HOLIDAY BRADLEY J
Form 4
November 05, 2004

FORM 4

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

OMB APPROVAL

OMB Number:	3235-0287
Expires:	January 31, 2005
Estimated average burden hours per response...	0.5

Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. *See* Instruction 1(b).

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person *
HOLIDAY BRADLEY J

(Last) (First) (Middle)

2180 RUTHERFORD ROAD

(Street)

CARLSBAD, CA 92008

(City) (State) (Zip)

2. Issuer Name **and** Ticker or Trading Symbol
CALLAWAY GOLF CO /CA [ELY]

3. Date of Earliest Transaction (Month/Day/Year)
01/30/2004

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer
(Check all applicable)
_____ Director _____ 10% Owner
__X__ Officer (give title below) _____ Other (specify below)
Senior Executive VP & CFO

6. Individual or Joint/Group Filing(Check Applicable Line)
_X_ Form filed by One Reporting Person
___ Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1.Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)		4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)			5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price			

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

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SEC 1474 (9-02)

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned
(*e.g.*, puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security	2. Conversion or Exercise	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any	4. Transaction Code	5. Number of Derivative Securities	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Amou Underlying Secur (Instr. 3 and 4)

(Instr. 3)	Price of Derivative Security	(Month/Day/Year)	(Instr. 8)	Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)							
			Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Am Nur Sha
Non-Qualified Stock Option (right to buy)	$ 17.91	01/30/2004	A		100,000		(1)	01/30/2014	Common Stock	10

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
HOLIDAY BRADLEY J 2180 RUTHERFORD ROAD CARLSBAD, CA 92008			Senior Executive VP & CFO	

Signatures

Brian P. Lynch Attorney-in-Fact for Bradley J. Holiday under a Limited Power of Attorney dated August 22, 2002	11/05/2004
**Signature of Reporting Person	Date

Explanation of Responses:

***** If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

****** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

(1) This stock option is scheduled to vest as follows: 33,334 shares on 1/30/05; 33,333 shares on 1/30/06; and 33,333 shares on 1/30/07.

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

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

Selling, general and administrative expenses. Selling, general and administrative expenses decreased by $5.1 million, or 16%, to $26.0 million for the three months ended September 30, 2018 compared to $31.1 million for the three months ended September 30, 2017. The decrease was primarily the result of lower spend on marketing efforts relating to HETLIOZ® and Fanapt® in the U.S. and sales force employee turnover.

Intangible asset amortization. Intangible asset amortization was $0.4 million for each of the three months ended September 30, 2018 and 2017.

Other income. Other income was $1.0 million for the three months ended September 30, 2018 compared to $0.4 million for the three months ended September 30, 2017. The increase was primarily the result of an increase in investment income due to an increase in our balance of marketable securities from the proceeds of the public offering of our common stock completed in March 2018 and a higher yield on investments.

Provision for income taxes. As a result of the tax valuation allowance against deferred tax assets in the U.S., there was no expense (benefit) for income taxes associated with the income (loss) before income taxes for three months ended September 30, 2018 and 2017. Taxes have been recorded related to certain U.S. state jurisdictions and non-U.S. income for the three months ended September 30, 2018 and 2017.

Nine months ended September 30, 2018 compared to nine months ended September 30, 2017

Revenues. Total revenues increased by $19.3 million, or 16%, to $140.1 million for the nine months ended September 30, 2018 compared to $120.8 million for the nine months ended September 30, 2017. Revenues were as follows:

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(in thousands)	Nine Months Ended September 30, 2018	September 30, 2017	Net Change	Percent
HETLIOZ® product sales, net	$83,391	$ 64,968	$18,423	28 %
Fanapt® product sales, net	56,686	55,839	847	2 %
	$140,077	$ 120,807	$19,270	16 %

HETLIOZ® product sales, net increased by $18.4 million, or 28%, to $83.4 million for the nine months ended September 30, 2018 compared to $65.0 million for the nine months ended September 30, 2017. The increase to net product sales was attributable to an increase in volume and an increase in price net of deductions.

Fanapt® product sales, net increased by $0.8 million, or 2%, to $56.7 million for the nine months ended September 30, 2018 compared to $55.8 million for the nine months ended September 30, 2017.

Cost of goods sold. Cost of goods sold increased by $1.8 million, or 14%, to $14.8 million for the nine months ended September 30, 2018 compared to $13.1 million for the nine months ended September 30, 2017. 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 are 10% of net sales of HETLIOZ® in the U.S. and 9% of net sales of Fanapt®.

In addition to third party royalty costs, HETLIOZ® and Fanapt® cost of goods sold as a percentage of revenue depends upon our cost to manufacture inventory at normalized production levels with our third party manufacturers. We expect that, in the future, total HETLIOZ® manufacturing costs included in cost of goods sold will continue to be less than 2% of our net HETLIOZ® product sales. We expect that, in the future, total U.S. Fanapt® manufacturing costs included in cost of goods sold will continue to be less than 4% of our net U.S. Fanapt® product sales.

Research and development expenses. Research and development expenses increased by $2.3 million, or 8%, to $30.7 million for the nine months ended September 30, 2018 compared to $28.4 million for the nine months ended September 30, 2017. The increase was primarily due to an increase in clinical trial expenses associated with the tradipitant gastroparesis program and preclinical expenses associated with the CFTR programs, partially offset by a decrease in expenses associated with the HETLIOZ® jet lag disorder program and a $2.0 million expense accrued during the nine months ended September 30, 2017 for a milestone obligation payable to Lilly for tradipitant. As a result of enrolling the first subject into a Phase III study for tradipitant in July 2018, we paid this $2.0 million milestone obligation to Lilly during the three months ended September 30, 2018. The following table summarizes the costs of our product development initiatives for the nine months ended September 30, 2018 and 2017:

(in thousands)	Nine Months Ended September 30, 2018	September 30, 2017
Direct project costs (1)		
HETLIOZ®	$9,009	$ 10,863
Fanapt®	2,018	1,599
Tradipitant	11,762	9,642
VTR-297	1,682	1,692
CFTR	2,764	1,521
Other	527	288
	27,762	25,605
Indirect project costs (1)		
Stock-based compensation	963	958
Other indirect overhead	1,947	1,830
	2,910	2,788
Total research and development expense	$30,672	$ 28,393

(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

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Explanation of Responses:

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development projects. We record indirect costs that support a number of our research and development activities in the aggregate, including stock-based compensation.

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

Selling, general and administrative expenses. Selling, general and administrative expenses decreased by $12.0 million, or 13%, to $80.8 million for the nine months ended September 30, 2018 compared to $92.8 million for the nine months ended September 30, 2017. The decrease was primarily the result of lower spend on marketing efforts relating to HETLIOZ® and Fanapt® in the U.S.

Intangible asset amortization. Intangible asset amortization was $1.1 million for the nine months ended September 30, 2018 compared to $1.3 million for the nine months ended September 30, 2017.

Other income. Other income was $2.4 million for the nine months ended September 30, 2018 compared to $1.1 million for the nine months ended September 30, 2017. The increase was primarily the result of an increase in investment income due to an increase in our balance of marketable securities from the proceeds of the public offering of our common stock completed in March 2018 and a higher yield on investments.

Provision for income taxes. As a result of the tax valuation allowance against deferred tax assets in the U.S., there was no expense (benefit) for income taxes associated with the income (loss) before income taxes for the nine months ended September 30, 2018 and 2017. Taxes have been recorded related to certain U.S. state jurisdictions and non-U.S. income for the nine months ended September 30, 2018 and 2017.

Liquidity and Capital Resources

As of September 30, 2018, our total cash and cash equivalents and marketable securities (Cash) were $240.6 million compared to $143.4 million at December 31, 2017. The increase in Cash of $97.2 million includes $100.9 million net cash proceeds from the public offering of our common stock completed in March 2018, after deducting the underwriting discounts and commissions and offering expenses. 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, government agencies and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored and corporate enterprises, commercial paper and asset-backed securities.

Our liquidity resources as of September 30, 2018 and December 31, 2017 are summarized as follows:

(in thousands)	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 60,778	$ 33,627
Marketable securities:		
U.S. Treasury and government agencies	67,412	60,618
Corporate debt	91,252	49,168
Asset-backed securities	21,137	—
Total marketable securities	179,801	109,786
Total cash, cash equivalents and marketable securities	$ 240,579	$ 143,413

As of September 30, 2018, we maintained all of our Cash 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.

We expect to incur substantial costs and expenses throughout 2018 and beyond in connection with our continued clinical development of tradipitant and our other products, U.S. commercial activities for HETLIOZ® and Fanapt®, the European commercial launch activities for HETLIOZ® and payments due upon achievement of milestones under our license agreements. Additionally, we continue to pursue market approval of HETLIOZ® and Fanapt® in other regions. The actual costs to advance our research and development projects and commercial activities for HETLIOZ® and Fanapt® are difficult to estimate and may vary significantly. Management believes that our existing funds will be sufficient to meet our operating plans for at least the next twelve months. Our future capital

requirements and the adequacy of our available funds will depend on many factors,

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primarily including our ability to generate revenue, the scope and costs of our commercial, manufacturing and process development activities, the magnitude of our discovery, preclinical and clinical development programs, and potential costs to acquire or license the rights to additional products.

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

Cash Flow

The following table summarizes our net cash flows from operating, investing and financing activities for the nine months ended September 30, 2018 and 2017:

(in thousands)	Nine Months Ended September 30, 2018	September 30, 2017	Net Change
Net cash provided by (used in):			
Operating activities:			
Net income (loss)	$14,848	$(13,729)	$28,577
Non-cash charges	9,715	10,021	(306)
Net change in operating assets and liabilities	(9,840)	(1,741)	(8,099)
Operating activities	14,723	(5,449)	20,172
Investing activities:			
Acquisition of intangible asset	(25,000)	—	(25,000)
Purchases of property and equipment	(346)	(1,473)	1,127
Net purchases of marketable securities	(68,510)	(16,119)	(52,391)
Investing activities	(93,856)	(17,592)	(76,264)
Financing activities:			
Net proceeds from offering of common stock	100,870	—	100,870
Proceeds from the exercise of stock options	5,464	5,170	294
Financing activities	106,334	5,170	101,164
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(14)	34	(48)
Net change in cash, cash equivalents and restricted cash	$27,187	$(17,837)	$45,024

The increase of $20.2 million in net cash provided by operating activities reflects an increase of $28.6 million in net income, partially offset by a decrease of $8.1 million from the net change in operating assets and liabilities. The decrease of $8.1 million from the net change in operating assets and liabilities primarily relates to an increase in accounts receivable attributable to the timing of shipments and payments and a decrease in accounts payable and other liabilities attributable to the timing of activities and payments and the payment of a $2.0 million milestone obligation during the nine months ended September 30, 2018.

Off-Balance Sheet Arrangements

We currently do not have any, and during the periods presented, did not have any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

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Contractual Obligations and Commitments

The following is a summary of our noncancellable long-term contractual cash obligations as of September 30, 2018:

	Cash Payments Due by Year (1)(2)						
(in thousands)	Total	2018	2019	2020	2021	2022	Thereafter
Operating leases (3)	$23,372	$599	$2,491	$2,501	$2,337	$2,355	$ 13,089
Purchase commitments (4)	8,372	197	5,982	847	890	456	—
	$31,744	$796	$8,473	$3,348	$3,227	$2,811	$ 13,089

(1) This table does not include potential future milestone obligations under our license agreement with Lilly for the exclusive rights to develop and commercialize tradipitant of $97.0 million, which consist of $2.0 million due upon the filing of the first marketing authorization for tradipitant in either the U.S. or the E.U., $10.0 million and $5.0 million for the first approval of a marketing authorization for tradipitant in the U.S. and the E.U., respectively, and up to $80.0 million for future sales milestones.

(2) This table does not include potential future milestone obligations under our license agreement with the University of California San Francisco for the exclusive rights to develop and commercialize a portfolio of CFTR activators and inhibitors under which we could be obligated to make potential future milestone payments of up to $46.0 million upon the achievement of regulatory and sales milestones.

(3) This table includes minimum annual future payments under operating leases and subleases for a total of 43,462 square feet of office space for our headquarters office at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. that generally expire in 2028, an operating lease for 2,880 square feet of office space for our European headquarters in London that has a noncancellable lease term ending in 2021, and 1,249 square feet of office space in Berlin under a short-term operating lease.

(4) Purchase commitments include noncancellable purchase commitments for agreements longer than one year and primarily relate to commitments for advertising and data services. This table does not include various other long-term agreements entered into for services with other third party vendors due to the cancelable nature of the services. Additionally, this table does not include rebates, chargebacks or discounts recorded as liabilities at the time that product sales are recognized as revenue.

ITEM 3 Quantitative and Qualitative Disclosures about Market Risk

Interest rate risks

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities and restricted cash. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

Concentrations of credit risk

We deposit our cash with financial institutions that we consider to be of high credit quality and purchase marketable securities which are generally investment grade, liquid, short-term fixed income securities and money-market instruments denominated in U.S. dollars. Our marketable securities consist of certificates of deposit, commercial paper, corporate notes, asset-backed securities and U.S. government agency notes.

Revenues and accounts receivable are concentrated with specialty pharmacies and wholesalers. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 90% of total revenues for the nine months ended September 30, 2018. There were five major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 95% of total accounts receivable at September 30, 2018. We mitigate our credit risk relating to accounts receivable from customers by performing ongoing credit evaluations.

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Foreign currency risk

We are exposed to risks related to changes in foreign currency exchange rates relating to our foreign operations. The functional currency of our international subsidiaries is the local currency. We are exposed to foreign currency risk to the extent that we enter into transactions denominated in currencies other than our subsidiaries' respective functional currencies. We are also exposed to unfavorable fluctuations of the U.S. dollar, which is our reporting currency, against the currencies of our operating subsidiaries when their respective financial statements are translated into U.S. dollars for inclusion in our condensed consolidated financial statements. We do not currently hedge our foreign currency exchange rate risk. Foreign currency has not had a material impact on our results of operations.

Effects of inflation

Inflation has not had a material impact on our results of operations.

ITEM 4 Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under 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 Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)) as of September 30, 2018. 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, 2018, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission'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 Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the third quarter of 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1 Legal Proceedings

Fanapt®. In June 2014, we filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware (Delaware District Court). The suit sought an adjudication that Roxane has infringed one or more claims of our U.S. Patent No. 8,586,610 ('610 Patent) by submitting to the U.S. Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of the '610 Patent in November 2027. In addition, pursuant to a settlement agreement with Novartis Pharma AG (Novartis), we assumed Novartis' patent infringement action against Roxane in the Delaware District Court. That suit alleges that Roxane has infringed one or more claims of U.S. Patent RE39198 ('198 Patent), which is licensed exclusively to us, by filing an ANDA for a generic version of Fanapt® prior to the expiration of the '198 Patent in November 2016. These two cases against Roxane were consolidated by agreement of the parties and were tried together in a five-day bench trial that concluded in March 2016. In August 2016, the Delaware District Court ruled that we are entitled to a permanent injunction against Roxane enjoining Roxane from infringing the '610 Patent, including the manufacture, use, sale, offer to sell, sale, distribution or importation of any generic iloperidone product described in the '610 Patent ANDA until the expiration of the '610 Patent in November 2027. If we obtain pediatric exclusivity, the injunction against Roxane would be extended until May 2028 under the Delaware District Court's order. In September 2016, Roxane filed a notice of appeal with the Federal Circuit Court of Appeals (Federal Circuit). In July 2017, Roxane, now a subsidiary of Hikma Pharmaceuticals PLC (Hikma), petitioned the Federal Circuit to substitute Roxane with new defendants West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp. (each of which is a subsidiary of Hikma and both of which are referred to collectively herein as West-Ward). In April 2018, the

Federal Circuit affirmed the Delaware District Court's decision that West-Ward infringed the '610 Patent. In June 2018, West-Ward filed with the Federal Circuit a petition

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seeking rehearing en banc. The Federal Circuit invited us to respond to West-Ward's petition; our response was filed in July 2018. In August 2018, the Federal Circuit denied West-Ward's petition for rehearing.

In 2015, we filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, Inventia Healthcare Pvt. Ltd. (Inventia), Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (Taro), and Apotex Inc. and Apotex Corp. (Apotex, and collectively with Roxane, Inventia, Lupin and taro, the Defendants). The lawsuits each seek an adjudication that the respective Defendants infringed one or more claims of the '610 Patent and/or our U.S. Patent No. 9,138,432 ('432 Patent) by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the '610 Patent in November 2027 or the '432 Patent in September 2025. The Defendants denied infringement and counterclaimed for declaratory judgment of invalidity and noninfringement of the '610 Patent and the '432 Patent. Certain Defendants have since entered into agreements resolving these lawsuits, as discussed below. The remaining matters have been stayed until the later of November 30, 2018 or 14 days after final disposition by the U.S. Supreme Court of any petition for a writ of certiorari filed by West-Ward. We entered into a confidential stipulation with each of Inventia and Lupin regarding any potential launch of Inventia's and Lupin's generic ANDA products.

Lupin filed counter claims for declaratory judgment of invalidity and noninfringement of seven of our method of treatment patents that are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) related to Fanapt® (such seven patents, the Method of Treatment Patents). We have not sued Lupin for infringing the Method of Treatment Patents. In October 2016, we, along with Lupin, filed a Stipulation of Dismissal in the Delaware District Court pursuant to which Lupin's counterclaims relating to the Method of Treatment Patents were dismissed without prejudice in recognition of an agreement reached between the parties by which we would not assert those patents against Lupin absent certain changes in Lupin's proposed prescribing information for its iloperidone tablets.

Taro and Apotex each entered into separate License Agreements (together, the License Agreements) resolving these lawsuits in October 2016 and December 2016, respectively. The License Agreements grant Taro and Apotex non-exclusive licenses to manufacture and commercialize a version of Fanapt® in the U.S. effective November 2027, unless prior to that date we obtain pediatric exclusivity for Fanapt®, in which case, the license will be effective May 2028. Taro and Apotex each may enter the market earlier under certain limited circumstances. The License Agreements, which are subject to review by the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ), provide for a full settlement and release of all claims that are the subject of the respective litigation with Taro and Apotex.

In February 2016, Roxane filed suit against us in the U.S. District Court for the Southern District of Ohio (Ohio District Court). The suit sought a declaratory judgment of invalidity and noninfringement of the Method of Treatment Patents. In December 2016, the Ohio District Court dismissed Roxane's suit without prejudice for lack of personal jurisdiction.

In February 2016, Roxane filed a Petition for Inter Partes Review (IPR) of the '432 Patent with the Patent Trials and Appeals Board (PTAB) of the U.S. Patent and Trademark Office. In August 2016, the PTAB denied the request by Roxane to institute an IPR of the '432 Patent. In September 2016, Roxane filed a Petition for Rehearing with the PTAB. In November 2016, the PTAB denied Roxane's Petition for Rehearing.

HETLIOZ®. In March 2018, we received a Paragraph IV certification notice letter from Teva Pharmaceuticals USA, Inc. (Teva) notifying us that Teva had submitted an ANDA for HETLIOZ® to the FDA requesting approval to market, sell and use a generic version of the 20mg HETLIOZ® capsules for Non-24-Hour-Sleep-Wake Disorder. In its notice letter, Teva alleges that our Orange Book listed U.S. Patent No. RE46,604, U.S. Patent No. 9,060,995, U.S. Patent 9,539,234, U.S. Patent 9,549,913, U.S. Patent 9,730,910 and U.S. Patent 9,885,241 (collectively, the Vanda Patents), which cover methods of using HETLIOZ®, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of the product described in its ANDA. We received similar notice letters in April 2018 from MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (together, MSN) and Apotex. In October 2018, we received an additional Paragraph IV certification notice letter from Teva concerning our Orange Book listed U.S. Patent No. 10,071,977, which expires in 2035 (the '977 Patent). The composition and use of HETLIOZ® are currently protected by eight patents that are listed in the FDA's Orange Book.

In April 2018, we filed a patent infringement lawsuit in the Delaware District Court against Teva and in May 2018, we filed patent infringement lawsuits in the Delaware District Court against MSN and Apotex. The lawsuits seek an adjudication that Teva, MSN and Apotex have infringed one or more claims of the Vanda Patents by submitting to the FDA an ANDA for a generic version of HETLIOZ® prior to the expiration of the latest to expire of the Vanda Patents in 2034. The relief requested by us in the lawsuits includes requests for permanent injunctions preventing Teva, MSN and Apotex from infringing the asserted claims of the Vanda Patents by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of HETLIOZ® before the last expiration date of the Vanda Patents. The lawsuits automatically preclude the FDA from approving the submitted ANDAs until the earlier of seven and one-half years after the January 2014 approval of our

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application for New Chemical Entity Status or entry of a district court decision finding the Vanda Patents invalid, unenforceable or not infringed. In June 2018, Teva and MSN each answered our complaint, and counterclaimed for declarations that the Vanda Patents are invalid. In July 2018, we answered Teva and MSN's counterclaims, denying their allegations. A trial date for these lawsuits has been set for June 2020.

ITEM 1A Risk Factors

We previously disclosed in Part I, Item 1A of our annual report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on February 15, 2018, 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 current 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. There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.

ITEM 2 Unregistered Sales of Equity Securities and Use of Proceeds

None

ITEM 3 Defaults Upon Senior Securities

None

ITEM 4 Mine Safety Disclosures

Not applicable

ITEM 5 Other Information

None

Table of Contents

ITEM 6 Exhibits

Exhibit Number	Description
3.1	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant's registration statement on Form S-1 (File No. 333-130759) on March 17, 2006 and incorporated herein by reference).
3.2	Fourth Amended and Restated Bylaws of the registrant, as amended and restated on December 17, 2015 (filed as Exhibit 3.1 to the registrant's current report on Form 8-K (File No. 001-34186) on December 21, 2015 and incorporated herein by reference).
10.41	Employment Agreement, dated August 13, 2018, by and between Timothy Williams and the registrant.
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2018 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and 2017; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three and nine months ended September 30, 2018 and 2017; (iv) Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2018; (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017; and (vi) Notes to Condensed Consolidated Financial Statements.

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SIGNATURES

Pursuant 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.

Vanda Pharmaceuticals Inc.

November 7, 2018

/s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

November 7, 2018

/s/ James P. Kelly

James P. Kelly
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)