THE ROSEN LAW FIRM, P.A.
Phillip Kim, Esq. (PK 9384)
Laurence M. Rosen, Esq. (LR 5733)
275 Madison Ave., 34th Floor
New York, New York 10016
Telephone: (212) 686-1060
Fax: (212) 202-3827
Email: pkim@rosenlegal.com
Email: lrosen@rosenlegal.com

Counsel for Plaintiff

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

KENNETH GORDON, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. VANDA PHARMACEUTICALS INC., MIHAEL H. POLYMEROPOULOS, and JAMES P. KELLY, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff Kenneth Gordon ("Plaintiff") individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Securities and Exchange Commission ("SEC") filings by Vanda Pharmaceuticals Inc. ("Vanda" or the "Company"), as well as media and analyst reports about the Company. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities, other than Defendants and their affiliates, who purchased publicly traded Vanda securities from November 4, 2015 through February 11, 2019, both dates inclusive ("Class Period"), seeking to recover compensable damages caused by Defendants' violations of federal securities laws and pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

3. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

4. Venue is proper in this judicial district pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b) as the Company conducts business in this District.

5. In connection with the acts, conduct and other wrongs alleged herein, Defendants either directly or indirectly used the means and instrumentalities of interstate commerce, including but not limited to the United States mails, interstate telephone communications, and the facilities of the national securities exchange.

PARTIES

6. Plaintiff, as set forth in the accompanying PSLRA Certification, acquired Vanda securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

7. Defendant Vanda, a biopharmaceutical company, focuses on the development and commercialization of products for the treatment of central nervous system disorders. The Company is incorporated in Delaware with its headquarters in Washington, D.C. Vanda sells, markets, and promotes its products throughout the United States, including New York. Vanda securities trade on NASDAQ under the symbol "VNDA."

8. Defendant Mihael H. Polymeropoulos ("Polymeropoulos") is a founder of Vanda and has been the Company's Chief Executive Officer ("CEO") during the Class Period.

9. Defendant James P. Kelly ("Kelly") has served as the Company's Senior Vice President and Chief Financial Officer ("CFO") during the Class Period.

10. Defendants Polymeropoulos and Kelly are herein referred to as "Individual Defendants."

11. Collectively, Vanda and Individual Defendants are herein referred to as "Defendants."

12. Each of the Individual Defendants:

a. directly participated in the management of the Company;

b. was directly involved in the day-to-day operations of the Company at the highest levels;

c. was privy to confidential proprietary information concerning the Company and its business and operations;

d. was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

e. was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

f. was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

g. approved or ratified these statements in violation of the federal securities laws.

13. Vanda is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency as all of the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

14. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Vanda under *respondeat superior* and agency principles.

SUBSTANTIVE ALLEGATIONS

Background

15. Vanda owns and markets two drugs, Fanapt and Hetlioz. Fanapt is a medication used to treat schizophrenia in adults. Fanapt was approved by the U.S. Food and Drug Administration ("FDA") in 2009, which at that time was marketed by Novartis. In December 2014, Vanda took over marketing Fanapt. Fanapt's prescribing information states in part:

> FANAPT is an atypical antipsychotic agent indicated for the acute treatment of schizophrenia in adults. In choosing among treatments, prescribers should consider the ability of FANAPT to prolong the QT interval and the use of other drugs first. Prescribers should also consider the need to titrate FANAPT slowly to avoid orthostatic hypotension, which may lead to delayed effectiveness compared to some other drugs that do not require similar titration.

16. Hetlioz is approved to treat Non-24-Hour Sleep-Wake Disorder ("Non-24"). Hetlioz is supposed to reset the body's clock and align it with the 24-hour day. On January 19,

2010, the FDA granted Hetlioz orphan drug status for Non-24 in blind individuals without light perception. On January 31, 2014, Vanda announced the FDA's approval of Hetlioz 20 mg capsules for the treatment of Non-24.

Defendants' False and Misleading Class Period Statements

17. On November 3, 2015, after the market closed, Vanda held a conference call to discuss the earnings for the third quarter of 2015. On this call, Defendant Polymeropoulos discussed the sales and marketing for Fanapt, stating in relevant part:

> We are seeking to stabilize the Fanapt revenue with active commercial efforts. Specifically, in early August, we launched a 12-person team in parallel territories around the United States. Early analysis of the data suggests that in these 12 territories, Fanapt revenue is beginning to stabilize. We're now in the process of further building out a small Fanapt dedicated sales force for a total of 50 territories around the country by the end of this year.
>
> * * *
>
> In July/August we launched our pilot, the Fanapt 12 looking at creating a competitive share of voice in certain territories to determine the promotional responsiveness of Fanapt when we had a competitive share of voice. And when we drilled down at the individual territory level, we were able to measure the promotional response based up on reach and frequency. And based upon the early data, it provided a strong signal confirming the promotional sensitivity of Fanapt.
>
> Based upon those data, we have decided to expand the Fanapt 12 to Fanapt 50, where we are going to be populating 50 of the most productive territories, creating a competitive share of voice, which we think we will be able to replicate the results that we saw within the Fanapt 12 and stabilize the Fanapt business exiting 2015.

18. On February 12, 2016, the Company filed a Form 10-K for the year ended December 31, 2015 ("2015 10-K") with the SEC, which provided the Company's full year 2015 financial results and position. The 2015 10-K was signed by Defendants Polymeropoulos and Kelly. The 2015 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Polymeropoulos and Kelly attesting to the accuracy of financial reporting,

the disclosure of any material changes to the Company's internal control over financial reporting and the disclosure of all fraud.

19. The 2015 10-K discussed the uses and marketing of Fanapt and Hetlioz, stating in relevant part:

> HETLIOZ®
>
> ***Commercial opportunity: Non-24***
>
> ***In January 2014, HETLIOZ® was approved in the U.S. for the treatment of Non-24.*** Non-24 is a serious, rare and chronic circadian rhythm 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 (SCN), 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. HETLIOZ® was launched commercially in the U.S. in April 2014. In addition, in July 2015, the EC granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults. This authorization is valid in the 28 countries that are members of the European Union, as well as European Economic Area members Iceland, Liechtenstein and Norway.
>
> ***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 is a serious, rare and chronic circadian rhythm disorder characterized by the inability to synchronize the master body clock with the 24-hour day-night cycle. ***Non-24 affects a majority of totally blind individuals, or between 65,000 and 95,000 people in the U.S.*** Non-24 occurs almost entirely in individuals who lack the light sensitivity necessary to synchronize the master body clock in the brain with 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.

While there are no FDA or EC approved treatments for Non-24, other than HETLIOZ®, 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.

* * *

Fanapt®

Commercial Opportunity: Schizophrenia
Fanapt® is a product 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. In October 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis in June 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanapt®. Pursuant to the amended and restated sublicense agreement, Novartis had 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 Vanda as part of the Settlement Agreement. See Note 3, Settlement Agreement with Novartis, to the consolidated financial statements included in Part II of this annual report on Form 10-K for additional information. In June 2015, we announced positive results from REPRIEVE, a Phase III long-term maintenance study that was conducted by Novartis. In September 2015, the FDA accepted for review a supplemental New Drug Application (sNDA) for Fanapt® for the maintenance treatment of schizophrenia in adults. The FDA has set a May 2016 PDUFA date for the Fanapt® sNDA.

* * *

Marketing and sales

HETLIOZ® was approved in the U.S. for the treatment of Non-24 in January 2014 and commercially launched in the U.S. in April 2014. Additionally, HETLIOZ® was approved in the Europe Union for the treatment of Non-24 in July 2015 and we expect to commercially launch the product in Germany in 2016.

Given the range of potential indications for HETLIOZ®, we may pursue one or more partnerships for the development and commercialization of HETLIOZ® worldwide.

Fanapt® was approved in the U.S. for the treatment of schizophrenia in May 2009 and commercially launched in the U.S. in January 2010. In October 2009, we entered into an amended and restated sublicense agreement with Novartis pursuant to which Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis began selling Fanapt® in the U.S. during the first quarter of 2010. Pursuant to the terms of the Settlement Agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to Vanda on December 31, 2014.

Fanapt® was launched in Israel and Mexico by our distribution partners in 2014. We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada.

(Emphasis added).

20. The 2015 10-K discussed reimbursement from government programs, stating in relevant part:

Third-party reimbursement and pricing controls

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, has changed and is expected to further significantly change the way healthcare is financed by both governmental and private insurers. The provisions of the ACA became effective over various periods from 2010 through 2014. We cannot predict the complete impact of the ACA on pharmaceutical companies because many of the ACA's reforms require the promulgation of detailed regulations to implement the statutory provisions, which has not yet occurred. While we cannot predict the complete impact on federal reimbursement policies this law will have in general or specifically on any product we commercialize, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. The rebates, discounts, taxes and other costs resulting from the ACA may have a significant effect on our profitability in the future. In addition, potential reductions of the per capita rate of growth in Medicare spending under the ACA, could potentially limit access to certain treatments or mandate price controls for our products. Moreover, although the United States Supreme Court has upheld the constitutionality of most of the ACA, some states have indicated that they intend not to implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal the ACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us or our partners.

In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are

> increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us or our partners to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us or our partners to sell our compounds on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes additional requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

21. On February 17, 2017, the Company filed a Form 10-K for the year ended December 31, 2016 ("2016 10-K") with the SEC, which provided the Company's full year 2016 financial results and position. The 2016 10-K was signed by Defendants Polymeropoulos and Kelly. The 2016 10-K contained signed SOX certifications by Defendants Polymeropoulos and Kelly attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting and the disclosure of all fraud.

22. The 2016 10-K discussed the uses and marketing of Fanapt and Hetlioz, stating in relevant part:

> **HETLIOZ®**
>
> ***Commercial opportunity: Non-24***
>
> ***In January 2014, HETLIOZ® was approved in the U.S. for the treatment of Non-24. Non-24 is a serious, rare and chronic circadian rhythm 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 (SCN), 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. HETLIOZ® was launched commercially in the U.S. in April 2014. In addition, in July 2015, the 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 is valid in the 28 countries that are members of the European Union, 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 is a serious, rare and chronic circadian rhythm disorder characterized by the inability to synchronize the master body clock with the 24-hour day-night cycle. ***Non-24 affects a majority of totally blind individuals, or approximately 80,000 people in the U.S.*** Non-24 occurs almost entirely in individuals who lack the light sensitivity necessary to synchronize the master body clock in the brain with 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.

While there are no FDA or EC approved treatments for Non-24 other than HETLIOZ®, 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.

* * *

Fanapt®

Commercial Opportunity: Schizophrenia

Fanapt® is a product 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. In October 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis in June 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanapt®. Pursuant to the

amended and restated sublicense agreement, Novartis had 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 Vanda as part of the Settlement Agreement. See Note 3, *Settlement Agreement with Novartis*, to the consolidated financial statements included in Part II of this annual report on Form 10-K for additional information. In June 2015, we announced positive results from REPRIEVE, a Phase III long-term maintenance study that was conducted by Novartis. In May 2016, the FDA approved a supplemental New Drug Application (sNDA) for Fanapt® for the maintenance treatment of schizophrenia in adults.

* * *

Marketing and sales

HETLIOZ® was approved in the U.S. for the treatment of Non-24 in January 2014 and commercially launched in the U.S. in April 2014. Additionally, HETLIOZ® was approved in the Europe Union for the treatment of Non-24 in July 2015. We commercially launched HETLIOZ® in Germany in the third quarter of 2016.

Given the range of potential indications for HETLIOZ®, we may pursue one or more partnerships for the development and commercialization of HETLIOZ® worldwide.

Fanapt® was approved in the U.S. for the treatment of schizophrenia in May 2009 and commercially launched in the U.S. in January 2010. In October 2009, we entered into an amended and restated sublicense agreement with Novartis pursuant to which Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis began selling Fanapt® in the U.S. during the first quarter of 2010***. Pursuant to the terms of the Settlement Agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to Vanda on December 31, 2014.***

(Emphasis added).

23. The 2016 10-K discussed reimbursement from government programs, stating in relevant part:

Third-Party Reimbursement and Pricing Controls

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (together, PPACA), has changed and is expected to further significantly change the way healthcare is financed by both governmental and private insurers. The provisions of PPACA became effective over various periods from 2010 through 2014. We cannot predict

> the complete impact of PPACA on pharmaceutical companies because many of PPACA's reforms require the promulgation of detailed regulations to implement the statutory provisions, which has not yet occurred. While we cannot predict the complete impact on federal reimbursement policies this law will have in general or specifically on any product we commercialize, PPACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. The rebates, discounts, taxes and other costs resulting from PPACA may have a significant effect on our profitability in the future. In addition, potential reductions of the per capita rate of growth in Medicare spending under PPACA, could potentially limit access to certain treatments or mandate price controls for our products. Moreover, although the United States Supreme Court has upheld the constitutionality of most of PPACA, some states have indicated that they intend not to implement certain sections of PPACA, and some members of the U.S. Congress are still working to repeal PPACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us or our partners.
>
> In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us or our partners to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us or our partners to sell our compounds on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes additional requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

24. On February 15, 2018, the Company filed a Form 10-K for the year ended December 31, 2017 ("2017 10-K") with the SEC, which provided the Company's full year 2017 financial results and position. The 2017 10-K was signed by Defendants Polymeropoulos and Kelly. The 2017 10-K contained signed SOX certifications by Defendants Polymeropoulos and Kelly attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting and the disclosure of all fraud.

25. The 2017 10-K discussed the uses and marketing of Fanapt and Hetlioz, stating in relevant part:

HETLIOZ®

Commercial opportunity: Non-24

In January 2014, HETLIOZ® was approved in the U.S. for the treatment of Non-24. Non-24 is a serious, rare and chronic circadian rhythm 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. HETLIOZ® was launched commercially in the U.S. in April 2014. In addition, in July 2015, the 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 is valid in the 28 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. In sighted individuals, decreased exposure or sensitivity to light and social and physical activity cues may contribute to a free-running circadian rhythm. With the high frequency of mental disorders involving social isolation and cases of Non-24 developing after a change in sleep habits, behavioral factors in combination with physiological tendency may precipitate and perpetuate this disorder in sighted individuals. Hospitalized individuals with neurological and psychiatric disorders can become insensitive to social cues, predisposing them to the development of Non-24.

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.

While there are no FDA or EC approved treatments for Non-24 other than HETLIOZ®, 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.

* * *

Fanapt®

Commercial Opportunity: Schizophrenia

Fanapt® is a product 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. In October 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis in June 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanapt®. Pursuant to the amended and restated sublicense agreement, Novartis had 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 Vanda as part of a settlement agreement. In June 2015, we announced positive results from REPRIEVE, a Phase III long-term maintenance study that was conducted by Novartis. In May 2016, the FDA approved a sNDA for Fanapt® for the maintenance treatment of schizophrenia in adults.

In July 2017, the EMA's Committee for Medicinal Products for Human Use (CHMP) issued a negative opinion recommending against approval of Fanaptum® (oral iloperidone tablets) for the treatment of schizophrenia in adult patients in the E.U. The CHMP was of the opinion that the benefits of Fanaptum® did not outweigh its risks and recommended against marketing authorization. The negative opinion was upheld upon appeal in November 2017.

We received market approval for the commercialization of Fanapt® in Israel in August 2012 and in Mexico in October 2013. Our distribution partners launched Fanapt® in Israel and Mexico in 2014. As of December 31, 2017, we no longer have an active distributor relationship in Mexico.

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®.

Pursuant to a settlement agreement with Novartis, we reacquired the U.S. and Canadian rights to the long-acting injectable (depot) formulation of Fanapt®. We are evaluating the commercial opportunity around the depot formulation.

* * *

Marketing and Sales

HETLIOZ® was approved in the U.S. for the treatment of Non-24 in January 2014 and commercially launched in the U.S. in April 2014. Additionally, HETLIOZ® was approved in the E.U. for the treatment of Non-24 in totally blind adults in July 2015. We commercially launched HETLIOZ® in Germany in August 2016.

Given the range of potential indications for HETLIOZ®, we may pursue one or more partnerships for the development and commercialization of HETLIOZ® worldwide.

Fanapt® was approved in the U.S. for the treatment of schizophrenia in May 2009 and commercially launched in the U.S. in January 2010. In October 2009, we entered into an amended and restated sublicense agreement with Novartis pursuant to which Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis began selling Fanapt® in the U.S. during the first quarter of 2010. ***Pursuant to the terms of a settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to Vanda on December 31, 2014.***

(Emphasis added).

26. The 2017 10-K discussed reimbursement from government programs, stating in relevant part:

Third-Party Reimbursement and Pricing Controls

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (together, PPACA), has changed and is expected to further significantly change the way healthcare is financed by both governmental and private insurers. The provisions of PPACA became effective over various periods from 2010 through 2014. We cannot predict the complete impact of PPACA on pharmaceutical companies because many of PPACA's reforms require the promulgation of detailed regulations to implement the statutory provisions, which has not yet occurred. While we cannot predict the complete impact on federal reimbursement policies this law will have in general or specifically on any product we commercialize, PPACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. The rebates, discounts, taxes and other costs resulting from PPACA may have a significant effect on our profitability in the future. In addition, potential reductions of the per capita rate of growth in Medicare spending under PPACA, could potentially limit access to certain treatments or mandate price controls for our products. Moreover, although the U.S. Supreme Court has upheld the constitutionality of most of PPACA, some states have indicated that they intend not to implement certain sections of PPACA, and some members of the U.S. Congress are still working to repeal PPACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us or our partners.

In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us or our partners to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us or our partners to sell our compounds on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes additional requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

27. The statements referenced in ¶¶17-26 above were materially false and/or misleading because they misinterpreted and failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) Vanda was engaged in a fraudulent scheme in which the Company

promoted the off-label use of Fanapt and Hetlioz; (2) Vanda was fraudulently receiving drug reimbursements from the government by abusing Medicare, Medicaid, and Tricare programs; (3) as a result of the scheme, Vanda faced legal action from the government; (4) Vanda's promotional materials for Fanapt and Hetlioz were false and misleading, garnering regulatory scrutiny from the FDA; and (5) as a result, Defendants' statements about Vanda's business, operations and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

The Truth Begins To Emerge

28. On October 22, 2018, the FDA sent Vanda a Warning Letter which was addressed to Defendant Polymeropoulos. The Warning Letter was in response to the FDA's review of Vanda's website which the FDA found "false and misleading" due to its failure to disclose risks of the Fanapt and Hetlioz and in violation of the Federal Food, Drug, and Cosmetic Act. The FDA raised its concerns with the promotional materials for these drugs. The Warning Letter stated in relevant part:

> The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the Vanda Pharmaceutical's (Vanda) webpage1 titled, "Products" for FANAPT® (iloperidone) tablets, for oral use (Fanapt), and HETLIOZ® (tasimelteon) capsules, for oral use (Hetlioz). This webpage is false or misleading in that it presents information about the benefits of Fanapt and Hetlioz, but fails to include any risk information about either drug. Thus, the webpage misbrands Fanapt and Hetlioz within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act) and makes their distribution violative. 21 U.S.C. 352(a) & (n); 321(n), 331(a). See 21 CFR 202.1(e)(5). This violation is concerning from a public health perspective because it creates a misleading impression about the safety of Fanapt and Hetlioz. Of particular concern is that Fanapt is a drug that bears a Boxed Warning due to serious, life-threatening risks, including increased mortality in elderly patients with dementia-related psychosis, as well as numerous other warnings.
>
> * * *

> **False or Misleading Risk Presentation**
>
> Promotional materials misbrand a drug if they are false or misleading with respect to risk. ***The determination of whether promotional materials are misleading includes, among other things, not only representations made or suggested in promotional materials, but also failure to reveal facts material in light of the representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the materials.*** The webpage includes claims and/or representations about the uses and/or benefits of Fanapt and Hetlioz; however, it fails to communicate any risk information about the products. We acknowledge that the webpage includes the statements, "For U.S. full prescribing information, including box warnings and safety information, please visit www.fanapt.com," and "Full HETLIOZ® Prescribing Information can be found at: www.hetlioz.com." However, this does not mitigate the omission of risk information from the webpage. ***By omitting the risks associated with Fanapt and Hetlioz, the webpage fails to provide material information about the consequences that may result from the use of the drugs and creates a misleading impression about the drugs' safety. This misleading presentation is especially problematic from a public health perspective due to the serious and potentially life-threatening risks associated with the drugs, such as those contained in Fanapt's Boxed Warning.***
>
> (Emphasis added).

29. On this news, shares of Vanda fell $2.00 per share or over 9% over the next two trading days to close at $20.00 per share on October 24, 2018, damaging investors.

30. On February 11, 2019, Aurelius Value published a report entitled, "Vanda: In the Land of The Blind, The One-Eyed Man in King." This report revealed a previous unreported qui tam lawsuit which disclosed Vanda's years of fraudulent promotion of Fanapt and Hetlioz as well as Vanda's scheme to defraud the government with fraudulent reimbursements.

31. The qui tam lawsuit, *United States of America, ex rel. Richard Gardner v. Vanda Pharmaceuticals*, Case No. 1:17-cv-00464-APM (D.D.C.) (the "Whistleblower Lawsuit"), was filed on March 10, 2017 but not unsealed until February 4, 2019 after the judge ordered it unsealed on January 31, 2019. The Aurelius Value report first disclosed the existence of the Whistleblower

Lawsuit and provided a summary of the claims and a link to the complaint filed in the Whistleblower Lawsuit. The Aurelius Value report, stated in relevant part:

> These new allegations amplify the findings from our own months-long investigation which yielded evidence of significant irregularities. They also corroborate certain allegations made by multiple former employees in private calls who described off-label promotion, suspect business practices, and internal turmoil that continued well after the whistleblower's departure.
>
> * * *
>
> Vanda has grown by selling two drugs, Fanapt and Hetlioz, that had previously been cast off by larger companies. Both drugs have narrow FDA approved indications that severely limit their respective potential patient populations and therefore also limit Vanda's on-label revenue potential. To juice sales, the whistleblower states that Vanda's senior management implemented a plan to illegally promote both drugs for off-label purposes and alleges that, as a result of fraudulent reimbursement claims, "the government has been defrauded and suffered a substantial loss".
>
> ***One former top-performing sales employee we spoke to explained that Fanapt, which accounts for just over 40% of Vanda's sales, "was a dud" because it is a second line drug approved solely to treat adult schizophrenia as compared to competitive antipsychotics which have much broader indications. To increase sales of Fanapt, the whistleblower states that Polymeropoulos crafted off-label messaging himself and trained sales reps to promote the drug for other indications using a variety of false claims regarding Fanapt's efficacy, dosing, and safety***. We note that several months ago, Vanda received a Warning Letter from the FDA instructing the company to immediately cease misbranding its drug with "false and misleading marketing materials" that failed to warn about the safety risks of Fanapt and Hetlioz.
>
> The lawsuit states that Vanda falsified documents relating to physician target lists in company systems that "*were a joke and were designed solely to shield Vanda from liability*". Instead, according to the complaint, sales reps were directed to target physicians prescribing drugs for other mental disorders as well as child psychologists, even though Fanapt has no FDA approval for children, according to the complaint.
>
> * * *
>
> ***Our research indicates that Vanda has had an extremely difficult time attracting and keeping blind patients on Hetlioz, the population the drug was tested on and designed to treat. In order to meet growth targets, we believe Vanda's "secret sauce" is a product of Polymeropoulos harnessing the Fanapt sales force to begin***

selling Hetlioz to psychiatrists as a sleep aide alternative to Ambien and Lunesta for sighted patients. The principal problem is that taxpayers appear to be on the hook for Polymeropoulos' alleged shenanigans.

Non-24 is so rare that Vanda had to cut patient enrollment of its FDA trials of Hetlioz in half because it could not identify enough patients with the condition. This makes it exceedingly difficult for Vanda to sell Hetlioz to patients with Non-24, which one former rep described as the classic "needle in the haystack" exercise. After launch in 2014, Vanda's strategy was centered on building awareness by sending sales reps to blind community centers and running tv and radio spots to target friends and family members, an effort that initially appears to have been somewhat fruitful.

But our research also indicates that Hetlioz has unfavorable levels of front-end patient churn, meaning patients who begin treatment often drop off in the first six months. One explanation is that the drug simply doesn't work very well for some patients.

* * *

We also examined data from the FDA Adverse Event Reporting System ("FAERS"), which contains information on medication error reports submitted to the FDA. **The single most frequently reported adverse event is the complaint of "drug ineffective**" which, when combined with similar complaints about efficacy, totals 888 complaints since 2014, an amount which exceeds the number of patients currently on Hetlioz. In fact, questions about Hetlioz's efficacy date back to 2013, when Health Care columnist Adam Feuerstein identified "a disturbingly large number of irregularities and red flags" related to Vanda's clinical trials of Hetlioz.

(Emphasis added).

32. The Whistleblower Lawsuit disclosed and stated in relevant part:

a. 47***. Defendant has, since at least November 2015, engaged in a scheme to promote its drugs Fanapt and Hetlioz for off-label uses, in addition to several other prohibited promotional strategies. Specifically, Defendant: (1) promoted Fanapt for uses outside of treating schizophrenia, the drug's sole indication; (2) promoted Fanapt off-label to pediatric patients; (3) overstated Fanapt's efficacy to providers; (4) made false and misleading statements regarding Fanapt's safety warnings; (5) misled providers about Fanapt's approved dosing schedule; (6) improperly provided titration packets which did not have adequate instructions for use; (7) promoted Fanapt as a first line therapy; (8) misused Fanapt copay cards; and (9) promoted Hetlioz for off-label uses. These prescriptions were reimbursed by federal health care programs, including Medicare, Medicaid and Tricare, and therefore were issued in violation of the***

FCA. As a result of Defendant's misconduct, the Government has been defrauded and suffered a substantial loss.

53. ***Twelve of the sales representatives, known as the Fanapt 12, had been selling Fanapt since December 2014 in the New York City, New York, and St. Louis, Missouri areas.*** The Fanapt 12 were primarily managed by David James, Vanda's National Sales Director, and Paul Ramirez, Defendant's Head of Sales. The other thirty-eight sales representatives were hired around the same time as Relator. The sales representatives, RBLs, and senior management attended a five-day national relaunch meeting in late November/early December 2015 at the Fairmount Hotel in Washington, D.C.

54. The Fanapt 12 were universally praised by Defendant's senior management. They were viewed as "experts" at selling Fanapt because they had been selling the drug for eleven months before the other sales representatives were hired, and therefore had real-life experience promoting the drug to providers. Vanda senior management even stated to the other sales representatives that they should thank the Fanapt 12 for their jobs because their success in selling the drug was the main factor which convinced senior management to hire additional sales representatives.

b. Vanda's Promotion of Fanapt for Off-Label Uses:

57. ***Fanapt was approved by the FDA solely to treat adult schizophrenia patients.*** This limited indication severely decreased the potential patient population that could be prescribed Fanapt on-label, especially compared to its competitors' antipsychotic drugs with more expansive indications. To overcome this obstacle, ***Vanda senior management implemented a plan to promote the drug for off-label uses, mainly bi-polar disorder and other conditions treated by competitors' antipsychotic medications. The training, provider targets and compensation, among other things Vanda provided to its sales force, were all designed to secure off-label Fanapt prescriptions.***

58. Specifically, and as discussed in more detail below, ***Vanda trained its sales force to market Fanapt to providers as an effective substitute for other atypical antipsychotics that have more expansive indications and are commonly prescribed for bipolar disorder rather than schizophrenia.*** After convincing a provider that Fanapt was an effective substitute for other atypical antipsychotics, regardless of the condition it was prescribed to treat, Fanapt sales representatives were trained to differentiate the drug from other antipsychotics by promoting Fanapt's

safety profile. Significantly, during their sales pitch, sales representatives were trained to avoid any discussion of schizophrenia, and if brought up by the provider, to steer the conversation back to Fanapt's efficacy and safety profile messaging. Further, the sales goals, physician target lists and incentive compensation plans all demonstrate that Vanda intended its sales representatives to promote Fanapt off-label.

59. ***Vanda was aware that the providers its sales representatives targeted were primarily prescribing atypical antipsychotics for bipolar disorder and conditions other than schizophrenia. Vanda was also aware that a significant portion of the prescriptions secured by its sales force were for off-label uses. However, this was Vanda's intended result – to promote Fanapt to physicians prescribing antipsychotics for any disorder and convert them to Fanapt prescribers.***

c. Vanda's Promotion of Fanapt Off-Label to Pediatric Patients

99. ***Vanda promoted Fanapt off-label to pediatric patients. As stated above, Fanapt is only indicated to treat schizophrenia in adult patients. Vanda encouraged its sales representatives to call on child psychiatrists, in part, by compensating them on all prescriptions secured, whether on- or off-label.*** This, combined with the fact that Vanda held sales representatives accountable for unrealistic sales goals, which included off-label prescriptions, provided significant pressure on the Fanapt sales force to call on and promote the drug to child psychiatrists.

d. Vanda Downplayed Safety Risks of Fanapt

120. In order to gain FDA approval, Fanapt was required to give certain safety warnings to patients and providers. Knowing Fanapt's safety profile may cause providers to prescribe their patients a different antipsychotic. Vanda implemented sales techniques to downplay the safety risks associated with its drug. This messaging was false and misleading, and ranged from broad claims about Fanapt's safety profile to messages tailored to address specific side effects caused by the drug.

122. During sales training, sales representatives were told to use the phrase "placebo- like" when discussing Fanapt's safety profile, even though Fanapt's side effect profile was not "placebo-like" across the board for all side effects. And this is demonstrated in Vanda's own sales aides. The Fanapt master sales aide demonstrates the side-effect rate for each of Fanapt's side effects and the rate at which patients taking a placebo in clinical studies suffered the same side effects. As the sales aide demonstrates, the side effect rate for Fanapt was higher for almost

all side effects than a placebo. For example, for weight gain, in the clinical studies, patients receiving a placebo lost 0.1kg on average while patients taking 20-24mg per day of Fanapt gained 2.7kg and patients taking 10-16mg per day gained 2.0kg. Further, Ramirez instructed sales representatives to tell providers, when reviewing all patients participating in clinical studies, that "Fanapt only showed a *2.1 increase in weight*." (Emphasis added). Ramirez then explained that physicians would think this was in reference to 2.1 pounds when in reality it was in reference to kilograms (approximately 5 pounds).

e. Vanda's False Titration Messaging for Fanapt

131. The FDA-approved Fanapt label states that patients starting on the drug should use titration to achieve the target dose. Specifically, Fanapt's label provides: The recommended target dosage of FANAPT tablets is 12 to 24 mg/day administered twice daily. This target dosage range is achieved by daily dosage adjustments, alerting patients to symptoms of orthostatic hypotension, starting at a dose of 1 mg twice daily, then moving to 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg twice daily on Days 2, 3, 4, 5, 6, and 7 respectively, to reach the 12 mg/day to 24 mg/day dose range. FANAPT can be administered without regard to meals.

132. The FDA, in approving Fanapt, also approved the titration schedule shown above. The official Fanapt titration pack, however, does not follow the FDA's approved titration schedule. Rather, the pack contains two 1 mg tablets for day one, two 2 mg tablets for day two, two 4 mg tablets for day three, and two 6 mg tablets for day four, as shown below.

133. Relator learned that Fanapt sales representatives in some territories were ignoring the FDA-approved titration schedule and giving providers two or three titration packs, rubber banded together, to give to their patients starting Fanapt. In some instances, multiple titration packs were provided to physicians as samples, however, in most cases they were provided for the purposes of titrating a patient.

f. Vanda's Misuse of Copay Cards

152. Relator then followed up with Ramirez regarding this issue. Ramirez conceded that ***the increase in prescriptions was the result of a fraudulent scheme between the physicians and local pharmacists to submit hundreds of Fanapt copay cards and prescriptions, receive reimbursement from the insurance provider, and then pocket the money because the prescriptions were never dispensed.*** Ramirez instructed Relator not to discuss the matter with anyone and not to email him or anyone else about the issue. Further, in regards to Harris, Ramirez stated, "we are removing [Harris] from the account. The less

she knows the better." ***Vanda was an active participant in this scheme. According to Relator, Fanapt copay cards can only be provided by a Fanapt sales representative or manager. Therefore, in order for these physicians to obtain such a large quantity of copay cards, Vanda must have supplied the copay cards and subsequently sought to cover it up after others took notice. And, as Fanapt's copay cards can be used by Medicare and Medicaid, which itself is a violation, the payments for these fake prescriptions were incurred by the Government.***

g. Vanda's Off-Label Promotion of Hetlioz

153. Vanda also promoted its drug Hetlioz for off-label purposes. Hetlioz was granted orphan drug status by the FDA on January 19, 2010 for Non-24 in blind patients without light perception. On January 31, 2014, Vanda announced that the FDA had approved Hetlioz 20 mg capsules for the treatment of Non-24.

157. To pitch Hetlioz to providers, CEO Polymeropoulos instructed the RBLs to direct their sales representatives to ask providers, "do you have any blind patients?" Regardless of the answer, sales representatives were instructed to state, "Hetlioz is a drug that is effective in treating circadian rhythm disruption" and to leave the provider with the Hetlioz slim-jim sales packet.

158. Polymeropoulos also told the RBLs that psychiatrists would connect the dots and easily determine that if Hetlioz treats circadian rhythm disruption in Non-24 that it would also be able to treat their non-blind patients with other sleep disorders caused by circadian rhythm disruption, such as shift work sleep disorder, jet lag, and insomnia. ***According to Relator, the RBLs and sales representatives were to focus on Hetlioz's ability to treat circadian rhythm disruption when pitching the drug to providers. Polymeropoulos continued that Vanda was also currently seeking additional indications for Hetlioz. Relator believes that Polymeropoulos said this to the RBLs with the intent that they would share this information with their sales representatives, who could use it in the field while promoting Hetlioz.***

162. ***Further, by promoting Hetlioz as a sleep aide that was not classified as a schedule drug by the FDA, Vanda intended to convince physicians to use Hetlioz instead of other sleep aides. As a significant majority of scheduled sleep aides are prescribed for conditions other than Non-24, and sales representatives were required to promote Hetlioz regardless of whether the provider had blind patients, it is obvious that Vanda intended its sales representatives to promote***

> ***Hetlioz as an effective substitute for all sleep aides to treat conditions outside of its indicated use (i.e., Non-24).***
>
> (Emphasis added).

33. On this news, shares of Vanda fell $0.95 per share or over 5% to close at $18.00 per share on February 11, 2019, damaging investors.

34. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common shares, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the publicly traded securities of Vanda during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether Defendants' acts as alleged violated the federal securities laws;

(b) whether Defendants' statements to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of the Company;

(c) whether Defendants' statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether the Individual Defendants caused the Company to issue false and misleading SEC filings and public statements during the Class Period;

(e) whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;

(f) whether the prices of the Company's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(g) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

41. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the Company's securities are traded in efficient markets;

(d) the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;

(e) the Company traded on the NASDAQ, and was covered by multiple analysts;

(f) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; Plaintiff and members of the Class purchased and/or sold the Company's securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts; and

(g) Unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

42. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

43. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Against All Defendants

44. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

45. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

46. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

47. The Company and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they: employed devices, schemes and artifices to defraud; made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff

and others similarly situated in connection with their purchases of the Company's securities during the Class Period.

48. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

49. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiff and the Class.

50. As a result of the foregoing, the market price of the Company's securities was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially

inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

51. Had Plaintiff and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company's and the Individual Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

52. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

53. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of the Company's securities during the Class Period.

COUNT II

Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

54. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

55. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

56. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the

Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

57. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company's securities.

58. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

59. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: February 25, 2019

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

/s/ Phillip Kim
Phillip Kim, Esq. (PK 9384)
Laurence M. Rosen, Esq. (LR 5733)
275 Madison Ave., 34th Floor
New York, New York 10016
Telephone: (212) 686-1060
Fax: (212) 202-3827
Email: pkim@rosenlegal.com
Email: lrosen@rosenlegal.com

Counsel for Plaintiff