TherapeuticsMD, Inc.
Form 10-Q
November 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

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

For the transition period from_____ to _____

Commission File No. **001-001000**

THERAPEUTICSMD, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**87-0233535**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

6800 Broken Sound Parkway NW, Third Floor, Boca Raton, FL 33487 **(561) 961-1900**

(Address of Principal Executive Offices) (Issuer's Telephone Number)

N/A

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of November 1, 2018 was 237,881,189.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
INDEX

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current Assets:		
Cash	$ 189,999,293	$ 127,135,628
Accounts receivable, net of allowance for doubtful accounts of $612,056 and $380,580, respectively	12,802,652	4,328,802
Inventory	2,378,221	1,485,358
Other current assets	6,509,646	6,604,284
Total current assets	211,689,812	139,554,072
Fixed assets, net	381,928	437,055
Other Assets:		
Intangible assets, net	3,771,530	3,099,747
License rights	20,000,000	—
Long term deferred financing fees	759,229	—
Security deposit	150,522	139,036
Total other assets	24,681,281	3,238,783
Total assets	$ 236,753,021	$ 143,229,910
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 11,382,093	$ 4,097,600
Accrued expenses and other current liabilities	17,894,582	9,223,595
Total current liabilities	29,276,675	13,321,195
Long-term Liabilities:		
Long-term debt	73,261,065	—
Total long-term liabilities	73,261,065	—
Total liabilities	102,537,740	13,321,195
Commitments and Contingencies - See Note 15		
Stockholders' Equity:		
Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - par value $0.001; 350,000,000 shares authorized:		
236,464,789 and 216,429,642 issued and outstanding, respectively	236,465	216,430
Additional paid-in capital	613,864,115	516,351,405
Accumulated deficit	(479,885,299)	(386,659,120)
Total stockholders' equity	134,215,281	129,908,715
Total liabilities and stockholders' equity	$ 236,753,021	$ 143,229,910

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues, net	$3,473,535	$4,417,598	$11,009,937	$12,653,495
Cost of goods sold	699,118	700,814	1,786,902	2,042,174
Gross profit	2,774,417	3,716,784	9,223,035	10,611,321
Operating expenses:				
Sales, general, and administration	30,354,072	12,057,868	80,578,079	43,524,412
Research and development	6,708,271	6,436,802	20,545,948	22,878,037
Depreciation and amortization	73,321	54,055	198,545	156,943
Total operating expense	37,135,664	18,548,725	101,322,572	66,559,392
Operating loss	(34,361,247)	(14,831,941)	(92,099,537)	(55,948,071)
Other income (expense):				
Miscellaneous income	809,022	167,300	1,457,817	442,322
Accreted interest	—	—	—	7,699
Interest expense	(2,053,077)	—	(2,584,459)	—
Total other (expense) income	(1,244,055)	167,300	(1,126,642)	450,021
Loss before taxes	(35,605,302)	(14,664,641)	(93,226,179)	(55,498,050)
Provision for income taxes	—	—	—	—
Net loss	$(35,605,302)	$(14,664,641)	$(93,226,179)	$(55,498,050)
Net loss per share, basic and diluted	$(0.16)	$(0.07)	$(0.42)	$(0.27)
Weighted average number of common shares outstanding	228,107,240	207,938,338	220,466,673	203,282,335

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended	
	September 30, 2018	September 30, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(93,226,179)	$ (55,498,050)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation of fixed assets	121,423	104,622
Amortization of intangible assets	77,123	52,321
Provision for doubtful accounts	231,475	1,555
Share-based compensation	6,388,635	5,037,783
Amortization of deferred financing costs	149,909	—
Changes in operating assets and liabilities:		
Accounts receivable	(8,705,325)	106,509
Inventory	(892,863)	(217,196)
Other current assets	1,233,482	(831,623)
Accounts payable	7,284,493	(3,159,145)
Accrued interest	59,375	—
Accrued expenses and other current liabilities	8,611,611	(946,853)
Net cash used in operating activities	(78,666,841)	(55,350,077)
CASH FLOWS FROM INVESTING ACTIVITIES		
Payment for intellectual property license	(20,000,000)	—
Patent costs	(748,906)	(439,770)
Purchase of fixed assets	(66,295)	(35,849)
Payment of security deposit	(11,485)	—
Net cash used in investing activities	(20,826,686)	(475,619)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net of costs	89,907,797	68,572,635
Proceeds from term loan	75,000,000	—
Payment of deferred financing fees	(3,786,918)	—
Proceeds from exercise of options	1,236,313	212,615
Proceeds from exercise of warrants	—	3,798,999
Net cash provided by financing activities	162,357,192	72,584,249
Increase in cash	62,863,665	16,758,553
Cash, beginning of period	127,135,628	131,534,101
Cash, end of period	$189,999,293	$ 148,292,654
Supplemental disclosure of cash flow information		
Interest paid	$1,759,316	$ —

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – THE COMPANY

TherapeuticsMD, Inc., a Nevada corporation, or TherapeuticsMD or the Company, has three wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed; BocaGreenMD, Inc., a Nevada corporation, or BocaGreen; and VitaCare Prescription Services, Inc., a Florida corporation, or VitaCare. Unless the context otherwise requires, TherapeuticsMD, VitaMed, BocaGreen, and VitaCare collectively are sometimes referred to as “our company,” “we,” “our,” or “us.”

Nature of Business

We are a women’s health care company focused on creating and commercializing products targeted exclusively for women. In July 2018, we launched our recently U.S. Food and Drug Administration, or FDA, approved product, IMVEXXY™ (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy, or VVA, due to menopause. We are also focused on commercialization activities necessary for commercialization of TX-001HR, or BIJUVA™, our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate, for the treatment of moderate to severe vasomotor symptoms, or VMS, due to menopause in menopausal women with a uterus, which was approved by the FDA on October 28, 2018. IMVEXXY™ and BIJUVA™ are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis and vaginal discomfort. With our SYMBODA™ technology, we are developing and commercializing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. On July 30, 2018, we entered into a license and supply agreement with Knight Therapeutics Inc., or Knight, pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY™ and BIJUVA™ in Canada and Israel. In addition, on July 30, 2018, we entered into an exclusive license agreement with the Population Council, Inc., or the Population Council, to commercialize in the U.S. ANNOVERA™ (segesterone acetate/ethinyl estradiol vaginal system), the first and only procedure-free, reversible prescription contraceptive to provide a full year of protection against unintended pregnancy, which was approved by the FDA on August 10, 2018. We also manufacture and distribute branded and generic prescription prenatal vitamins.

NOTE 2 – BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

Interim Financial Statements

The accompanying unaudited interim consolidated financial statements of TherapeuticsMD, Inc., which include our wholly owned subsidiaries, should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission, or the SEC, from which we derived the accompanying consolidated balance sheet as of December 31, 2017. The accompanying unaudited interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP , for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited interim consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited interim consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year or any other interim period in the future.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Recently Issued Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2018-13 that eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The FASB developed the amendments to Accounting Standards Codification 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. The new guidance is effective for all entities for fiscal years beginning after December 15, 2019 and for interim periods within those fiscal years. An entity is permitted to early adopt either the entire standard or only the provisions that eliminate or modify requirements. We are currently evaluating the effect of this guidance on our disclosures.

In June 2018, FASB issued ASU 2018-07 to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of Accounting Standards Codification, or ASC, 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity’s own operations and supersedes the guidance in ASC 505-50. The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASC 606. We are currently evaluating the effect of this guidance on our consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets but recognize expenses on their income statements in a manner similar to current accounting. The guidance also eliminates current real estate-specific provisions for all entities. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The standard is effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. We are in the process of analyzing the quantitative impact of this guidance on our results of operations and financial position. In July 2018, FASB amended the new leases standard by issuing ASU 2018-10, Codification improvements to Topic 842, Leases as well as ASU 2018-11, Leases, (Topic 842): Targeted improvements. ASU 2018-11 gives entities another option for transition and to provide lessors with a practical expedient. We plan to adopt ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed for under ASU 2018-11. We continue to assess all potential impacts of the standard and we currently believe the impact of this standard will be primarily related to the accounting for our current operating lease and a new operating lease entered into in the third quarter of 2018.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under previous guidance. This may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB approved the proposal to defer the effective date of ASU 2014-09 standard by one year. Early adoption is permitted after December 15, 2016, and the standard is effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods therein. In 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations (ASU 2016-08), accounting for licenses of intellectual property and identifying performance obligations (ASU 2016- 10), narrow-scope improvements and practical expedients (ASU 2016-12) and technical corrections and improvements to topic 606 (ASU 2016-20) in its new revenue standard. We adopted this standard under the modified retrospective method to all contracts not completed as of January 1, 2018 and the adoption did not have a material effect on our financial statements but we expanded our disclosures related to contracts with customers in Note 3.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair Value of Financial Instruments

Our financial instruments consist primarily of cash, accounts receivable, accounts payable and accrued expenses and long-term debt. The carrying amount of cash, accounts receivable, accounts payable and accrued expenses approximates their fair value because of the short-term maturity of such instruments, which are considered Level 1 assets under the fair value hierarchy.

We categorize our assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy as defined by Accounting Standards Codification, or ASC, 820, *Fair Value Measurements.* The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). Assets and liabilities recorded or disclosed in the consolidated balance sheet at fair value are categorized based on a hierarchy of inputs, as follows:

Level 1	unadjusted quoted prices in active markets for identical assets or liabilities;
Level 2	quoted prices for similar assets or liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and
Level 3	unobservable inputs for the asset or liability.

At September 30, 2018 and 2017, we had no assets or liabilities that were valued at fair value on a recurring basis.

The fair value of indefinite-lived assets or long-lived assets is measured on a non-recurring basis using significant unobservable inputs (Level 3) in connection with our impairment test. There was no impairment of intangible assets or long-lived assets during the three and nine months ended September 30, 2018 and 2017.

The carrying amounts for the Term Loan (as discussed in Note 9) approximates fair value based on market activity for other debt instruments with similar characteristics and comparable risk .

Trade Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are customer obligations due under normal trade terms. We review accounts receivable for uncollectible accounts and credit card charge-backs and provide an allowance for doubtful accounts, which is based upon a review of outstanding receivables, historical collection information, and existing economic conditions. We consider trade accounts receivable past due for more than 90 days to be delinquent. We write off delinquent receivables against our allowance for doubtful accounts based on individual credit evaluations, the results of collection efforts, and specific circumstances of customers. We record recoveries of accounts previously written off when received as an increase in the allowance for doubtful accounts. To the extent data we use to calculate these estimates does not accurately reflect bad debts, adjustments to these reserves may be required.

Inventories

Inventories are valued at the lower of cost or net realizable value. Inventories related to packaged vitamins, nutritional products and supplements and raw materials are valued using the average-cost method and inventories related to our progesterone and estradiol products are valued using first in first out method. We review our inventory for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. Obsolescence may occur due to product expiring or product improvements rendering previous versions obsolete.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Pre-Launch Inventory

Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if we believe there is probable future commercial use and future economic benefit. If the probability of future commercial use and future economic benefit cannot be reasonably determined, then pre-launch inventory costs associated with such product candidates are expensed as research and development expenses during the period the costs are incurred. We had no capitalized pre-launch inventory as of September 30, 2018 or 2017.

Revenue Recognition

We adopted Accounting Standards Codification, or ASC, 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. ASC 606 states that a contract is considered "completed" if all (or substantially all) of the revenue was recognized in accordance with revenue guidance that was in effect before the date of initial application. Because all (or substantially all) of the revenue related to sales of our products has been recognized under ASC 605 prior to the date of initial application of the new standard, the contracts are considered completed under ASC 606. Based on our evaluation of ASC 606, we concluded that a cumulative adjustment was not necessary upon implementation of ASC 606 on January 1, 2018.

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods or services. The provisions of ASC 606 include a five-step process by which we determine revenue recognition, depicting the transfer of goods or services to customers in amounts reflecting the payment to which we expect to be entitled in exchange for those goods or services. ASC 606 requires us to apply the following steps: (1) identify the contract with the customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, we satisfy the performance obligation.

Prescription Products

Our products consist primarily of prescription vitamins and our recently approved product IMVEXXY,™ which we began selling during the third quarter of 2018. We sell our name brand and generic prescription products primarily

through wholesale distributors and retail pharmacy distributors. We have one performance obligation related to prescription products sold through wholesale distributors which is to transfer promised goods to a customer and two performance obligations related to products sold through retail pharmacy distributors, which are to: (1) transfer promised goods and (2) provide customer service for an immaterial fee. We treat shipping as a fulfillment activity rather than as a separate obligation. We recognize prescription revenue only when we satisfy performance obligations by transferring a promised good or service to a customer. A good or service is considered to be transferred when the customer receives the goods or service or obtains control. Control refers to the customer's ability to direct the use of, and obtain substantially all of the remaining benefits from, an asset. All of our performance obligations, and associated revenue, are transferred to customers at a point in time. Based on our contracts, we invoice customers once our performance obligations have been satisfied, at which point payment is unconditional. We disclose receivables from contracts with customers separately in the statement of financial position. Payment for goods or services sold by us is typically due between 30 and 60 days after an invoice is sent to the customer.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

The transaction price of a contract is the amount of consideration which we expect to be entitled to in exchange for transferring promised goods or services to a customer. Prescription products are sold at fixed wholesale acquisition cost, or WAC, determined based on our list price. However, the total transaction price is variable as it is calculated net of estimated product returns, chargebacks, rebates, coupons, discounts and wholesaler fees. These estimates are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). In order to determine the transaction price, we estimate the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract or each variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. In determining amounts of variable consideration to include in a contract's transaction price, we rely on our historical experience and other evidence that supports our qualitative assessment of whether revenue would be subject to a significant reversal. We consider all the facts and circumstances associated with both the risk of a revenue reversal arising from an uncertain future event and the magnitude of the reversal if that uncertain event were to occur. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our original estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such changes in estimates become known.

We accept returns of unsalable prescription products sold through wholesale distributors within a return period of six months prior to and up to 12 months following product expiration. Our prescription products currently have a shelf life of 24 months from the date of manufacture. We do not allow product returns for prescription products that have been dispensed to a patient. We estimate the amount of our product sales that may be returned by our customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. Where historical rates of return exist, we use history as a basis to establish a returns reserve for products shipped to wholesalers. For our newly launched products, for which the right of return exists but for which we currently do not have history of product returns, we estimate returns based on available industry data, our own sales information and our visibility into the inventory remaining in the distribution channel. At the end of each reporting period, we may decide to constrain revenue for product returns based on information from various sources, including channel inventory levels and dating and sell-through data, the expiration dates of products currently being shipped, price changes of competitive products and any introductions of generic products. We recognize the amount of expected returns as a refund liability, representing the obligation to return the customer's consideration. Since our returns primarily consist of expired and short dated products that will not be resold, we do not record a return asset for the right to recover the goods returned by the customer at the time of the initial sale. Return estimates are recorded in the other current liabilities on the consolidated balance sheet.

We offer various rebate and discount programs in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. We estimate the allowance for consumer rebates and coupons that we have offered based on our experience and industry averages, which is reviewed, and adjusted if necessary, on a quarterly

basis. Estimates relating to these rebates and coupons are deducted from gross product revenues at the time the revenues are recognized. We record distributor fees based on amounts stated in contracts. Rebates estimates are recorded in accrued expenses and coupon estimates and distributor fees are recorded in the other current liabilities on the consolidated balance sheet. We estimate chargebacks based on number of units sold during the period taking into account prices stated in contracts and our historical experience. We provide invoice discounts to our customers for prompt payment. Estimates relating to invoice discounts and chargebacks are deducted from gross product revenues at the time the revenues are recognized. Estimates related to distributors fees, rebates, coupons and returns are disclosed in Note 8.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

As part of the commercial launch for IMVEXXY™ during the third quarter of 2018, we introduced a co-pay assistance program where enrolled patients do not pay more than $35 for up to 12 IMVEXXY™ prescription fills. This allows patients to access the product at a reasonable cost regardless of insurance coverage. We reimburse pharmacies for this discount through third-party vendors. We consider these payments as consideration paid to the customer and reflect such payments as a reduction of the transaction price as we do not receive a distinct good or service related to these payments. The variable consideration is estimated based on contract prices, the estimated percentage of patients that will utilize the copay assistance, the average assistance paid based on reporting from the third-party vendors, the estimated levels of inventory in the distribution channel and the current level of prescriptions covered by patients' insurance. We record an accrual to reduce gross sales for the estimated co-pay and other patient assistance based on currently available third-party data and our internal analyses. Payers may change coverage levels for IMVEXXY™, positively or negatively, at any time up to the time that we have formally contracted coverage with the payer. As such, the net transaction price of IMVEXXY™ is susceptible to such changes in coverage levels, which are outside the influence of the Company. As a result, we constrain revenue recognized for IMVEXXY™ to an amount that will not result in a significant revenue reversal in future periods. Our ability to estimate the net transaction price for IMVEXXY™ is constrained by our estimates of the amount to be paid for the co-pay assistance program for IMVEXXY™ which is directly related to the level of prescriptions paid for by insurance. During the third quarter of 2018, following the commercial launch of IMVEXXY™, only a small portion of IMVEXXY™ prescriptions were covered by insurance. We re-evaluate any constraint each reporting period.

OTC Products

Our over the counter, or OTC, and prescription prenatal vitamin products are generally variations of the same product with slight modifications in formulation and marketing. As of January 1, 2017, we decided to focus on selling our prescription vitamins and ceased manufacturing and distributing our OTC product lines, except for Iron 21/7 which we ceased manufacturing in October 2017. We generated OTC revenue from product sales primarily to retail consumers. We recognized revenue from product sales upon shipment, when the rights of ownership and risk of loss have passed to the consumer. We included outbound shipping and handling fees, if any, in revenues, net, and bill them upon shipment. We included shipping expenses in cost of goods sold. A majority of our OTC customers paid for our products with credit cards, and we usually received the cash settlement in two to three banking days. Credit card sales minimized accounts receivable balances relative to OTC sales. We provided an unconditional 30-day money-back return policy under which we accept product returns from our retail and eCommerce OTC customers. We recognized revenue from OTC sales, net of estimated returns and sales discounts.

Disaggregation of revenue

The following table provides information about disaggregated revenue by product mix for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Prescription vitamins	$3,261,459	$4,407,464	$10,797,861	$12,623,152
IMVEXXY™	212,076	—	212,076	—
OTC products	—	10,134	—	30,343
Net revenue	$3,473,535	$4,417,598	$11,009,937	$12,653,495

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Share-Based Compensation

We measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share-based compensation arrangements may include options, restricted stock, restricted stock units, performance-based awards, share appreciation rights, and employee share purchase plans. We amortize such compensation amounts, if any, over the respective service periods of the award. We use the Black-Scholes-Merton option pricing model, or the Black-Scholes Model, an acceptable model in accordance with ASC 718, Compensation-Stock Compensation, to value options. Option valuation models require the input of assumptions, including the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate, and the expected dividend yield. The risk-free interest rate assumption is based upon observed interest rates on zero coupon U.S. Treasury bonds whose maturity period is appropriate for the term of the instrument. Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of the award. Prior to January 1, 2017, the expected volatility of share options was estimated based on a historical volatility analysis of peer entities whose stock prices were publicly available that were similar to the Company with respect to industry, stage of life cycle, market capitalization, and financial leverage. On January 1, 2017, we began using our own stock price in our volatility calculation along with the other peer entities whose stock prices were publicly available that were similar to our company. Our calculation of estimated volatility is based on historical stock prices over a period equal to the expected term of the awards. The average expected life is based on the contractual terms of the stock option using the simplified method. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including forfeiture rates, estimates of expected life of the share-based award, stock price volatility and risk-free interest rates. The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

Equity instruments (“instruments”) issued to non-employees are recorded on the basis of the fair value of the instruments, as required by ASC 505, Equity - Based Payments to Non-Employees, or ASC 505. ASC 505 defines the measurement date and recognition period for such instruments. In general, the measurement date is when either (a) a performance commitment, as defined, is reached or (b) the earlier of (i) the non-employee performance is complete or (ii) the instruments are vested. The estimated expense is recognized each period based on the current fair value of the award. As a result, the amount of expense related to awards to non-employees can fluctuate significantly during the period from the date of the grant through the final measurement date. The measured value related to the instruments is recognized over a period based on the facts and circumstances of each particular grant as defined in ASC 505. We recognize the compensation expense for all share-based compensation granted based on the grant date fair value estimated in accordance with ASC 718. We generally recognize the compensation expense on a straight-line basis over the employee’s requisite service period. We account for forfeitures when they occur.

12

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Research and Development Expenses

Research and development, or R&D, expenses include internal R&D activities, services of external contract research organizations, or CROs, costs of their clinical research sites, manufacturing, scale-up and validation costs, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting and legal fees and costs. The activities undertaken by our regulatory consultants that were classified as R&D expenses include assisting, consulting with, and advising our in-house staff with respect to various FDA submission processes, clinical trial processes, and scientific writing matters, including preparing protocols and FDA submissions. Legal activities that were classified as R&D expenses include professional research and advice regarding R&D, patents and regulatory matters. These consulting and legal expenses were direct costs associated with preparing, reviewing, and undertaking work for our clinical trials and investigative drugs. We charge internal R&D activities and other activity expenses to operations as incurred. We make payments to CROs based on agreed-upon terms, which may include payments in advance of a study starting date. We expense nonrefundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when the goods have been received rather than when the payment is made. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion stage of a study as provided by CROs. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. We charge revisions to expense in the period in which the facts that give rise to the revision become known.

Segment Reporting

We are managed and operated as one business, which is focused on creating and commercializing products targeted exclusively for women. Our business operations are managed by a single management team that reports to the President of our company. We do not operate separate lines of business with respect to any of our products and we do not prepare discrete financial information with respect to separate products. All product sales are derived from sales in the United States. Accordingly, we view our business as one reportable operating segment.

NOTE 4 – INVENTORY

Inventory consists of the following:

	September 30, 2018	December 31, 2017
Finished product	$2,254,822	$1,485,358
Work in process	83,911	—
Raw materials	39,488	—
TOTAL INVENTORY	$2,378,221	$1,485,358

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	September 30, 2018	December 31, 2017
Prepaid sales and marketing costs	$1,341,899	$5,335,936
Debt financing fees	1,138,844	—
Prepaid insurance	1,127,416	680,243
Other prepaid costs	2,682,952	523,694
Prepaid vendor deposits	218,535	64,411
TOTAL OTHER CURRENT ASSETS	$6,509,646	$6,604,284

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 6 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	September 30, 2018	December 31, 2017
Accounting system	$301,096	$301,096
Equipment	339,832	273,536
Furniture and fixtures	116,542	116,542
Computer hardware	80,211	80,211
Leasehold improvements	37,888	37,888
TOTAL	875,569	809,273
Accumulated depreciation	(493,641)	(372,218)
TOTAL FIXED ASSETS, NET	$381,928	$437,055

Depreciation expense for the three months ended September 30, 2018 and 2017 was $42,221 and $35,622, respectively, and $121,423 and $104,622 for the nine months ended September 30, 2018 and 2017, respectively.

NOTE 7 – INTANGIBLE ASSETS

The following tables sets forth the gross carrying amount, accumulated amortization and net carrying amount of our intangible assets, (excluding licenses) as of September 30, 2018 and December 31, 2017:

	September 30, 2018			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$31,951	$ (9,985)	$21,966	11

Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	1,991,790	(247,536)	1,744,254	14.25
Hormone therapy drug candidate patents (pending)	1,749,561	—	1,749,561	n/a
Non-amortizable intangible assets:				
Multiple trademarks	255,749	—	255,749	indefinite
Total	$4,120,794	$ (349,264)	$3,771,530	

14

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

	December 31, 2017			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$31,951	$ (8,487)	$23,464	11.75
Development costs				