereby certify, to the best of such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2023 (the Form 10-K) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.

February 8, 2024

/s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President, Chief Executive Officer and
Chairman of the Board of Directors
(Principal Executive Officer)

February 8, 2024

/s/ Kevin Moran

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission (SEC) or its staff upon request. This certification "accompanies" the Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

VANDA PHARMACEUTICALS INC.

AMENDED AND RESTATED COMPENSATION CLAWBACK POLICY

(As of June 8, 2023)

1. Recoupment

If Vanda Pharmaceuticals Inc. (the "***Company***") is required to undertake a Restatement, then the Company shall recover, reasonably promptly, all Recoverable Compensation from any Covered Person during the Applicable Period (including those Covered Persons who are not Executive Officers at the time of the Restatement), unless the Compensation Committee determines it Impracticable to do so, after exercising a normal due process review of all the relevant facts and circumstances. Such recovery, shall be made without regard to any individual knowledge or responsibility related to the Restatement or the Recoverable Compensation. Further, if the achievement of one or more Financial Reporting Measures was considered in determining the Incentive-Based Compensation Received by a Covered Person, but the Incentive-Based Compensation was not paid or awarded on a formulaic basis, the Compensation Committee will in its good faith discretion determine the amount of any Recoverable Compensation that must be recouped with respect thereto.

The Compensation Committee has sole discretion to administer this Policy and, subject to applicable law, may seek to recoup such Recoverable Compensation by requiring any Covered Person to repay such amount to the Company; an adjustment to future cash or equity-based compensation payments or awards; by set-off of a Covered Person's other compensation; or by such other means or combination of means as the Compensation Committee, in its sole discretion, determines to be appropriate.

2. Definitions

For purposes of this Policy, the following terms shall have the following meanings:

Applicable Period. "Applicable Period" means the three completed fiscal years of the Company immediately preceding the earlier of (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes (or reasonably should have concluded) that a Restatement is required or (ii) the date a regulator, court or other legally authorized entity directs the Company to undertake a Restatement. The "Applicable Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence.

Board. "Board" means the Board of Directors of the Company.

Compensation Committee. "Compensation Committee" means the Company's committee of independent directors responsible for executive compensation decisions, or in the absence of such a committee, a majority of the independent directors serving on the Board.

Covered Person. "Covered Person" means any person who is, or was *at any time,* during the Applicable Period, an Executive Officer of the Company. For the avoidance of doubt, Covered Person may include a former Executive Officer that left the Company, retired, or transitioned to an employee role (including after serving as an Executive Officer in an interim capacity) during the Applicable Period.

Executive Officer. "Executive Officer" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person (including an officer of the Company's parent(s) or subsidiaries) who performs similar policy-making functions for the Company.

Financial Reporting Measure. "Financial Reporting Measure" means a measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements (including "non-GAAP" financial measures, such as those appearing in the Company's earnings releases or Management Discussion and Analysis), and any measure that is derived wholly or in part from such measure. Examples of Financial Reporting Measures include measures based on: revenues, net income, operating income, financial ratios, EBITDA, liquidity measures, return measures (such as return on assets), profitability of one or more segments, sales per square foot, same store sales, revenue per user, and cost per employee. Stock price and total shareholder return are also Financial Reporting Measures.

Impracticable. The Compensation Committee may determine in good faith that recovery of Recoverable Compensation is "Impracticable" if: (i) pursuing such recovery would violate applicable law and the Company provides an opinion of counsel to that effect to the Company's listing exchange; (ii) the direct expense paid to a third party to assist in enforcing this Policy would exceed the Recoverable Compensation and the Company has (A) made a reasonable attempt to recover such amounts and (B) provided documentation of such attempts to recover to the Company's applicable listing exchange; or (iii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of the Internal Revenue Code of 1986, as amended.

Incentive-Based Compensation. "Incentive-Based Compensation" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation does not include any base salaries (except with respect to any salary increases earned wholly or in part based on the attainment of a Financial Reporting Measure performance goal); bonuses paid solely at the discretion of the Compensation Committee or Board that are not paid from a "bonus pool" that is determined by satisfying a Financial Reporting Measure performance goal; bonuses paid solely upon satisfying one or more subjective standards and/or completion of a specified employment period; non-equity incentive plan awards earned solely upon satisfying one or more strategic measures or operational measures; and equity awards that vest solely based on the passage of time and/or attaining one or more non-Financial Reporting Measures.

Policy. "Policy" means this Clawback Policy.

Received. Incentive-Based Compensation is deemed "Received" in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period.

Recoverable Compensation. "Recoverable Compensation" means the amount of any Incentive-Based Compensation (calculated on a pre-tax basis) Received by a Covered Person during the Applicable Period that is in excess of the amount that otherwise would have been Received if the calculation were based on the Restatement. For the avoidance of doubt, Recoverable Compensation does not include any Incentive-Based Compensation Received by a person (i) before such person began service in a position or capacity meeting the definition of a "Covered Person," (ii) if such person did not meet the definition of a "Covered Person" at any time during the Applicable Period, or (iii) during any period the Company did not have a class of its securities listed on a national securities exchange or a national securities association. For the avoidance of doubt, Recoverable Compensation may include Incentive-Based Compensation Received by a person while serving as an employee if such person previously served as an Executive Officer and then transitioned to an employee role. For the avoidance of doubt, if the subject Incentive-Based Compensation (calculated on a pre-tax basis) was based on stock price or total shareholder return, where the Recoverable Compensation is not subject to mathematical recalculation directly from the information in a Restatement, the Recoverable Compensation must be based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received, and documentation of such reasonable estimate must be provided to the Company's applicable listing exchange.

Restatement. "Restatement" means an accounting restatement of any of the Company's financial statements filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended, due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, regardless of whether Company or Covered Person misconduct was the cause for such restatement. "Restatement" includes any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (commonly referred to as "Big R" restatements), or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (commonly referred to as "little r" restatements).

3. <u>Other Actions</u>

In addition, the Compensation Committee may, in its sole discretion and in the reasonable exercise of its business judgment, determine whether and to what extent additional action is appropriate to address the circumstances surrounding a Restatement to minimize the likelihood of any recurrence and to impose such other discipline as it deems appropriate.

4. <u>No Indemnification or Reimbursement</u>

Notwithstanding the terms of any other policy, program, agreement or arrangement, in no event will the Company or any of its affiliates indemnify or reimburse a Covered Person for any loss under this Policy and in no event shall the Company or any of its affiliates pay premiums on

any insurance policy that would cover a Covered Person's potential obligations with respect to Recoverable Compensation under this Policy.

5. Administration of Policy

The Compensation Committee shall have full authority to administer this Policy. Actions of the Compensation Committee pursuant to this Policy shall be taken by the vote of a majority of its members. The Compensation Committee shall, subject to the provisions of this Policy, make such determinations and interpretations and take such actions in connection with this Policy as it deems necessary, appropriate or advisable. All determinations and interpretations made by the Compensation Committee shall be final, binding and conclusive.

6. Acknowledgement by Covered Persons

The Company shall provide notice and seek written acknowledgement of this Policy from each Executive Officer, provided that the failure to provide such notice or obtain such acknowledgement shall have no impact on the applicability or enforceability of this Policy.

7. Other Laws

The remedies under this Policy are in addition to, and not in lieu of, any legal and equitable claims the Company or any of its affiliates may have or any actions that may be imposed by law enforcement agencies, regulators, administrative bodies or other authorities. Further, the exercise by the Compensation Committee of any rights pursuant to this Policy shall be without prejudice to any other rights that the Company or the Compensation Committee may have with respect to any Executive Officer or other Covered Person subject to this Policy. To the extent applicable, this Policy will be administered in a manner that complies with applicable law and listing exchange requirements and shall be interpreted and construed accordingly.

8. Amendment; Termination

The Board or the Compensation Committee may amend or terminate this Policy at any time.

9. Interpretation; Enforcement

This Policy will be interpreted and enforced, and appropriate disclosures and other filings with respect to this Policy will be made, in accordance with Rule 10D-1 of the Securities Exchange Act of 1934, as amended, and the Company's applicable exchange listing standards.

10. Effectiveness

Except as otherwise determined in writing by the Compensation Committee, this Policy shall apply to any Incentive-Based Compensation that is Received by Covered Persons prior to or following the effectiveness of this Policy.