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Table of ContentsUNITED STATESSECURITIES AND EXCHANGE COMMISSIONWashington, D.C. 20549Form 10-Q (Mark One)â˜’QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934For the quarterly period ended September 30, 2024orâ˜TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934For the transition period from Â to Â Commission File Number: 001-34186VANDA PHARMACEUTICALS INC. (Exact name of registrant as specified in its charter)Delaware03-0491827(State or other jurisdiction of incorporation or organization)(I.R.S. Employer Identification No.)2200 Pennsylvania Avenue NW, Suite 300E Washington, DC 20037 (202) 734-3400 (Registrantâ€™s telephone number, including area code)Securities registered pursuant to SectionÂ 12(b) of the Exchange Act:Title of Each ClassTrading Symbol(s)Name of Exchange on Which RegisteredCommon Stock, par value $0.001 per shareVNDAThe Nasdaq Global MarketSeries A Junior Participating Preferred Stock Purchase Right, par value $0.001 per share-The Nasdaq Global MarketIndicate by check mark whether the registrant (1)Â has filed all reports required to be filed by SectionÂ 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)Â has been subject to such filing requirements for the past 90 days.Â Â Â Â YesÂ Â xÂ Â Â Â NoÂ Â oIndicate 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 (Â§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).Â Â Â Â YesÂ Â xÂ Â Â Â NoÂ Â oIndicate 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 â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmaller reporting companyâ€ and â€œemerging growth companyâ€ in Rule 12b-2 of the Exchange Act.Â Large accelerated filerÂ˜Accelerated filerxNon-accelerated filerÂ˜SmallerÂ reportingÂ companyÂ˜EmergingÂ growthÂ companyÂ˜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 SectionÂ 13(a) of the Exchange Act.Â Â oIndicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).Â Â Â Â YesÂ Â Â˜Â Â Â Â NoÂ Â xAs of OctoberÂ 31, 2024, there were 58,308,144 shares of the registrantâ€™s common stock issued and outstanding.Table of ContentsVanda Pharmaceuticals Inc.Quarterly Report on Form 10-QFor the Quarter Ended September 30, 2024 Table of ContentsÂ PagePART I â€“ FINANCIAL INFORMATIONITEMÂ 1Financial Statements (Unaudited)5Condensed Consolidated Balance Sheets as of September 30, 2024 and December 31, 20235Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2024 and 20236Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2024 and 20237Condensed Consolidated Statements of Changes in Stockholdersâ€™ Equity for the three and nine months ended September 30, 2024 and 20238Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2024 and 202310Notes to Condensed Consolidated Financial Statements11ITEMÂ 2Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations26ITEMÂ 3Quantitative and Qualitative Disclosures about Market Risk37ITEMÂ 4Controls and Procedures38PARTÂ IIÂ â€“ OTHER INFORMATIONITEMÂ 1Legal Proceedings38ITEMÂ 1ARisk Factors38ITEMÂ 2Unregistered Sales of Equity Securities and Use of Proceeds39ITEMÂ 3Defaults Upon Senior Securities39ITEMÂ 4Mine Safety Disclosures39ITEMÂ 5Other Information39ITEMÂ 6Exhibits40Signatures412Table of ContentsCAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTSThis quarterly report on Form 10-Q (Quarterly Report) contains â€œforward-looking statementsâ€ 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, â€œbelieve,â€ â€œexpect,â€ â€œanticipate,â€ â€œestimate,â€ â€œintend,â€ â€œplan,â€ â€œproject,â€ â€œtarget,â€ â€œgoal,â€ â€œlikely,â€ â€œwill,â€ â€œwould,â€ and â€œcould,â€ 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 Quarterly Report may include, but are not limited to, statements about:â€¢our ability to commercialize FanaptÂ® (iloperidone) oral tablets for the acute treatment of manic or mixed episodes associated with bipolar I disorder;â€¢our ability to continue to generate United States (U.S.) sales of FanaptÂ® oral tablets for the treatment of schizophrenia;â€¢our ability to continue to commercialize HETLIOZÂ® (tasimelteon) capsules for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S., in light of existing and potential generic competition, and Europe and HETLIOZÂ® capsules and oral suspension (HETLIOZ LQÂ®) for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in the U.S.;â€¢our ability to obtain approval from the U.S. Food and Drug Administration (FDA) for HETLIOZÂ® beyond the currently approved indications;â€¢our ability to increase market awareness of Non-24 and SMS and market acceptance of HETLIOZÂ®;â€¢our ability to commercialize PONVORYÂ® (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;â€¢our ability to obtain approval from the FDA for PONVORYÂ® beyond the currently approved indications;â€¢our ability to obtain regulatory approval for tradipitant from the FDA;â€¢our level of success in commercializing FanaptÂ® and HETLIOZÂ® in new markets;â€¢our ability to overcome the continued reimbursement and patient access challenges we face as a result of third-party payor coverage;â€¢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;â€¢our dependence on third-party manufacturers to manufacture FanaptÂ®, HETLIOZÂ®, HETLIOZ LQÂ® and PONVORYÂ® in sufficient quantities and quality;â€¢our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;â€¢our ability to maintain rights to develop and commercialize our products under our license agreements;â€¢our ability to obtain and maintain regulatory approval of our products, and the labeling for any approved products;â€¢our expectations regarding the timing and success of preclinical studies and clinical trials;â€¢the safety and efficacy of our products;â€¢regulatory developments in the U.S., Europe and other jurisdictions;â€¢limitations on our ability to utilize some or all of our prior net operating losses and orphan drug and research and development credits;â€¢our expectations regarding the size and growth of the current and potential markets for our products and our ability to serve those markets;â€¢our expectations regarding trends with respect to our revenues, costs, expenses, liabilities and cash, cash equivalents and marketable securities;3Table of Contentsâ€¢our ability to identify or obtain rights to new products;â€¢our ability to attract and retain key scientific or management personnel;â€¢our expectations regarding the cost, time frame, outcome, insurance coverage and effects of any litigation or other dispute;â€¢our ability to obtain the capital necessary to fund our research and development or commercial activities;â€¢potential losses incurred from product liability claims made against us; andâ€¢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 Quarterly 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 Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations and our unaudited condensed consolidated financial statements contained in this Quarterly Report. In addition to the risks described in Part I, ItemÂ 1A, Risk Factors, of our annual report on Form 10-K (Annual Report) for the fiscal year ended December 31, 2023 and Item 1A, Risk Factors, of this Quarterly 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 FormÂ 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.4Table of ContentsPart I â€” FINANCIAL INFORMATIONÂ ITEMÂ 1Financial Statements (Unaudited)VANDA PHARMACEUTICALS INC.CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)Â (in thousands, except for share and per share amounts)September 30,2024December 31, 2023ASSETSCurrent assets:Cash and cash equivalents$100,497Â $135,821Â Marketable securities275,764Â 252,443Â Accounts receivable, net42,753Â 34,155Â Inventory1,614Â 1,357Â Prepaid expenses and other current assets11,759Â 9,170Â Total current assets432,387Â 432,946Â Property and equipment, net2,178Â 2,037Â Operating lease right-of-use assets6,016Â 7,103Â Intangible assets, net115,848Â 121,369Â Deferred tax assets79,363Â 75,000Â Non-current inventory and other9,323Â 9,985Â Total assets$645,115Â $648,440Â LIABILITIES AND STOCKHOLDERSâ€™ EQUITYCurrent liabilities:Accounts payable and accrued liabilities$39,304Â $38,460Â Product revenue allowances49,786Â 49,237Â Total current liabilities89,090Â 87,697Â Operating lease non-current liabilities5,486Â 7,006Â Other non-current liabilities9,316Â 8,827Â Total liabilities103,892Â 103,530Â Commitments and contingencies (Notes 9 and 14)Stockholdersâ€™ equity:Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding at September 30, 2024 and December 31, 2023â€”Â Â â€”Â Common stock, $0.001 par value; 150,000,000 shares authorized; 58,306,144 and 57,534,499 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively58Â 58Â Additional paid-in capital709,843Â 700,274Â Accumulated other comprehensive income (loss)702Â (30)Accumulated deficit(169,380)(155,392)Total stockholdersâ€™ equity541,223Â 544,910Â Total liabilities and stockholdersâ€™ equity$645,115Â $648,440Â The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.5Table of ContentsVANDA PHARMACEUTICALS INC.CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)Â Â Three Months EndedNine Months Ended(in thousands, except for share and per share amounts)September 30,2024September 30,2023September 30,2024September 30,2023Revenues:Net product sales$47,651Â $38,815Â $145,587Â $147,369Â Total revenues47,651Â 38,815Â 145,587Â 147,369Â Operating expenses:Cost of goods sold excluding amortization2,551Â 3,063Â 8,724Â 11,336Â Research and development16,776Â 16,600Â 54,591Â 52,484Â Selling, general and administrative37,573Â 24,767Â 107,132Â 89,270Â Intangible asset amortization1,751Â 380Â 5,521Â 1,137Â Total operating expenses58,651Â 44,810Â 175,968Â 154,227Â Loss from operations(11,000)(5,995)(30,381)(6,858)Other income 4,756Â 5,875Â 13,957Â 14,858Â Income (loss) before income taxes(6,244)(120)(16,424)8,000Â Provision (benefit) for income taxes(920)(257)(2,436)3,091Â Net income (loss)$(5,324)$137Â $(13,988)$4,909Â Net income (loss) per share:Basic(0.09)0.00Â (0.24)0.09Â Diluted(0.09)0.00Â (0.24)0.09Â Weighted average shares outstanding:Basic58,261,961Â 57,519,031Â 58,095,566Â 57,329,969Â Diluted58,261,961Â 57,595,344Â 58,095,566Â 57,512,225Â The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.6Table of ContentsVANDA PHARMACEUTICALS INC.CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) (Unaudited)Â Â Three Months EndedNine Months Ended(in thousands)September 30,2024September 30,2023September 30,2024September 30,2023Net income (loss)$(5,324)$137Â $(13,988)$4,909Â Other comprehensive income (loss):Net foreign currency translation gain (loss)36Â (18)14Â (6)Change in net unrealized gain (loss) on marketable securities1,283Â (109)924Â 301Â Tax benefit (provision) on other comprehensive income (loss)(287)25Â (206)(69)Other comprehensive income (loss), net of tax1,032Â (102)732Â 226Â Comprehensive income (loss)$(4,292)$35Â $(13,256)$5,135Â The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.7Table of ContentsVANDA PHARMACEUTICALS INC.CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERSâ€™ EQUITY (Unaudited)Â Common StockAdditionalPaid-inCapitalAccumulated OtherComprehensiveIncome (Loss)AccumulatedDeficitTotal(in thousands, except for share amounts)SharesParÂ ValueBalances at December 31, 202357,534,499Â $58Â $700,274Â (30)(155,392)$544,910Â Issuance of common stock from the exercise of stock options and settlement of restricted stock units662,024Â â€”Â Â â€”Â Â â€”Â Â â€”Â Â â€”Â Stock-based compensation expenseâ€”Â Â â€”Â 3,584Â Â â€”Â Â â€”Â 3,584Â Net lossâ€”Â Â â€”Â Â â€”Â Â â€”Â (4,146)(4,146)Other comprehensive loss, net of taxâ€”Â Â â€”Â Â â€”Â (353)â€”Â (353)Balances at March 31, 202458,196,523Â $58Â $703,858Â (383)(159,538)$543,995Â Issuance of common stock from the exercise of stock options and settlement of restricted stock units90,785Â â€”Â Â â€”Â Â â€”Â Â â€”Â Â â€”Â Stock-based compensation expenseâ€”Â Â â€”Â 2,986Â Â â€”Â Â â€”Â 2,986Â Net lossâ€”Â Â â€”Â Â â€”Â Â â€”Â (4,518)(4,518)Other comprehensive income, net of taxâ€”Â Â â€”Â Â â€”Â 53Â Â â€”Â 53Â Balances at June 30, 202458,287,308Â $58Â $706,844Â (330)(164,056)$542,516Â Issuance of common stock from the exercise of stock options and settlement of restricted stock units18,836Â â€”Â Â â€”Â Â â€”Â Â â€”Â Â â€”Â Stock-based compensation expenseâ€”Â Â â€”Â 2,999Â Â â€”Â Â â€”Â 2,999Â Net lossâ€”Â Â â€”Â Â â€”Â Â â€”Â (5,324)(5,324)Other comprehensive income, net of taxâ€”Â Â â€”Â Â â€”Â 1,032Â Â â€”Â 1,032Â Balances at September 30, 202458,306,144Â $58Â $709,843Â $702Â $(169,380)$541,223Â The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.8Table of ContentsVANDA PHARMACEUTICALS INC.CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERSâ€™ EQUITY (Unaudited) (Continued)Â Common StockAdditionalPaid-inCapitalAccumulated OtherComprehensive LossAccumulatedDeficitTotal(in thousands, except for share amounts)SharesParÂ ValueBalances at December 31, 202256,783,764Â $57Â $686,235Â $(1,193)$(157,901)$527,198Â Issuance of common stock from the exercise of stock options and settlement of restricted stock units657,228Â â€”Â Â â€”Â Â â€”Â Â â€”Â Â â€”Â Stock-based compensation expenseâ€”Â Â â€”Â 4,351Â Â â€”Â Â â€”Â 4,351Â Net incomeâ€”Â Â â€”Â Â â€”Â Â â€”Â 3,252Â 3,252Â Other comprehensive income, net of taxâ€”Â Â â€”Â Â â€”Â 938Â Â â€”Â 938Â Balances at March 31, 202357,440,992Â $57Â $690,586Â (255)(154,649)$535,739Â Issuance of common stock from the exercise of stock options and settlement of restricted stock units55,921Â â€”Â Â â€”Â Â â€”Â Â â€”Â Â â€”Â Stock-based compensation expenseâ€”Â Â â€”Â 3,249Â Â â€”Â Â â€”Â 3,249Â Net incomeâ€”Â Â â€”Â Â â€”Â 1,520Â 1,520Â Other comprehensive loss, net of taxâ€”Â Â â€”Â (610)â€”Â (610)Balances at June 30, 202357,496,913Â $57Â $693,835Â (865)(153,129)$539,898Â Issuance of common stock from the exercise of stock options and settlement of restricted stock units32,586Â 1Â (1)â€”Â Â â€”Â Â â€”Â Stock-based compensation expenseâ€”Â Â â€”Â 3,167Â Â â€”Â Â â€”Â 3,167Â Net incomeâ€”Â Â â€”Â Â â€”Â Â â€”Â 137Â 137Â Other comprehensive loss, net of taxâ€”Â Â â€”Â Â â€”Â (102)â€”Â (102)Balances at September 30, 202357,529,499Â $58Â $697,001Â (967)(152,992)$543,100Â The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.9Table of ContentsVANDA PHARMACEUTICALS INC.CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)Â Nine Months Ended(in thousands)September 30,2024September 30,2023Cash flows from operating activitiesNet income (loss)$(13,988)$4,909Â Adjustments to reconcile net income (loss) to net cash provided by operating activities:Depreciation of property and equipment638Â 715Â Stock-based compensation9,569Â 10,767Â Amortization of premiums and accretion of discounts on marketable securities(5,479)(7,053)Loss on sale of marketable securitiesâ€”Â 655Â Intangible asset amortization5,521Â 1,137Â Deferred income taxes(4,568)6,198Â Other non-cash adjustments, net1,643Â 2,772Â Changes in operating assets and liabilities:Accounts receivable(8,581)4,129Â Prepaid expenses and other assets(3,179)1,333Â Inventory78Â (344)Accounts payable and other liabilities3,835Â (14,315)Product revenue allowances571Â 5,630Â Net cash provided by (used in) operating activities(13,940)16,533Â Cash flows from investing activitiesAsset acquisition(4,229)â€”Â Purchases of property and equipment(276)(130)Purchases of marketable securities(272,369)(457,628)Sales and maturities of marketable securities255,451Â 489,485Â Net cash provided by (used in) investing activities(21,423)31,727Â Effect of exchange rate changes on cash, cash equivalents and restricted cash39Â (103)Net change in cash, cash equivalents and restricted cash(35,324)48,157Â Cash, cash equivalents and restricted cashBeginning of period136,290Â 135,498Â End of period$100,966Â $183,655Â The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.10Table of ContentsVANDA PHARMACEUTICALS INC.NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)1. Business Organization and PresentationBusiness OrganizationVanda Pharmaceuticals Inc. (the Company or Vanda) 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 Companyâ€™s commercial portfolio is currently comprised of three products, FanaptÂ® for the acute treatment of manic or mixed episodes associated with bipolar I disorder and the treatment of schizophrenia, HETLIOZÂ® 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), and PONVORYÂ® 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. HETLIOZÂ® 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: â€¢Milsaperidone (VHX-896), the active metabolite of FanaptÂ® (iloperidone), for the acute treatment of manic or mixed episodes associated with bipolar I disorder and for the treatment of schizophrenia and major depressive disorder; â€¢FanaptÂ®Â (iloperidone) long acting injectable (LAI) formulation for the treatment of schizophrenia; â€¢HETLIOZÂ®Â (tasimelteon) for the treatment of jet lag disorder, insomnia, pediatric insomnia, delayed sleep phase disorder (DSPD) and pediatric Non-24; â€¢PONVORYÂ® (ponesimod) for the treatment of psoriasis and ulcerative colitis;â€¢Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness and atopic dermatitis; â€¢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; â€¢VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of onychomycosis and hematologic malignancies and with potential use as a treatment for several oncology indications; â€¢VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, for the treatment of social/performance anxiety and psychiatric disorders; and â€¢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 the IGHMBP2 gene.Basis of PresentationThe accompanying unaudited condensed consolidated financial statements include the accounts of Vanda Pharmaceuticals Inc. and its wholly-owned subsidiaries and have been prepared in accordance with United States generally accepted accounting principles (GAAP) for interim financial information and the instructions to FormÂ 10-Q and ArticleÂ 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Companyâ€™s consolidated financial statements and accompanying notes included in the Companyâ€™s annual report on Form 10-K (Annual Report) for the fiscal year ended December 31, 2023. The financial information as of September 30, 2024 and for the three and nine months ended September 30, 2024 and 2023 is unaudited, but in the opinion of management, all adjustments considered necessary for a fair statement of the results for these interim periods have been included. All intercompany accounts and transactions have been eliminated in consolidation. The condensed consolidated balance sheet data as of December 31, 2023 was derived from audited financial statements but does not include all disclosures required by GAAP. The results of the Companyâ€™s operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or any future year or period. 2. Summary of Significant Accounting PoliciesThere have been no material changes to the significant accounting policies previously disclosed in the Annual Report. 11Table of ContentsUse of EstimatesThe 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 managementâ€™s evaluation could change. Actual results could differ from those estimates.Cash, Cash Equivalents and Restricted CashFor purposes of the Condensed Consolidated Balance Sheets and Condensed 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.Â Restricted cash relates primarily to amounts held as collateral for letters of credit for leases for office space at the Companyâ€™s Washington, D.C. headquarters.Â The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Condensed Consolidated Balance Sheets to the total end of period cash, cash equivalents and restricted cash reported within the Condensed Consolidated Statements of Cash Flows:(in thousands)September 30,2024September 30,2023Cash and cash equivalents$100,497Â $183,186Â Restricted cash included in non-current inventory and other469Â 469Â Total cash, cash equivalents and restricted cash$100,966Â $183,655Â Revenue from Net Product SalesThe Companyâ€™s net product sales consist of sales of FanaptÂ®, HETLIOZÂ® and PONVORYÂ®. Net sales by product for the three and nine months ended September 30, 2024 and 2023 were as follows:Â Three Months EndedNine Months Ended(in thousands)September 30,2024September 30,2023September 30,2024September 30,2023FanaptÂ® net product sales$23,919Â $21,315Â $67,648Â $68,274Â HETLIOZÂ® net product sales17,870Â 17,500Â 56,631Â 79,095Â PONVORYÂ® net product sales5,862Â â€”Â 21,308Â â€”Â Total net product sales$47,651Â $38,815Â $145,587Â $147,369Â The Companyâ€™s HETLIOZÂ® 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 at March 31, 2023. During the remainder of 2023, although there was continued destocking at specialty pharmacy customers, inventory levels remained elevated relative to inventory levels prior to the entrance of generic competition and remained elevated at March 31, 2024, June 30, 2024 and September 30, 2024. Going forward, HETLIOZÂ® net product sales may reflect lower unit sales as a result of reduction of the elevated inventory levels at specialty pharmacy customers or may be variable depending upon when specialty pharmacy customers need to purchase again. Further, HETLIOZÂ® net product sales will likely decline in future periods, potentially significantly, related to continued generic competition in the U.S. The Company constrained HETLIOZÂ® net product sales for the three and nine months ended September 30, 2024 and 2023 to an amount not probable of significant revenue reversal. The amount of revenue recognized during the three months ended September 30, 2024 and 2023 related to changes in estimates on revenue constrained during the second quarter of 2024 and 2023 was $0.8 million and $0.3 million, respectively. The amount of revenue recognized during the nine months ended September 30, 2024 related to changes in estimates on revenue constrained during the year ended December 31, 2023 was $1.4 million. HETLIOZÂ® 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.Major CustomersFanaptÂ® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. HETLIOZÂ® is available in the United States (U.S.) for distribution through a limited number of specialty pharmacies and is not available in retail pharmacies. PONVORYÂ® is available in the U.S. for distribution primarily through specialty distributors and 12Table of Contentsspecialty pharmacies. The Company invoices and records revenue when its customers, wholesalers, specialty pharmacies and specialty distributors, receive product from the third-party logistics warehouse, which is the point at which control is transferred to the customer. Outside the U.S., the Company has a distribution agreement for the commercialization of FanaptÂ® in Israel and sells HETLIOZÂ® in Germany. There were four major customers that each accounted for more than 10% of total revenues and, as a group, represented 68% of total revenues for the nine months ended September 30, 2024. There were four major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 60% of total accounts receivable at September 30, 2024. 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.Recent Accounting PronouncementsIn 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 the enhanced disclosures that will be required upon adoption in its Annual Report for the year ending December 31, 2024.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 Companyâ€™s consolidated financial statements.In November 2024, the FASB issued ASU 2024-03, Income Statementâ€”Reporting Comprehensive Incomeâ€”Expense Disaggregation Disclosures (Topic 220-40), which addresses the disaggregation of income statement expenses. This standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The Company is currently evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.3. PONVORYÂ® 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 PONVORYÂ® from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company, and the closing of the transaction took place simultaneously with signing. PONVORYÂ® 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. 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 Companyâ€™s activities pertaining to PONVORYÂ® after the closing. Simultaneously and in connection with the Purchase Agreement, the parties also entered into certain supporting agreements, including a customary transition agreement, pursuant to which, during a transition period, Janssen will continue PONVORYÂ® operations. The Company announced in May 2024 that ownership of the U.S. New Drug Application (NDA) and Investigational New Drug applications for PONVORYÂ® had been transferred to Vanda from a Johnson & Johnson Company, fully allowing the Company to commercialize PONVORYÂ® in the U.S. The acquisition of PONVORYÂ® 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 PONVORYÂ® product rights. The PONVORYÂ® 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 Canadian rights to PONVORYÂ®. The straight-line method is used to amortize the intangible asset, as disclosed in Note 7, Intangible Assets.13Table of Contents4. Marketable SecuritiesThe following is a summary of the Companyâ€™s available-for-sale marketable securities as of September 30, 2024, which all have contractual maturities of less than two years:AmortizedCostGrossUnrealizedGainsGrossUnrealizedLossesFairMarketValue(in thousands)U.S. Treasury and government agencies$172,505Â $797Â (56)173,246Â Corporate debt102,412Â 108Â (2)102,518Â Total marketable securities$274,917Â $905Â (58)275,764Â The following is a summary of the Companyâ€™s available-for-sale marketable securities as of December 31, 2023, which all have contractual maturities of less than two years:AmortizedCostGrossUnrealizedGainsGrossUnrealizedLossesFairMarketValue(in thousands)U.S. Treasury and government agencies$185,168Â $227Â (280)185,115Â Corporate debt67,352Â 2Â (26)67,328Â Total marketable securities$252,520Â $229Â (306)252,443Â 5. Fair Value MeasurementsAuthoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:â€¢Level Â 1 â€” defined as observable inputs such as quoted prices in active marketsâ€¢Level Â 2 â€” defined as inputs other than quoted prices in active markets that are either directly or indirectly observableâ€¢Level Â 3 â€” defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptionsThe Companyâ€™s assets classified in Level Â 1 and Level Â 2 as of September 30, 2024 and December 31, 2023 consist of cash equivalents and available-for-sale marketable securities. The valuation of Level Â 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 Â 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 Â 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 September 30, 2024, as follows:Â Â Fair Value Measurement as of September 30, 2024 UsingTotal Fair ValueQuoted Prices inActive Â MarketsÂ forIdentical AssetsSignificantÂ OtherObservable Â InputsSignificantUnobservableInputs(in thousands)(Level 1)(Level 2)(Level 3)U.S. Treasury and government agencies$173,246Â $173,246Â $â€”Â $â€”Â Corporate debt102,518Â $â€”Â 102,518Â â€”Â Total assets measured at fair value$275,764Â $173,246Â $102,518Â $â€”Â 14Table of ContentsThe 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 UsingTotal Fair ValueQuoted Prices inActive Â MarketsÂ forIdentical AssetsSignificantÂ OtherObservable Â InputsSignificantUnobservableInputs(in thousands)(Level 1)(Level 2)(Level 3)U.S. Treasury and government agencies$209,103Â $209,103Â $â€”Â $â€”Â Corporate debt107,108Â â€”Â 107,108Â â€”Â Total assets measured at fair value$316,211Â $209,103Â $107,108Â $â€”Â Total assets measured at fair value as of September 30, 2024 include no cash equivalents. Total assets measured at fair value as of December 31, 2023 include $63.8 million 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. InventoryInventory consisted of the following as of September 30, 2024 and December 31, 2023:(in thousands)September 30,2024December 31, 2023Current assetsWork-in-process$52Â $27Â Finished goods1,562Â 1,330Â Total inventory, current$1,614Â $1,357Â Non-Current assetsRaw materials$934Â $934Â Work-in-process6,496Â 7,177Â Finished goods494Â 737Â Total inventory, non-current7,924Â 8,848Â Total inventory$9,538Â $10,205Â 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 the risk of excess inventory and product expiry by evaluating current and future product demand relative to product shelf life, taking into account all possible alternative uses for the inventory available in the ordinary course of business. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance, patient usage, and generic competition. The Companyâ€™s inventory balance included $2.1 million and $3.0 million of FanaptÂ® product and $7.3 million and $7.2 million of HETLIOZÂ® product as of September 30, 2024 and December 31, 2023, respectively.7. Intangible AssetsHETLIOZÂ®.Â In January 2014, the Company announced that the FDA had approved the NDA for HETLIOZÂ®. 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 HETLIOZÂ®Â 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 HETLIOZÂ®Â 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. PONVORYÂ®. On December 7, 2023, the Company acquired the U.S. and Canadian rights to PONVORYÂ® from Janssen. The total purchase price was allocated to the acquired intangible asset for the U.S. and Canadian rights to PONVORYÂ®. See Note 3, PONVORYÂ® Acquisition, for additional details. The PONVORYÂ® intangible asset is being amortized on a straight-line basis over the estimated economic useful life of the related product rights. During the first quarter of 2024, the estimated useful life 15Table of Contentsfor the PONVORYÂ® intangible asset was changed from 2035 to 2042 based on a change in the estimated economic useful life of the related product rights.The following is a summary of the Companyâ€™s amortizing intangible assets as of September 30, 2024:Â Â September 30, 2024(in thousands)EstimatedUseful LifeGrossCarryingAmountAccumulatedAmortizationNetCarryingAmountHETLIOZÂ®2035$33,000Â $17,034Â $15,966Â PONVORYÂ®2042104,894Â 5,012Â 99,882Â Total amortizing intangible assets$137,894Â $22,046Â $115,848Â The following is a summary of the Companyâ€™s amortizing intangible assets as of December 31, 2023:Â Â December 31, 2023(in thousands)EstimatedUseful LifeGrossCarryingAmountAccumulatedAmortizationNetCarryingAmountHETLIOZÂ®2035$33,000Â $15,937Â $17,063Â PONVORYÂ®2035104,894Â 588Â 104,306Â Total amortizing intangible assets$137,894Â $16,525Â $121,369Â As of September 30, 2024 and December 31, 2023, the Company also had $27.9 million of fully amortized intangible assets related to FanaptÂ®. Intangible assets are amortized over their estimated useful economic life using the straight-line method. Amortization expense was $1.8 million and $0.4 million for the three months ended September 30, 2024 and 2023, respectively. Amortization expense was $5.5 million and $1.1 million for the nine months ended September 30, 2024 and 2023, respectively. The following is a summary of the future intangible asset amortization schedule as of September 30, 2024:(in thousands)Total20242025202620272028ThereafterHETLIOZÂ®$15,966Â $365Â $1,463Â $1,463Â $1,463Â $1,463Â $9,749Â PONVORYÂ®99,882Â 1,387Â 5,544Â 5,544Â 5,544Â 5,544Â 76,319Â Total future amortizing intangible assets$115,848Â $1,752Â $7,007Â $7,007Â $7,007Â $7,007Â $86,068Â 8. Accounts Payable and Accrued LiabilitiesThe following is a summary of the Companyâ€™s accounts payable and accrued liabilities as of September 30, 2024 and December 31, 2023:(in thousands)September 30,2024December 31, 2023Research and development expenses$12,861Â $15,691Â Consulting and other professional fees10,013Â 4,404Â Compensation and employee benefits6,687Â 6,413Â Operating lease liabilities2,454Â 2,398Â Royalties payable1,480Â 2,409Â Accounts payable and other accrued liabilities5,809Â 7,145Â Total accounts payable and accrued liabilities$39,304Â $38,460Â 9. Commitments and ContingenciesGuarantees and IndemnificationsThe 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 Companyâ€™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 Companyâ€™s products. The term of these indemnification agreements is generally perpetual from the date of 16Table of Contentsexecution 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 AgreementsThe Companyâ€™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.FanaptÂ®.Â Pursuant to the terms of a settlement agreement with Novartis Pharma AG (Novartis), Novartis transferred all U.S. and Canadian rights in the FanaptÂ® franchise to the Company on DecemberÂ 31, 2014. The Company paid directly to Sanofi S.A. (Sanofi) a fixed royalty of 3% of net sales through DecemberÂ 2019 related to manufacturingÂ know-how.Â The Company is also obligated to pay Sanofi a fixed royalty on FanaptÂ®Â net sales equal to 6% on SanofiÂ know-howÂ 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. HETLIOZÂ®.Â 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 HETLIOZÂ®. As of September 30, 2024, 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 7, Intangible Assets). The Company has no remaining milestone obligations to BMS. Additionally, the Company is obligated to make royalty payments on HETLIOZÂ®Â net sales to BMS. The royalty period in each territory where the Company commercializes HETLIOZÂ®Â 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 decreased from 10% to 5% in December 2022. This U.S. royalty ended 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 theÂ mid-twenties.Â The Company is obligatedÂ to use its commercially reasonable efforts to develop and commercialize HETLIOZÂ®.Tradipitant.Â 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 anÂ NK-1 receptorÂ 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 September 30, 2024, 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 September 30, 2024, 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 asÂ single-digitÂ royalties on net sales. As of September 30, 2024, the Company has paid UCSF $1.6 million in upfront fees and development milestones. As of September 30, 2024, remaining milestone obligations include $11.9 millionÂ for development milestones andÂ $33.0 millionÂ for future regulatory approval and sales milestones. Included in theÂ $11.9 millionÂ of development milestones are $1.1 million of milestone obligations due upon the conclusion of clinical studies for each licensed product but not to exceedÂ $3.2 millionÂ in total for the CFTR portfolio.VQW-765.Â In connection with a settlement agreement with Novartis relating to FanaptÂ®, 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,Â a Phase IIÂ alpha-7Â nicotinic acetylcholine receptor partial agonist. Pursuant to the license agreement, the Company is obligated to use its commercially reasonable efforts to develop and commercializeÂ VQW-765Â and is responsible 17Table of Contentsfor 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 theÂ mid-teens.Other AgreementsOlipass. In September 2022, the Company entered into an agreement with OliPass Corporation (OliPass) to jointly develop a set of ASO molecules based on OliPassâ€™ proprietary modified peptide nucleic acids. As consideration for entering into the arrangement, the Company paid OliPass an upfront fee of $3.0Â million, which was recorded as research and development expense in 2022. The Company is funding the research and development activities and has the option to license jointly developed intellectual property upon successful development. Shareholder Rights Plan. On April 17, 2024, the Companyâ€™s board of directors authorized and declared a dividend distribution of one right (each, a Right) for each outstanding share of common stock of the Company to stockholders of record as of the close of business on April 29, 2024 (the Record Date). Each Right entitles the registered holder to purchase from the Company, subject to certain conditions which have not yet occurred, one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share (the Preferred Stock), of the Company at an exercise price of $25.00 (the Exercise Price), subject to adjustment. The complete terms of the Rights are set forth in a Rights Agreement, dated as of April 17, 2024, between the Company and Equiniti Trust Company, LLC, as rights agent (the Rights Agent), as amended by that certain Amendment No. 1 to the Rights Agreement, and that certain Amendment No. 2 to the Rights Agreement, each, by and between the Company and the Rights Agent (as amended, the Rights Agreement).In general terms, subject to certain enumerated exceptions, the Rights Agreement works by imposing a significant penalty upon any person or group that acquires beneficial ownership of 10% or more of the shares of common stock without the prior approval of the board of directors. In general, any person will be deemed to beneficially own any securities (a) as to which such person has any agreement,

arrangement or understanding with another person for the purpose of acquiring, holding, voting or disposing of any shares of Common Stock or (b) that are the subject of a derivative transaction or constitute a derivative security. As a result, the overall effect of the Rights Agreement and the issuance of the Rights may be to render more difficult or discourage a merger, tender or exchange offer or other business combination involving the Company that is not approved by the board of directors. However, neither the Rights Agreement nor the Rights should interfere with any merger, tender or exchange offer or other business combination approved by the board of directors.Lease Agreements. In August 2024, the Company entered into a master lease agreement for vehicles to be utilized by the Company's sales force. As of September 30, 2024, none of the individual vehicle leases had been executed, none of the vehicles had been delivered, and no amounts have been paid pertaining to the vehicle leases. The individual car leases will commence upon delivery of the vehicles, which is expected to begin in the fourth quarter of 2024. Total fixed payments under this contract are estimated to total $5.5Â million, payable over initial terms of three years, and subject to change upon finalization of each vehicle lease contract. For further information regarding the Company's lease agreements, see Note 8, Leases, to the condensed consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.Purchase CommitmentsIn 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 daysâ€™ 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 Companyâ€™s contractors in closing out work in progress as of the effective date of termination. The Companyâ€™s non-cancellable purchase commitments for agreements longer than one year primarily relate to commitments for data services. 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.10. Accumulated Other Comprehensive Income (Loss)The accumulated balances related to each component of other comprehensive income (loss), net of taxes, were as follows as of September 30, 2024 and December 31, 2023:(in thousands)September 30,2024December 31, 2023Foreign currency translation$35Â $21Â Unrealized gain (loss) on marketable securities 667Â (51)Accumulated other comprehensive income (loss)$702Â $(30)18Table of Contents11. Stock-Based CompensationAs of September 30, 2024, there were 7,648,463 shares subject to outstanding options and restricted stock units (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 Companyâ€™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 Companyâ€™s stockholders. There is a total of 15,690,000 shares of common stock authorized for issuance under the 2016 Plan, 4,655,745 shares of which remained available for future grant as of September 30, 2024.Stock OptionsThe 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 directorâ€™s service terminates as a result of the directorâ€™s death or total and permanent disability. As of September 30, 2024, $3.8 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 0.9 years. No option awards are classified as a liability as of September 30, 2024.A summary of option activity under the Plans for the nine months ended September 30, 2024 follows:(in thousands, except for share and per share amounts)NumberÂ ofSharesWeightedÂ AverageExerciseÂ PriceÂ atGrant DateWeightedÂ AverageRemainingÂ Term(Years)AggregateIntrinsicValueOutstanding at December 31, 20234,792,506Â $12.95Â 6.00$â€”Â Granted190,514Â 5.41Â Expired(58,253)11.39Â Outstanding at September 30, 20244,924,767Â 12.67Â 5.48â€”Â Exercisable at September 30, 20243,973,865Â 13.65Â 4.81â€”Â Vested and expected to vest at September 30, 20244,856,293Â 12.75Â 5.44â€”Â The weighted average grant date fair value of options granted was $2.95 and $3.53 per share for the nine months ended September 30, 2024 and 2023. There were no proceeds from the exercise of stock options for the nine months ended September 30, 2024 and 2023. Restricted Stock UnitsAn RSU is a stock award that entitles the holder to receive shares of the Companyâ€™s common stock as the award vests. The fair value of each RSU is based on the closing price of the Companyâ€™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 September 30, 2024, $13.9 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.6 years. No RSUs are classified as a liability as of September 30, 2024.19Table of ContentsA summary of RSU activity for the Plans for the nine months ended September 30, 2024 is as follows:Number ofSharesWeightedAverageGrantÂ Date FairÂ ValueUnvested at December 31, 20231,905,310Â $10.87Â Granted1,638,903Â 4.47Â Forfeited(47,872)10.15Â Vested(772,645)11.53Â Unvested at September 30, 20242,723,696Â 6.84Â The grant date fair value for the 772,645 shares underlying RSUs that vested during the nine months ended September 30, 2024 was $8.9 million.Stock-Based Compensation ExpenseStock-based compensation expense recognized for the three and nine months ended September 30, 2024 and 2023 was comprised of the following:Â Three Months EndedNine Months Ended(in thousands)September 30,2024September 30,2023September 30,2024September 30,2023Research and development$703Â $739Â $2,241Â $2,538Â Selling, general and administrative2,296Â 2,428Â 7,328Â 8,229Â Total stock-based compensation expense$2,999Â $3,167Â $9,569Â $10,767Â 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 Companyâ€™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 nine months ended September 30, 2024 and 2023 were as follows:Â Nine Months EndedSeptember 30, 2024September 30,2023Expected dividend yield0Â %0Â %Weighted average expected volatility50Â %47Â %Weighted average expected term (years)6.276.16Weighted average risk-free rate4.52Â %3.89Â %12. Income TaxesFor the three months ended September 30, 2024 and 2023, the Company recorded an income tax benefit ofÂ $0.9 million and $0.3 million, respectively. The income tax benefit for the three months ended September 30, 2024 and 2023 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $0.2Â million.For the nine months ended September 30, 2024 and 2023, the Company recorded an income tax benefit ofÂ $2.4Â million and a provision for income taxes of $3.1Â million, respectively. The income tax expense (benefit) for the nine months ended September 30, 2024 and 2023 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $1.0 million and $2.1 million, respectively.The Company assesses the need for a valuation allowance against its 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 or all of the deferred tax assets will not be realized. The analysis is highly dependent upon historical and projected pretax income. As of September 30, 2024, after considering all available positive and negative evidence, including but not limited to cumulative income in recent periods, historical, current and future projected results and significant risks and uncertainties related to forecasts, the Company concluded, consistent with prior 20Table of Contentsperiods, that it was more likely than not that substantially all of its deferred tax assets in the U.S. are realizable in future periods. The Company maintains a valuation allowance against certain state net deferred tax assets. The Company generated a pretax loss for the nine months ended September 30, 2024. If the Company continues to generate pretax losses and if the Company's projections indicate pretax losses in future periods, the conclusion about the appropriateness of the valuation allowance could change in a future period. An increase in the valuation allowance would result in a non-cash income tax expense during the period of change. The potential timing and amount of any future valuation allowance has yet to be determined and requires an analysis that is highly dependent upon historical and future projected earnings, among other factors. Any such adjustment could have a material impact on the Companyâ€™s results of operations but not a material impact on the Company's cash position.13. Earnings per ShareBasic earnings per share (EPS) is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding. Diluted EPS is computed by dividing the net income (loss) 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 (loss) per share of common stock for the three and nine months ended September 30, 2024 and 2023:Â Three Months EndedNine Months Ended(in thousands, except for share and per share amounts)September 30,2024September 30,2023September 30,2024September 30,2023Numerator:Net income (loss)$(5,324)$137Â $(13,988)$4,909Â Denominator:Weighted average shares outstanding, basic58,261,961Â 57,519,031Â 58,095,566Â 57,329,969Â Effect of dilutive securitiesâ€”Â 76,313Â â€”Â 182,256Â Weighted average shares outstanding, diluted58,261,961Â 57,595,344Â 58,095,566Â 57,512,225Â Net income (loss) per share, basic and diluted:Basic(0.09)0.00Â (0.24)0.09Â Diluted(0.09)0.00Â (0.24)0.09Â Antidilutive securities excluded from calculations of diluted net income (loss) per share6,383,154Â 6,724,127Â 6,603,367Â 6,526,562Â The Company incurred a net loss for the three and nine months ended September 30, 2024 causing inclusion of any potentially dilutive securities to have an anti-dilutive effect, resulting in dilutive loss per share and basic loss per share attributable to common stockholders being equivalent.14. Legal MattersHETLIOZÂ®. 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 HETLIOZÂ® Defendants) asserting that U.S. Patent Nos. RE46,604 (â€˜604 Patent), 9,060,995, 9,539,234, 9,549,913, 9,730,910 (â€˜910 Patent), 9,844,241, 10,071,977, 10,149,829 (â€˜829 Patent), 10,376,487 (â€˜487 Patent), 10,449,176, 10,610,510, 10,610,511, 10,829,465, and 10,611,744 will be infringed by the HETLIOZÂ® Defendantsâ€™ generic versions of HETLIOZÂ® for which they were seeking FDA approval. As initially disclosed in the Companyâ€™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 MSNâ€™s generic version of HETLIOZÂ® in the U.S. effective as of March 13, 2035, unless prior to that date the Company obtains pediatric exclusivity for HETLIOZÂ®, 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 HETLIOZÂ® earlier under certain limited circumstances. In January 2023, MSN and its commercial partner, Amneal Pharmaceuticals, Inc. (Amneal), informed the Company of their belief that such circumstances have occurred and have since launched their generic 21Table of Contentsversion. The Company disagreed with this position and sought to defend its legal rights to exclusivity for HETLIOZÂ®. The consolidated lawsuits against the remaining HETLIOZÂ® Defendants were tried in March 2022.In December 2022, the Delaware District Court ruled that Teva and Apotex did not infringe the â€˜604 Patent, and that the asserted claims of the â€˜604, â€˜910, â€˜829 and â€˜487 Patents were invalid. In December 2022, the Company appealed the Delaware District Courtâ€™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 Courtâ€™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 Companyâ€™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 Circuitâ€™s decision. In April 2024, the U.S. Supreme Court denied the Companyâ€™s petition for a writ of certiorari.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 (â€˜129 Patent), will be infringed by Tevaâ€™s and Apotexâ€™ generic versions of HETLIOZÂ®, 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 FDAâ€™s approval of Tevaâ€™s and Apotexâ€™ generic versions of HETLIOZÂ® be a date that is no earlier than the expiration of the â€˜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 HETLIOZÂ® until the expiration of the â€˜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. In April 2023, Teva and Apotex moved for judgment on the pleadings. In June 2024, the Delaware District Court denied those motions, allowing the Companyâ€™s lawsuit to proceed. The Companyâ€™s lawsuit remains pending.In January 2023, the Company filed a lawsuit in the NJ District Court against Teva challenging Tevaâ€™s advertising and marketing practices related to its at risk launch of its generic version of HETLIOZÂ® for the single indication of Non-24. The Company believes that Tevaâ€™s advertising and marketing practices related to its generic version of HETLIOZÂ® 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. The Companyâ€™s lawsuit remains pending. 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 FDAâ€™s approval of Tevaâ€™s Abbreviated New Drug Application (ANDA) for its generic version of HETLIOZÂ® 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 HETLIOZÂ® includes Braille, but Tevaâ€™s generic version does not. On this basis, the Company believes that Tevaâ€™s approved labeling does not comply with applicable requirements. The Company has asked the DC District Court to, among other things, vacate the FDAâ€™s approval of Tevaâ€™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 HETLIOZÂ® 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 FDAâ€™s July 2023 denial of the Companyâ€™s citizen petition, originally filed with the FDA in January 2023. In April 2024, the Company filed a motion for summary judgment. The Companyâ€™s lawsuit remains pending.In September 2023, the Company filed a lawsuit in the DC District Court against the FDA challenging the FDAâ€™s approval of MSNâ€™s ANDA for its generic version of HETLIOZÂ® capsules under the APA, the FDCA, FDA regulations and the Appointments Clause of the U.S. Constitution. The Company believes that MSNâ€™s underlying approval data, particularly its bioequivalence studies, are faulty. On this basis, the Company asked the DC District Court to, among other things, vacate the FDAâ€™s approval of MSNâ€™s ANDA, declare that the approval of the ANDA was unlawful, arbitrary, and capricious, is unconstitutional under the Appointments Clause, and compel the FDA to order MSN to recall its generic HETLIOZÂ® product. In December 2023, the Company filed a motion for summary judgment. In January 2024, the FDA opposed the Companyâ€™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 issued an order compelling the FDA to serve the administrative record and has set deadlines for further proceedings. In April 2024, the Company filed a motion for summary judgment. In July 2024, the DC District Court held an oral argument on the motion to dismiss that the FDA filed in January 2024, which the Company opposed in February 2024. In September 2024, the DC District Court granted in part the FDAâ€™s motion to dismiss as to the Companyâ€™s APA claims and denied the FDAâ€™s motion to

dismiss as to the Companyâ€™s claims under the Appointments Clause. The Companyâ€™s lawsuit remains pending.22Table of ContentsIn April 2024, the Company filed a lawsuit in the Delaware District Court against MSN, Amneal, and Impax alleging claims for false advertising in violation of the Lanham Act and unfair competition under several state laws as well as claims for breach of express representation and fraudulent inducement of a license agreement. In July 2024, the defendants filed a motion to dismiss and in September 2024, the Company opposed the motion. The Companyâ€™s lawsuit remains pending.HETLIOZ LQÂ®. In July 2024, the Company filed a Hatch-Waxman lawsuit against MSN in the Delaware District Court asserting that U.S. Patent Nos. 10,179,119, 11,266,622, 11,285,129, 11,850,229, 10,610,510, 10,980,770, and 11,759,446 (together, the Asserted Patents) will be infringed by MSNâ€™s generic version of HETLIOZ LQÂ® for which MSN is seeking FDA approval. The Company has asked the Delaware District Court to, among other things, enter judgment that MSN has infringed at least one claim of each of the Asserted Patents by submitting or causing to be submitted its ANDA to obtain FDA approval for the commercial manufacture, use, import, offer for sale and/or sale in the U.S. of its generic version of HETLIOZ LQÂ® before the expiration of each of the Asserted Patents, enter judgment that the use of MSNâ€™s generic version of HETLIOZ LQÂ® in the U.S. before the expiration of each of the Asserted Patents will directly infringe at least one claim of each of the Asserted Patents, order that the effective date of any approval by the FDA of MSNâ€™s generic version of HETLIOZ LQÂ® be a date that is no earlier than the expiration of the last expiring Asserted Patent(s), or such later date as the Court may determine, enjoin MSN from the commercial manufacture, use, import, offer for sale and/or sale of its generic version of HETLIOZ LQÂ® until the expiration of each of the Asserted Patents or such later date as the Court may determine, and award monetary damages, to the extent applicable. The Companyâ€™s lawsuit remains pending.Other Matters. From April 2022 to July 2024, the Company filed eighteen 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 FDAâ€™s denial of the Companyâ€™s supplemental New Drug Application (sNDA) for HETLIOZÂ® 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, HETLIOZÂ® and FanaptÂ®; a warning letter that the FDA sent to the Company concerning its webpages for HETLIOZÂ® and FanaptÂ®; the FDAâ€™s removal of a clinical trials design presentation from its website; discipline reviews relating to the FDAâ€™s evaluations of the Companyâ€™s sNDA for HETLIOZÂ® and a third-party sNDA for jet lag; internal standard operating procedures or guidance relating to the FDAâ€™s processing of incoming FOIA requests; and bioequivalence and other study reports submitted relating to the FDAâ€™s consideration of tasimelteon ANDAs. Five of these lawsuits have since been resolved in the Companyâ€™s favor, one is pending resolution and the other twelve remain outstanding. The FDA has failed to respond and provide the requested documents within the statutory timeframe with respect to each of these twelve 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 CMSâ€™ rule broadly interpreting the defined terms â€œline extensionâ€ and â€œnew formulationâ€ 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 Companyâ€™s products would be treated as line extensions and new formulations subject to enhanced rebates, despite the statutory text and CMSâ€™ 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 CMSâ€™ interpretation of the terms was reasonable and consistent with Congressâ€™ 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. In April 2024, the Fourth Circuit ruled against the Company. In September 2024, the Company filed a petition for a writ of certiorari with the U.S. Supreme Court to review the Fourth Circuitâ€™s decision.In May 2022, the Company filed a lawsuit in the DC District Court against the FDA challenging the FDAâ€™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 Companyâ€™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 FDAâ€™s denial is unlawful. The Company has asked the DC District Court to, among other things, set aside and vacate the FDAâ€™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 23Table of Contentsfor the District of Columbia Circuit and in September 2024, the Court of Appeals held an oral argument. 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 Companyâ€™s sNDA for HETLIOZÂ® 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 in part the Companyâ€™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 Companyâ€™s application or commence a hearing on or before March 5, 2024. In March 2024, the Company and the FDA filed a consent motion for entry of final judgment in the Companyâ€™s favor on its Administrative Procedure Act claim for the FDAâ€™s unreasonable delay in resolving the hearing request.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 Companyâ€™s trade secrets and confidential information. The Company believes that the FDA violated the Fifth Amendmentâ€™s due process clause by improperly providing confidential details from the Companyâ€™s drug master files for HETLIOZÂ® and FanaptÂ® to generic drug manufacturers during the FDAâ€™s review of the manufacturersâ€™ ANDAs. The Company has asked the Federal Claims Court to, among other things, declare that the FDAâ€™s disclosure of the Companyâ€™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 governmentâ€™s motion, allowing the Companyâ€™s takings claim to proceed. The Companyâ€™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 FDAâ€™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 Companyâ€™s sNDA for HETLIOZÂ® 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 FDAâ€™s complete response letter and 60-day filing regulations unlawful. In June 2024, the Company filed a motion for summary judgment and the FDA published a notice of opportunity for a hearing. In July 2024, the FDA opposed the Companyâ€™s motion for summary judgment. In September 2024, the DC District Court held an oral argument on the dispositive cross motions. The Company's lawsuit remains pending.In March 2024, the Company filed a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit (DC Circuit) seeking review of the FDAâ€™s final order refusing to hold a hearing or to approve the Companyâ€™s sNDA for HETLIOZÂ® in the treatment of jet lag disorder. Under the FDCA, the FDA has an obligation to either approve an sNDA or to hold a hearing on the applicationâ€™s approvability. The Companyâ€™s petition asks the DC Circuit to set aside the FDAâ€™s order refusing to hold a hearing and refusing approval. The Companyâ€™s petition remains pending.On April 22, 2024, a purported stockholder of the Company filed a lawsuit in the Court of Chancery of the State of Delaware (Delaware Chancery Court) against the members of the Companyâ€™s board of directors and the Rights Agent, along with the Company as nominal defendant (collectively, the Defendants), captioned Steamfitters Local 449 Pension Fund v. Mihael H. Polymeropoulos, et al., CA No. 2024-0416-KSJM. The lawsuit contended, among other things, that the members of the Companyâ€™s board of directors breached their fiduciary duties in adopting the Rights Agreement. The lawsuit sought relief declaring, in part, that provisions of the Rights Agreement be deemed unenforceable and sought to enjoin the use of such provisions as well as damages, costs, and other remedies, and also sought to enjoin for 30 days the Companyâ€™s 2024 Annual Meeting of Stockholders (the Annual Meeting) that was held on May 17, 2024. At a hearing on May 7, 2024, the Delaware Chancery Court denied the plaintiffâ€™s request to enjoin the Annual Meeting. A three-day trial in the case was scheduled to begin on November 4, 2024. On August 7, 2024, the Company amended the Rights Agreement to, among other things, clarify certain of the provisions that were the subject of the lawsuit. On August 12, 2024, the parties filed with the Delaware Chancery Court a stipulation and order dismissing the lawsuit with prejudice, pursuant to which, the plaintiff agreed that the amendment to the Rights Agreement mooted the plaintiffâ€™s claims. The plaintiff filed a petition in the Delaware Chancery Court for an award of attorneyâ€™s fees and reimbursement of expenses, which the Company intends to oppose. The Company does not anticipate that 24Table of Contentsthis litigation will have a material adverse effect on its business, results of operations or financial condition and the Company believes it is entitled to coverage under its relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient to cover any such award.In August 2024, the Company filed a lawsuit against the FDA in the DC District Court challenging FDA decisionmakersâ€™ authority under the Appointments Clause of the U.S. Constitution to render a decision on Vandaâ€™s new drug application for tradipitant to treat symptoms of gastroparesis. In September 2024, the Company filed a motion for a preliminary injunction to enjoin the FDA from subjecting Vandaâ€™s NDA for tradipitant for the treatment of symptoms of gastroparesis to a final decision prior to the PDUFA target date of September 18, 2024. In September 2024, the DC District Court denied the motion. The Companyâ€™s lawsuit remains pending.25Table of ContentsITEMÂ 2Managementâ€™s Discussion and Analysis of Financial Condition and Results of OperationsOverviewVanda Pharmaceuticals Inc. (we, our, us 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, FanaptÂ® for the acute treatment of manic or mixed episodes associated with bipolar I disorder and the treatment of schizophrenia, HETLIOZÂ® 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), and PONVORYÂ® 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. HETLIOZÂ® 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, we have a number of drugs in development, including:â€¢Milsaperidone (VHX-896), the active metabolite of FanaptÂ® (iloperidone), for the acute treatment of manic or mixed episodes associated with bipolar I disorder and for the treatment of schizophrenia and major depressive disorder;â€¢FanaptÂ®Â (iloperidone) long acting injectable (LAI) formulation for the treatment of schizophrenia;â€¢HETLIOZÂ®Â (tasimelteon) for the treatment of jet lag disorder, insomnia, pediatric insomnia, delayed sleep phase disorder (DSPD) and pediatric Non-24;â€¢PONVORYÂ® (ponesimod) for the treatment of psoriasis and ulcerative colitis;â€¢Tradipitant (VLY-686), a small molecule neurokinin-1 (NK-1) receptor antagonist, for the treatment of gastroparesis, motion sickness and atopic dermatitis;â€¢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; â€¢VTR-297, a small molecule histone deacetylase (HDAC) inhibitor for the treatment of onychomycosis and hematologic malignancies and with potential use as a treatment for several oncology indications; â€¢VQW-765, a small molecule nicotinic acetylcholine receptor partial agonist, for the treatment of social/performance anxiety and psychiatric disorders; andâ€¢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 the IGHMBP2 gene.Operational HighlightsPsychiatry Portfolioâ€¢FanaptÂ®: We initiated the commercial launch of FanaptÂ® for the acute treatment of bipolar I disorder in adults in the third quarter of 2024, which included the expansion of our existing sales force and the introduction of prescriber awareness and comprehensive marketing programs. Several lead indicators suggest a strong initial market response including new patient starts as reflected by new to brand prescriptions (NBRx), increasing by over 90% in the third quarter of 2024 as compared to the third quarter of 2023.â€¢Milsaperidone: We expect to submit a New Drug Application (NDA) for milsaperidone (also known as VHX-896 and P-88), the active metabolite of FanaptÂ®, for the treatments of schizophrenia and acute bipolar I disorder to the FDA in early 2025. We expect to initiate a Phase III program for milsaperidone for major depressive disorder (MDD) by the end of 2024.â€¢Iloperidone LAI: We expect to initiate a Phase III program for the LAI formulation of FanaptÂ® in the fourth quarter of 2024.HETLIOZÂ®26Table of Contentsâ€¢We have initiated a HETLIOZ LQÂ® program in pediatric insomnia. Although the prevalence of insomnia in children is difficult to determine, it is estimated that 20-40% of children experience significant sleep problems. There are currently no approved treatments for pediatric insomnia. â€¢We continue to pursue FDA approval for HETLIOZÂ® for the treatments of jet lag disorder and insomnia. We are challenging the FDAâ€™s rejection of our supplemental New Drug Application (sNDA) for the treatment of jet lag disorder in the U.S. Court of Appeals for the D.C. Circuit. We have accepted the opportunity for a hearing with the FDA on the approvability of the insomnia sNDA.â€¢Our litigation asserting HETLIOZÂ® Patent No. 11,285,129 against generic manufacturers is currently pending in the U.S. District Court for the District of Delaware. A jury trial has been scheduled for the first quarter of 2026.â€¢European Medicines Agency action on our Marketing Authorization Application for HETLIOZÂ® and HETLIOZ LQÂ® for SMS is expected in the first quarter of 2025.PONVORYÂ®â€¢We initiated the commercial launch of PONVORYÂ® for the treatment of relapsing forms of multiple sclerosis in the third quarter of 2024, which included the deployment of a specialty sales force. â€¢We expect IND applications for PONVORYÂ® in the treatments of psoriasis and ulcerative colitis to be completed in the fourth quarter of 2024.Tradipitant â€¢Gastroparesis NDA: In September 2024, the FDA declined to approve our NDA for tradipitant for the treatment of symptoms of gastroparesis. We plan to continue to pursue the marketing authorization for tradipitant and support the expanded access program that is currently serving several dozen patients with gastroparesis.â€¢Motion Sickness NDA: We expect to submit an NDA for tradipitant for the treatment of motion sickness to the FDA in the fourth quarter of 2024. The NDA for the treatment of motion sickness is expected to include the positive results of three placebo controlled clinical studies where tradipitant was effective in preventing vomiting associated with motion.â€¢We plan to initiate a clinical trial to study tradipitant in the prevention of vomiting induced by a GLP-1 analog (semaglutide) in the fourth quarter of 2024.Early-Stage Programsâ€¢We plan to proceed with studies of VSJ-110, a CFTR activator, for the treatment of dry eye disorder. An ongoing proof of concept study indicates an effect in improving the signs (fluorescein corneal staining) of dry eye disease.â€¢VPO-227, a CFTR inhibitor for the treatment of cholera, has received approval to proceed in a Phase I study in Bangladesh, a country where the treatment of cholera remains a significant and unmet need. We plan to initiate this study by the end of 2024.â€¢The Phase I clinical study for 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, expects to enroll the patient by the end of 2024.â€¢The Phase I clinical study for VTR-297 for the treatment of onychomycosis, a fungal infection of the nail, was initiated in April 2024. The study is fully enrolled, and results are expected by the end of 2024.â€¢VQW-765, an alpha-7 nicotinic acetylcholine receptor partial agonist, is currently in clinical development for the treatment of acute performance anxiety in social situations.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 FanaptÂ® and HETLIOZÂ® in the U.S. and Europe and PONVORYÂ® 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, ItemÂ 1A, Risk Factors, of our annual report on Form 10-K (Annual Report) for the year ended December 31, 2023 and Item 1A, Risk Factors, of this Quarterly Report.27Table of ContentsCritical Accounting

Policies and EstimatesThe preparation of our condensed 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.There have been no significant changes in our critical accounting policies including estimates, assumptions and judgments from those described in Part II, ItemÂ 7, Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations, included in the Annual Report.Â A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements included in the 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 condensed 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. FanaptÂ® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. HETLIOZÂ® is available in the U.S. for distribution through a limited number of specialty pharmacies and is not available in retail pharmacies. PONVORYÂ® is available in the U.S. for distribution primarily through specialty distributors and specialty pharmacies. We invoice and record revenue when customers, wholesalers, specialty pharmacies and specialty distributors, 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 have a distribution agreement for the commercialization of FanaptÂ®Â in Israel and sell HETLIOZÂ®Â in Germany. 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.Â 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 nine months ended September 30, 2024 and 2023, we constrained the variable consideration for HETLIOZÂ® 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.Reserves for variable consideration are classified as product revenue allowances on the Condensed 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 Condensed 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 HETLIOZÂ® in 2024 and 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:28Table of ContentsPrompt-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:Â The Medicare PartÂ D prescription drug benefit requires manufacturers to fund approximately 70% of the Medicare PartÂ 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.Â Estimates for expected Medicare PartÂ 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 of 2022. The implementation of the new discounting program is expected to result in higher discounts for our Medicare payor segment relative to the current Medicare Part D prescription drug benefit program. 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 products to be resalable. There was no right of return asset as of September 30, 2024 or December 31, 2023.The following table summarizes sales discounts and allowance activity as of and for the nine months ended September 30, 2024:(in thousands)Rebates & ChargebacksDiscounts,ReturnsÂ and OtherTotalBalances at December 31, 2023$40,151Â $10,427Â $50,578Â Provision related to current period sales57,526Â 22,237Â 79,763Â Adjustments for prior period sales(3,251)11Â (3,240)Credits/payments made(53,027)(22,955)(75,982)Balances at September 30, 2024$41,399Â $9,720Â $51,119Â The provision of $57.5 million for rebates and chargebacks for the nine months ended September 30, 2024 and its ending balance at September 30, 2024 primarily represents Medicaid rebates applicable to sales of FanaptÂ® and, to a lesser extent, HETLIOZÂ®. The provision of $22.2 millionÂ for discounts, returns and other for the nine months ended September 30, 2024 primarily represents wholesaler distribution fees applicable to sales of FanaptÂ® and estimated product returns of FanaptÂ®, and co-pay assistance costs and prompt-pay discounts across our commercial products.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 29Table of Contentsaffected 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 Condensed 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)Â an evaluation by the project manager of the work that has been completed during the period, (ii)Â measurement of progress prepared internally and/or provided by the third-party service provider, (iii)Â analyses of data that justify the progress, and (iv)Â managementâ€™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 2022 and 2023 related to the HETLIOZÂ® patent litigation (see Note 14, Legal Matters, to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q (Quarterly Report)) we performed impairment reviews for our HETLIOZÂ® asset group in those years and determined, based upon our review of undiscounted cash flows, that the carrying value of our HETLIOZÂ® asset group, inclusive of the intangible asset, is recoverable. Accordingly, we have not recorded an intangible asset impairment charge in any period. The litigation and subsequent developments do not affect the sale of HETLIOZÂ® in the E.U. and there is no generic litigation pending outside of the U.S. with respect to HETLIOZÂ®. Furthermore, the litigation and subsequent events do not relate to the HETLIOZ LQÂ® oral suspension formulation. Our expected cash flows continue to support our estimated useful economic life of the intangible asset through 2035.Income taxes.Â We assess the need for a valuation allowance against our deferred tax assets 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. Since 2018, we have generated annual pretax income in the U.S. Projected taxable income includes significant assumptions related to revenue, commercial expenses and research and development activities, which could be affected by the HETLIOZÂ® generic competition, the commercial launches of FanaptÂ® in bipolar disorder and PONVORYÂ® in relapsing forms of MS, and our ability to obtain regulatory approval from the FDA for 30Table of Contentsproducts 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 PronouncementsSee Note 2, Summary of Significant Accounting Policies, to the condensed consolidated financial statements included in Part I of this Quarterly Report for information on recent accounting pronouncements.Results of OperationsWe anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including our and our partnersâ€™ ability to continue to successfully commercialize our products, including activities related to the approval of FanaptÂ® for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults in April 2024 and acquired rights to PONVORYÂ® in the U.S. and Canada in December 2023, 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.For HETLIOZÂ®, the FDA has approved ANDAs for Teva and Apotex, both of which have since launched their generic versions of HETLIOZÂ® at risk in the U.S. 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 HETLIOZÂ® in the U.S. The Federal Circuit affirmed this ruling, and the U.S. Supreme Court denied our petition for a writ of certiorari in April 2024. The FDA has also approved the ANDA for MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (MSN). The license agreement that we entered into when we settled our patent litigation with MSN (MSN/Impax License Agreement) grants MSN and Impax Laboratories LLC (Impax) a non-exclusive license to manufacture and commercialize MSNâ€™s generic version of HETLIOZÂ® in the U.S. effective as of March 13, 2035, unless prior to that date we obtain pediatric exclusivity for HETLIOZÂ®, in which case the license will be effective as of July 27, 2035, or 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. In April 2024, we filed litigation against MSN, Impax, and Amneal alleging fraudulent inducement of the license agreement. See Note 14, Legal Matters, to the condensed consolidated financial statements in Part I of this Quarterly Report. HETLIOZÂ® 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. In addition, sales of generic versions of HETLIOZÂ® have resulted in and could continue to result in a reduction in the demand for HETLIOZÂ® 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.On September 18, 2024, the U.S. Food and Drug Administration (FDA) declined to approve Vandaâ€™s New Drug Application (NDA) of tradipitant for the treatment of symptoms in gastroparesis, providing Vanda with a Complete Response Letter (CRL). Vanda will continue to pursue the marketing authorization for tradipitant and will continue to support the expanded access program that is currently serving several dozen patients with gastroparesis.Three months ended September 30, 2024 compared to three months ended September 30, 2023 Revenues. Total revenues increased by $8.8 million, or 23%, to $47.7 million for the three months ended September 30, 2024 compared to $38.8 million for the three months ended September 30, 2023. Revenues were as follows:Â Three Months Ended(in thousands)September 30,2024September 30,2023NetChangePercentFanaptÂ® net product sales$23,919Â $21,315Â $2,604Â 12Â %HETLIOZÂ® net product sales17,870Â 17,500Â 370Â 2Â %PONVORYÂ® net product sales5,862Â â€“Â 5,862Â N/ATotal net product sales$47,651Â $38,815Â $8,836Â 23Â %FanaptÂ® net product sales increased by $2.6 million, or 12%, to $23.9 million for the three months ended September 30, 2024 compared to $21.3

million for the three months ended September 30, 2023. The increase to net product sales was attributable to an increase in price net of deductions and volume. We initiated the commercial launch of FanaptÂ® for bipolar I disorder in adults in the third quarter of 2024.31Table of ContentsHETLIOZÂ® net product sales increased by $0.4 million, or 2%, to $17.9 million for the three months ended September 30, 2024 compared to $17.5 million for the three months ended September 30, 2023. The increase to net product sales was attributable to an increase in volume, partially offset by a decrease in price net of deductions, including the impact of changes in constrained revenue. Our HETLIOZÂ® 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 at March 31, 2023. During the remainder of 2023, although there was continued destocking at specialty pharmacy customers, inventory levels remained elevated relative to inventory levels prior to the entrance of generic competition and remained elevated at March 31, 2024, June 30, 2024 and September 30, 2024. Going forward, HETLIOZÂ® net product sales may reflect lower unit sales as a result of reduction of the elevated inventory levels at specialty pharmacy customers or may be variable depending upon when specialty pharmacy customers need to purchase again. Further, HETLIOZÂ® net product sales will likely decline in future periods, potentially significantly, related to continued generic competition in the U.S. We constrained HETLIOZÂ® net product sales for the three months ended September 30, 2024 and 2023 to an amount not probable of significant revenue reversal. The amount of revenue recognized during the three months ended September 30, 2024 and 2023 related to changes in estimates on revenue constrained during the second quarter of 2024 and 2023 was $0.8 million and $0.3 million, respectively. HETLIOZÂ® 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.In December 2023, we completed the acquisition of the U.S. and Canadian rights to PONVORYÂ® from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company. PONVORYÂ® net product sales decreased by $2.8 million, or 32%, to $5.9 million for the three months ended September 30, 2024 compared to $8.6 million for the three months ended June 30, 2024. The decrease in net product sales was attributable to a decrease in volume and price net of deductions. We initiated the commercial launch of PONVORYÂ® in relapsing forms of MS in the third quarter of 2024. Cost of goods sold. Cost of goods sold decreased by $0.5 million, or 17%, to $2.6 million for the three months ended September 30, 2024 compared to $3.1 million for the three months ended September 30, 2023. 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 6% of FanaptÂ® net product sales and 5% of HETLIOZÂ® net product sales in Germany. Third-party royalty costs on HETLIOZÂ® net product sales in the U.S. decreased from 10% to 5% in December 2022 and ended in April 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 included $2.1 million and $3.0 million of FanaptÂ® product and $7.3 million and $7.2 million of HETLIOZÂ® product as of September 30, 2024 and December 31, 2023, respectively.Research and development expenses. Research and development expenses increased by $0.2 million, or 1.1%, to $16.8 million for the three months ended September 30, 2024 compared to $16.6 million for the three months ended September 30, 2023. The increase was primarily due to an increase in expenses associated with our milsaperidone development program partially offset by expenses associated with our tradipitant development program. 32Table of ContentsThe following table summarizes the costs of our product development initiatives for the three months ended September 30, 2024 and 2023: Â Three Months Ended(in thousands)September 30,2024September 30,2023Direct project costs (1)FanaptÂ®$1,876Â $3,316Â Milsaperidone2,864Â 620Â HETLIOZÂ®2,840Â 2,150Â PONVORYÂ®1,027Â â€”Â Tradipitant4,392Â 6,903Â VTR-297712Â 390Â CFTR806Â 310Â VQW-765194Â 165Â Other318Â 1,006Â Total direct project costs15,029Â 14,860Â Indirect project costs (1)Stock-based compensation703Â 739Â Other indirect overhead1,044Â 1,001Â Total indirect project costs1,747Â 1,740Â Total research and development expense$16,776Â $16,600Â (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 increased by $12.8 million, or 52%, to $37.6 million for the three months ended September 30, 2024 compared to $24.8 million for the three months ended September 30, 2023. The increase in selling, general and administrative expenses was primarily the result of an increase in spending on commercial activities related to our commercial launches of FanaptÂ® in bipolar disorder and PONVORYÂ® in relapsing forms of MS, as well as legal and other corporate activities. During the first nine months of 2024, we commenced a host of commercial activities as part of our commercial launches of FanaptÂ® in bipolar disorder and PONVORYÂ® in multiple sclerosis, including an expansion of our sales force and the development of prescriber awareness and comprehensive marketing programs. Selling, general and administrative expenses may increase in future periods as a result of the ongoing commercial launches of FanaptÂ® in bipolar disorder and PONVORYÂ® in relapsing forms of MS, which were initiated in the third quarter of 2024. Intangible asset amortization. Intangible asset amortization was $1.8Â million and $0.4 million for the three months ended September 30, 2024 and 2023, respectively. Amortization expense increased in 2024 due to amortization on the intangible asset from the rights to PONVORYÂ® in the U.S. and Canada which were acquired in December 2023.Other income. Other income was $4.8 million for the three months ended September 30, 2024 compared to $5.9 million for the three months ended September 30, 2023. Other income primarily consists of investment income on our marketable securities.Provision for income taxes. An income tax benefit of $0.9Â million and $0.3Â million was recorded for the three months ended September 30, 2024 and 2023, respectively. The income tax benefit for each of the three months ended September 30, 2024 and 2023 was primarily driven by the estimated effective tax rate for the year as well as discrete income tax expense of $0.2Â million.Nine months ended September 30, 2024 compared to nine months ended September 30, 2023 Revenues. Total revenues decreased by $1.8 million, or 1%, to $145.6 million for the nine months ended September 30, 2024 compared to $147.4 million for the nine months ended September 30, 2023. Revenues were as follows:33Table of ContentsÂ Â Nine Months Ended(in thousands)September 30,2024September 30,2023NetChangePercentFanaptÂ® net product sales$67,648Â $68,274Â $(626)(1)%HETLIOZÂ® net product sales56,631Â 79,095Â (22,464)(28)%PONVORYÂ® net product sales21,308Â â€”Â 21,308Â N/ATotal net product sales$145,587Â $147,369Â $(1,782)(1)%FanaptÂ® net product sales decreased by $0.6 million, or 1%, to $67.6 million for the nine months ended September 30, 2024 compared to $68.3 million for the nine months ended September 30, 2023. The decrease to net product sales was attributable to a decrease in volume, partially offset by an increase in price net of deductions. We initiated the commercial launch of FanaptÂ® for bipolar I disorder in adults in the third quarter of 2024.HETLIOZÂ® net product sales decreased by $22.5 million, or 28%, to $56.6 million for the nine months ended September 30, 2024 compared to $79.1 million for the nine months ended September 30, 2023. The decrease to net product sales was attributable to a decrease in volume, partially offset by an increase in price net of deductions. Our HETLIOZÂ® 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 at March 31, 2023. During the remainder of 2023, although there was continued destocking at specialty pharmacy customers, inventory levels remained elevated relative to inventory levels prior to the entrance of generic competition and remained elevated at March 31, 2024, June 30, 2024 and September 30, 2024. Going forward, HETLIOZÂ® net product sales may reflect lower unit sales as a result of reduction of the elevated inventory levels at specialty pharmacy customers or may be variable depending on when specialty pharmacy customers need to purchase again. Further, HETLIOZÂ® net product sales will likely decline in future periods, potentially significantly, related to continued generic competition in the U.S. We constrained HETLIOZÂ® net product sales for the nine months ended September 30, 2024 and 2023 to an amount not probable of significant revenue reversal. The amount of revenue recognized during the nine months ended September 30, 2024 related to changes in estimates on revenue constrained during 2023 was $1.4 million. HETLIOZÂ® 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.In December 2023, we completed the acquisition of the U.S. and Canadian rights to PONVORYÂ® from Janssen. PONVORYÂ® net product sales were $21.3 million for the nine months ended September 30, 2024. We initiated the commercial launch of PONVORYÂ® in relapsing forms of MS in the third quarter of 2024. Cost of goods sold. Cost of goods sold decreased by $2.6 million, or 23%, to $8.7 million for the nine months ended September 30, 2024 compared to $11.3 million for the nine months ended September 30, 2023. 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 6% of FanaptÂ® net product sales and 5% of HETLIOZÂ® net product sales in Germany. Third-party royalty costs on HETLIOZÂ® net product sales in the U.S. decreased from 10% to 5% in December 2022 and ended in April 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 included $2.1 million and $3.0 million of FanaptÂ® product and $7.3 million and $7.2 million of HETLIOZÂ® product as of September 30, 2024 and December 31, 2023, respectively.Research and development expenses. Research and development expenses increased by $2.1 million, or 4%, to $54.6 million for the nine months ended September 30, 2024 compared to $52.5 million for the nine months ended September 30, 2023. The increase in research and development expenses was associated an increase in expenses associated with our PONVORYÂ® and CFTR development programs, partially offset by a decrease in expenses associated with our FanaptÂ®, tradipitant and other development programs, which include expenses incurred on product discovery such as ASO.The following table summarizes the costs of our product development initiatives for the nine months ended September 30, 2024 and 2023:34Table of ContentsÂ Â Nine Months Ended(in thousands)September 30,2024September 30,2023Direct project costs (1)FanaptÂ®$5,848Â $7,934Â Milsaperidone4,390Â 2,695Â HETLIOZÂ®7,271Â 7,078Â PONVORYÂ®4,052Â â€”Â Tradipitant18,609Â 21,269Â VTR-2971,985Â 1,203Â CFTR4,927Â 1,066Â VQW-765564Â 805Â Other1,154Â 4,446Â Total direct project costs48,800Â 46,496Â Indirect project costs (1)Stock-based compensation2,241Â 2,538Â Other indirect overhead3,550Â 3,450Â Total indirect project costs5,791Â 5,988Â Total research and development expense$54,591Â $52,484Â Â (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 increased by $17.9 million, or 20%, to $107.1 million for the nine months ended September 30, 2024 compared to $89.3 million for the nine months ended September 30, 2023. The increase in selling, general and administrative expenses was primarily the result of an increase in spending on commercial activities related to our commercial launches of FanaptÂ® in bipolar disorder and PONVORYÂ® in relapsing forms of MS, as well as legal and other corporate activities. During the first nine months of 2024, we commenced a host of commercial activities as part of our commercial launches of FanaptÂ® in bipolar disorder and PONVORYÂ® in multiple sclerosis, including an expansion of our sales force and the development of prescriber awareness and comprehensive marketing programs. Selling, general and administrative expenses may increase in future periods as a result of the ongoing commercial launches of FanaptÂ® in bipolar disorder and PONVORYÂ® in relapsing forms of MS, which were initiated in the third quarter of 2024. Intangible asset amortization. Intangible asset amortization was $5.5 million and $1.1 million for the nine months ended September 30, 2024 and 2023, respectively. Amortization expense increased in 2024 due to amortization on the intangible asset from the rights to PONVORYÂ® in the U.S. and Canada which were acquired in December 2023.Other income. Other income was $14.0 million for the nine months ended September 30, 2024 compared to $14.9 million for the nine months ended September 30, 2023. Other income primarily consists of investment income on our marketable securities.Provision for income taxes. We recorded an income tax benefit of $2.4 million and provision for income taxes of $3.1 million for the nine months ended September 30, 2024 and 2023, respectively. The income tax expense (benefit) for the nine months ended September 30, 2024 and 2023 was primarily driven by the estimated effective tax rate for the year, as well as discrete income tax expense of $1.0 million and $2.1 million, respectively.Liquidity and Capital Resources35Table of ContentsAs of September 30, 2024, our total cash and cash equivalents and marketable securities were $376.3 million compared to $388.3 million at December 31, 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 September 30, 2024 and December 31, 2023 are summarized as follows:(in thousands)September 30,2024December 31, 2023Cash and cash equivalents$100,497Â $135,821Â Marketable securities:U.S. Treasury and government agencies173,246Â 185,115Â Corporate debt102,518Â 67,328Â Total marketable securities275,764Â 252,443Â Total cash, cash equivalents and marketable securities$376,261Â $388,264Â As of September 30, 2024, 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 daysâ€™ 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 primarily relate to commitments for data services. 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. Other than the lease agreement discussed in Note 9, Commitments and Contingencies, to the condensed consolidated financial statements in Part I of this Quarterly Report, there have been no material changes to our long-term contractual obligations as disclosed in Part II, Item 7, Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report. For further information regarding our license agreements, see Note 9, Commitments and Contingencies, to the condensed consolidated financial statements included in Part I of this Quarterly Report.We do not have any off-balance sheet arrangements.Based on our current operating plans, which include costs and expenses in connection with our U.S. commercial activities, continued clinical development of tradipitant and our other products, pursuit of regulatory approval of tradipitant, pursuit of further regulatory approvals of our current approved products 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.36Table of ContentsCash FlowThe following table summarizes our net cash flows from operating and investing activities for the nine months ended September 30, 2024 and 2023:Â Nine Months Ended(in thousands)September 30,2024September 30,2023NetChangeNet cash provided by (used in):Operating activities:Net income (loss)$(13,988)$4,909Â $(18,897)Non-cash charges7,324Â 15,191Â (7,867)Net change in operating assets and liabilities(7,276)(3,567)(3,709)Operating activities(13,940)16,533Â (30,473)Investing activities:Asset acquisition(4,229)â€”Â (4,229)Purchases of property and equipment(276)(130)(146)Net purchases, sales and maturities of marketable securities(16,918)31,857Â (48,775)Investing activities(21,423)31,727Â (53,150)Effect of exchange rate changes on cash, cash equivalents and restricted cash39Â (103)142Â Net change in cash, cash equivalents and restricted cash$(35,324)$48,157Â $(83,481)Operating Activities: Cash flows used in

operating activities during the nine months ended September 30, 2024 were $13.9 million, a decrease of $30.5 million compared to $16.5 million during the nine months ended September 30, 2023. The decrease reflects a decrease of $18.9 million in net income, non-cash charges, including the change in deferred income taxes, as well as the net change in operating assets and liabilities. The decrease in net change in operating assets and liabilities is primarily due to timing of payments for expenses and receipt of cash for accounts receivable. Investing Activities: Cash flows used in investing activities during the nine months ended September 30, 2024 were $21.4 million, an increase of $53.2 million compared to $31.7 million during the nine months ended September 30, 2023. The change in investing activities primarily reflects the timing of net reinvestment of available cash and cash equivalents in our portfolio of marketable securities. Additionally, the $4.2 million asset acquisition cash flow during the nine months ended September 30, 2024 relates to the payment of the remaining consideration for the PONVORYÂ® acquisition that was accrued as of December 31, 2023.ITEMÂ 3Quantitative and Qualitative Disclosures about Market RiskOur 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 subsidiariesâ€™ 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 condensed 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.37Table of ContentsITEMÂ 4Controls and ProceduresConclusion Regarding the Effectiveness of Disclosure Controls and ProceduresUnder the supervision and with the participation of our management, including our 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 RulesÂ 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)) as of September 30, 2024. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2024, the end of the period covered by this quarterly report on Form 10-Q, 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 Securities and Exchange Commissionâ€™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.Changes in Internal Control over Financial ReportingThere 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 third quarter of 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. PART II â€” OTHER INFORMATIONÂ ITEMÂ 1Legal ProceedingsInformation with respect to this item may be found in Note 14, Legal Matters, to the condensed consolidated financial statements in Part I of this quarterly report on Form 10-Q, which is incorporated herein by reference. ITEMÂ 1ARisk FactorsWe previously disclosed in Part I, Item 1A of our annual report on Form 10-K (Annual Report) for the year ended December 31, 2023, filed with the Securities and Exchange Commission on February 8, 2024, important factors which could affect our business, financial condition, results of operations and future operations under the heading 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 as risk factors, 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. Other than as set forth below, there have been no material changes in our risk factors subsequent to the filing of our Annual Report for the fiscal year ended December 31, 2023.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:â€¢authorize the issuance of â€œblank checkâ€ preferred stock that could be issued by our board of directors to thwart a takeover attempt;â€¢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;â€¢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;38Table of Contentsâ€¢require that directors only be removed from office for cause;â€¢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;â€¢limit who may call special meetings of stockholders;â€¢prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders; andâ€¢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.Moreover, in April 2024, our board of directors adopted a rights agreement which provided each stockholder of record as of the close of business on April 29, 2024 a right for each outstanding share of common stock of the Company held by such stockholder (each, a Right), which entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share, of the Company at an exercise price of $25.00, subject to adjustment. The complete terms of the Rights are set forth in the Rights Agreement, dated as of April 17, 2024, between the Company and Equiniti Trust Company, LLC, as rights agent (Rights Agent), as amended by that certain Amendment No. 1 to the Rights Agreement, by and between the Company and the Rights Agent, and that certain Amendment No. 2 to the Rights Agreement, by and between the Company and the Rights Agent (as amended, the Rights Agreement). The Rights Agreement has a one-year term, expiring on April 16, 2025, and could have 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.ITEMÂ 2Unregistered Sales of Equity Securities and Use of ProceedsNone.ITEMÂ 3Defaults Upon Senior SecuritiesNone.ITEMÂ 4Mine Safety DisclosuresNot applicable.ITEMÂ 5Other InformationDuring the fiscal quarter ended September 30, 2024, none of our directors or officers informed us of the adoption, modification or termination of a â€œRule 10b5-1 trading arrangementâ€ or â€œnon-Rule 10b5-1 trading arrangement,â€ as those terms are defined in Regulation S-K, Item 408. Furthermore, during the fiscal quarter ended September 30, 2024, we did not adopt or terminate a â€œRule 10b5-1 trading arrangementâ€ or â€œnon-Rule 10b5-1 trading arrangement,â€ as those terms are defined in Regulation S-K, Item 408.39ITEMÂ 6ExhibitsExhibitNumberDescription3.1Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrantâ€™s registration statement on Form S-1 (File No.Â 333-130759) on MarchÂ 17, 2006 and incorporated herein by reference).3.2Amended and Restated Bylaws of the registrant, as amended and restated on October 2, 2024 (filed as ExhibitÂ 3.1 to the registrantâ€™s current report on Form 8-K (File No.Â 001-34186) on OctoberÂ 3, 2024 and incorporated herein by reference).3.3Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Junior Participating Preferred Stock of Vanda Pharmaceuticals Inc. (filed as Exhibit 3.1 to the registrantâ€™s current report on Form 8-K (File No. 001-34186) on April 17, 2024 and incorporated herein by reference).4.1Rights Agreement, dated as of April 17, 2024, by and between Vanda Pharmaceuticals Inc. and Equiniti Trust Company, LLC as rights agent (filed as Exhibit 4.1 to the registrantâ€™s current report on Form 8-K (File No. 001-34186) on April 17, 2024 and incorporated herein by reference).4.2Amendment No. 1 to the Rights Agreement, dated as of May 3, 2024, by and between Vanda Pharmaceuticals Inc. and Equiniti Trust Company, LLC as rights agent (filed as Exhibit 4.1 to the registrantâ€™s current report on Form 8-K (File No. 001-34186) on May 3, 2024 and incorporated herein by reference).4.3Amendment No. 2 to the Rights Agreement, dated as of August 7, 2024, by and between Vanda Pharmaceuticals Inc. and Equiniti Trust Company, LLC as rights agent (filed as Exhibit 4.1 to the registrantâ€™s current report on Form 8-K (File No. 001-34186) on August 7, 2024 and incorporated herein by reference).31.1*Certification of the Chief Executive Officer, as required by SectionÂ 302 of the Sarbanes-Oxley Act of 2002.31.2*Certification of the Chief Financial Officer, as required by SectionÂ 302 of the Sarbanes-Oxley Act of 2002.32.1**Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by SectionÂ 906 of the Sarbanes-Oxley Act of 2002.101The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2024 formatted in Inline Extensible Business Reporting Language (iXBRL) and filed electronically herewith: (i)Â Condensed Consolidated Balance Sheets as of September 30, 2024 and December 31, 2023; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2024 and 2023; (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2024 and 2023; (iv) Condensed Consolidated Statements of Changes in Stockholdersâ€™ Equity for the three and nine months ended September 30, 2024 and 2023; (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2024 and 2023; and (vi)Â Notes to Condensed Consolidated Financial Statements.104Cover Page Interactive Data File (embedded within the Inline XBRL document).*Filed herewith.**Furnished herewith.40Table of ContentsSIGNATURESPursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.Â Â Â Vanda Pharmaceuticals Inc.November 7, 2024Â Â /s/Â Mihael H. Polymeropoulos, M.D.Â Â Mihael H. Polymeropoulos, M.D.Â Â President, Chief Executive Officer and Chairman of the Board(Principal Executive Officer)November 7, 2024Â Â /s/Â Kevin MoranÂ Â Kevin MoranÂ Â Senior Vice President, ChiefÂ FinancialÂ Officer and Treasurer(PrincipalÂ FinancialÂ OfficerÂ andÂ PrincipalÂ AccountingÂ Officer)41DocumentEXHIBIT 31.1CERTIFICATION OF CHIEF EXECUTIVE OFFICERPURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002I, Mihael H. Polymeropoulos, certify that:1.I have reviewed this quarterly report on Form 10-Q 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 registrantâ€™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 registrantâ€™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; andd.Disclosed in this report any change in the registrantâ€™s internal control over financial reporting that occurred during the registrantâ€™s most recent fiscal quarter (the registrantâ€™s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrantâ€™s internal control over financial reporting; and5.The registrantâ€™s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrantâ€™s auditors and the audit committee of the registrantâ€™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 registrantâ€™s ability to record, process, summarize and report financial information; andb.Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrantâ€™s internal control over financial reporting.Â Â November 7, 2024/s/Â Mihael H. Polymeropoulos, M.D.Mihael H. Polymeropoulos, M.D.President, Chief Executive Officer and Chairman of the Board(Principal Executive Officer)DocumentEXHIBIT 31.2CERTIFICATION OF CHIEF FINANCIAL OFFICERPURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002I, Kevin Moran, certify that:1.I have reviewed this quarterly report on Form 10-Q 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 registrantâ€™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 registrantâ€™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; andd.Disclosed in this report any change in the registrantâ€™s internal control over financial reporting that occurred during the registrantâ€™s most recent fiscal quarter (the registrantâ€™s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrantâ€™s internal control over financial reporting; and5.The registrantâ€™s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrantâ€™s auditors and the audit committee of the registrantâ€™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 registrantâ€™s ability to record, process, summarize and report financial information; andb.Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrantâ€™s internal control over financial reporting.November 7, 2024/s/Â Kevin MoranKevin MoranSenior ViceÂ President, ChiefÂ FinancialÂ OfficerÂ andÂ Treasurer(PrincipalÂ FinancialÂ OfficerÂ andÂ PrincipalÂ AccountingÂ Officer)DocumentEXHIBIT 32.1CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICERPursuant to SectionÂ 906 of the Sarbanes-Oxley Act of 2002(Subsections (a)Â and (b)Â of SectionÂ 1350, Chapter 63 of Title 18, United States Code)Pursuant to SectionÂ 906 of the Sarbanes-Oxley Act of 2002 (subsections (a)Â and (b)Â 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 officerâ€™s knowledge, that:The Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the Form 10-Q) of the Company fully complies with the requirements of SectionÂ 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.Â November 7, 2024/s/Â Mihael H. Polymeropoulos, M.D.Mihael H. Polymeropoulos, M.D.President, Chief Executive Officer and Chairman of the Board(Principal Executive Officer)November 7, 2024/s/Â Kevin MoranKevin MoranSenior ViceÂ President,Â ChiefÂ FinancialÂ OfficerÂ andÂ Treasurer(PrincipalÂ FinancialÂ OfficerÂ andÂ PrincipalÂ AccountingÂ Officer)A signed original of this written statement required by SectionÂ 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 â€œaccompaniesâ€ the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.