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.

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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.

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.

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.

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.

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.

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.

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

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.

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

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	

	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 of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	1,293,614	(171,911)	1,121,703	15
Hormone therapy drug candidate patents (pending)	1,721,305	—	1,721,305	n/a
Non-amortizable intangible assets:				
Multiple trademarks	233,275	—	233,275	indefinite
Total	$ 3,371,888	$ (272,141)	$ 3,099,747	

We capitalize external costs, consisting primarily of legal costs, related to securing our patents and trademarks. Once a patent is granted, we amortize the approved hormone therapy drug candidate patents using the straight-line method over the estimated useful life of approximately 20 years, which is the life of intellectual property patents. If the patent is not granted, we write-off any capitalized patent costs at that time. Trademarks are perpetual and are not amortized. During the three and nine months ended September 30, 2018 and year ended December 31, 2017, there was no impairment recognized related to intangible assets.

We have numerous pending foreign and domestic patent applications. As of September 30, 2018, we had 22 issued foreign patents and 20 issued domestic, or U.S., patents including:

- 14 domestic utility patents that relate to our combination progesterone and estradiol product candidates, which are owned by us. These domestic utility patents will expire in 2032. In addition, we have pending patent applications with respect to our combination progesterone and estradiol product candidates in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- Three domestic patents that relate to IMVEXXY™. These patents establish an important intellectual property foundation for IMVEXXY™ and are owned by us. These domestic patents will expire in 2032 or 2033. In addition, we have pending patent applications related to IMVEXXY™ in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea;
- One domestic utility patent that relates to our pipeline transdermal patch technology, which is owned by us. The domestic utility patent will expire in 2032. We have pending patent applications with respect to this technology in the U.S., Australia, Brazil, Canada, Europe, Mexico, Japan, and South Africa;
- One domestic utility patent that relates to our OPERA® information-technology platform, which is owned by us and will expire in 2029; and
- One domestic utility patent that relates to TX-009HR, our progesterone and estradiol product candidate, which is owned by us and will expire in 2037.

Amortization expense was $31,100 and $18,433 for the three months ended September 30, 2018 and 2017, respectively and $77,123 and $52,321 for the nine months ended September 30, 2018 and 2017, respectively. Estimated amortization expense for the next five years for the patent cost currently being amortized is as follows:

Year Ending December 31,	Estimated Amortization
2018 (3 months)	$ 31,100
2019	$ 124,400
2020	$ 124,400
2021	$ 124,400
2022	$ 124,400
Thereafter	$ 1,237,520

License Agreement with the Population Council

On July 30, 2018, we entered into an exclusive license agreement, or the Council License Agreement, with the Population Council to commercialize in the U.S. ANNOVERA™. We currently estimate that the ANNOVERA™ will be commercially available as early as the third quarter of 2019 with a planned commercial launch in the fourth quarter of 2019.

Under the terms of the Council License Agreement, we paid the Population Council a milestone payment of $20,000,000 within 30 days following approval by the FDA of the New Drug Application, or NDA, for ANNOVERA™ and will be required to pay the Population Council $20,000,000 within 30 days following the release of the first commercial batch of ANNOVERA™. The Population Council is also eligible to receive milestone payments and royalties from commercial sales of ANNOVERA™. We will assume responsibility for marketing expenses related to the commercialization of ANNOVERA™. The milestone payment of $20,000,000 upon the FDA's approval of ANNOVERA™ in the third quarter of 2018 was recorded as a finite-lived intangible asset in the consolidated balance sheet and will be amortized on a straight-line basis once it becomes available for use which is expected to be upon release of first commercial batch of ANNOVERA™.

The Council License Agreement includes exclusive rights for us to negotiate co-development of two other investigational vaginal contraceptive systems in development by the Population Council. In addition, we are required to pay the Population Council, on a quarterly basis, step-based royalty payments based on annual net sales of ANNOVERA™ in the U.S. by the Company and its affiliates and permitted licensees as follows: (i) if annual net sales are less than or equal to $50,000,000, a royalty of 5% of net sales; (ii) for annual net sales greater than $50,000,000 and less than or equal to $150,000,000, a royalty of 10% of such net sales; and (iii) for net sales greater than $150,000,000, a royalty of 15% of such net sales. The annual royalty rate will be reduced to 50% of the initial rate during the six-month period beginning on the date of the first arms-length commercial sale of a generic equivalent of the one-year vaginal contraceptive system that is launched by a third party in the U.S., and thereafter will be reduced to 20% of the initial rate. The Population Council has agreed to perform and pay the costs and expenses associated with four post-approval studies required by the FDA for ANNOVERA™ and we have agreed to perform and pay the costs and expenses associated with a post approval study required by the FDA to measure risk for venous thromboembolism, provided that if the costs and expenses associated with such post-approval study exceed $20,000,000, half of such excess will be offset against royalties or other payments owed by us to the Population Council under the Council License Agreement. We and the Population Council have agreed to form a joint product committee responsible for overseeing activities under the Council License Agreement. We will be responsible for all aspects of promotion, product positioning, pricing, education programs, publications, sales messages and any additional desired clinical studies for the one-year vaginal contraceptive system, subject to oversight and decisions made by the joint product committee.

We assess our intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. If impairment indicators are present or changes in circumstance suggest that impairment may exist, we perform a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, we would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value. We also evaluate the remaining useful life of intangible assets subject to amortization on a periodic basis to determine whether events and circumstances would indicate impairment or warrant a revision to the remaining useful life. If the estimate of an intangible asset's remaining useful life is changed, we will amortize the remaining carrying value of the intangible asset prospectively over the revised remaining useful life.

License Agreement with Knight Therapeutics Inc.

On July 30, 2018, we entered into a license and supply agreement, or the Knight License Agreement, with Knight pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY™ and BIJUVA™ in Canada and Israel. Pursuant to the terms of the Knight License Agreement, Knight will pay us a milestone fee upon first regulatory approval in Canada of each of IMVEXXY™ and BIJUVA™, sales milestone fees based upon certain aggregate annual sales in Canada and Israel of each of IMVEXXY™ and BIJUVA™ and royalties based on aggregate annual sales of each of IMVEXXY™ and BIJUVA™ in Canada and Israel. Knight will be responsible for all regulatory and commercial activities in Canada and Israel related to IMVEXXY™ and BIJUVA™. We may terminate the Knight License Agreement if Knight does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize IMVEXXY™ and BIJUVA™ in Canada and Israel within certain specified time periods. We also may terminate the Knight License Agreement if Knight challenges our patents. Either party may terminate the Knight License Agreement for any material breach by the other party that is not cured within certain specified time periods or if the other party files for bankruptcy or other related matters. In connection with the Knight License Agreement, Knight entered into a subscription agreement with us pursuant to which Knight agreed to purchase from us $20,000,000 of shares of Common Stock concurrently with the closing of our first underwritten public offering of Common Stock to occur within 60 days following the date of the Knight License Agreement with gross proceeds to us of not less than $50,000,000, at a price per share equal to the price per share to the public in such underwritten public offering, which Knight purchased in connection with the August 2018 underwritten public offering described in Note 11.

NOTE 8 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	September 30, 2018	December 31, 2017
Accrued payroll, bonuses and commission costs	$ 3,683,863	$ 4,240,379
Accrued patient assistance program	4,389,948	—
Allowance for coupons and returns	1,817,112	1,432,846
Accrued sales and marketing costs	1,982,872	420,162
Accrued compensated absences	1,115,615	945,457
Accrued legal and accounting expense	576,522	600,350
Other accrued expenses	2,450,022	525,999
Accrued research and development	587,220	366,933
Accrued interest	59,375	—
Accrued rent	354,490	327,099
SAR liability	36,392	—
Accrued rebates	44,297	76,917
Allowance for wholesale distributor fees	796,854	172,973
Accrued royalties	—	114,480
TOTAL OTHER CURRENT LIABILITIES	$ 17,894,582	$ 9,223,595

NOTE 9 – DEBT

On May 1, 2018, we entered into a Credit and Security Agreement, or the Credit Agreement, with MidCap Financial Trust, or MidCap, as agent, or Agent, and as lender, and the additional lenders party thereto from time to time (together with MidCap as a lender, the Lenders).

On July 30, 2018, we entered into Amendment No. 1 to the Credit Agreement in order to permit our entry into the Council License Agreement. Pursuant to the amendment, we were required to receive aggregate net cash proceeds of at least $75,000,000 from the issuance of our equity securities within thirty days of entering into the Council License Agreement, which we did in connection with the August 2018 underwritten public offering described in Note 11.

The Credit Agreement provides a secured term loan facility in an aggregate principal amount of up to $200,000,000, or the Term Loan. Under the terms of the Credit Agreement, the Term Loan will be made in three separate tranches, each, a Tranche, with each Tranche to be made available to us, at our option, upon our achievement of certain milestones. The first Tranche of $75,000,000, or Tranche 1, was drawn by us on June 7, 2018, following approval by the FDA of the NDA for IMVEXXY™. The second Tranche of $75,000,000, or Tranche 2, may be drawn by us on or before May 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including (i) that Tranche 1 has been drawn, (ii) the approval by the FDA of the NDA for BIJUVA™ and (iii) we have consummated our first commercial sale in the United States of BIJUVA™. The third Tranche of $50,000,000, or Tranche 3, may be drawn by us on or before December 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including that (i) Tranche 2 has been drawn and (ii) we have generated at least $75,000,000 of consolidated net revenue attributable to commercial sales of BIJUVA™ and IMVEXXY™ during the twelve-month period ending immediately prior to the funding of Tranche 3.

Amounts borrowed under the Term Loan bear interest at a rate equal to the sum of (i) one-month LIBOR (subject to a LIBOR floor of 1.50%) plus (ii) 7.75% per annum. Interest on amounts borrowed under the Term Loan is due and payable monthly in arrears. Principal on each Tranche is payable in 36 equal monthly installments beginning May 1, 2020 until paid in full on May 1, 2023, or the Maturity Date. However, if we generate at least $95,000,000 of consolidated net revenue attributable to commercial sales of BIJUVA™ and IMVEXXY™ by December 31, 2019, we may extend the interest-only period by an additional 12 months to May 1, 2021. Interest expense related to this Term Loan for the three and nine months ending September 30, 2018 was $1,933,324 and $2,434,550, respectively.

The Term Loan may be prepaid, in whole or in part, subject to a prepayment fee on the amount being prepaid (or required to be prepaid, if such amount is greater) of (i) 4.0% for the first year following the Tranche 1 funding date, (ii) 3.0% for the second year following the Tranche 1 funding date and (iii) 2.0% thereafter. Upon repayment of the Term Loan at the Maturity Date or prepayment on any earlier date, we will be required to pay a termination payment based on the principal amount paid or prepaid. In connection with the execution of the Credit Agreement, we paid the Agent, for the benefit of all Lenders, an origination fee equal to 1.00% of the maximum potential amount of the Term Loan. We are also required to pay the Agent an annual administration fee of 0.25% based on the amounts borrowed under the Term Loan, in addition to other fees and expenses.

Our obligations under the Credit Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a first priority perfected security interest in all of our existing and after-acquired assets. Our obligations under the Credit Agreement are guaranteed by each of our future direct and indirect subsidiaries (other than certain non-U.S. subsidiaries of ours and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, subject to certain exceptions). The Credit Agreement contains customary restrictions and covenants. Among other requirements, we must (i) maintain a minimum cash balance of $50,000,000 and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of our products. As of September 30, 2018, we were in compliance with the covenants under the Credit Agreement.

The Credit Agreement also contains customary covenants that limit, among other things, our ability to (i) incur indebtedness, (ii) incur liens on our property, (iii) pay dividends or make other distributions, (iv) sell our assets, (v) make certain loans or investments, (vi) merge or consolidate, (vii) voluntarily repay or prepay certain permitted indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions. The Credit Agreement contains customary representations and warranties and events of default relating to, among other things, payment defaults, breaches of covenants, the occurrence of any fact, event or circumstance that could reasonably be expected to result in a Material Adverse Effect (as defined in the Credit Agreement), delisting of our common stock, par value $0.001 per share, or Common Stock, bankruptcy and insolvency, cross defaults with certain material indebtedness and certain material contracts, judgments and inaccuracies of representations and warranties. Upon or after an event of default, the agent and the Lenders may declare all or a portion of our obligations under the Credit Agreement to be immediately due and payable and exercise other rights and remedies provided for under the Credit Agreement.

As of September 30, 2018, we had $75,000,000 in borrowings outstanding under the Term Loan, which are classified as long-term debt in the accompanying unaudited consolidated financial statements. We incurred $3,786,918 in debt issuance costs related to the Term Loan. Debt financing fees related to the entire Term Loan have been allocated pro rata between the funded and unfunded portions of each tranche. Allocated debt financing fees related to Tranche 1 of $1,888,844 have been reclassified to debt discount and are accreted to interest expense using the effective interest method. Debt financing fees associated with unfunded tranches are deferred as assets until Tranche 2 and Tranche 3 milestones have been met. Deferred financing fees related to Tranche 2 are included in Other current assets and deferred financing fees related to Tranche 3 are included in Total other assets in the accompanying unaudited consolidated financial statements. During the three and nine months ended September 30, 2018, we amortized $119,753 and $149,909, respectively, of debt issuance costs related to Tranche 1 as interest expense in our accompanying unaudited consolidated financial statements. The overall effective interest rate was 10.9% as of September 30, 2018. As of September 30, 2018, the carrying value of debt consists of the following:

	September 30, 2018
Term Loan	$ 75,000,000
Debt discount and financing fees	(1,738,935)
Total long-term debt	$ 73,261,065

NOTE 10 – NET LOSS PER SHARE

We calculate earnings per share, or EPS, in accordance with ASC 260, Earnings Per Share, which requires the computation and disclosure of two EPS amounts: basic and diluted. We compute basic EPS based on the weighted-average number of shares of Common Stock outstanding during the period. We compute diluted EPS based on the weighted-average number of shares of our Common Stock outstanding plus all potentially dilutive shares of our Common Stock outstanding during the period. Such potentially dilutive shares of our Common Stock consist of options and warrants and were excluded from the calculation of diluted earnings per share because their effect would have been anti-dilutive due to the net loss reported by us. The table below presents potentially dilutive securities that could affect our calculation of diluted net loss per share allocable to common stockholders for the periods presented.

	Three and Nine months ended September 30,	
	2018	2017
Stock options	24,837,349	23,383,100
Warrants	3,007,571	3,115,905
	27,844,920	26,499,005

NOTE 11 – STOCKHOLDERS' EQUITY

Preferred Stock

At September 30, 2018, we had 10,000,000 shares of preferred stock, par value $0.001, authorized for issuance, of which no shares of preferred stock were issued or outstanding.

Common Stock

At September 30, 2018, we had 350,000,000 shares of Common Stock authorized for issuance, of which 236,464,789 shares of Common Stock were issued and outstanding.

On August 1, 2018, we entered into an underwriting agreement with Goldman Sachs & Co. LLC, as representative of the underwriters, relating to an underwritten public offering of 12,745,098 shares of our Common Stock at a price of $5.10 per share. We granted the underwriters an option, exercisable for a period of 30 days, to purchase up to 1,911,764 additional shares of Common Stock. On August 2, 2018, the underwriters exercised the option in full. The net proceeds from the offering, including the exercise of the option to purchase additional shares, were approximately $69,908,000, after deducting the underwriting discount and offering expenses payable by us. The offering closed on August 6, 2018.

In connection with the Knight License Agreement, Knight entered into a subscription agreement with us, pursuant to which Knight purchased $20,000,000 of shares of our Common Stock concurrently with the closing of the underwritten public offering of Common Stock on August 6, 2018.

Issuances During the Three and Nine Months Ended September 30, 2018

During the three months ended September 30, 2018, certain individuals exercised stock options to purchase 1,052,300 shares of Common Stock for $107,318 in cash. During the nine months ended September 30, 2018, certain individuals exercised stock options to purchase 1,446,876 shares of Common Stock for $1,236,313 in cash. Also, during the nine months ended September 30, 2018, stock options to purchase 10,000 shares of Common Stock were exercised pursuant to the options' cashless exercise provisions, wherein 9,841 shares of Common Stock were issued.

Issuances During the Three and Nine Months Ended September 30, 2017

On September 25, 2017, we entered into an underwriting agreement with J.P. Morgan Securities LLC relating to an underwritten public offering of 12,400,000 shares of our Common Stock at a price of $5.55 per share. The net proceeds to us from the offering were approximately $68,573,000, after deducting estimated offering expenses payable by us. The offering closed on September 28, 2017 and we issued 12,400,000 shares of Common Stock.

During the three months ended September 30, 2017, certain individuals exercised stock options to purchase 2,500 shares of Common Stock for $255 in cash. During the nine months ended September 30, 2017, certain individuals exercised stock options to purchase 102,546 shares of Common Stock for $212,615 in cash.

Warrants to Purchase Common Stock

As of September 30, 2018, we had warrants outstanding to purchase an aggregate of 3,007,571 shares of Common Stock with a weighted-average contractual remaining life of approximately 1.8 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $2.78 per share.

The valuation methodology used to determine the fair value of our warrants is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions, including volatility of the stock price, the risk-free interest rate, dividend rate and the term of the warrant. During the nine months ended September 30, 2018, we granted warrants to purchase 175,000 shares of Common Stock to outside consultants at an exercise price of $5.16. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of 5 years; volatility of 62.1%; risk free rate of 2.36%; and dividend yield of 0%. The grant date fair value of the warrants was $2.79 per share. The warrants vest ratably over a 12-month period and have an expiration date of March 15, 2023. During the nine months ended September 30, 2017, we granted warrants to purchase 125,000 shares of Common Stock to outside consultants at an exercise price of $6.83 per share. The fair value for these warrants was determined by using the Black-Scholes Model on the date of the grant using a term of five years; volatility of 63.24%; risk free rate of 1.47%; and dividend yield of 0%. The grant date fair value of the warrants was $3.67 per share. The warrants vest ratably over a 12-month period and have an expiration date of March 15, 2022.

During the three months ended September 30, 2018 and 2017, we recorded $150,977 and $101,376, respectively, and during the nine months ended September 30, 2018 and 2017, we recorded $407,292 and $217,150, respectively, as share based compensation expense in the accompanying consolidated financial statements related to warrants. As of September 30, 2018, total unrecognized estimated compensation expense related to the unvested portion of these warrants was approximately $218,000 which is expected to be recognized over a weighted-average period of 0.5 years.

In May 2012, we issued warrants to purchase an aggregate of 1,300,000 shares of Common Stock to Sancilio and Company, Inc. for services to be rendered over approximately five years beginning in May 2012. The warrants vested upon issuance. Services provided are to include (a) services in support of our drug development efforts, including services in support our ongoing and future drug development and commercialization efforts, regulatory approval efforts, third-party investment and financing efforts, marketing efforts, chemistry, manufacturing and controls efforts, drug launch and post-approval activities, and other intellectual property and know-how transfer associated therewith; (b) services in support of our efforts to successfully obtain new drug approval; and (c) other consulting services as mutually agreed upon from time to time in relation to new drug development opportunities. The warrants were valued at $1,532,228 on the date of the issuance using an exercise price of $2.57; a term of five years; a volatility of 44.71%; risk free rate of 0.74%; and a dividend yield of 0%. During the three months ended September 30, 2018 and 2017, we did not record any expenses with respect to these warrants, and during the nine months ended September 30, 2018 and 2017, we recorded $0 and $128,898, respectively, as non-cash compensation with respect to these warrants in the accompanying consolidated financial statements. This warrant was fully exercised, of which 800,000 shares were exercised in 2017 and 500,000 shares were exercised in 2016.

During both the three months ended September 30, 2018 and 2017, no warrants were exercised. During the nine months ended September 30, 2018, no warrants were exercised. During the nine months ended September 30, 2017, certain individuals exercised warrants to purchase 2,476,666 shares of Common Stock for $3,798,999 in cash. In addition, during the nine months ended September 30, 2017, certain individuals exercised warrants to purchase 6,590,000 shares of Common Stock pursuant to the warrants' cashless exercise provisions, wherein 4,762,208 shares of Common Stock were issued.

Options to Purchase Common Stock

In 2009, we adopted the 2009 Long Term Incentive Compensation Plan, or the 2009 Plan, to provide financial incentives to employees, directors, advisers, and consultants of our company who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other stock and cash incentives, or the Awards. The Awards available under the 2009 Plan consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, and other stock or cash awards as described in the 2009 Plan. There are 25,000,000 shares of Common Stock authorized for issuance thereunder. Generally, the options vest annually over four years or as determined by our board of directors, upon each option grant. Options may be exercised by paying the price for shares or on a cashless exercise basis after they have vested and prior to the specified expiration date provided and applicable exercise conditions are met, if any. The expiration date is generally ten years from the date the option is issued. As of September 30, 2018, there were non-qualified stock options to purchase 18,558,875 shares of Common Stock outstanding under the 2009 Plan. As of September 30, 2018, there were 900,037 shares of Common Stock available to be issued under 2009 Plan.

In 2012, we adopted the 2012 Stock Incentive Plan, or the 2012 Plan, a non-qualified plan that was amended in August 2013. The 2012 Plan was designed to serve as an incentive for retaining qualified and competent key employees, officers, directors, and certain consultants and advisors of our company. The Awards available under the 2012 Plan consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, and other stock or cash awards as described in the 2012 Plan. Generally, the options vest annually over four years or as determined by our board of directors, upon each option grant. Options may be exercised by paying the price for shares or on a cashless exercise basis after they have vested and prior to the specified expiration date provided and applicable exercise conditions are met, if any. The expiration date is generally ten years from the date the option is issued. There are 10,000,000 shares of Common Stock authorized for issuance thereunder. As of September 30, 2018, there were non-qualified stock options to purchase 6,278,474 shares of Common Stock outstanding under the 2012 Plan. As of September 30, 2018, there were 3,473,333 shares of Common Stock available to be issued under 2012 Plan.

The valuation methodology used to determine the fair value of stock options is the Black-Scholes Model. The Black-Scholes Model requires the use of a number of assumptions including volatility of the stock price, the risk-free interest rate, and the expected life of the stock options. The assumptions used in the Black-Scholes Model for options granted during the nine months ended September 30, 2018 and 2017 are set forth in the table below.

	Nine Months Ended September 30,	
	2018	2017
Risk-free interest rate	2.78-2.82%	1.84-2.01%
Volatility	61.80-63.34%	61.56-63.95%
Term (in years)	5.5-6.25	5.5-6.25
Dividend yield	0.00%	0.00%

A summary of activity under the 2009 and 2012 Plans and related information follows:

	Number of Shares Underlying Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at December 31, 2017	23,365,225	$ 3.78	5.1	$ 64,664,821
Granted	3,006,500	$ 5.50		
Exercised	(1,456,876)	$ 0.85		$ 8,025,055
Expired/Forfeited	(77,500)	$ 7.41		
Balance at September 30, 2018	24,837,349	$ 4.15	5.2	$ 68,682,857
Vested and Exercisable at September 30, 2018	19,661,975	$ 3.65	4.3	$ 64,794,996
Unvested at September 30, 2018	5,175,374	$ 6.04	8.9	$ 3,887,861

At September 30, 2018, our outstanding stock options had exercise prices ranging from $0.10 to $8.92 per share. The weighted average grant date fair value per share of options granted was $3.27 and $3.82 during the nine months ended September 30, 2018 and 2017, respectively. Share-based compensation expense for options recognized in our results of operations for the three months ended September 30, 2018 and 2017 ($2,109,218 and $1,885,050, respectively) and for the nine months ended September 30, 2018 and 2017 ($5,981,343 and $4,691,735, respectively) is based on vested awards. At September 30, 2018, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $14,203,000 which may be adjusted for future forfeitures. This cost is expected to be recognized over a weighted-average period of 2.2 years. No tax benefit was realized due to a continued pattern of operating losses.

Cash-Settled Stock Appreciation Rights (SARs)

On July 1, 2018, we issued cash-settled SARs to certain consultants and employees. The SARs plan year begins on July 1 and ends on or immediately following June 30, 2019. SARs are granted with a grant price equal to the market value of a share of our Common Stock on the date of grant. Cash-settled SARs provide for the cash payment of the excess of the fair market value of our Common Stock on June 30, 2019 over the grant price. Cash-settled SARs have no effect on dilutive shares or shares outstanding as any appreciation of our Common Stock over the grant price is paid in cash and not in Common Stock.

Cash settled SARs are recorded in our consolidated balance sheets as a liability until the date of exercise. The fair value of each SAR award is estimated using the Black-Scholes valuation model. In accordance with ASC Topic 718, “Stock Compensation,” the fair value of each SAR award is recalculated at the end of each reporting period and the liability and expense adjusted based on the new fair value and the percent vested. At September 30, 2018, we had 106,000 SARs outstanding and the liability related to SAR calculation was $36,392. The assumptions used to determine the fair value of the cash settled SAR awards at September 30, 2018 were expected life of 1 year, 52.2% volatility, 2.45% risk-free rate, and zero annual dividends. As of September 30, 2018, the fair value of SARs outstanding was $1.36 per award.

NOTE 12 – INCOME TAXES

Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We do not expect to pay any significant federal or state income tax for 2018 as a result of (i) the losses recorded during the nine months ended September 30, 2018, (ii) additional losses expected for the remainder of 2018, and/or (iii) net operating loss carry forwards from prior years. Accounting standards require the consideration of a valuation allowance for deferred tax assets if it is "more likely than not" that some component or all of the benefits of deferred tax assets will not be realized. As of September 30, 2018, we maintain a full valuation allowance for all deferred tax assets. Based on these requirements, no provision or benefit for income taxes has been recorded. There were no recorded unrecognized tax benefits at the end of the reporting period.

NOTE 13 – RELATED PARTIES

In July 2015, J. Martin Carroll, a director of our company, was appointed to the board of directors of Catalent, Inc. From time to time, we have entered into agreements with Catalent, Inc. and its affiliates, or Catalent, in the normal course of business. Agreements with Catalent have been reviewed by independent directors of our company or a committee consisting of independent directors of our company since July 2015. During the three months ended September 30, 2018 and 2017, we were billed by Catalent approximately $830,000 and $186,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. During the nine months ended September 30, 2018 and 2017, we were billed by Catalent approximately $2,774,000 and $2,460,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of September 30, 2018 and December 31, 2017, there were amounts due to Catalent of approximately $4,000 and $523,000, respectively. In addition, we have minimum purchase requirements in place with Catalent as disclosed in Note 15, Commitments and Contingencies.

NOTE 14 – BUSINESS CONCENTRATIONS

Approximately 100% of our products were manufactured by one vendor related to each prenatal vitamins and IMVEXXY™ for the nine months ended September 30, 2018. Approximately 100% of our products were supplied from one vendor for our prenatal vitamins for the nine months ended September 30, 2017.

We sell our prescription prenatal vitamin products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. During both the nine months ended September 30, 2018 and 2017, four customers each generated more than 10% of our total revenues. Revenue generated from the four customers combined accounted for approximately 71% of our recognized revenue for the nine months ended September 30, 2018 and approximately 60% of our recognized revenue for the nine months ended September 30, 2017.

During the nine months ended September 30, 2018, PI Services accounted for approximately $1,559,000 of our net revenue, Pillpack, Inc. accounted for approximately $3,057,000 of our net revenue, AmerisourceBergen accounted for approximately $1,834,000 of our net revenue and Cardinal Health accounted for approximately $1,399,000 of our net revenue. During the nine months ended September 30, 2017, Pharmacy Innovations PA accounted for approximately $2,715,000 of our net revenue, AmerisourceBergen accounted for approximately $1,716,000 of our net revenue, Cardinal Health accounted for approximately $1,764,000 of our net revenue and McKesson Corporation accounted for approximately $1,458,000 of our net revenue.

NOTE 15 – COMMITMENTS AND CONTINGENCIES

Operating Lease

We lease administrative office space in Boca Raton, Florida pursuant to a non-cancelable operating lease that commenced on July 1, 2013 and originally provided for a 63-month term. On February 18, 2015, we entered into an agreement with the same lessors to lease additional administrative office space in the same location, pursuant to an addendum to such lease. In addition, on April 26, 2016, we entered into an agreement with the same lessors to lease additional administrative office space in the same location. This agreement was effective beginning May 1, 2016 and extended the original expiration of the lease term to October 31, 2021. On October 4, 2016, we entered into an agreement with the same lessors to lease additional administrative office space in the same location, pursuant to an addendum to such lease. This addendum is effective beginning November 1, 2016.

The rental expense related to our current lease during both the three months ended September 30, 2018 and 2017 was approximately $257,000 and the rental expense related to our current lease during both the nine months ended September 30, 2018 and 2017 was approximately $772,000.

As of September 30, 2018, future minimum rental payments on non-cancelable operating leases are as follows:

Years Ending December 31,		
2018 (3 months)	$	270,073
2019		1,094,116
2020		1,113,069
2021		943,127
2022		—
Total minimum lease payments	$	3,420,385

Intellectual Property Licenses

We have license agreements with third parties that provide for minimum royalty, license, and exclusivity payments to be paid by us for access to certain technologies. In addition, we pay royalties as a percent of revenue as described in Note 7, Intangible Assets, to these consolidated financial statements.

Purchase commitments

We have a manufacturing and supply agreement whereby we are required to purchase from Catalent a minimum of number of softgels during the first contract year and a higher number or softgels after the first contract year. If the minimum order quantities of specific products are not met, we are required to pay Catalent 50% of the difference between the total amount we would have paid to Catalent if the minimum requirement had been fulfilled and the sum of all purchases of our products from Catalent during the contract year.

NOTE 16 – SUBSEQUENT EVENTS

In October 2018, we entered into a lease for new corporate offices in Boca Raton, Florida, pursuant to an eleven-year lease. The lease provides for total future minimum payments over the life of the lease of approximately $19.6 million, inclusive of estimated operating expenses and sales tax.

October 28, 2018, the FDA approved BIJUVA™ (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate to severe vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

General

The following discussion and analysis provides information that we believe to be relevant to an assessment and understanding of our results of operations and financial condition for the periods described. This discussion should be read together with our consolidated financial statements and the notes to the financial statements, which are included in this Quarterly Report on Form 10-Q. This information should also be read in conjunction with the information contained in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission, or the SEC, on February 23, 2018, or the Annual Report, including the audited financial statements and notes included therein. The reported results will not necessarily reflect future results of operations or financial condition.

In addition, this Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are made as of the date of this Quarterly Report on Form 10-Q and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise, except as required by law or by the rules and regulations of the SEC. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our Annual Report, and include the following: our ability to maintain or increase sales of our approved products; our ability to develop and commercialize IMVEXXY™, BIJUVA™, ANNOVERA™ and our hormone therapy drug candidates and obtain additional financing necessary therefor; our commercialization, marketing and manufacturing capabilities and strategy for our approved products; the size of markets and the potential market opportunity for which our products are approved and our ability to penetrate such markets; the rate and degree of market acceptance of our products; the willingness of healthcare providers to prescribe and patients to use our products; our ability to obtain additional financing when needed; our competitive position and the success of competing products that are or become available for the indications that we are pursuing; our intellectual property position; whether we will be able to comply with the covenants and conditions under our term loan agreement; the length, cost and uncertain results of our clinical trials, the potential of adverse side effects or other safety risks that could adversely affect the commercialization of our current or future approved products; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the ability of our licensees to commercialize and distribute IMVEXXY™ and BIJUVA™; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits; and the influence of extensive and costly government regulation.

Throughout this Quarterly Report on Form 10-Q, the terms "we," "us," "our," "TherapeuticsMD," or "our company" refer to TherapeuticsMD, Inc., a Nevada corporation, and unless specified otherwise, include our 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.

Overview

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 the activities necessary for commercialization of TX-001HR, or BIJUVA™ (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate to severe vasomotor symptoms, or VMS (commonly known as hot flashes or flushes), due to menopause in women with a uterus, which was approved by the FDA on October 28, 2018, and 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 and which we have exclusively licensed from the Population Council, Inc., or the Population Council, to commercialize in the U.S. 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. We also manufacture and distribute branded and generic prescription prenatal vitamins.

Our common stock, par value $0.001 per share, or the Common Stock, is traded on the Nasdaq Global Select Market of The Nasdaq Stock Market LLC, or the Nasdaq, under the symbol "TXMD." We maintain websites at www.therapeuticsmd.com, www.vitamedmdrx.com, www.bocagreenmd.com, www.IMVEXXY.com and www.BIJUVA.com. The information contained on our websites or that can be accessed through our websites does not constitute part of this Quarterly Report on Form 10-Q.

IMVEXXY™ Commercialization Update

On July 9, 2018, we initiated our early experience program for IMVEXXY™ with a limited launch of the 10-mcg dose to a targeted sample of healthcare providers, or HCPs, throughout the U.S. During the period from July 9, 2018 until September 30, 2018, approximately 2,200 HCPs have initiated at least one patient on treatment of the starter pack of IMVEXXY™ and sent in the follow-on prescription for continuation of treatment on the maintenance pack. The national launch of the 10-mcg dose of IMVEXXY™ began in August 2018, and our BIO-IGNITE™ compounding pharmacy partners also began to receive IMVEXXY™ in August 2018. We launched the 4-mcg dose of IMVEXXY™ on September 13, 2018.

Since FDA approval of our New Drug Application, or NDA, for IMVEXXY™, we have been focused on executing our launch plan, with the first objective of making IMVEXXY™ widely available through retail pharmacies during the third quarter of 2018. The key objectives of our launch plan include: (i) broad commercial access at the retail level and with commercial payors, (ii) increasing awareness and appreciation of the clinical and patient features of IMVEXXY™ amongst HCPs, (iii) designing and deploying our customer facing model, and (iv) developing our internal capabilities (for example, in the areas of finance, human resources, information technology, data analytics and compliance) to support our commercial stage company. We have made progress in each of these key strategic areas:

- **Commercial Access:** We have entered into commercial supply agreements with our key suppliers, spent significant time with our suppliers to oversee product production and quality management, and manufactured our initial commercial supply of IMVEXXY™. We have also entered into contracts with our third-party logistics partner and our distribution partners. Both the 10-mcg and 4-mcg doses of IMVEXXY™ are now broadly available in major pharmacy chains in the U.S. as well as with our BIO-IGNITE™ partners. We have also begun to enable commercial access for IMVEXXY™ patients through commercial payors. Many commercial payors employ "new-to-market blocks" for launch brands until the payors have the opportunity to make a coverage decision based upon their internal review the product. When a product is not covered, the patient is responsible to pay the full price for the medication, which can significantly limit utilization of the product. If a payor decides to cover a medication, payors will typically classify products based upon tiers, which determine the out-of-pocket costs for a patient. For example, a product that is covered on a preferred tier may typically require a co-pay by the patient of between $20 to $40 per prescription while a product that is covered on a non-preferred tier may typically require a co-pay by the patient of between $60 to $80 per prescription. Where commercial access is not available, or the price is at a non-preferred tier level, we have introduced a co-pay assistance program where enrolled patients do not pay more than $35 for a prescription of IMVEXXY™. This allows patients to access the product at a reasonable cost during the launch phase. We continue to work with payors to ensure that we have maximum coverage of commercially insured lives in a plan in that covers IMVEXXY™ in an unrestricted formulary position (meaning no step edits or prior authorizations are necessary before a prescription is covered). However, payors may change coverage levels for IMVEXXY™ or controls such as step edits and prior authorizations, positively or negatively, at any time. As we seek to increase the number of lives covered by commercial payors, it is our objective to continue to seek unrestricted coverage that involves a low "hassle factor" for physicians and patients. We use the term "hassle factor" to characterize the level of difficulty that physicians and patients must overcome to prescribe and fill IMVEXXY™ prescriptions. We define a low "hassle factor" as unrestricted coverage. Our goal is for 40% of commercially insured lives to have unrestricted access to IMVEXXY™ with a low "hassle factor" by the end of 2018, with continued growth during 2019.

- **Brand Awareness and Adoption:** In addition to our focus on direct selling from our sales organization, we have executed a branded multichannel awareness campaign for HCPs leveraging digital, non-personal promotion and journal advertising and have already reached virtually all the active writing HCPs within the VVA category with IMVEXXY™ branded messages. Our launch strategy included our sales organization targeting 150 territories, including approximately 30,800 HCPs. During the third quarter of 2018, we called on approximately 22,500 of those targeted HCPs. The focus of our interactions with HCPs included: (i) introducing IMVEXXY™ and highlighting the unmet medical that IMVEXXY™ can fulfill for many women, (ii) increasing awareness of the clinical data and patient features of IMVEXXY™, and (iii) familiarizing HCPs with our patient support services for IMVEXXY™. Based on our early sales effectiveness research, more than 90% of HCPs that responded to Company surveys indicated that they have prescribed or intend to prescribe IMVEXXY™.

- **Patient Engagement Programs:** We believe the patient engagement programs that we created and piloted around our prescription prenatal vitamin business have the potential to improve patient compliance for IMVEXXY™, compared to other products in the VVA category. For example, in our prescription prenatal vitamin business, our patient co-pay programs have achieved over 73% utilization in the twelve months ended August 31, 2018 compared to an industry standard of 18%. We launched our patient engagement program for IMVEXXY™ to help patients manage out-of-pocket costs (eligible patients pay no more than $35 per prescription) and improve education regarding VVA and IMVEXXY™ with the goal of increasing patient adherence and compliance for an improved treatment experience.

- **Customer Model:** We have defined a sales force targeting 150 territories, covering approximately 30,800 HCPs and are deploying a hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our target customer universe. Additionally, we have an internal sales team that covers areas of the U.S. where key HCPs are located but where we do not have defined territories and have launched our Key Account Management Organization, or KAM, to engage with our BIO-IGNITE™ partners.

- **Infrastructure:** We continue to develop our internal capabilities and sales force to support the launch of IMVEXXY™. We have launched KAM to support our BIO-IGNITE™ partners and continue to build our internal capabilities to support both organizations, including compliance professionals and programs and key data support systems that provide real time data for the sales force and KAM.

FDA Approval of BIJUVA™

On October 28, 2018, the FDA approved BIJUVA™ (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate to severe vasomotor symptoms, or VMS (commonly known as hot flashes or flushes), due to menopause in women with a uterus.

As part of the approval of BIJUVA™, the FDA has required a post-approval commitment to further develop and validate our in-vitro dissolution method to show how BIJUVA™ is released from the capsule in an in-vitro setting for quality control assessments. The development of this method is underway and we do not believe that the costs will be material.

License Agreement with Knight Therapeutics Inc.

On July 30, 2018, we entered into a license and supply agreement, or the Knight License 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.

Pursuant to the terms of the Knight License Agreement, Knight will pay us a milestone fee upon first regulatory approval in Canada of each of IMVEXXY™ and BIJUVA™, sales milestone fees based upon certain aggregate annual sales in Canada and Israel of each of IMVEXXY™ and BIJUVA™ and royalties based on aggregate annual sales of each of IMVEXXY™ and BIJUVA™ in Canada and Israel. Knight will be responsible for all regulatory and commercial activities in Canada and Israel related to IMVEXXY™ and BIJUVA™.

We may terminate the Knight License Agreement if Knight does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize IMVEXXY™ and BIJUVA™ in Canada and Israel within certain specified time periods. We also may terminate the Knight License Agreement if Knight challenges our patents. Either party may terminate the Knight License Agreement for any material breach by the other party that is not cured within certain specified time periods or if the other party files for bankruptcy or other related matters.

License Agreement with the Population Council

License Agreement

On July 30, 2018, we entered into an exclusive license agreement, or the Council License Agreement, with the Population Council to commercialize in the U.S. ANNOVERA™ ANNOVERA™ is in the shape of a ring and combines a novel progestin, segesterone acetate (Nestorone®), with a widely used estrogen (ethinyl estradiol) to prevent ovulation for an entire year (13 cycles).

On August 10, 2018, the FDA approved ANNOVERA™, which is the first and only procedure-free, reversible prescription contraceptive to provide a full year of protection against unintended pregnancy while fully under a woman's control.

ANNOVERA™ was classified by the FDA as a "new chemical entity," or NCE, and thus has five years of regulatory exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act.

Under the terms of the Council License Agreement, we paid the Population Council a milestone payment of $20 million within 30 days following approval by the FDA of the NDA for ANNOVERA™ and will be required to pay the Population Council an additional $20 million within 30 days following the release of the first commercial batch of ANNOVERA™ The Population Council is also eligible to receive milestone payments and royalties from commercial sales of ANNOVERA™, as detailed below.

We will assume responsibility for marketing expenses related to the commercialization of ANNOVERA™.

The Council License Agreement includes exclusive rights for us to negotiate co-development of two other investigational vaginal contraceptive systems in development by the Population Council.

We are required to pay the Population Council milestone payments of $40 million upon cumulative net sales of ANNOVERA™ in the U.S. by us and our affiliates and permitted sublicensees of each of $200.0 million, $400.0 million and $1.0 billion.

In addition, we are required to pay the Population Council, on a quarterly basis, step-based royalty payments based on annual net sales of ANNOVERA™ in the U.S. by us and our affiliates and permitted sublicensees as follows:

Annual Net Sales	Royalty Rate
Less than or equal to $50.0 million	5%
Greater than $50.0 million and less than or equal to $150.0 million	10%
Greater than $150.0 million	15%

The annual royalty rate will be reduced to 50% of the initial rate during the six-month period beginning on the date of the first arms-length commercial sale of a generic equivalent of ANNOVERA™ that is launched by a third party in the U.S., and thereafter will be reduced to 20% of the initial rate.

As part of the approval of ANNOVERA™, the FDA has required a post-approval observational study be performed to measure the risk of venous thromboembolism. A protocol submission for the study is due to the FDA in August 2019. We have agreed to perform and pay the costs and expenses associated with this post-approval study, provided that if the costs and expenses associated with such post-approval study exceed $20 million, half of such excess will offset against royalties or other payments owed by us to the Population Council under the Council License. Given the observational nature of the study, we do not believe that the costs of the study will be material on an annual basis.

Unless earlier terminated, the Council License Agreement will remain in effect until the later of the expiration of the last-to-expire of the Population Council's U.S. patents that are licensed to us, or the date following such expiration that follows a continuous period of six months during which we and our affiliates have not made a commercial sale of ANNOVERA™ in the U.S. The Council License Agreement may also be terminated for certain breach and bankruptcy-related events and by us on 180 days prior notice to the Population Council.

As part of the Council License Agreement, we have the exclusive right to negotiate co-development and U.S. marketing rights for two other investigational vaginal contraceptive systems in development by the Population Council: a three-month contraceptive ring using Nestorone plus bio-identical estradiol, which is currently in phase 2 clinical trials, and a new one-year contraceptive ring using Nestorone plus ethinyl estradiol, which is designed as a life cycle management product for the one-year vaginal contraceptive system that we have licensed.

Commercialization Strategy

We currently estimate that ANNOVERA™ will be commercially available as early as the third quarter of 2019 with a planned commercial launch in the fourth quarter of 2019.

We intend to leverage our existing infrastructure, including our sales force, to commercialize ANNOVERA™, together with our recently-approved IMVEXXY™ and BIJUVA™.

We believe that our existing sales force overlaps with over 80% of existing prescribers of the leading monthly contraceptive ring and that no additional sales representatives would be needed for us to commercialize ANNOVERA™. We intend to add a dedicated marketing team exclusively focused on ANNOVERA™.

We currently intend to price ANNOVERA™ at parity or discount to current prescription contraceptive pricing levels and anticipate an annual wholesale acquisition cost, or WAC, of between $1000 and $1400, which reflects a 40% decrease to the annual WAC of NuvaRing. We believe that the unique characteristics of ANNOVERA™ will assist us in pursuing favorable commercial payor coverage, including only one pharmacy fill fee per year, an estimated savings of $33 annually per patient, and no office visit or procedure fees, an estimated savings of several hundred dollars annually per patient. However, obtaining and maintaining favorable reimbursement can be a time-consuming and expensive process, and there is no guarantee that we will be able to negotiate or continue to negotiate reimbursement or pricing terms for our products, including ANNOVERA™, with payors at levels that are profitable to us, or at all.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, mandates that private health plans provide coverage for women's preventative services, without imposing patient cost-sharing requirements, as recommended by the Health Resources and Services Administration, or HRSA. HRSA Guidelines require private health plans to cover, without cost-sharing, at least one form of contraception, or product, in each of the methods, or classes, identified by the FDA for women in its Birth Control Guide, which currently includes 18 separate classes. For classes with more than one type of treatment, private payors need only provide no-cost coverage for one product in each class, and may use reasonable medical management to determine whether and to what extent to cover other products in the class. We believe that the FDA's determination that a "vaginal system" constitutes a new class of birth control could allow for coverage of ANNOVERA™ by private health plans with no out-of-pocket cost for patients. However, it is possible that other FDA-approved products could also be included in this new class. To the extent ANNOVERA™ is not the only FDA-approved product in a designated class of contraception, private payors may choose not to cover ANNOVERA™, or may require patient cost-sharing obligations.

As part of the Council License Agreement, we have agreed to provide significantly reduced pricing to federally designated Title X family planning clinics serving underrepresented women.

The Population Council has previously entered into a supply agreement with Crystal Pharma SAU for the supply of Nestorone, one of the active pharmaceutical ingredients for ANNOVERA™, and a letter agreement with QPharma AB for the optimization of the commercial manufacturing process for ANNOVERA™. We intend to enter into agreements Crystal Pharma SAU and QPharma AB for the supply of Nestorone for, and the manufacturing of, ANNOVERA™, respectively, and the Population Council has agreed to use commercially reasonable efforts to assist us in doing so. However, either or both of these contract manufacturers could decline to enter into similar agreements with us on the terms we anticipate, or at all.

Research and Development

TX-001HR: BIJUVA™

We submitted the NDA for TX-001HR to the FDA on December 28, 2017. On October 28, 2018, the FDA approved BIJUVA™ (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate to severe VMS due to menopause in women with a uterus. As part of the approval of BIJUVA™, the FDA has required a post-approval commitment to further develop and validate our in-vitro dissolution method to show how BIJUVA™ is released from the capsule in an in-vitro setting for quality control assessments. The development of this method is underway and we do not believe that the costs will be material.

TX-002HR

TX-002HR is a natural progesterone formulation for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The hormone therapy drug candidate is bioidentical to – or having the same chemical and molecular structure as - the hormones that naturally occur in a woman's body. In July 2014, we suspended enrollment and in October 2014 we stopped the SPRY Trial, our phase 3 clinical trial for TX-002HR, to update the phase 3 protocol based on discussions with the FDA. Our Investigational New Drug Application, or IND, related to TX-002HR is currently in inactive status. We have currently suspended further development of this drug candidate to prioritize our leading drug candidates.

TX-003HR

TX-003HR is a natural estradiol formulation. This hormone therapy drug candidate is bioidentical to the hormones that naturally occur in a woman's body. We currently do not have plans to further develop this hormone therapy drug candidate. Our IND related to TX-003HR is currently inactive.

TX-004HR: IMVEXXY™

On May 30, 2018, we announced that the FDA had approved the 4 mcg and 10 mcg doses of IMVEXXY™ (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of VVA, due to menopause. The 4-mcg formulation of IMVEXXY™ represents the lowest FDA-approved dose of vaginal estradiol available. IMVEXXY™ 10-mcg became available for commercial distribution in late July 2018 and both doses were commercially available by September 2018.

As part of the FDA's approval of IMVEXXY™, we have committed to conduct a post-approval observational study to evaluate the risk of endometrial cancer in post-menopausal women with a uterus who use a low-dose vaginal estrogen unopposed by a progestogen, such as IMVEXXY™. In connection with the observational study, we will be required to provide progress reports to the FDA on an annual basis. In addition, the FDA asked for post-approval information with respect to certain characteristics related to the product's specifications, which we expect to submit to FDA before the end of 2018.

As of September 30, 2018, we had 22 issued foreign patents and 20 issued domestic or, U.S., patents, which included 14 domestic utility patents that relate to our combination progesterone and estradiol formulations, three domestic utility patents that relate to IMVEXXY™, which establish an important intellectual property foundation for IMVEXXY™, one domestic utility patent that relates to a pipeline transdermal patch technology, one domestic utility patent that relates to our OPERA® information technology platform and one domestic utility patent that relates to TX-009HR, our progesterone and estradiol drug candidate.

Research and Development Expenses

A significant portion of our operating expenses to date have been incurred in research and development activities. Research and development expenses relate primarily to the discovery and development of our drug candidates. Our business model is dependent upon our company continuing to conduct a significant amount of research and development. Our research and development expenses consist primarily of expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies; employee-related expenses, which include salaries and benefits, and non-cash share-based compensation; the cost of developing our chemistry, manufacturing and controls capabilities, and costs associated with other research activities and regulatory approvals. Other research and development costs listed below consist of costs incurred with respect to drug candidates that have not received IND application approval from the FDA.

The following table indicates our research and development expense by project/category for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(000s)		(000s)	
TX 001-HR	$ 3,017	$ 3,066	$ 8,432	$ 11,971
TX 002-HR	—	—	—	—
TX 004-HR	764	1,580	3,922	6,292
Other research and development	2,927	1,791	8,192	4,615
Total	$ 6,708	$ 6,437	$ 20,546	$ 22,878

Research and development expenditures will continue to be incurred as we continue development of our drug candidates and advance the development of our proprietary pipeline of novel drug candidates. We expect to incur ongoing research and development costs as we develop our drug pipeline, continue stability testing and validation on our drug candidates, prepare regulatory submissions and work with regulatory authorities on existing submissions.

The costs of clinical trials may vary significantly over the life of a project owing to factors that include, but are not limited to, the following: per patient trial costs; the number of patients that participate in the trials; the number of sites included in the trials; the length of time each patient is enrolled in the trial; the number of doses that patients receive; the drop-out or discontinuation rates of patients; the amount of time required to recruit patients for the trial; the duration of patient follow-up; and the efficacy and safety profile of the drug candidate. We base our expenses related to clinical trials on estimates that are based on our experience and estimates from CROs and other third parties. Research and development expenditures for the drug candidates will continue after the trial completes for on-going stability and laboratory testing, regulatory submission and response work.

Results of Operations

Three months ended September 30, 2018 compared with three months ended September 30, 2017

	Three Months Ended September 30,		
	2018	2017	Change
	(000s)		
Revenues, net	$ 3,474	$ 4,417	$ (943)
Cost of goods sold	699	701	(2)
Operating expenses	37,136	18,548	18,588
Operating loss	(34,361)	(14,832)	19,529
Other (expense) income, net	(1,244)	167	(1,411)
Net loss	$ (35,605)	$ (14,665)	$ 20,940

Revenues and Cost of Goods Sold

Revenues, net for the three months ended September 30, 2018 decreased approximately $943,000, or 21%, to approximately $3,474,000, compared with approximately $4,417,000 for the three months ended September 30, 2017. Revenues, net decreased primarily due to a decrease in prenatal vitamin sales by $1,155,000 partially offset by an increase in sales of IMVEXXY™ by $212,000. The decrease related to our prenatal vitamins was primarily affected by lower number of units sold and higher utilization of coupons offered to customers during the three months ended September 30, 2018 as compared to the same period last year. We launched sales of IMVEXXY™ in the third quarter of 2018. During this launch period, revenues, net related to our newly approved drug were greatly affected by the co-pay assistance program that we introduced to launch IMVEXXY™ which allowed patients to access the product at a reasonable cost regardless of the insurance coverage. We expect our revenues, net to improve as commercial payer coverage for IMVEXXY™ increases.

Cost of goods sold decreased approximately $2,000 or 0.3%, to approximately $699,000 for the three months ended September 30, 2018, compared with approximately $701,000 for the three months ended September 30, 2017. Our gross margin was approximately 80% and 84% for the three-month periods ended September 30, 2018 and 2017, respectively. Our gross margin decreased during the three months ended September 30, 2018 as compared to the same period last year primarily due to higher utilization of coupons/co-pay assistance offered.

Operating Expenses

Our principal operating costs include the following items as a percentage of total operating expenses.

	Three Months Ended September 30,	
	2018	2017
Sales and marketing costs, excluding human resource costs	44.6%	17.0%
Human resource related costs, including salaries, benefits and taxes	24.0%	32.2%
Research and development costs	18.1%	34.7%
Professional fees for legal, accounting and consulting	4.4%	6.9%
Other operating expenses	8.9%	9.2%

Operating expenses increased by approximately $18,588,000, or 100%, to approximately $37,136,000 for the three months ended September 30, 2018, from approximately $18,548,000 for the three months ended September 30, 2017 as a result of the following items:

	Three Months Ended September 30,		
	2018	2017	Change
	(000s)		
Research and development costs	$ 6,708	$ 6,437	$ 271
Human resources related costs, including salaries, benefits and taxes	8,911	5,966	2,945
Sales and marketing, excluding human resources costs	16,577	3,163	13,414
Professional fees for legal, accounting and consulting	1,650	1,271	379
Other operating expenses	3,290	1,711	1,579
Total operating expenses	$ 37,136	$ 18,548	$ 18,588

Research and development costs for the three months ended September 30, 2018 increased by approximately $271,000, or 4%, to approximately $6,708,000, compared with approximately $6,437,000 for the three months ended September 30, 2017. Research and development costs include costs related to clinical trials as well as salaries, wages, non-cash compensation and benefits of personnel involved in research and development activities. Research and development costs increased due to scale up and manufacturing activities for BIJUVA™, our combination estradiol and progesterone drug, prior to the FDA approval as well as an increase in pre-clinical work to support our product pipeline, which was partially offset by the completion of the REPLENISH Trial for BIJUVA™ and FDA approval of IMVEXXY™, our applicator-free vaginal estradiol softgel drug. Research and developments costs during the three months ended September 30, 2018 included the following research and development projects.

During the three months ended September 30, 2018 and the period from February 2013 (project inception) through September 30, 2018, we have incurred approximately $3,017,000 and $123,829,000, respectively, in research and development costs with respect to BIJUVA™.

During the three months ended September 30, 2018 and the period April 2013 (project inception) through September 30, 2018, we have incurred approximately $0 and $2,525,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the three months ended September 30, 2018 and the period from August 2014 (project inception) through September 30, 2018, we have incurred approximately $764,000 and $44,771,000, respectively, in research and development costs with respect to IMVEXXY™.

For a discussion of the nature of efforts and steps necessary to complete these projects, see "Item 1. Business — Pharmaceutical Regulation" in our Annual Report and "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview – Research and Development" above. For a discussion of the risks and uncertainties associated with completing development of our products, see "Item 1A. Risk Factors — Risks Related to Our Business" in our Annual Report. For a discussion of the extent and nature of additional resources that we may need to obtain if our current liquidity is not expected to be sufficient to complete these projects, see "— Liquidity and Capital Resources" below. For a discussion as to whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency or approval from a regulatory agency can be reliably determined, see "Item 1. Business — Our Hormone Therapy Drug Candidates," and "Item 1. Business — Pharmaceutical Regulation" in our Annual Report. Future milestones, including NDA submission dates and potential approval dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, scale-up and manufacturing activities.

Sales and marketing costs for the three months ended September 30, 2018 increased by approximately $13,414,000, or 424%, to approximately $16,577,000, compared with approximately $3,163,000 for the three months ended September 30, 2017, primarily as a result of increased expenses associated with sales and marketing efforts to support launch and commercialization of IMVEXXY,™ our pre-commercialization efforts for BIJUVA™, including costs related to outsourced sales personnel and their related expenses, physician education, conferences and travel expenses related to product commercialization. We expect sales and marketing expenses to continue to increase as we prepare for the launch of BIJUVA™ and ANNOVERA™ and continue to support our growing business and commercialization of our products.

Other operating expense for the three months ended September 30, 2018 increased by approximately $1,579,000 or 92%, to approximately $3,290,000, compared with approximately $1,711,000 for the three months ended September 30, 2017, as a result of increased information technology, allowance for bad debt expense, insurance, travel and other office expenses primarily to support commercialization of our new drugs.

Human resource costs, including salaries, benefits and taxes, for the three months ended September 30, 2018 increased by approximately $2,945,000, or 49%, to approximately $8,911,000, compared with approximately $5,966,000 for the three months ended September 30, 2017, primarily as a result of an increase of approximately $2,447,000 in personnel costs in sales, marketing and regulatory areas to support the commercialization of IMVEXXY™, pre-commercialization expenses for BIJUVA™ and an increase of approximately $498,000 in non-cash compensation expense included in this category related to employee stock based compensation during the three months ended September 30, 2018 as compared to the same period in 2017.

Professional fees for the three months ended September 30, 2018 increased by approximately $379,000, or 30%, to approximately $1,650,000, compared with approximately $1,271,000 for the three months ended September 30, 2017, primarily as a result of increased legal, accounting and consulting expenses, as well as increased board of director fees.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $19,529,000, or 132%, to approximately $34,361,000 for the three months ended September 30, 2018, compared with approximately $14,832,000 for the three months ended September 30, 2017, primarily as a result of increased personnel costs, sales and marketing expenses to support the commercialization of IMVEXXY™ and pre-commercialization expenses for BIJUVA™, including costs related to outsourced sales personnel and their related expenses, professional fees and other operating expenses, as well a decrease in revenue.

As a result of the continued development of our hormone therapy drug candidates, IMVEXXY™ and BIJUVA™, we anticipate that we will continue to have operating losses for the near future until we successfully commercialize IMVEXXY™ and BIJUVA™, although there is no assurance that any commercialization of IMVEXXY™ and BIJUVA™ will be successful.

Other (expense) income, net

Other non-operating (expense) income, net changed by approximately $1,411,000, or 845%, to other expense, net of approximately $1,244,000 for the three months ended September 30, 2018 compared with other income, net of approximately $167,000 for the comparable period in 2017, primarily as a result of increased interest expense related to term loan that we obtained in 2018, partially offset by increased interest income for the three months ended September 30, as compared to the same period in 2017.

Net Loss

As a result of the net effects of the foregoing, net loss increased approximately $20,940,000, or 143%, to approximately $36,605,000 for the three months ended September 30, 2018, compared with approximately $14,665,000 for the three months ended September 30, 2017. Net loss per share of Common Stock, basic and diluted, was ($0.16) for the three months ended September 30, 2018 and ($0.07) for the three months ended September 30, 2017.

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

	Nine Months Ended September 30,		
	2018	2017	Change
		(000s)	
Revenues, net	$ 11,010	$ 12,653	$ (1,643)
Cost of goods sold	1,787	2,042	(255)
Operating expenses	101,323	66,559	34,764
Operating loss	(92,100)	(55,948)	36,152
Other (expense) income, net	(1,126)	450	(1,576)
Net loss	$ (93,226)	$ (55,498)	$ 37,728

Revenues and Cost of Goods Sold

Revenues, net for the nine months ended September 30, 2018 decreased approximately $1,643,000, or 13%, to approximately $11,010,000, compared with approximately $12,653,000 for the nine months ended September 30, 2017. Revenues, net decreased primarily due to a decrease in prenatal vitamin sales by $1,855,000, partially offset by an increase in sales of IMVEXXY™ by $212,000. The decrease related to our prenatal vitamins was primarily affected by higher coupons, rebates, chargebacks and wholesaler fees. We launched sales of IMVEXXY™ in the third quarter of 2018. During this launch period, revenues, net related to our newly approved drug were greatly affected by the co-pay assistance program that we introduced to launch IMVEXXY™ which allowed patients to access the product at a reasonable cost regardless of the insurance coverage. We expect revenues, net to improve as commercial payer coverage for IMVEXXY™ increases.

Cost of goods sold decreased approximately $255,000, or 12%, to approximately $1,787,000 for the nine months ended September 30, 2018, compared with approximately $2,042,000 for the nine months ended September 30, 2017. Our gross margin was approximately 84% for both the nine-month periods ended September 30, 2018 and 2017.

Operating Expenses

Our principal operating costs include the following items as a percentage of total operating expenses.

	Nine Months Ended September 30,	
	2018	2017
Sales and marketing costs, excluding human resource costs	43.1%	24.9%
Human resource related costs, including salaries, benefits and taxes	23.0%	26.2%
Research and development costs	20.3%	34.4%
Professional fees for legal, accounting and consulting	5.3%	6.1%
Other operating expenses	8.3%	8.4%

Operating expenses increased by approximately 34,764,000, or 52%, to approximately $101,323,000 for the nine months ended September 30, 2018, from approximately $66,559,000 for the nine months ended September 30, 2017 as a result of the following items:

	Nine Months Ended September 30,		
	2018	2017	Change
	(000s)		
Research and development costs	$ 20,546	$ 22,878	$ (2,332)
Human resources related costs, including salaries, benefits and taxes	23,296	17,415	5,881
Sales and marketing, excluding human resources costs	43,695	16,590	27,105
Professional fees for legal, accounting and consulting	5,411	4,062	1,349
Other operating expenses	8,375	5,614	2,761
Total operating expenses	$ 101,323	$ 66,559	$ 34,764

Research and development costs for the nine months ended September 30, 2018 decreased by approximately $2,332,000, or 10%, to approximately $20,546,000, compared with $22,878,000 for the nine months ended September 30, 2017. Research and development costs include costs related to clinical trials as well as salaries, wages, non-cash compensation and benefits of personnel involved in research and development activities. Research and development costs decreased as a direct result of the completion of the REPLENISH Trial for BIJUVA™ and FDA approval of IMVEXXY™, partially offset by an increase in scale-up and manufacturing activities for both IMVEXXY™ and BIJUVA™ prior to FDA approval. Research and developments costs during the nine months ended September 30, 2018 included the following research and development projects.

During the nine months ended September 30, 2018 and the period from February 2013 (project inception) through September 30, 2018, we have incurred approximately $8,432,000 and $123,829,000, respectively, in research and development costs with respect to BIJUVA™.

During the nine months ended September 30, 2018 and the period April 2013 (project inception) through September 30, 2018, we have incurred approximately $0 and $2,525,000, respectively, in research and development costs with respect to TX-002HR, our progesterone only drug candidate.

During the nine months ended September 30, 2018 and the period from August 2014 (project inception) through September 30, 2018, we have incurred approximately $3,922,000 and $44,771,000, respectively, in research and development costs with respect to IMVEXXY™.

For a discussion of the nature of efforts and steps necessary to complete these projects, see "Item 1. Business — Pharmaceutical Regulation" in our Annual Report and "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview – Research and Development" above. For a discussion of the risks and uncertainties associated with completing development of our products, see "Item 1A. Risk Factors — Risks Related to Our Business" in our Annual Report. For a discussion of the extent and nature of additional resources that we may need to obtain if our current liquidity is not expected to be sufficient to complete these projects, see "— Liquidity and Capital Resources" below. For a discussion as to whether a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency or approval from a regulatory agency can be reliably determined, see "Item 1. Business — Our Hormone Therapy Drug Candidates," and "Item 1. Business — Pharmaceutical Regulation" in our Annual Report. Future milestones, including NDA submission dates and potential approval dates, are not easily determinable as such milestones are dependent on various factors related to our clinical trials, scale-up and manufacturing activities.

Sales and marketing costs for the nine months ended September 30, 2018 increased by approximately $27,105,000, or 163%, to approximately $43,695,000, compared with approximately $16,590,000 for the nine months ended September 30, 2017, primarily as a result of increased expenses associated with sales and marketing efforts to support launch and the commercialization of IMVEXXY™ and pre-commercialization efforts for BIJUVA™, including costs related to outsourced sales personnel and their related expenses, physician education, conferences and travel expenses related to product commercialization. We expect sales and marketing expenses to continue to increase as we continue to support our growing business and commercialization of our products.

Other operating expense for the nine months ended September 30, 2018 increased by approximately $2,761,000 or 49%, to approximately $8,375,000, compared with approximately $5,614,000 for the nine months ended September 30, 2017, as a result of increased information technology, travel, allowance for bad debt expense, insurance and other office expenses primarily to support the commercialization of our new drugs.

Human resource costs, including salaries, benefits and taxes, for the nine months ended September 30, 2018 increased by approximately $5,881,000, or 34%, to approximately $23,296,000, compared with approximately $17,415,000 for the nine months ended September 30, 2017, primarily as a result of an increase of approximately $4,151,000 in personnel costs in sales, marketing and regulatory areas to support the commercialization of IMVEXXY™, pre-commercialization expenses for BIJUVA™ and an increase of approximately $1,730,000 in non-cash compensation expense included in this category related to employee stock based compensation during the nine month period ended September 30, 2018 as compared to the same period in 2017.

Professional fees for the nine months ended September 30, 2018 increased by approximately $1,349,000, or 33%, to approximately $5,411,000, compared with approximately $4,062,000 for the nine months ended September 30, 2017, primarily as a result of increased legal and accounting expenses as well as increased board of directors' fees.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $36,152,000, or 65%, to approximately $92,100,000 for the nine months ended September 30, 2018, compared with approximately $55,948,000 for the nine months ended September 30, 2017, primarily as a result of increased personnel costs, sales and marketing expenses to support commercialization of IMVEXXY™ and pre-commercialization expenses for BIJUVA™, including costs related to outsourced sales personnel and their related expenses, professional fees and other operating expenses, as well a decrease in revenue, partially offset by a decrease in research and development costs.

As a result of the continued development of our hormone therapy drug candidates, BIJUVA™ and IMVEXXY™, we anticipate that we will continue to have operating losses for the near future until we successfully commercialize IMVEXXY™ and BIJUVA™, although there is no assurance that any commercialization of IMVEXXY™ and BIJUVA™ will be successful.

Other (expense) income, net

Other non-operating (expense) income, net changed by approximately $1,576,000, or 350%, to other expense, net of approximately $1,126,000 for the nine months ended September 30, 2018 compared with other income, net of approximately $450,000 for the comparable period in 2017, primarily as a result of increased interest expense related to term loan that we obtained in 2018 partially offset by increased interest income in the nine months ended September 30, 2018 as compared to the same period in 2017.

Net Loss

As a result of the net effects of the foregoing, net loss increased approximately $37,728,000, or 68%, to approximately $93,226,000 for the nine months ended September 30, 2018, compared with approximately $55,498,000 for the nine months ended September 30, 2017. Net loss per share of Common Stock, basic and diluted, was ($0.42) for the nine months ended September 30, 2018 and ($0.27) for the nine months ended September 30, 2017.

Liquidity and Capital Resources

We have funded our operations primarily through public offerings of our Common Stock and private placements of equity and debt securities. For the year ended December 31, 2017, we received approximately $68,573,000 in net proceeds from the issuance of shares of our Common Stock. As of September 30, 2018, we had cash totaling approximately $189,999,000, however, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We currently intend to fund the next phase of our commercialization expenses for IMVEXXY™ and pre-commercialization expenses for BIJUVA™ through funds available under our Term Loan.

On August 1, 2018, we entered into an underwriting agreement with Goldman Sachs & Co. LLC, as representative of the underwriters, relating to an underwritten public offering of 12,745,098 shares of our Common Stock at a price of $5.10 per share. We granted the underwriters an option, exercisable for a period of 30 days, to purchase up to 1,911,764 additional shares of Common Stock. On August 2, 2018, the underwriters exercised the option in full. The net proceeds from the offering, including the exercise of the option to purchase additional shares, were approximately $69,908,000, after deducting the underwriting discount and offering expenses payable by us. The offering closed on August 6, 2018.

In connection with the Knight License Agreement, Knight entered into a subscription agreement with us to, pursuant to which, on August 6, 2018, Knight purchased $20,000,000 of shares of our Common Stock concurrently with the closing of the underwritten public offering of Common Stock at a price per share equal to the price per share to the public in underwritten public offering.

On May 1, 2018, we entered into a Credit and Security Agreement, or the Credit Agreement, by and among us and our subsidiaries party thereto from time to time, each as a borrower, MidCap Financial Trust, as an agent and as lender, and the additional lenders party thereto from time to time, which provides a secured term loan facility in an aggregate principal amount of up to $200,000,000, or the Term Loan. Under the terms of the Credit Agreement, the Term Loan will be made in three separate tranches, each, a Tranche, with each Tranche to be made available to us, at our option, upon our achievement of certain milestones. The first Tranche of $75,000,000, or Tranche 1, was drawn by us on June 7, 2018, following approval by FDA of the NDA for IMVEXXY™. We intend to use the proceeds from the first draw down to support the commercial launch of IMVEXXY™. The second Tranche of $75,000,000, or Tranche 2, may be drawn by us on or before May 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including (i) that Tranche 1 has been drawn, (ii) the approval by the FDA of the NDA for BIJUVA™ and (iii) we have consummated our first commercial sale in the United States of BIJUVA™. The third Tranche of $50,000,000, or Tranche 3, may be drawn by us on or before December 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including that (i) Tranche 2 has been drawn and (ii) we have generated at least $75,000,000 of consolidated net revenue attributable to commercial sales of IMVEXXY™ and BIJUVA™ during the twelve-month period ending immediately prior to the funding of Tranche 3.

During the nine months ended September 30, 2018, certain individuals exercised options to purchase 1,446,876 shares of Common Stock for $1,236,313.

Our net days sales outstanding, or net DSO, is calculated by dividing gross accounts receivable less the reserve for chargebacks and payment discounts divided by the average daily net sales for the period. We also disclose gross DSO, which includes the calculation of gross accounts receivable divided by the average gross sales to distributors including constrained revenue during the period. For the nine months ended September 30, 2018, our gross DSO was 90 days compared to 67 days for the year ended December 31, 2017 and our net DSO was 339 days for the nine months ended September 30, 2018 compared to 97 days for the year ended December 31, 2017. The increase in our gross DSO as of September 30, 2018 was primarily related to extended terms given to our customers in connection with the launch of IMVEXXY™. Our net DSO excluded the effect of constrained revenue and was affected by extended terms, increased coupons and discounts given to our customers in connection with the launch of IMVEXXY™. We anticipate that our DSO will fluctuate in the future based upon a variety of factors, including longer payment terms associated with the centralization of the distribution channel for both our retail pharmacy distributors and wholesale distributors, as compared to the terms previously provided to our retail pharmacy distributors, changes in the healthcare industry and specific terms that may be extended in connection with the launch of IMVEXXY™, BIJUVA™ and ANNOVERA™.

We believe that our existing cash and availability under the Term Loan will allow us to fund our operating plan through at least the next 12 months from the date of this quarterly report. However, if the commercialization of IMVEXXY™, BIJUVA™ and ANNOVERA™ is delayed, our existing cash may be insufficient to satisfy our liquidity requirements until we are able to commercialize IMVEXXY™, BIJUVA™ and ANNOVERA™ and we may not be able to access funds under the Term Loan. If our available cash is insufficient to satisfy our liquidity requirements, we may curtail our sales, marketing and other commercialization and pre-commercialization efforts and we may seek to sell additional equity or debt securities. Our ability to obtain additional debt financing is restricted pursuant to the Credit Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, to the extent permitted under the Credit Agreement, the ownership interests of our existing shareholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, certain of which are restricted under the Credit Agreement, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products, if permitted under the Credit Agreement. Additionally, we may have to grant licenses on terms that may not be favorable to us.

We need substantial amounts of cash to commercialize IMVEXXY™, BIJUVA™ and ANNOVERA™ and to complete the clinical development of and commercialize of our other hormone therapy drug candidates. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Summary of (Uses) and Sources of Cash

	Nine Months Ended September 30,	
	2018	2017
	(000s)	
Net cash used in operating activities	$ (78,667)	$ (55,350)
Net cash used in investing activities	$ (20,827)	$ (476)
Net cash provided by financing activities	$ 162,357	$ 72,584

Operating Activities

The principal use of cash in operating activities for the nine months ended September 30, 2018 was to fund our current expenses primarily related to supporting clinical development, scale-up and manufacturing activities and future commercial activities, adjusted for non-cash items. The increase of approximately $23,317,000 in cash used in operating activities for the nine months ended September 30, 2018 compared with the comparable period in the prior year was due primarily to an increase in our net loss and non-cash compensation expense coupled with changes in the components of working capital.

Investing Activities

During the third quarter of 2018, we paid $20,000,000 to the Population Council, upon FDA approval of ANNOVERA™ based on the license agreement that we entered into with the Population Council. In addition, an increase in spending on patent and trademarks resulted in an increase in cash used in investing activities for the nine months ended September 30, 2018 compared with the same period in 2017.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the nine months ended September 30, 2018 provided net cash of approximately $162,357,000 which primarily consisted of approximately $89,908,000 in proceeds from the sale of our Common Stock, funding from our Term Loan of approximately $75,000,000 offset by payment of financing fees of approximately $3,787,000, as well as net cash of $1,236,000 from the exercise of options. The cash provided by financing activities during the nine months ended September 30, 2017 included approximately $68,573,000 in proceeds from the sale of Common Stock and $4,011,000 in proceeds from the exercise of options and warrants.

New 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 to the consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. To minimize this risk, we intend to maintain an investment portfolio that may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We are also subject to market risk in connection with borrowings under our Term Loan. Amounts borrowed under our Term Loan bear interest at a rate equal to the sum of (i) one-month LIBOR (subject to a LIBOR floor of 1.50%) plus (ii) 7.75% per annum. At September 30, 2018, the outstanding principal balance on our Term Loan, net of issuance costs, was approximately $73,261,065. Considering the total outstanding balance of approximately $75,000,000, as of September 30, 2018, a 1.0% change in interest rates would result in an impact to income before income taxes of approximately $750,000 per year.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports filed or submitted under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms and is accumulated and communicated to our principal executive officer and principal financial officer, as appropriate, in order to allow timely decisions in connection with required disclosure.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q were effective in providing reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, misstatements, errors, and instances of fraud, if any, within our company have been or will be prevented or detected. Further, internal controls may become inadequate as a result of changes in conditions, or through the deterioration of the degree of compliance with policies or procedures.

Changes in Internal Controls

During the three months ended September 30, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

We have been informed by the staff ("Staff") of the Securities and Exchange Commission (the "SEC") that the Staff is conducting a formal investigation concerning whether certain of our communications during 2017 regarding TX-004HR may have violated Regulation FD. We are cooperating with the Staff in connection with the investigation. Any determination that our actions violated Regulation FD could result in penalties or other remedies being imposed. While we believe that any such penalties and other remedies would be immaterial from a financial perspective, no assurance can be made about the ultimate outcome of the investigation, and there can be no assurance that any such penalties and remedies would not have a material adverse effect on our business.

From time to time, we are involved in litigation and proceedings in the ordinary course of our business. We are not currently involved in any legal proceeding that we believe would have a material effect on our business or financial condition.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, together with the risk factors previously disclosed in our Annual Report and our other filings with the SEC, before you decide to purchase shares of our common stock. We believe the risks and uncertainties described below and in our other filings with the SEC are the most significant we face. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us. If any of the risks included in our filings with the SEC occur, our business, financial condition, or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

We may not be able to complete the development and commercialization of our hormone therapy drug candidates if we fail to obtain additional financing.

We need substantial amounts of cash to complete the commercialization of IMVEXXY™, BIJUVA™ and ANNOVERA™ and the clinical development and commercialization of our hormone therapy drug candidates. Our existing cash may not be sufficient to fund these requirements. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected on these programs. We may attempt to raise additional capital from the issuance of equity securities, collaborations with third parties, licensing of rights to our products, the issuance of debt securities and the incurrence of debt, to the extent permitted under the Credit Agreement, or other means, or a combination of any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of management's attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations.

We cannot guarantee that future debt or equity financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to take one or more of the following actions:

- significantly delay, scale back, or discontinue our product development and commercialization efforts;

- seek collaborators for our hormone therapy drug products and candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be the case; or

- license, potentially on unfavorable terms, our rights to our hormone therapy drug products and candidates that we otherwise would seek to develop or commercialize ourselves.

The Credit Agreement does, and any agreements governing future debt financing, if available, may, include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing discovery, development and commercialization efforts, and our ability to generate revenue and achieve or sustain profitability will be substantially harmed.

We are subject to extensive and costly government regulation.

The products we currently market, including IMVEXXY™ and our prenatal vitamins, the products that we are currently commercializing, including BIJUVA™ and ANNOVERA™, and the pharmaceutical products we are developing and planning to develop in the future, are subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, including its Office of Inspector General, the U.S. Department of Justice, the Departments of Defense and Veterans Affairs, to the extent our products are paid for directly or indirectly by those departments, state and local governments, and their respective foreign equivalents. The FDA regulates dietary supplements, cosmetics, and drugs under different regulatory schemes. For example, the FDA regulates the processing, formulation, safety, manufacturing, packaging, labeling, and distribution of dietary supplements and cosmetics under its dietary supplement and cosmetic authority, respectively. The FDA also regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products under various regulatory provisions. If any drug products we develop are tested or marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

We are also subject to additional health care regulation and enforcement by the federal government and the states in which we conduct our business. Applicable federal and state health care laws and regulations include the following:

- The federal health care Anti-Kickback Statute, or AKS, prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal health care programs, such as Medicare, Medicaid, TriCare, and Children's Health Insurance Program. Liability may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, federal law provides that the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA, described below. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in government health care programs.

- The Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services, including outpatient drugs, reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary.

- The federal False Claims Act, or FCA, imposes criminal and civil penalties, and authorizes civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment involving federally funded programs that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money with respect to a federal program. The FCA prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items, or services. Government enforcement agencies and private whistleblowers have asserted liability under the FCA for, among other things, claims for items or services not provided as claimed, with inaccurate coding or for medically unnecessary items or services, kickbacks, promotion of off-label uses, and misreporting of drug prices to federal agencies.

- Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, or collectively, HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, including private payors, or falsifying, concealing, or covering up a material fact, or making any materially false statements in connection with the delivery of or payment for health care benefits, items, or services. HIPAA also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information. State laws may also govern the privacy and security of health information or other personal information in certain circumstances.

- Federal laws require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government health care programs.

- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, imposes annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under certain government health care programs for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Numerous state laws may also require disclosure of transfers of value to health care providers, pharmaceutical pricing information and marketing expenditures.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to interactions between pharmaceutical manufacturers and health care providers, sales or marketing arrangements, and claims involving health care items or services reimbursed by commercial third-party payors, including private health care insurers and health maintenance organizations; further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

Many aspects of these laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations that increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Many state laws differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts. Moreover, the number and complexity of both federal and state laws continues to increase, and additional governmental resources are being used to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the ACA includes a number of provisions aimed at strengthening the government's ability to pursue AKS and FCA cases against pharmaceutical manufacturers and other health care entities, including substantially increased funding for health care fraud enforcement activities, enhanced investigative powers, and amendments to the FCA that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations. We anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. For example, federal enforcement agencies recently have shown interest in pharmaceutical companies' product and patient assistance programs, including manufacturer reimbursement support services and relationships with specialty pharmacies. Some of these investigations have resulted in significant civil and criminal settlements.

Efforts to ensure that our operations, including our business arrangements with third parties, comply with applicable health care laws and regulations could be costly. In connection with the commercial launch of IMVEXXY™, we have grown our compliance program and are in the process of expanding our compliance team to focus on developing a program based on industry best practices. As this program has not yet been tested and the requirements in this area are constantly evolving, our program may not eliminate all areas of potential exposure. Although effective compliance programs can help mitigate the risk of investigation, regulatory and enforcement actions, and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state fraud, privacy, security, and reporting laws may prove costly. Although we believe that our business practices are structured to be compliant with applicable laws, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other health care laws and regulations. If our past or present operations, including activities conducted by our sales team or agents, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government health care programs, and the curtailment or restructuring of our operations. If any of the physicians, providers, or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusion from government health care programs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and damage our reputation. In addition, even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, and could result in related shareholder suits, any of which could also have an adverse effect on our business, financial condition and results of operations.

In addition, from time to time in the future, we may become subject to additional laws or regulations administered by the FDA, the FTC, or by other federal, state, local, or foreign regulatory authorities, to the repeal of laws or regulations that we generally consider favorable, such as the Dietary Supplement Health and Education Act of 1994, or to more stringent interpretations of current laws or regulations. We are not able to predict the nature of such future laws, regulations, repeals, or interpretations, and we cannot predict what effect additional governmental regulation, if it occurs, would have on our business in the future. Such developments could, however, require reformulation of certain products to meet new standards, recalls or discontinuance of certain products not able to be reformulated, additional record-keeping requirements, increased documentation of the properties of certain products, additional or different labeling, additional scientific substantiation, additional personnel, or other new requirements. Any such developments could have a material adverse effect on our business.

Coverage and reimbursement may not be available for our products, which could make it difficult for us to sell our products profitably, or if available, government mandated rebates may be too high and may adversely affect our profitability.

Market acceptance and sales of our products, including IMVEXXY™, BIJUVA™ and ANNOVERA™, and our hormone therapy drug candidates or prescription vitamins, will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government health care programs and third-party payors decide which prescription drug products they will pay for and establish reimbursement levels. Payors generally do not cover OTC products, and coverage for prescription vitamins and dietary supplements varies. Many private third-party payors, such as managed care plans, manage access to drug products' coverage partly to control costs to their plans, and may use drug formularies and medical policies to limit their exposure. Factors considered by these payors include product efficacy, cost effectiveness, and safety, as well as the availability of other treatments including generic prescription drugs. Our ability to commercialize IMVEXXY™, BIJUVA™ and ANNOVERA™, successfully depends on coverage and reimbursement levels set by government health care programs and third-party private payors. Obtaining and maintaining favorable reimbursement can be a time-consuming and expensive process, and we may not be able to negotiate or continue to negotiate reimbursement or pricing terms for our products, including IMVEXXY™, BIJUVA™ and ANNOVERA™, our hormone therapy drug candidates with payors at levels that are profitable to us, or at all.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain others by establishing a new Part D to the Medicare program. However, unlike Medicare Part A and Part B—through which Medicare provides coverage for certain drugs in certain circumstances—coverage under Part D is provided by private insurers operating under contract with CMS. In addition, this legislation provided authority for limiting the number of certain outpatient drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These and future cost-reduction initiatives could decrease the coverage and price that we receive for our products from Medicare, if any, including IMVEXXY™, BIJUVA™ and ANNOVERA™, our other hormone therapy drug candidates, if approved, and could significantly harm our business. It was historically unclear whether products approved to treat moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause, such as IMVEXXY™, were excluded under Medicare Part D, which resulted in limited Medicare coverage for such products. Recent clarification issued by CMS in May 2018 indicated that drugs, such as IMVEXXY™, that are approved for the treatment of moderate to severe dyspareunia (as well as drugs approved for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause) are not excluded from Medicare Part D coverage. CMS's clarification, however, is no guarantee that such coverage will be obtained for IMVEXXY™, and obtaining Medicare or other government health care program reimbursement for any new drug products may take up to several years following FDA approval. While the MMA applies only to drug benefits for Medicare beneficiaries, third-party payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under Medicare may result in a similar reduction in payments from third-party payors.

Our ability to commercialize ANNOVERA™ depends on coverage and reimbursement levels set by government health care programs and third-party private payors. The ACA mandates that private health plans provide coverage for women's preventative services, without imposing patient cost-sharing requirements, as recommended by HRSA. HRSA Guidelines require private health plans to cover, with no patient out-of-pocket costs, at least one form of treatment (e.g., one product) in each of the methods (e.g., classes of contraception) identified by the FDA for women in its Birth Control Guide. ANNOVERA™ was deemed a new class of contraception by the FDA, which designation could allow for coverage by private health plans with no patient out-of-pocket costs. However, there is no guarantee that such coverage will be obtained and it is possible that other FDA-approved products could also be included in this new class. Pursuant to HRSA Guidelines, private payors need only provide no-cost coverage for one product in each class, and may use reasonable medical management to determine whether and to what extent to cover other products in the class. To the extent ANNOVERA™ is not the only FDA-approved product in a designated class of contraception, private payors may choose not to cover our one-year vaginal contraceptive system, or may require patient cost-sharing obligations.

To the extent we obtain coverage for our products by state Medicaid programs, we may be required to pay a rebate to each state Medicaid program for any covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program, and to comply with all Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Healthcare Act of 1992. Moreover, federal law requires that any company participating in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B Program, which impose additional requirements. In addition, if our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration or to low income patients of certain hospitals, additional laws and requirements may apply.

We expect to experience pricing pressures in connection with the sale of our products generally due to the trend toward managed health care, the increasing influence of health maintenance organizations, the scrutiny of pharmaceutical pricing, the ongoing debates on reducing government spending and additional legislative proposals. As discussed more below, the goal of the ACA, as enacted in 2010, was to reduce the cost of health care and substantially change the way health care is financed by both government health care programs and third-party payors. Among other measures, the ACA increased rebates on manufacturers for certain covered drug products reimbursed by state Medicaid programs. While we cannot predict the full effect that the ACA will have on government health care programs' reimbursement policies in general or on our business specifically, the ACA may result in downward pressure on drug reimbursement, which could negatively affect market acceptance of our products. In addition, we cannot predict whether new proposals will be made or adopted, when they may be adopted, or what impact they may have on us if they are adopted.

The availability of generic products at lower prices than branded products may substantially reduce the likelihood of reimbursement for branded products, such as IMVEXXY™, BIJUVA™ and ANNOVERA™, or our other hormone therapy drug candidates, if approved.

If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we could have difficulty achieving market acceptance of our products and our business, financial condition, results of operations, and prospects could be harmed.

Future legislation or regulations may adversely affect reimbursement from government health care programs and third-party payors.

Legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, triggering the legislation's automatic reduction of several government programs. This includes aggregate reductions to Medicare payments to health care providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of health care providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the ACA. If the ACA or parts of it are repealed, it is unclear what impact that would have on drug reimbursements or coverage and it is also unclear what programs, if any, Congress might enact to replace the repealed portions of the ACA. The Trump administration may also take executive action in the absence of legislative action. For example, in October 2017, the President announced that the administration will withhold the cost-sharing subsidies paid to health insurance exchange plans serving low-income enrollees. With respect to IMVEXXY™, BIJUVA™ and ANNOVERA™, and to the extent we ever obtain regulatory approval and commercialization of our other drug candidates, these new laws and policies (as well as proposed legislation, if enacted) may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

On December 13, 2016, President Obama signed into law the 21st Century Cures Act, which, among other things, may increase the types of clinical trial designs that would be acceptable to support an NDA. It is unclear, at this time, how these provisions will be implemented or whether they would have any effect on our company. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on our drug product and drug candidates may be.

There have also been efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals; proposed and enacted legislation generally have focused on increasing transparency around drug costs or limiting drug prices. For example, in 2017, California enacted a new law, which went into effect on January 1, 2018, to facilitate greater transparency in brand-name and generic drug pricing through the implementation of specific price reporting requirements for pharmaceutical manufacturers. If adequate reimbursement levels are not maintained by government and third-party payors for our products, our ability to sell our products may be limited and/or our ability to establish acceptable pricing levels may be impaired, thereby reducing anticipated revenues and profitability.

Our dependence upon third parties for the manufacture and supply of our existing women's health care products and our hormone therapy drug candidates may cause delays in, or prevent us from, successfully developing, commercializing, and marketing our products.

We do not currently have, nor do we currently plan to build or acquire, the infrastructure or capability to internally manufacture our existing women's health care products, ANNOVERA™, or our hormone therapy drug candidates. We have relied, and will continue to rely, on third parties to manufacture these products in accordance with our specifications and in compliance with applicable regulatory requirements. We have entered into long-term supply agreements with Catalent for the commercial supply of IMVEXXY™ and BIJUVA™. Under the terms of the agreements, we will be obligated to purchase certain minimum annual amounts of each product once we commence commercial sales of such product following regulatory approval of Catalent as a manufacturer of such product. We depend on Lang, a full-service, private label and corporate brand manufacturer, to supply approximately 100% of our vitaMedMD and BocaGreen products. We do not have long-term contracts for the commercial supply of our existing women's health care products, however, in certain circumstances, including our failure to satisfy our production forecasts to Lang, we may be obligated to reimburse Lang for the costs of excess raw materials purchased by Lang that it cannot use in another product category that it then sells. We intend to enter into agreements with Crystal Pharma SAU and QPharma AB for the commercial supply of one of the active pharmaceutical ingredients for, and the manufacturing of, ANNOVERA™, respectively. However, if we experience delays in finalizing these agreements or are unable to execute these agreements on commercially reasonable terms, we may need to find alternative manufacturing facilities, which would result in disruption in our commercialization of ANNOVERA™.

Regulatory requirements could pose barriers to the manufacture of our existing women's health care products and our hormone therapy drug product and drug candidates. Our third-party manufacturers are required to comply with cGMP regulations. As a result, the facilities used by any of our current or future manufacturers may be subject to an NDA pre-approval inspection, or PAI, by the FDA, and any noncompliance could cause the NDA to be disapproved or delayed in approval. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are ultimately responsible for compliance with manufacturing obligations even if the manufacturing is conducted by a third-party contract manufacturing organization, or CMO. All of our existing products are, and our hormone therapy drug candidates, if approved, will be manufactured by CMOs. These CMOs are required by the terms of our contracts to manufacture our products in compliance with the applicable regulatory requirements. The CMO that will manufacture IMVEXXY™ and BIJUVA™ has previously been inspected by the FDA and received Form 483 observations with respect to its softgel manufacturing plant that will be used for the manufacture of the commercial supply of IMVEXXY™ and BIJUVA™. QPharma, the CMO that will manufacture ANNOVERA™, has previously been inspected by the FDA and received Form 483 observations on December 15, 2017, with respect to its facility that will be used for the commercial supply of ANNOVERA™. The FDA classified the inspection as Voluntary Action Indicated, meaning that the FDA found instances of noncompliance, but the problems likely would not result in further regulatory action. QPharma submitted its written response to the Form 483 observations to the FDA on December 22, 2017, however neither we nor QPharma has been informed by the FDA as to whether QPharma's response addresses and remediates these observations in a manner satisfactory to the FDA. If QPharma is unable to address and remediate the FDA's observations, it could have a material adverse effect on the manufacture of ANNOVERA™.

If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, our regulatory submissions may be delayed or disapproved, and our marketed products may be affected. If these facilities are not in compliance for the manufacture of our vitamin products, our hormone therapy drug product and our drug candidates, we may need to find alternative manufacturing facilities, which would result in disruptions of our sales and significant delays of up to several years in obtaining approval for our hormone therapy drug candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMP regulations or other applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, violation letters, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts, and criminal prosecutions, any of which could have a material adverse impact on our business, financial condition, results of operations, and prospects. We do not currently have alternative manufacturers, and we may not be able to enter into a long-term agreement with alternative manufacturers, or do so on commercially reasonable terms, which could have a material adverse impact on our business. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products and proposed products to the delay or other detriment of our products and proposed products, or otherwise do not satisfactorily perform according to the terms of their agreements with us.

We also do not have long-term contracts for the supply of the active pharmaceutical ingredient, or API, used in IMVEXXY™, BIJUVA™ and ANNOVERA™. If any supplier of the API or other products used in our approved products or hormone therapy drug candidates experiences any significant difficulties in its respective manufacturing processes, does not comply with the terms of an agreement between us, or does not devote sufficient time, energy, and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our approved products or hormone therapy drug candidates, which could impair our ability to supply our approved products or hormone therapy drug candidates at the levels required for commercialization and prevent or delay their successful commercialization.

Even after the approval of IMVEXXY™, BIJUVA™ and ANNOVERA™, and even if we obtain regulatory approval for our other hormone therapy drug candidates, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.

With respect to IMVEXXY™, BIJUVA™ and ANNOVERA™, the FDA may still impose significant restrictions on a product's indicated uses or marketing or to the conditions for approval, or impose ongoing requirements for potentially costly post-approval studies, including phase 4 clinical trials or post-market surveillance. As a condition to granting marketing approval of a product, the FDA may require a company to conduct additional clinical trials. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. For example, the labeling for IMVEXXY™, BIJUVA™ and ANNOVERA™ contains restrictions on use and warnings. The Food and Drug Administration Amendments Act of 2007, or FDAAA, gives the FDA enhanced post-market authority, including the Risk Evaluation and Mitigation Strategy, explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved REMS programs. IMVEXXY™, BIJUVA™ and ANNOVERA™ will also be subject to ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record keeping, and reporting of safety and other post-market information. The FDA's exercise of its authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements, and potential restrictions on sales of approved products. As part of the FDA's approval of IMVEXXY™, we have committed to conduct a post-approval observational study to evaluate the risk of endometrial cancer in post-menopausal women with a uterus who use a low-dose vaginal estrogen unopposed by a progestogen such as IMVEXXY™. Foreign regulatory agencies often have similar authority and may impose comparable costs. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our hormone therapy drug candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

The holder of an approved NDA also is subject to obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. Legal requirements have also been enacted to require disclosure of certain clinical trial results on a publicly available database.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's cGMPs regulations and other regulatory requirements, such as adverse event reporting. If we or a regulatory agency discovers problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the drug, requiring that we conduct additional clinical trials, imposing new monitoring requirements, or requiring that we establish a REMS program. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws, and are subject to review by FDA. If the FDA raises concerns regarding our promotional materials or messages, we may be required to modify or discontinue using them and may be required to provide corrective information. Should we fail to comply with these requirements, we may be subject to significant liability including civil and administrative actions as well as criminal sanctions. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act and its implementing regulations.

Our activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party collaborators fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions:

- conduct an investigation into our practices and any alleged violation of law;

- issue warning letters or untitled letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- require that we suspend or terminate any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- exclude us from providing our products to those participating in government health care programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

Recent government enforcement has targeted pharmaceutical companies for violations of fraud and abuse laws.

The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, pharmacies, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, or engagement of speakers or consultants, may be subject to scrutiny if they do not fit squarely within an exemption or safe harbor. Our practices with respect to interactions with health care professionals, including but not limited to consultant relationships, speaker programs, advisory boards, and scientific/educational grant programs, as well as our arrangements with pharmacies, may not in all cases meet all of the criteria for safe harbor protection from AKS liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient assistance programs. In addition, several states have recently enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or codes of conduct and/or to file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Several states have also adopted laws that prohibit certain marketing-related activities, including the provision of gifts, meals or other items to certain health care providers.

Though we are continuing to develop our compliance program, we cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate federal or state fraud and abuse laws or other applicable requirements.

Federal enforcement agencies and private whistleblowers recently have shown interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support, co-pay support, nursing, adherence and educational services, referrals to other providers, donations to independent patient assistance charities, and relationships with specialty pharmacies. Co-pay assistance programs are intended to assist qualified patients with private insurance with any out-of-pocket financial obligations, but must exclude any government health care program beneficiaries. A number of investigations into patient assistance practices have resulted in significant civil and criminal settlements. We offer co-pay assistance for our vitamin products ,and will offer patient assistance including co-pay assistance and free drug sample starter packs for IMVEXXY™, and potentially will do so for BIJUVA™ and ANNOVERA™. If we fail to structure these and other support programs to comply with applicable law, we risk becoming subject to government investigations, and potentially, facing penalties or consequences for violations under fraud and abuse laws. In addition, to the extent we, our subsidiary, VitaMed, or our other contractors or agents receive or obtain individually identifiable health information from patients, health care professionals, pharmacies, or other individuals or entities, although we are not directly subject to HIPAA, we could be subject to criminal penalties if we mishandle individually identifiable health information in a manner that is not authorized or permitted by HIPAA. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

The occurrence of any of the foregoing events or penalties may force us to expend significant amounts of time and money and may significantly inhibit our ability to bring to market or continue to market our products and generate revenue. Similar regulations apply in foreign jurisdictions.

Any failure to adequately expand a direct sales force will impede our growth.

We expect to be substantially dependent on a direct sales force to attract new business and to manage customer relationships. We plan to expand our direct sales force and believe that there is significant competition for qualified, productive direct sales personnel with advanced sales skills and technical knowledge. Our ability to achieve significant growth in revenue in the future will depend, in large part, on our success in recruiting, training, and retaining sufficient direct sales personnel. New and future hires may not become as productive as expected, and we may be unable to hire sufficient numbers of qualified individuals in the future in the markets in which we do business. If we are unable to hire and develop sufficient numbers of productive sales personnel or are required to hire more sales personnel than we expect our business prospects could suffer.

Other pharmaceutical companies with which we compete for qualified personnel may have greater financial and other resources, different risk profiles, and longer histories than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we offer. If we are unable to continue to attract and retain high-quality personnel, our ability to commercialize IMVEXXY™, BIJUVA™ and ANNOVERA™ may be limited.

Licensing of intellectual property involves complex legal, business and scientific issues, and disputes could jeopardize our rights under such agreements. Additionally, our current licensing agreements contain limitations and restrictions that could limit or adversely affect our ability to develop and commercialize other products in the future.

We are currently and may in the future be a party to license agreements of importance to our business and to our current product and product candidates, and we expect to be subject to additional such agreements in the future. Disputes may arise between us and any of these counterparties regarding intellectual property subject to and each parties' obligations under such agreements, including:

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product and product candidates, and what activities satisfy those diligence obligations;

- the scope of rights granted under the agreement and other interpretation-related issues;
- our obligations to make milestone, royalty or other payments under those agreements;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- the ownership of inventions and know-how arising under the agreement or resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign the license; and
- the effects of termination.

These or other disputes over our obligations or intellectual property that we have licensed may prevent or impair our ability to maintain our current arrangements on acceptable terms, or may impair the value of the arrangement to us. Any such dispute could have an adverse effect on our business.

If we fail to meet our obligations under a license agreement in a material respect, the respective licensor could have the right to terminate the respective agreement and upon the effective date of such termination, have the right to re-obtain the related technology as well as, potentially, aspects of any intellectual property controlled by us and developed during the period the agreement was in force that relate to the applicable technology. This means that the licensor to each of these agreements could effectively take control of the development and commercialization of the applicable product or product candidate after an uncured, material breach of the agreement by us. This may also be the case if we voluntarily terminate the relevant agreement. Any uncured, material breach under a license agreement could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for the applicable product or product candidates.

In July 2018, we entered into a license agreement with the Population Council to obtain exclusive U.S. rights to commercialize the Population Council's segesterone acetate/ethinyl estradiol one-year vaginal system for human contraceptive indications, which was approved by the FDA in August 2018 and which we intend to commercialize under the name ANNOVERA™. The agreement requires us to use commercially reasonable efforts to commercialize this product and enter into certain manufacturing agreements, make timely milestone and other payments, provide certain information regarding our activities under the agreement, and indemnify the other party with respect to our development and commercialization activities under the terms of the agreements.

In addition, our current licensing agreement with the Population Council contains limitations and restrictions, including limitations that could limit or adversely affect our ability to develop and commercialize this or other product candidates including the following:

- we cannot sublicense the rights licensed to us without the consent of the Population Council;
- neither we nor the Population Council may develop a competitive product (as defined with respect to each party in the agreement) for six years from the date of the agreement;
- currently there are no Orange Book listable patents or patent applications covering this system; and

- the Population Council owns any program improvements, as defined in the agreement.

Our level of indebtedness and the terms of the Credit Agreement could adversely affect our operations and limit our ability to plan for or respond to changes in our business. If we are unable to satisfy certain conditions in our Credit Agreement, we will be unable to draw down the remaining the facility and if we are unable to comply with restrictions in the Credit Agreement, the repayment of our existing indebtedness could be accelerated.

Under the Credit Agreement, we have incurred a substantial amount of debt, which could adversely affect our business. In June 2018, we drew down the first tranche of $75.0 million under the Credit Agreement and we currently intend to draw down up to an additional $125.0 million in the aggregate in two additional tranches under the terms of the Credit Agreement, when and if the conditions precedent to such tranches have been met. Our high level of indebtedness could affect our business in the following ways, among other things: make it more difficult for us to satisfy our contractual and commercial commitments; require us to use a substantial portion of our cash flow from operations to pay interest and principal, which would reduce funds available for working capital, capital expenditures and other general corporate purposes; limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other investments or general corporate purposes; heighten our vulnerability to downturns in our business, our industry or in the general economy; place us at a disadvantage compared to those of our competitors that may have proportionately less debt; limit management's discretion in operating our business; and limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy.

We must satisfy certain conditions to be eligible to draw down the second tranche of $75.0 million and the third tranche of $50.0 million. The second tranche may be drawn by us on or before May 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including (i) the approval by the FDA of the NDA for BIJUVA™ and (ii) that we have consummated our first commercial sale in the United States of BIJUVA™. The third tranche of $50.0 million may be drawn by us on or before December 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including that (i) tranche 2 has been drawn and (ii) we and our subsidiaries party to the Credit Agreement have generated at least $75.0 million of consolidated net revenue attributable to commercial sales of BIJUVA™ and IMVEXXY™ during the twelve-month period ending immediately prior to the funding of tranche 3. If we are unable to satisfy those conditions, we would not be able to draw down the respective tranche of financing and may not be able to obtain alternative financing on commercially reasonable terms or at all.

The Credit Agreement requires us to make certain payments of principal and interest over time and contains a number of other restrictive covenants. Among other requirements of the Credit Agreement, we and our subsidiaries party to the Credit Agreement must (i) maintain a minimum cash balance of $50.0 million and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of our products. The Credit Agreement also contains covenants that limit, among other things, the ability of us and our subsidiaries party to the Credit Agreement to (i) incur indebtedness, (ii) incur liens on our property, (iii) pay dividends or make other distributions, (iv) sell our assets, (v) make certain loans or investments, (vi) merge or consolidate, (vii) voluntarily repay or prepay certain permitted indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions. These and other terms in the Credit Agreement have to be monitored closely for compliance and could restrict our ability to grow our business or enter into transactions that we believe would be beneficial to our business.

Our business may not generate cash flow from operations in the future sufficient to service our debt and support our growth strategies. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including under our current debt obligations.

Item 6. Exhibits

Exhibit	Date	Description
10.1+*	July 30, 2018	Population Council License Agreement, by and between TherapeuticsMD, Inc. and The Population Council, Inc.
10.2*	July 30, 2018	Amendment No. 1 to the Credit and Security Agreement, by and among TherapeuticsMD, Inc., as borrower, its subsidiaries party thereto from time to time, each as a borrower, MidCap Financial Trust, as agent and as lender, and the additional lenders party thereto from time to time.
31.1*	November 8, 2018	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	November 8, 2018	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1*	November 8, 2018	Section 1350 Certification of Chief Executive Officer
32.2*	November 8, 2018	Section 1350 Certification of Chief Financial Officer
101.INS*	n/a	XBRL Instance Document
101.SCH*	n/a	XBRL Taxonomy Extension Schema Document
101.CAL*	n/a	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	n/a	XBRL Taxonomy Extension Definition Linkbase Instance Document
101.LAB*	n/a	XBRL Taxonomy Extension Label Linkbase Instance Document
101.PRE*	n/a	XBRL Taxonomy Extension Presentation Linkbase Instance Document

* Filed herewith.
+ Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DATE: November 8, 2018

THERAPEUTICSMD, INC.

By: */s/ Robert G. Finizio*
Robert G. Finizio
Chief Executive Officer
(Principal Executive Officer)

By: */s/ Daniel A. Cartwright*
Daniel A. Cartwright
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITS THE INFORMATION SUBJECT TO THE CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED AS [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Execution Copy

CONFIDENTIAL

LICENSE AGREEMENT

This License Agreement (the "Agreement") is made as of July 30, 2018 (the "Effective Date") by and between The Population Council, Inc., having a principal place of business of One Dag Hammarskjold Plaza, New York, NY, 10017 ("Council") and TherapeuticsMD, Inc., a Nevada Corporation having a principal place of business at 6800 Broken Sound Parkway, NW, 3rd Floor, Boca Raton, Florida 33487 ("LICENSEE").

RECITALS

A. Council is the owner of the Licensed Product (as defined below) and of certain regulatory filings and intellectual property related thereto;

B. LICENSEE wishes to acquire the regulatory filings and to license from Council the right to develop and commercialize the Licensed Product; and

C. Council wishes to license such rights to LICENSEE.

NOW, THEREFORE, in consideration of the mutual agreements contained herein and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

I. DEFINITIONS AND CONSTRUCTION

For purposes of this Agreement, the following definitions will apply:

1.1 "Act" means the United States Food, Drug and Cosmetic Act of 1938, as amended from time to time, and its implementing regulations.

1.2 "Additional Requirements" has the meaning ascribed to that term in Section 4.2.2(c).

1.3 "Affiliate" means, with respect to any specified Person, a Person that, directly or indirectly, through one or more intermediaries, controls, or is controlled by, or is under common control with, such specified Person. For purposes of this definition, "control," when used with respect to any specified Person, will mean (a) the direct or indirect ownership of more than fifty percent (50%) of the total voting power of securities or other evidences of ownership interest in such Person or (b) the power to direct or cause the direction of the management and policies of such Person, directly or indirectly, whether through ownership of voting securities, by contract or otherwise; and the terms "controlling" and "controlled" have meanings correlative to the foregoing.

1.4 "Agreement" has the meaning ascribed to that term in the first paragraph of this agreement.

1.5 "Agreement Patent" means a patent or patent application disclosing and claiming a Program Improvement.

1.6 "API" or "Active Pharmaceutical Ingredient" means a substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product and are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body of a patient receiving the drug product.

1.7 "Applicable Senior Officers" mean the President of LICENSEE or his or her designee, and President of the Council or his or her designee.

1.8 "Application for Regulatory Approval" means each application accepted for filing submitted to a Regulatory Authority to obtain Regulatory Approval in the Territory.

1.9 "Business Day" means any day that banks are open for business in New York City, State of New York, United States of America.

1.10 "Claim" means any action, appeal, petition, plea, charge, complaint, claim, suit, demand, litigation, arbitration, mediation, hearing, inquiry, investigation, or similar event, occurrence, or proceeding made by a Third Party.

1.11 "Commercialize" or "Commercialization" means all activities undertaken with respect to commercialization of a pharmaceutical product in the Territory, including the ongoing process and activities generally engaged in by a pharmaceutical company to establish and maintain a nationwide presence in applicable marketplaces and to sell and market a pharmaceutical product.

1.12 "Commercially Reasonable Efforts" means, in respect of the level of efforts in carrying out an obligation by a Party under this Agreement, within the range of efforts and resources commonly used by pharmaceutical companies of a similar size to such Party to develop and Commercialize in the Territory a product owned by such a pharmaceutical company or to which such pharmaceutical company has rights, which product is at a similar stage in its development or product life and is of similar market potential to the Licensed Product, not taking into account any milestone payments or royalties that may be owed under this Agreement.

1.13 "Confidential Information" means (i) in the case of Council, Council Know-How and financial or other non-scientific or non-technical business information regarding Council or its Affiliates made available to LICENSEE, Program Improvements, and any and all know-how and information relating to the Licensed Product or the use, development, manufacturing, or Commercialization of any of the foregoing; (ii) in the case of LICENSEE, all know-how and information relating to LICENSEE products other than the Licensed Product (whether commercialized or in development), or the use, development, manufacturing, or Commercialization of any of the foregoing; and (iii) in the case of either Party, clinical or regulatory affairs, and financial or other non-scientific or non-technical business information regarding such Party or its Affiliates or its sublicensees made available to the other Party; and in each case, which is owned or Controlled by the applicable Party hereto or any of its Affiliates. Confidential Information may exist in written, electronic or graphic form and may be disclosed orally. Notwithstanding the foregoing, Confidential Information will not include:

(a) information which is or becomes part of the public domain through no breach of this Agreement by the recipient or any of its Affiliates;

(b) information which the recipient can demonstrate by its written records was known by the recipient or any of its Affiliates prior to the disclosure thereof by the disclosing Party;

(c) information which is independently developed by the recipient or any of its Affiliates, so long as such development does not result from use of Confidential Information of the other Party, and such independent development can be demonstrated by written records of the Party claiming such independent development or any of its Affiliates; and

(d) information that becomes available to the receiving Party or its Affiliates on a non-confidential basis, whether directly or indirectly, from a Third Party who is not bound by a duty of confidentiality to the non-disclosing party.

1.14 "Confidentiality Agreement" means those certain Confidentiality Agreements between Council and LICENSEE dated March 13, 2018 and each such Confidentiality Agreement dated June 28, 2018.

1.15 "Control" or "Controlled" means, with respect to any product, material, information, or intellectual property right, that a Party has the legal right or authority (whether by ownership, license or otherwise), as of the Effective Date or during the Term, to grant to the other Party access to, ownership of, a license or a sublicense (as applicable under this Agreement) under, such product, material, information, or intellectual property right as provided for herein without a need to make payments related to such grant and without violating (i) the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such license or sublicense or misappropriating the proprietary or trade secret information of a Third Party, or (ii) any law or governmental regulation applicable to such license or sublicense.

1.16 "Council" has the meaning ascribed to that term in the first paragraph of this Agreement.

1.17 "Council Technology" means Council Patent Rights and Council Know-How.

1.18 "Council Know-How" means all confidential know-how and information to the extent relating to and necessary for the development, manufacture or Commercialization of the Licensed Product, including clinical, technical, scientific, and medical information, know-how, methods, inventions, practices, and trade secrets, quality control information and procedures, pharmacological, toxicological and clinical test data and results and regulatory information, in each case, which Council Controls as of the Effective Date or at any time thereafter. Notwithstanding the foregoing, Council Know-How will not include (a) information which is or becomes part of the public domain through no breach of this Agreement by LICENSEE; (b) information which LICENSEE can demonstrate by its written records was known by LICENSEE or its Affiliates prior to the disclosure thereof by Council; (c) information which is independently developed by LICENSEE or its Affiliates outside of the Program, so long as such development does not result from use of Council Know-How, and such independent development can be demonstrated by written records; and (d) information that becomes available to LICENSEE or its Affiliates on a non-confidential basis, whether directly or indirectly, from a Third Party who is not bound by a confidentiality obligation to Council. For the avoidance of doubt, the Drug Master File jointly owned by the Council with [***] shall not be considered Council Know-How or Council Technology Controlled by Council for purposes of this Agreement until such time as Council may seek and thereafter obtains consent of [***] to the licensing thereof hereunder.

1.19 "Council Patent Rights" means: (a) the patents and patent applications that are listed on Exhibit A, and (b) all patents and patent applications Controlled by The Council in the Territory that claim a Licensed Product, or its use or manufacture, in each case, as of the Effective Date or after the Effective Date, including all provisionals, substitutions, continuations, continuations-in-part, divisionals, supplementary protection certificates, renewals, all letters patent granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations, patents of addition thereof, PCTs of all such patents and patent applications.

1.20 "Damages" means all damages, losses (including any diminution in value), liabilities, payments, amounts paid in settlement, obligations, fines, penalties, costs, or expenses of any kind or nature whatsoever incurred or paid in connection with any Claim or threatened Claim (including reasonable fees and expenses of outside attorneys, accountants and other professional advisors, and of expert witnesses and other costs of investigation, preparation, and litigation in connection with such Claim or threatened Claim), and specifically excluding all special, punitive, incidental and consequential damages of any kind other than as expressly permitted under Section 13.5.

1.21 "Effective Date" has the meaning ascribed to that term in the first paragraph of this Agreement.

1.22 "Exclusivity Term" has the meaning set forth in Section 10.2.1.

1.23 "FDA" means the United States Food and Drug Administration or any successors to its responsibilities with respect to pharmaceutical products such as the Licensed Product.

1.24 "Field" means human contraceptive indications.

1.25 "First Commercial Batch Release" means the first occurrence of the delivery by LICENSEE's manufacturer of Licensed Product of a batch of Licensed Product to LICENSEE's distributor's warehouse (as of the Effective Date, using 3PL (third party logistics)).

1.26 "GAAP" means United States generally accepted accounting principles in effect as of the date of determination thereof.

1.27 "Generic Equivalent" means, with respect to the Licensed Product which has received Regulatory Approval in the United States of America, a generic version of the Licensed Product which has received Regulatory Approval from the FDA (x) under an abbreviated NDA which refers to the Licensed Product as the Reference Listed Drug (as defined in 21 C.F.R. 314.3(b)), (y) under an NDA described in Section 505(b)(2) of the Act as to which information necessary for approval is contained in the NDA filed as part of the Program for the Licensed Product but as to which the applicant in the NDA for such potential Generic Equivalent does not have a right of reference, or (z) by any means by which such generic version can obtain Regulatory Approval based, in part, on information contained in the NDA filed for the Licensed Product but as to which the applicant in the application for Regulatory Approval for such potential Generic Equivalent does not have a right of reference.

1.28 "Joint Product Committee" means the committee described in Section 4.1.1.

1.29 "LICENSEE" has the meaning ascribed to that term in the first paragraph of this Agreement.

1.30 "Launch" means the occurrence of the first delivery to a pharmacy of the Licensed Product billed or invoiced by LICENSEE (or one of LICENSEE's Affiliates or permitted sublicensees) to a non-sublicensee Third Party in the Territory following Regulatory Approval.

1.31 "Law" means all laws, statutes, regulations, or governmental, regulatory, or judicial orders or judgments.

1.32 "License" has the meaning set forth in in Section 2.1.

1.33 "Licensed Product" means the Nestorone® (segesterone acetate)/ethinyl estradiol ring that is the subject of the NDA.

1.34 "Marketing Plan" means the marketing plan for the Licensed Product in the Territory developed by LICENSEE and reviewed by the Joint Product Committee as described in Section 5.1, as amended from time to time by the LICENSEE and reviewed by Joint Product Committee during the Product Term.

1.35 "Marketing Strategy" means the marketing strategy for the Licensed Product in the Territory developed by LICENSEE and reviewed by the Joint Product Committee, including the budget for promotion, product positioning, pricing, education programs, publications, sales messages, and Phase IV clinical studies, as such strategy may be amended by the LICENSEE and reviewed by Joint Product Committee from time to time during the Product Term.

1.36 "NDA" means, (a) for the Licensed Product, United States New Drug Application #209627, filed with the FDA, as such application may be amended or supplemented from time to time, and (b) generally, a New Drug Application in the United States submitted to the FDA for authorization to market a pharmaceutical Product.

1.37 "NDA Response Date" means the date that the FDA first provides either a complete response letter or approval of the NDA for the Licensed Product.

1.38 "Net Sales" means the amount of gross invoiced sales of the Licensed Product in the Territory for a specified period less the following amounts actually and reasonably incurred by LICENSEE, its sublicensees or any of their respective Affiliates selling such Licensed Product:

(a) customer directed commissions and quantity, trade and cash discounts actually allowed or given;

(b) discounts, replacements, credits or refunds actually allowed for the return of rejected, outdated, damaged or returned Licensed Product;

(c) rebates, chargebacks and price adjustments actually allowed or given;

(d) sales or similar taxes (including duties or other governmental charges or assessments) levied, absorbed or otherwise imposed on the sale of Licensed Product; and

(e) charges for freight, handling, postage, transportation, insurance and other shipping charges;

(f) a reasonable allowance for bad debts to the extent actually written off and not to exceed 5% of such gross invoiced sales during the applicable period;

(g) provided, however, that:

(h) sales or transfers of Licensed Product between or among LICENSEE, any permitted sublicensee or any Affiliate of LICENSEE will be excluded from Net Sales calculations for all purposes;

(i) Licensed Product that is made, sold or used in connection with any pre-clinical or clinical trials, or for any testing, quality control, evaluation or other development purposes, or distributed as samples, will be excluded from Net Sales calculations for all purposes;

(j) LICENSEE will not, and will cause its Affiliates and permitted sublicensees to not, apply any discount to the price of the Licensed Product for bundled sales of the Licensed Product with any other product Commercialized by LICENSEE its Affiliates and permitted sublicensees; and

(k) amounts relevant to the determination of Net Sales, and the timing of sales, will be determined from the books and records of LICENSEE (or, as applicable, any permitted sublicensee or any Affiliate of LICENSEE) which will be maintained in accordance with generally accepted accounting principles (GAAP) in the United States.

1.39 "New Product" is defined in Section 10.2.2(b).

1.40 "Other Information" means (a) information relating to a disapproval or cancellation of Regulatory Approval of the Licensed Product by the relevant Regulatory Authority of any jurisdiction; (b) information on modifications required to be made in the contents of a Regulatory Approval of the Licensed Product or an application therefor in any jurisdiction in order to prevent, or to warn against risks of, death, bodily harm, or other severe adverse event; (c) information on withdrawal of the Licensed Product from the marketplace in any jurisdiction; (d) information on important revisions of the warnings or precautions in the usage of the Licensed Product as set forth in the labeling pursuant to a Regulatory Approval or an application therefor in any jurisdiction; and (e) any information about the Licensed Product which would reasonably be expected to adversely impact the continued development or marketing of a Licensed Product in any jurisdiction.

1.41 "Outreach Plan" is defined in Section 5.4.1.

1.42 "Party" means Council or LICENSEE and "Parties" means Council and LICENSEE.

1.43 "Person" means any individual, corporation (including any nonprofit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, labor union, or other entity.

1.44 "Product Term" means the period beginning as of the Effective Date and ending upon the earlier of (i) such time as the Licensed Product is no longer being developed, Commercialized, or sold by LICENSEE or any of its Affiliates, assignees, licensees, sublicensees, transferees, distributors, or marketing partners in the Territory, or (ii) termination or expiration of this Agreement as provided herein.

1.45 "Program" means all activities related to the development, manufacture and Commercialization of Licensed Product performed by or on behalf of Council (or its Affiliates) or LICENSEE (or its Affiliates) pursuant to this Agreement.

1.46 "Program Improvements" means any and all inventions, developments, results, know-how, and information (including clinical, technical, scientific, and medical information, know-how, methods, inventions, practices, and trade secrets, quality control information and procedures, pharmacological, toxicological and clinical test data and results and regulatory information) and all intellectual property relating to any of the foregoing, in each case that is developed by or on behalf of LICENSEE (or its Affiliates) or Council (or its Affiliates) or jointly by LICENSEE and Council or any of their respective Affiliates, in connection with the Program.

1.47 "Program Transfer Provisions" has the meaning ascribed to that term in Section 12.2.3.

1.48 "Protective Action" has the meaning ascribed to that term in Section 7.2.1.

1.49 "Public Organization" will mean the Title X family planning clinics listed in the most recently published Office of Population Affairs Title X Family Planning Directory.

1.50 "Quarter" means a calendar quarter consisting of any of the three-month periods ending on March 31, June 30, September 30 and December 31 in any particular year.

1.51 "Regulatory Approval" means written notice of marketing approval by the FDA based on approval of the NDA.

1.52 "Regulatory Authority" means the agency, if any, of the national government of any country with which a pharmaceutical or biological therapeutic product must be registered or by which a pharmaceutical or biological therapeutic product must be approved prior to its manufacture, use, or sale in such country. Regulatory Authority will include the FDA.

1.53 "Right of Reference" means the "right of reference" defined in 21 CFR 314.3(b), or its equivalents outside the United States, and will in any event include the right to allow the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in regulatory materials (and any data contained therein) filed with such Regulatory Authority.

1.54 "Royalty Period" will have the meaning described in Section 3.2.1.

1.55 "Royalty Report" will have the meaning described in Section 3.3.4.

1.56 "Territory" means the United States of America including its possessions and territories.

1.57 "Third Party" means any Person other than Council or LICENSEE or an Affiliate or an employee of Council or LICENSEE.

1.58 "Watson Agreement" means that certain License Agreement made as of February 9, 2010 by and between the Council and Watson Pharma Inc.

1.59 "WCG Agreement" means that certain License Agreement made as of October 1, 2015 by and between the Council and WomanCare Global Trading CIC,.

1.60 "Wholesale Acquisition Cost" means the wholesale acquisition cost for the Licensed Product as determined by Licensee and published by First Data Bank, Medispan or other nationally recognized database as of the date the Licensed Product was dispensed.

1.61 Construction. For purposes of this Agreement: (a) words in the singular will be held to include the plural and vice versa as the context requires; (b) the word "including" and "include" will mean "including, without limitation," unless otherwise specified; (c) the terms "hereof," "herein," "herewith," and "hereunder," and words of similar import will, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; and (d) all references to "Section," "Article," "Schedule" and "Exhibit," unless otherwise specified, are intended to refer to a Section, Article, Schedule or Exhibit of or to this Agreement.

II. LICENSE; MANUFACTURING

2.1 License Grant. Subject to the terms and conditions of this Agreement, including the payment by LICENSEE to Council of the payment due for Regulatory Approval of the Licensed Product as set forth in Section 3.1, Council hereby grants LICENSEE the sole and exclusive right and license (even as to the Council except for a retained non-exclusive right to perform research and development activities on Licensed Product as necessary or useful to fulfil Council's obligations under this Agreement) under all Council Technology and Council's interest in, to and under all Program Improvements solely to develop, Commercialize, manufacture, make, have made, use, import, export, offer to sell, sell, have sold and distribute Licensed Product in the Field and in the Territory and to make or have made Licensed Product outside the Territory solely for use in the Territory (the "License").

2.2 Sublicensing.

2.2.1 LICENSEE will have the right to sublicense its rights under the License to LICENSEE Affiliates and to Third Parties only with Council's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed. The terms of any sublicense permitted under the foregoing sentence will be set forth in a written agreement and fully consistent with the terms of this Agreement, including in the case of any sublicensee obtaining sublicense rights to Commercialize any Licensed Product, that such writing incorporates the terms of Sections 10.2.1, 12.4 and Article XI. With respect to all sublicenses granted under this Agreement, for purposes of determining whether any breach has occurred under this Agreement, the acts and omissions in relation to this Agreement of any sublicensee of LICENSEE hereunder will be attributable to LICENSEE as though taken or omitted by LICENSEE, itself, (ii) LICENSEE will be jointly and severally liable for any damage arising out of the acts or omissions of any of LICENSEE's sublicensees of the LICENSEE's licensed rights hereunder and (iii) LICENSEE will remain obligated to perform LICENSEE's own obligations under this Agreement.

2.2.2 Any sublicense under the License will automatically terminate upon any termination of the License.

2.2.3 No sublicensee of LICENSEE under the License will have the right to further sublicense its rights under any such sublicensing arrangement without the prior written consent of the Council, which consent will not be unreasonably withheld or delayed.

2.3 Manufacturing.

2.3.1 The Parties acknowledge that (a) Council has entered into that particular Supply Agreement with Crystal Pharma dated [***] for the supply of the Active Pharmaceutical Ingredient for the Licensed Product attached as Schedule 2.3.1(a) ("API Supply Agreement") and (b) Council has entered into that particular letter agreement with QPharma AB ("QPharma") dated [***] for the optimization of the commercial manufacturing process for the Licensed Product ("Letter Agreement"). It is the intention of the Parties for LICENSEE to enter into agreements with each of Crystal and QPharma for the manufacture and supply of Licensed Product for sale in the Territory. LICENSEE will use Commercially Reasonable Efforts to enter into such agreements promptly after the Effective Date, and Council will use Commercially Reasonable Efforts to assist LICENSEE to enter into such agreements until each such agreement has been entered into by LICENSEE. Upon LICENSEE's reasonable written request to Council, Council will use reasonable efforts at LICENSEE's cost and expense to enforce Council's rights with respect to such negotiation obligations of Crystal Pharma and QPharma, as applicable.

2.3.2 Council hereby consents to a sublicense to QPharma AB for manufacture and supply of Licensed Product to LICENSEE and/or LICENSEE's sublicensees.

2.3.3 Trademarks. Following grant of a registration therefor in the United States by the United States Patent and Trademark Office and upon request by LICENSEE, Council will grant to LICENSEE an exclusive license, on customary terms but without additional consideration above that set forth in this Agreement, to the specific trademarks set forth on Schedule 2.3.3 for use in connection with the Commercialization, marketing, offering for sale and sale of any Licensed Product in the Territory, in each case effective as of the date such trademark is used on such Licensed Product in commerce; provided, however, that nothing herein will require LICENSEE or any sublicensee to market or sell any Licensed Product using a Council Controlled trademark. To the extent LICENSEE Controls any Licensed-Product-specific registered trademarks that are used for Commercialization of the Licensed Product in the Territory and are available for registration in any country or region outside the Territory, Licensee agrees, upon request of Council, to grant a license to Council to such trademarks for use by Council or its designees in Commercialization of the Licensed Product in such country or region outside the Territory.

III. CONSIDERATION

As partial consideration for the rights and licenses granted to LICENSEE in this Agreement, LICENSEE will pay to Council the following amounts by wire transfer in immediately available funds to an account designated by Council in the United States.

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITS THE INFORMATION SUBJECT TO THE CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED AS [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

3.1 Milestone Payments. In addition to (and not in lieu of) the royalty payments due under this Agreement, LICENSEE will pay to Council each of the following one-time milestone non-refundable, non-creditable and no-recourse payments (each a "Milestone Payment") no later than thirty (30) days following the occurrence of each of the following events:

3.1.1 upon the first Regulatory Approval by the FDA of the Licensed Product, twenty million United States Dollars (US $20,000,000) provided that LICENSEE has not terminated the Agreement in accordance with, and within the applicable time period specified in, Section 4.2.2(c), and further provided that, if LICENSEE has made the five million United States Dollars (US $5,000,000) payment to Council set forth in Section 4.2.2(c)iv, then such Milestone Payment shall be reduced to fifteen million United States Dollars (US $15,000,000);

3.1.2 upon the First Commercial Batch Release of a Licensed Product by LICENSEE, a Milestone Payment of twenty million United States Dollars (US $20,000,000);

3.1.3 upon first achieving two-hundred million United States Dollars (US $200,000,000) in cumulative Net Sales in the aggregate for all Licensed Product sold by LICENSEE, its sublicensees and their respective Affiliates selling the Licensed Product in the Territory, a Milestone Payment of forty million United States Dollars (US $40,000,000); and

3.1.4 upon first achieving four-hundred million United States Dollars (US $400,000,000) in cumulative Net Sales in the aggregate for all Licensed Product sold by LICENSEE, its sublicensees and their respective Affiliates selling the Licensed Product in the Territory, a Milestone Payment of forty million United States Dollars (US $40,000,000).

3.1.5 upon first achieving one billion United States Dollars (US $1,000,000,000) in cumulative Net Sales in the aggregate for all Licensed Product sold by LICENSEE, its sublicensees and their respective Affiliates selling the Licensed Product in the Territory, a Milestone Payment of forty million United States Dollars (US $40,000,000).

3.2 Royalties.

3.2.1 Royalties on Licensed Product. As partial consideration of the licenses granted to LICENSEE hereunder, the royalties described in this Section 3.2.1 will be payable on Net Sales occurring during the period of time beginning on the Effective Date and ending on the date the first arms-length commercial sale of a Generic Equivalent of the Licensed Product is launched by a Third Party unaffiliated with LICENSEE in the Territory (the "Royalty Period"). LICENSEE will pay to Council such royalties equal to the applicable percentages of aggregate annual Net Sales of all Licensed Product sold in the Territory during the applicable calendar year as follows:

(a) five percent (5%) of Net Sales of all Licensed Product aggregated across the Territory in a calendar year during the Royalty Period with respect to such Net Sales in such calendar year that are less than or equal to fifty million United States Dollars (US $50,000,000); and

(b) ten percent (10%) of Net Sales of all Licensed Product aggregated across the Territory in a calendar year during the Royalty Period with respect to such Net Sales in such calendar year that are greater than fifty million United States Dollars (US $50,000,000) and less than one-hundred fifty million United States Dollars (US $150,000,000); and

(c) fifteen percent (15%) of Net Sales of all Licensed Product aggregated across the Territory in a calendar year during the Royalty Period with respect to such Net Sales in such calendar year that are one-hundred fifty million United States Dollars (US $150,000,000) or greater.

3.2.2 Generic Royalties. Following the expiration of the Royalty Period, LICENSEE will pay to Council the royalties described in Section 3.2.1(a) at a reduced rate equal to fifty percent (50%) of the applicable rate under Section 3.2.1 for the time period beginning on the expiration of the Royalty Period and ending six (6) months thereafter, and (b) after the expiration of the time period described in (a), twenty percent (20%) of the applicable rate under Section 3.2.1 for the remainder of the Term.

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITS THE INFORMATION SUBJECT TO THE CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED AS [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

3.2.3 Payment and Reports.

(a) LICENSEE will pay to Council, in United States dollars, not later than forty-five (45) calendar days after the end of each Quarter the royalties owed to Council under the terms of Section 3.2 Each royalty payment will be accompanied by a report in writing (the "Royalty Report") specifying the Quarter to which such royalty payment applies and detailing the calculation of the royalties due to Council for such Quarter, including details as to: gross sales of the Licensed Product; units sold of the Licensed Product; sales and similar taxes paid; refunds made; credits provided; freight and distribution fees paid; other allowable deductions taken; reconciliation, if any, of estimated to actual sales due to timing of financial reporting; computation of Net Sales; computation of royalties; reasonable documentation regarding any amounts deducted pursuant to Section 4.2.2. Except as otherwise expressly permitted in Section 3.4 with respect to taxes, all payments by LICENSEE will be made without set-off or deduction of any kind.

3.2.4 Records. LICENSEE will keep, and will require any Affiliates and sublicensees selling the Licensed Product to keep, for three (3) years from the date of each payment of royalties, complete and accurate records of Net Sales and net units sold of the Licensed Product in sufficient detail to allow the royalties to be determined accurately. Council will have the right for a period of three (3) years after receiving any report or statement with respect to royalties due and payable to appoint an independent Certified Public Accountant reasonably acceptable to LICENSEE to inspect the relevant records solely for the purpose of verifying such report or statement. LICENSEE will make its records and the records of its Affiliates available for inspection by such independent certified public accountant during regular business hours on a reasonably mutually agreed-upon date and at such place or places where such records are customarily kept, upon reasonable notice from Council, to verify the accuracy of the reports and payments. Such inspection right will not be exercised more than once in any calendar year except that, following any audit that reveals an underpayment sufficient to shift the cost of the audit to Licensee, until such time as two consecutive audits show no such discrepancy, Council will have the right to have such audit performed on a quarterly basis. Council will bear all of its and the auditor's costs and expenses associated with an audit conducted pursuant to this Section 3.2.4, provided, however, that if the designated auditor discovers an underpayment at of least the lesser of (i) twenty thousand United States dollars (US $20,000) and (ii) five percent (5%), for any Quarter between the amount of royalties LICENSEE has paid under this Agreement and the amount of royalties actually owed to Council under this Agreement, then LICENSEE will bear all costs and expenses associated with such audit and, for the avoidance of doubt, such underpayment will be considered a late payment subject to interest pursuant to the terms of Section 14.12. Council agrees to treat all information learned in the course of any audit or inspection as Confidential Information of LICENSEE except to the extent necessary for Council to (i) reveal such information in order to enforce its rights under this Agreement, or (ii) if disclosure is required by law. The results of each inspection, if any, will be binding on both Parties. LICENSEE will include substantially the same audit rights in any sublicense it grants in order to verify the correctness of payments due hereunder.

3.3 Taxes.

3.3.1 LICENSEE will make all payments to Council under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by applicable Law in effect in the Territory at the time of payment.

3.3.2 Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by LICENSEE on behalf of Council to the appropriate governmental authority, and LICENSEE will furnish Council with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by Council.

3.3.3 LICENSEE and Council will cooperate in good faith with respect to all documentation required by any taxing authority or reasonably requested by LICENSEE or Council to secure a reduction in the rate of applicable withholding taxes.

3.3.4 If LICENSEE had a duty to withhold taxes in connection with any payment it made to Council under this Agreement but LICENSEE failed to withhold, and such taxes were assessed against and paid by LICENSEE, then LICENSEE will furnish Council with proof of payment of such taxes (not including any interest or penalty) and Council will reimburse LICENSEE for such amount within forty-five (45) days after Council's receipt of written notice from LICENSEE of such payment by LICENSEE.

3.4 Without limiting Section 2.2.1, in the event that LICENSEE or any successor in interest to LICENSEE sublicenses rights under this Agreement to any Person or Persons in accordance with the terms of this Agreement, LICENSEE or such successor will ensure that any such sublicensee, agrees to provisions whereby the Net Sales of Licensed Product by such sublicensee are considered in determining the royalty rates and milestone and royalty payment amounts owed and paid to the Council hereunder and that such sublicensee is liable for any non-payment of any such amount that related to such Net Sales of such sublicensee.

IV. JOINT PRODUCT COMMITTEE, PRODUCT DEVELOPMENT, CLINICAL TRIALS AND REGULATORY APPROVALS

4.1 Joint Product Committee.

4.1.1 Formation. Within 30 days of the Effective Date of the Agreement, the Parties will establish a joint product committee (the "JPC"). The JPC will be composed of six (6) members, three (3) members appointed by each Party, including at least one research and development executive or his or her designee from each Party, and will have the right to create subcommittees as needed. Promptly following the Effective Date, each Party will appoint its initial representatives to the JPC. Each Party may replace its JPC representatives at any time upon written notice to the other Party. LICENSEE will designate one of its representatives as the Chairperson of the JPC. The Chairperson will be responsible for scheduling meetings, preparing and circulating an agenda in advance of each meeting, preparing and issuing minutes of each meeting within thirty (30) days thereafter, revising such minutes to reflect timely comments thereon, and overseeing the ratification of such revised minutes.

4.1.2 Meetings. The JPC will meet at such times and such places as will be determined from time to time by LICENSEE and the Council, but in any event, not less than twice in each calendar year. Members of the JPC may participate in meetings of the JPC in person or by conference telephone call. A quorum for the conduct of business by the Joint Product Committee will consist of a majority of the members designated by LICENSEE and a majority of the members designated by the Council.

4.1.3 Duties of the Joint Product Committee. The JPC will

(a) Oversee the planning and implementation of development activities, including post-Regulatory Approval activities;

(b) Review results of the development activities and discuss modifications to any planned development activities;

(c) Facilitate the exchange of regulatory documents and other regulatory information between the Parties;

(d) Review the Marketing Plan developed by LICENSEE and its implementation;

(e) Discuss the state of the markets for Licensed Product in the Territory and opportunities and issues concerning the Commercialization of Licensed Product, including consideration of marketing and promotional strategy, marketing research plans, labeling, Licensed Product positioning and Licensed Product profile issues;

(f) Monitor the sales efforts of Licensee in the Territory;

(g) Oversee and update the Outreach Plan; provided that any changes during the Exclusivity Term to Paragraph 4 of the Outreach Plan will not be subject to decision by the JPC and must be made, if at all, by amendment or modification of this Agreement.

(h) Have authority to establish one or more other committees that report to the JPC and assist the JPC in carrying out its responsibilities, which other committees will be subordinate to the JPC, will have such membership and responsibilities as the JPC will determine, and may be disbanded by the JPC at any time;

(i) Resolve, or attempt to resolve any disputes not resolved by any subordinate committee created by the JPC; and

(j) Perform such other functions as appropriate to further the purposes of this Agreement and as allocated to it jointly in writing by the Parties.

4.1.4 Decision Making; Authority. The JPC will make its decisions by consensus, with each Party's representatives collectively having one vote. If the JPC is unable to reach consensus regarding a matter before it, the issue will be presented by the JPC to the Parties' Applicable Senior Officers for resolution. Once an issue has been presented to the Applicable Senior Officers, they will have fifteen (15) days to make a final determination regarding the issue in dispute. In the event that the Applicable Senior Officers are unable to reach a final determination within such fifteen (15) day period, then:

(a) Council will have authority to make the final decision with respect to all issues relating to all clinical, regulatory, and development matters prior to the NDA Response Date and any matters thereafter for which the Council has sole financial responsibility under this Agreement; and

(b) LICENSEE will have authority to make the final decision with respect to all issues not set forth in the foregoing (a) or Section 4.2.2(c), subject to LICENSEE fulfilling its obligations under this Agreement, including with respect to using Commercially Reasonable Efforts as required hereunder. For the avoidance of any doubt, LICENSEE will have exclusive right to establish pricing of the Licensed Product in the Territory.

4.1.5 General Principles.

(a) The JPC and any subordinate committees have no authority beyond the specific responsibilities set forth in this Agreement with respect to such committee. Any subordinate committee created by the JPC will have such duties and responsibilities delegated to such committee by the JPC, so long as such duties and responsibilities do not exceed the power and authority assigned to the JPC hereunder. In particular, and without limiting the generality of the foregoing, no committee may amend or modify the terms or provisions of this Agreement.

(b) Each Party will ensure that its representatives to a committee have appropriate expertise and authority to serve as members of such committee. With the consent of the representatives of each Party serving on a particular committee, other representatives of each Party may attend meetings of that committee as observers. Each Party will be responsible for all of its own expenses of participating in committee meetings. Each Party will use good faith and cooperative efforts to facilitate and assist the efforts of the committees.

(c) Each committee will continue to exist until the first to occur of (i) the Parties mutually agreeing to dissolve it, or (ii) the expiration of all payment obligations described in Article III.

(d) The Parties may form any other committees as they will mutually agree.

4.2 Licensed Product Development.

4.2.1 Prior to the NDA Response Date, the Council in reasonable consultation with LICENSEE will use Commercially Reasonable Efforts to undertake the development and regulatory approval efforts toward obtaining a first approval of the NDA for the Licensed Product in the United States, at Council's cost and expense.

4.2.2 Phase 4 Studies Required upon Regulatory Approval.

(a) To the extent required by the FDA upon Regulatory Approval of the Licensed Product, Council will perform and pay the associated costs and expenses for the four post-approval studies described on Schedule 4.2.2(a).

(b) The Parties anticipate that in order to obtain and/or maintain Regulatory Approval for the Licensed Product a post-approval study may be required by the FDA on such Regulatory Approval to measure risk for venous thromboembolism (VTE) ("VTE Study"), and that as of the Effective Date the scope of the study the FDA has requested is described on Schedule 4.2.2(b). The Parties agree to cooperate in good faith to provide that the scope and cost of a VTE Study is appropriate. To the extent required by the FDA upon Regulatory Approval of the Licensed Product, LICENSEE will perform the VTE Study, provided that (i) fifty percent (50%) of the reasonable and direct costs and expenses incurred by LICENSEE for performance of such Phase IV Study in excess of twenty million United States Dollars ($20,000,000), after payment thereof by LICENSEE, will be deductible by LICENSEE from the royalties or other payments owed to the Council hereunder to the extent actually paid and not previously deducted by LICENSEE as of the time that the applicable royalty or other payment is owed to Council, and (ii) any costs and expenses below such twenty million United States Dollars ($20,000,000) will be the sole responsibility of LICENSEE and will not be deductible from royalties or other payments owed by LICENSEE to Council.

(c) If (x) a complete response letter or continuance of greater than ninety (90) days is received by Council with respect to the Licensed Product, (y) post-marketing requirements or commitments in addition to the studies set forth on Schedule 4.2.2(a) or the VTE Study are required by the FDA upon the initial Regulatory Approval of the Licensed Product ("Additional Requirements"), or (z) the shelf life for the Licensed Product permitted by the FDA upon the initial Regulatory Approval thereof is less than eighteen (18) months, then in each case the Joint Product Committee will meet promptly to determine the strategy to be implemented to address any such issue, provided that:

i. If a complete response letter or continuance of greater than ninety (90) days is received by Council with respect to the Licensed Product, to the extent that, within thirty (30) days following the notification and sharing by Council to LICENSEE of the complete response letter or notice of continuance, as applicable, the Parties, acting reasonably, are unable to agree on a strategy to address such response or continuance, as applicable (including with respect to each Party's share of the costs and expenses associated with any such required studies), then each Party will have the right to terminate this Agreement immediately upon written notice by such Party to the other Party delivered not later than the last day of such thirty (30) day period;

ii. If (A) Additional Requirements are required by the FDA upon Regulatory Approval of the Licensed Product that would involve a Clinical Study or, in the good faith judgment of either Party, would require expenditures in excess of one million United States Dollars ($1,000,000) in the aggregate, and (B) within thirty (30) days following the notification and sharing by Council to LICENSEE of the Regulatory Approval letter from the FDA, the Parties, acting reasonably, are unable to agree on a strategy to address such additional post-marketing requirements (including with respect to each Party's share of the costs and expenses associated with any such required additional requirements), then each Party will have the right to terminate this Agreement immediately upon written notice by such Party to the other Party delivered not later than the last day of such thirty (30) day period;

iii. If the FDA permitted shelf life is less than eighteen (18) months in the Regulatory Approval for the Licensed Product, then LICENSEE shall have the right to terminate the Agreement with immediate effect on written notice to Council made not later than five (5) Business Days following the notification and sharing by Council to LICENSEE of the Regulatory Approval letter from the FDA; and

iv. If neither Party terminates the Agreement in accordance with Section 4.2.2(c)i above, then LICENSEE shall promptly make a one-time non-refundable, non-creditable (except as set forth in Section 3.1.1) and no-recourse payment to Council of five million United States Dollars (US $5,000,000).

4.2.3 Subject to Section 4.2.2, LICENSEE (itself or through an Affiliate or permitted Third Party sublicensee) will use Commercially Reasonable Efforts to maintain the NDA for the Licensed Product in the Territory. Without limiting the obligation of LICENSEE in the previous sentence, in the event that LICENSEE determines that LICENSEE will not maintain the NDA for the Licensed Product, LICENSEE will promptly notify COUNCIL of such determination and will provide the Council a reasonable opportunity within five (5) Business Days of such notification to discuss such determination and to offer suggestions regarding potential avenues to maintain the NDA, and if the Parties cannot agree within ten (10) Business Days after such notification on a pathway reasonably likely to permit the LICENSEE to maintain the NDA, then such notification will constitute a notice of Termination by LICENSEE under Section 12.3.1(a) (termination for reason other than for Council's material breach), provided that the one hundred eighty (180) day notice period for effectiveness of such termination may be shortened by mutual agreement of the Parties to any lesser time period down to an immediate termination as of the expiration of such ten (10) day period following such notification.

4.2.4 Except as provided in Sections 4.2.1 and 4.2.2, as between the Parties, LICENSEE will be responsible for all development costs with respect to the Licensed Product incurred after the Effective Date by or on behalf of LICENSEE, provided that any costs incurred by Council for development activities under this Agreement shall only be reimbursable by LICENSEE to the extent agreed to by LICENSEE in advance in writing.

4.2.5 Except as provided in Sections 4.2.1 and 4.2.2, LICENSEE will use Commercially Reasonable Efforts to perform the development activities related to the Licensed Product in the Territory. Without limiting the foregoing or Council's other remedies, if Council notifies LICENSEE that it believes LICENSEE is not using Commercially Reasonable Efforts to develop the Licensed Product: (i) the Joint Product Committee will meet within fifteen (15) days of any such notice and, at such meeting, Council will provide its rationale to the Joint Product Committee regarding why it believes LICENSEE has not been using Commercially Reasonable Efforts and LICENSEE will provide its rationale regarding why it believes it has been using Commercially Reasonable Efforts; and (ii) the Parties will use good faith efforts for a period of up to thirty (30) days following such Joint Product Committee meeting to attempt to resolve any such disputes after which time Council may pursue resolution pursuant to the terms of Section 14.3.

4.3 Trademarks. The Joint Product Committee will determine which trademark or trademarks will be used in marketing the Licensed Product in the Territory, provided that no trademark identifying Council will be used on the Licensed Product in the Territory except as required by law or as consented to by Council, such consent to be in Council's sole and absolute discretion. Subject to Section 2.3.3, LICENSEE will be the sole and exclusive owner of any trademark or trademarks used in marketing in a Licensed Product, provided that with respect to any termination of this Agreement that results in reversion of Commercialization rights to Council in relation to the Licensed Product Commercialization in the Territory, upon such termination or reversion, the Council shall be deemed to have a license to the Licensed Product-specific Trademarks in the Territory for purposes of commercializing the Licensed Product therein, and LICENSEE shall thereafter promptly assign all right, title and interest to such Trademarks to the Council.

4.4 Regulatory Activities.

4.4.1 Transfer to LICENSEE.

(a) Council will continue to hold the Investigational New Drug Application ("IND") prior to Regulatory Approval by the FDA.

(b) Upon Regulatory Approval by the FDA and payment of the associated milestone set forth in Section 3.1.1, LICENSEE will own and hold the NDA and all other Applications for Regulatory Approval, licenses, and authorizations from the FDA, provided that (i) all data and information in the NDA will be owned solely by Council and licensed to LICENSEE in the Territory pursuant to the terms of this Agreement, and (ii) Council and its other licensees will have an irrevocable and perpetual a Right of Reference to such Applications for Regulatory Approval, licenses, and authorizations for (A) purposes of obtaining Regulatory Approval and Commercialization of the Licensed Product and other products outside the Territory, and (B) for all purposes with respect to products other than the Licensed Product (but not including any Generic Equivalent of the Licensed Product) within the Territory. Upon approval by the FDA of the NDA, Council will promptly transfer the NDA to LICENSEE and LICENSEE will accept such transfer from Council. Council agrees to use Commercially Reasonable Efforts in agreements related to licensing the Licensed Product outside the Territory to obtain a Right of Reference for LICENSEE similar to that described for Council above with respect to applications for Regulatory Approval outside the Territory. LICENSEE will not transfer any rights under the Licensed Product NDA to any Affiliate or Third Party (including by granting any Right of Reference thereto) under any circumstance other than as expressly permitted under this Agreement, including (x) in conjunction with an assignment to such Third Party or Affiliate of this Agreement as permitted under Section 14.4, and (y) under a sublicense pursuant to Section 2.2.

(c) Following payment by LICENSEE of the full payment set forth in Section 3.1.1, on an ongoing basis at LICENSEE's expense, Council will provide LICENSEE, in the form specified by the Joint Product Committee, with material relevant information and data that is part of the Council Know-How, including upon approval an electronic copy of the Licensed Product NDA as filed with the FDA. Each Party will provide the other Party with a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate the Right of Reference described in this Section 4.1.1.

V. COMMERCIALIZATION.

5.1 Pre-Marketing Activities. LICENSEE, with input from the Joint Product Committee, will be responsible for pre-marketing activities for the Licensed Product in the Territory. For the avoidance of any doubt, input from the JPC on Commercialization issues is advisory in nature. LICENSEE has sole decision making authority for Commercialization issues.

5.2 Marketing Plan. Not later than ninety (90) days prior to the anticipated Launch for the Licensed Product, LICENSEE, will prepare and submit to the Joint Product Committee for its review and comment a marketing plan for the Licensed Product (the "Marketing Plan") which plan will provide a three-year budget, market assessment, strategic drivers, pricing, and a reasonably detailed summary of operating strategies and tactics, advertising, marketing and educational materials, and sales and marketing promotional materials and activities intended to promote and support sales of the Licensed Product in the Territory (the "Marketing Plan"). The Marketing Plan will be updated by LICENSEE and reviewed by the Joint Product Committee on an annual three-year rolling basis, which update will be submitted to the Council not later than one-hundred eighty (180) days in advance of the first day of the next applicable fiscal year.

5.3 Sales and Marketing. LICENSEE will be responsible for sales, marketing and promotional activities for the Licensed Product in the Territory in accordance with the Marketing Plan and will bear all related costs and expenses. LICENSEE will use Commercially Reasonable Efforts to Commercialize Licensed Product in the Territory in all counties of the Territory, provided that:

5.3.1 if the Licensed Product is not Launched in the United States within sixty (60) days after the date of the First Commercial Batch Release LICENSEE will be deemed to have committed a material breach of its obligations under this Agreement; and

5.3.2 unless determined otherwise by the Joint Product Committee (which determination will be subject to a veto by The Council), (a) by the end of the second year after approval by the FDA of the first Regulatory Approval for a Licensed Product, LICENSEE will ensure that audited detailing visits promoting the Licensed Product are made by its sales representatives not less than once a calendar quarter to the OB/GYN prescribers in the United States that account for at least [***] of the prescriptions by OB/GYN prescribers of contraceptive products, (b) in-person detailing visits will be augmented by commercially-reasonable digital efforts and professional education.

5.4 Public Sector.

5.4.1 LICENSEE (itself or through a permitted sublicensee) will use Commercially Reasonable Efforts (without regard to profitability of the Licensed Product to LICENSEE or any permitted sublicensee) to perform the outreach activities described in the plan attached as Schedule 5.4.1 hereto ("Outreach Plan"). As part of the Outreach Plan, Licensee will publicly announce a reduced price program for underrepresented communities to the extent not already described in the press release described in Section 11.2.

5.4.2 LICENSEE agrees that the price for the Licensed Product charged by or on behalf of LICENSEE to Public Organizations will be no more than [***] of the Wholesale Acquisition Cost.

5.5 Medical Inquiries. During the Term, LICENSEE will have responsibility for all correspondence with physicians in the Territory relating to the Licensed Product, and for providing information to physicians in response to medical inquiries, all in accordance with LICENSEE's standard operating procedures and in compliance with applicable Laws and regulations. Council will promptly refer to LICENSEE all medical or patient questions emanating from the Territory relating to the Licensed Product.

5.6 Distribution and Customer Service. LICENSEE will have the sole responsibility for Licensed Product distribution, inventory, returns, accounts receivable and customer service. All customer complaints and inquiries regarding the Licensed Product will be referred by Council to LICENSEE for response in a timely manner after receipt by Council, and LICENSEE will handle such matters in a timely manner and in compliance with applicable laws and regulations.

5.7 Procedures. Prior to Launch, LICENSEE will prepare and provide to Council reasonable written procedures for Council to follow if Council receives complaints, medical inquiries, adverse event reports or orders for the Licensed Product.

5.8 Licensed Product Recalls. LICENSEE will have the responsibility for, and will bear all costs related to, any total or partial recall or market withdrawal of the Licensed Product (whether voluntary or not).

5.9 Global Coordination. LICENSEE will reasonably cooperate with Council and Council's other licensees of Nestorone®-containing products other than the Licensed Product with respect to safety, and pharmacovigilance, and will enter into one or more safety and pharmacovigilance agreements as may be necessary or useful to effect such cooperation, and Council will require its other licensees of Nestorone®-containing products other than the Licensed Product to cooperate with LICENSEE, or its permitted sublicensees, as the case may be, with respect to safety and pharmacovigilance, including safety data.

VI. OWNERSHIP AND INTELLECTUAL PROPERTY

6.1 Ownership. Subject to LICENSEE's license rights under the License, Council is and will be sole owner of Council Technology, Council Confidential Information and Program Improvements. Subject to any license granted to Council pursuant to the terms of Article XII, LICENSEE is and will be the sole owner of LICENSEE Confidential Information. Council (or its designated Affiliate) will own any product-specific trademarks set forth on Schedule 2.3.3 used in Commercializing Licensed Product by or on behalf of LICENSEE or its Affiliates or permitted sublicensees in the Territory that are owned by Council as of the Effective Date.

6.2 Patent Applications on Council Know-How.

6.2.1 With respect to applications for patents that relate to Council Know-How, (a) Council will remain the owner of the application for patent, (b) Council will continue to bear the full costs of and responsibility for preparing, filing, and prosecuting, in its sole discretion, the application and (c) to the extent that any claims of such application for patent cover a Licensed Product, or the manufacture, use or sale thereof, such application for patent and any patents issuing thereon will constitute Council Patent Rights for purposes of this Agreement.

6.2.2 Where applications for patents covering any Council Know-How have not been filed:

(a) Council will, in its sole discretion subject only to the terms of Section 6.2.2(b), determine whether or not to file an application for patent in the Territory for such Council Know-How. If Council elects to file such an application, Council will bear the full costs of preparing, filing and prosecuting the application and maintaining any patents that issue thereon and Council will control the prosecution of such application using counsel reasonably acceptable to LICENSEE.

(b) If Council elects not to file an application for patent in the Territory covering any such Council Know-How that Council reasonably believes is likely to result in a material patent with respect to the License, then the following provisions will apply: (1) Council will notify the Joint Product Committee in writing of its decision not to file such an application for patent; (2) if LICENSEE disagrees with Council's decision not to file such application, LICENSEE will have a reasonable opportunity to consult with Council though the Joint Product Committee in order to convince Council to file such an application; (3) if Council maintains its election not to file such application then (i) the information will remain Council Know-How; and (ii) LICENSEE will not have the right to file any applications for patent disclosing or claiming such Council Know-How anywhere in the world without the prior written consent of Council; and (4) if Council permits LICENSEE to file such application, then LICENSEE will have the right to file such applications for patent.

(c) Council will notify the Joint Product Committee regarding each application for patent filed by Council pursuant to this Section 6.2.2 and any patent issuing thereon that covers a Licensed Product, or the manufacture, use or sale thereof. Each such application and each such patent will constitute a Council Patent Right for purposes of this Agreement and (subject to any restrictions imposed by Third Party transferors or licensors of such Council Know-How) will be licensed to LICENSEE by Council as part of the License without any royalty or other payment other than the royalties and payments specified herein.

(d) In the event that Council decides to abandon an application or not to maintain a patent on an application that falls under Section 6.2.2(c), Council will give written notice to LICENSEE at least sixty (60) days prior to Council allowing such application to go abandoned or prior to Council not taking a necessary step to maintain such patent and LICENSEE will have the option of taking over the prosecution or maintenance of such application or patent at its sole expense. If LICENSEE elects to take over the prosecution or maintenance of such application pursuant to this Section 6.2.2(d), or if Council gives LICENSEE written permission to file any applications for patent pursuant to Section 6.2.2(b), Council will, to the extent permitted by applicable law, assign all its right, title and interest in such application or patent in the Territory to LICENSEE.

6.3 Patent Applications on Program Improvements. Council will be deemed the sole owner of all Program Improvements, provided that, to the extent any Program Improvement that is made solely by LICENSEE has utility outside the field of reproductive health and contraception in humans, then Council will be deemed hereby to have granted to LICENSEE a perpetual, irrevocable, fully-paid-up sublicensable exclusive license to such Program Improvement to research, develop, make, have made, sale, have sold, import and export products (for avoidance of doubt, other than Licensed Product) in fields outside of reproductive health and contraception in humans. To the extent that a Program Improvement is developed by or on behalf of one Party, that Party will promptly disclose such Program Improvement to the Joint Product Committee in writing with all relevant data supporting such Program Improvement. Council will determine whether or not to file an application for patent in the Territory for all Program Improvements. If Council elects to file such an application, Council will bear the full costs of preparing, filing, and prosecuting such application for patent and maintaining any patents that issue thereon and Council will control the prosecution of such application using counsel reasonably acceptable to LICENSEE.

6.4 Cooperation. Each Party will cooperate, and will cause its employees, consultants and subcontractors to cooperate with all reasonable requests of the other Party for assistance in preparation and prosecution and maintenance of any applications for patent and any patent issuing therefrom and any trademark and any registration issuing therefrom that is owned by the requesting Party hereunder. To the extent that any right, title, or interest in or to any intellectual property conceived, created, developed, or otherwise made by or on behalf of either Party or its Affiliates during the Term vests in a Party or its Affiliates, by operation of Law or otherwise, in a manner contrary to the ownership as set forth in this Article VI, such Party will, and hereby does, on behalf of itself and its Affiliates, irrevocably assign to the other Party any and all of such Party's and its Affiliates right, title, and interest in and to such intellectual property without the need for any further action by any Party. Upon a Party's reasonable request and at its expense, the other Party promptly will execute and deliver to the requesting Party any and all further documents and instruments or take other reasonable actions which may be necessary or appropriate to achieve and confirm the requesting Party's ownership of the intellectual property that is the subject of this Article VI.

6.5 Patent Filing Procedures.

6.5.1 Once a determination has been made by Council to file a patent application for Council Know-How or Program Improvements, each Party will, for patents prosecuted by it pursuant to this Agreement, make Commercially Reasonable Efforts to:

(a) file applications for letters patent;

(b) prosecute all pending and new patent applications and defend against oppositions filed against the grant of letters patent for such applications, including by avoiding where reasonably practicable, the use of extensions of deadlines that could reasonably impact the term and potential adjustment to the term of any patent that might issue thereon;

(c) upon and after the grant of any letters patent, maintain such letters patent in force by duly filing all necessary papers and paying any fees required for such purpose;

(d) keep the other Party reasonably informed of the status of all such applications for patent in the Territory, including by providing copies of material correspondence with the United States Patent and Trademark Office ("USPTO") regarding such applications far enough in advance to permit such other Party a reasonable opportunity (if available) to comment on any proposed response to any such material correspondence received from the USPTO, which comments, if any and if received by a prosecuting Party in a timely manner, shall be reasonably considered by Council in formulating its response, and if rejected, the Parties shall discuss the Council's reasons for rejecting such comments; to that end, each Party agrees to instruct applicable prosecution counsel to send copies of any material correspondence with the USPTO not later than seven (7) days following receipt by such prosecution counsel thereof; and

(e) obtain such patent extensions, adjustments or restorations of patent terms as may become available from time to time.

6.6 Council Patent Rights.

6.6.1 Council will use Commercially Reasonable Efforts to (a) prosecute and maintain Council Patent Rights by duly filing all necessary papers and paying any fees required for such purpose by the patent laws of the particular country in which such Council Patent Right was granted, and (b) obtain such patent extensions or restorations of patent terms as may become available from time to time in any country regarding Council Patent Rights.

6.6.2 In the event Council decides not to prosecute or maintain a Council Patent Right or seek a patent extension or restoration, Council will give LICENSEE written notice at least 60 days prior to Council allowing such application to go abandoned or prior to Council not taking a necessary step to maintain such patent or seek such a patent extension or restoration, and LICENSEE will have the option of taking over the prosecution or maintenance of such application or patent or seeking such patent extension or restoration, in each case at its sole expense. If LICENSEE elects to take over the prosecution or maintenance of any application or patent or to seek such a patent extension or restoration, in each case pursuant to this Section 6.2.2, Council will, to the extent permitted by applicable law, assign all its right, title and interest in such application or patent in the Territory to LICENSEE.

6.7 No Challenge. LICENSEE will not and will ensure that its sublicensees and their respective Affiliates and do not challenge the validity or enforceability of any of the patents that are licensed to Licensee hereunder or assist any Third Parties to do the same. If LICENSEE or any of its distributors, or sublicensees or their respective Affiliates challenges or supports a Third Party challenge to the validity or enforceability of any such patent or assists any Third Party to do the same, LICENSEE will pay Council's reasonable costs and expenses (including attorneys' fees) for defending against such challenge, which payments will be made on a monthly basis in arrears.

VII. INFRINGEMENT BY OR CLAIMS AGAINST THIRD PARTIES

7.1 Notices. Each Party will advise the Joint Product Committee promptly upon its becoming aware of: (a) any unlicensed activities which such Party believes may be an actual or impending infringement in the Territory of any patent or other proprietary right owned or applied for by it or the other Party and related to the Licensed Product or the development, manufacture, use, importation, or sale thereof; (b) any attack on or appeal of the grant of any patent owned or applied for by it or the other Party and related to the Licensed Product or the development, manufacture, use, or sale thereof; (c) any application for patent by, or the grant of a patent to, a Third Party in respect of rights which may be related to the Licensed Product so as to potentially affect the development, manufacture, use, importation, or sale thereof or which may claim the same subject matter as or conflict with any patent owned or applied for by it or the other Party and related to the Licensed Product, or the development, manufacture, use, importation, or sale thereof; or (d) any application made for a compulsory license under any patent owned or applied for by it or the other Party and related to the Licensed Product or the development, manufacture, use, importation, or sale thereof.

7.2 Control of Enforcement.

7.2.1 The Parties will determine through discussions at the Joint Product Committee whether or not to take whatever legal or other action is required in response to activities requiring notice under Section 7.1 ("Protective Action"). If the Joint Product Committee determines that such Protective Action is warranted, then, unless the Joint Product Committee determines otherwise, LICENSEE will, at LICENSEE's expense, commence and prosecute such Protective Action at the direction of the Joint Product Committee or its designee. Council will, at LICENSEE's expense, cooperate with LICENSEE in such action, including, without limitation, being joined as a Party to such action if such joinder is necessary for standing. Notwithstanding, Council will be responsible for its own internal costs associated with such action. Each Party may be represented by counsel of its own selection at its own expense in such Protective Action. Any recovery obtained as a result of such Protective Action, whether by judgment, award, decree, or settlement, will, after reimbursement of the Parties for their reasonable costs and expenses associated with such Protective Action, be retained by LICENSEE and included in and added to the total gross amounts invoiced for sales of Licensed Product for purposes of calculating royalties under the terms of Section 3.3. To the extent such recovery is insufficient to reimburse the Parties' associated reasonable costs and expenses fully, then a Party's share of the recovery will be the product of the total amount recovered with that Party's reasonable costs and expenses divided by the sum of both Parties' reasonable costs and expenses.

VIII. INFRINGEMENT OF THIRD PARTY RIGHTS

8.1 Third Party Claims. LICENSEE and Council will each promptly notify the Joint Product Committee of any Claim by a Third Party against LICENSEE or Council, or any Affiliate or sublicensee of Council or LICENSEE, alleging infringement of such Third Party's intellectual property rights as a result of the development, manufacture, marketing, sale, importation, or use of the Licensed Product anywhere in the Territory. As directed by the Joint Product Committee, the Parties will cooperate and use Commercially Reasonable Efforts to resolve such claimed infringement, with each Party entitled to participate in the defense and to be represented by counsel of its choice, with each Party being responsible for the fees of its counsel; provided, however, that if it appears reasonably likely that the claimed infringement will give rise to a Claim for indemnification hereunder, then the Party against whom such Claim for indemnification would be made will have the first right to defend against such Claim in accordance with Article XIII below.

8.2 Payments to Third Parties. If a Third Party has or receives a patent in the United States that covers the development, manufacture, sale, importation, or use of the Licensed Product as the License Product was manufactured and composed as of the Effective Date, and the LICENSEE reasonably determines, after reasonable consultation with the Council and reasonable consideration of any arguments with respect thereto raised by the Council, that LICENSEE is required to obtain a license to such patent as to such Licensed Product for a royalty or other payment to such Third Party (including that any Licensed Product at issue cannot be reasonably manufactured differently so as to avoid the requirement), then LICENSEE may enter into such a license agreement and will pay all costs and expenses associated therewith, provided that LICENSEE will be entitled to deduct from royalties owed to Counsel hereunder an amount not to exceed [***] of the royalties actually paid to such Third Party up to a maximum deduction of [***] of the royalties otherwise owed by LICENSEE to Council in the aggregate for all such royalties for which LICENSEE is entitled to make such deduction. To the extent Council has, prior to the Effective Date, entered into any agreement with any Third Party for rights under such Third Party's intellectual property, Council will be solely responsible for payment of any amounts owed under such agreement to such Third Party as a result of sales of Licensed Product pursuant to this Agreement.

IX. REPRESENTATIONS AND WARRANTIES

9.1 Representations and Warranties of Both Parties. Council and LICENSEE each hereby represents and warrants to the other, as of the Effective Date, as follows:

9.1.1 It is an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation and has all requisite power and authority, corporate or otherwise, to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Agreement.

9.1.2 Neither it, nor any of its employees or consultants who will be undertaking any activities related to this Agreement or the subject matter thereof, has been debarred or is the subject of debarment or other disciplinary proceedings by the FDA or any Regulatory Authority in the Territory.

9.1.3 No consent, approval, order or authorization of, or registration, declaration or filing with, any governmental agency is required to be obtained or made by or with respect to such Party in connection with its execution, delivery and performance of this Agreement.

9.1.4 The execution, delivery and performance by it of this Agreement and the transactions contemplated thereby have been duly authorized by all necessary corporate action and stockholder action and will not (i) violate any applicable laws or regulations or (ii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license, permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected.

9.1.5 It is not under any contractual obligation to any Third Party that conflicts with the terms of this Agreement or that limits the rights of such Party to fulfill its obligations hereunder.

9.2 Representations and Warranties of Council. Council hereby represents and warrants to LICENSEE, as of the Effective Date, as follows:

9.2.1 Except as set forth on Exhibit A, it owns each of the Council Patent Rights set forth on Exhibit A.

9.2.2 it has sufficient rights and power to grant the exclusive license to LICENSEE which it purports to grant herein.

9.2.3 all inventors of any Council Patents have assigned their entire right, title and interest in, to and under such Council Patents to Council.

9.2.4 the patents and patent applications listed on Exhibit A hereto constitute all the Council Patent Rights in existence as of the Effective Date.

9.2.5 all payments, fees or other obligations to be made or satisfied by Council to any regulatory authority, patent office or Third Party in any jurisdiction have been, and are as of the Effective Date, fully satisfied with respect to each item within the Council Technology and no action with any regulatory authority, patent office or Third Party with respect to the Council Technology is required to be taken within sixty (60) days after the Effective Date.

9.2.6 as of the Effective Date, no patent application or patent within the Council Patent Rights is the subject of any inter partes review, interference, derivation proceeding or other protest proceeding in any patent office in the Territory.

9.2.7 to its knowledge, as of the Effective Date, there is no information, material, fact or circumstance that would constitute inequitable conduct, fraud or misrepresentation with respect to any Licensed Patents.

9.2.8 Council has received no notice and has no reason to expect such notice of any Claim by any Third Party or any Council employee that (a) such Third Party or employee has any rights to Council Technology or the Licensed Product that prevent Council from granting to LICENSEE the License; (b) manufacture, sale, importation or use of the Licensed Product currently in clinical development within the Field as contemplated hereby infringes any Third Party rights; or (c) Council Patent Rights (to the extent representing issued patents) are invalid or unenforceable.

9.2.9 To Council's knowledge as of the Effective Date, there are no errors in the inventorship set forth in any of the patent applications comprising Council Patent Rights.

9.2.10 the API Supply Agreement attached as Schedule 2.3.1(a) and the Letter Agreement attached as Schedule 2.3.1(b) are true and accurate copies of such agreements other than with respect to redacted terms.

9.2.11 Council is not in breach of (a) the API Supply Agreement or (b) the Letter Agreement.

9.2.12 Council has not received any written notice that the API Supply Agreement or the Letter Agreement has been terminated or breached.

9.3 Representations and Warranties of LICENSEE. LICENSEE hereby represents and warrants to Council, as of the Effective Date, as follows:

9.3.1 LICENSEE has sufficient resources, experience and expertise available to it to enable it to perform its obligations under this Agreement reasonably in accordance with pharmaceutical industry standards and strictly in accordance with all applicable Laws.

9.4 Mutual Limitations on Warranties. OTHER THAN THE REPRESENTATIONS AND WARRANTIES MADE BY THE PARTIES PURSUANT TO SECTIONS 9.1, 9.2 AND 9.3, THE PARTIES DISCLAIM ANY AND ALL OTHER REPRESENTATIONS AND WARRANTIES WHETHER EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATIONS OR WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OR ANY REPRESENTATIONS OR WARRANTY ARISING FROM COURSE OF DEALING OR USAGE OF TRADE.

X. COVENANTS

10.1 Covenants of the Parties.

10.1.1 Throughout the Term, Council and LICENSEE will comply in all material respects with all applicable Laws and regulations, including the Act, concerning the development, manufacture, use and sale of the Licensed Product.

10.1.2 Each of Council and LICENSEE will promptly notify the Joint Product Committee if it becomes aware of any Other Information from sources other than LICENSEE. If any such Other Information relates to fatal, life threatening, or other serious adverse events (as defined in ICH-E2A, Section II.B.), the Party first becoming aware of it will promptly advise the Joint Product Committee by telephone, fax, email, or other instantaneous method of communication and will within fifteen (15) days thereafter provide written confirmation of such Other Information. Council will allow LICENSEE to comply (and LICENSEE will be responsible for complying) with the adverse reaction reporting requirements of the Act, and other comparable applicable Laws outside the United States with respect to the Licensed Product. Prior to the first commercial sale of the Licensed Product by LICENSEE or its designee, the Parties or their designees will enter into a pharmacovigilance and safety agreement concerning their respective reporting and investigation responsibilities.

10.1.3 The Parties will execute and deliver any further or additional instruments or documents and perform any acts which may be reasonably necessary in order to effectuate and carry out the purposes of this Agreement.

10.2 Exclusivity.

10.2.1 Beginning with the Effective Date and ending on the first to occur of (i) the date of the first commercial sale of the first Generic Equivalent by a Third Party in the Territory, and (ii) six (6) years after the Effective Date ("Exclusivity Term"), neither LICENSEE, nor any sublicensee of LICENSEE that is Commercializing Licensed Product hereunder, nor any of their respective Affiliates that are Commercializing Licensed Product, will enter into contractual arrangements to (a) own, (b) manage or operate, (c) be engaged in, (d) provide services to, or (e) have an economic interest in, in each case, any business that is Commercializing [***] other than a Licensed Product (a "Competing Product"). Notwithstanding the foregoing sentence, subject to the terms and conditions of this Agreement:

(a) LICENSEE and any of its Affiliates or sublicensees may, under the license granted, use, distribute, sell, offer for sale, have sold and import Licensed Product as a generic product ("Authorized Generic Product") in the Territory at any time after a Third Party launches a Generic Equivalent in the Territory. LICENSEE will send to the Council any and all verifiable evidence that a Third Party intends to launch a Generic Equivalent in the United States and will notify the Council promptly in writing in the event that LICENSEE or any of its Affiliates or sublicensees decides to use, distribute, sell, offer for sale, have sold and import Technology as an Authorized Generic Product in the Territory.

(b) In the event that LICENSEE or any of its affiliates or sublicensees obtains information showing that it is reasonably likely, based on objective evidence, which may include, without limitation, written notification of filing of an ANDA for such Generic Licensed Product, to the extent such notification is then required by applicable law, or filing of an action challenging Patent(s) pertaining to Council Technology in the United States, or similar verifiable evidence, that a Third Party intends to Commercialize a Generic Licensed Product in the United States, the Joint Product Committee may determine, subject to a veto right of the Council, that LICENSEE and any of its affiliates or sublicensees may, under the license granted, use, distribute, sell, offer for sale, have sold and import Licensed Product as an Authorized Generic Product prior to the launch of a Generic Licensed Product by a Third Party.

(c) In the event that LICENSEE is acquired by or acquires a Third Party through a merger, sale of stock or sale of all or substantially all of LICENSEE's assets, if such Third Party has, prior to and at the time of such acquisition, a Competing Product, then the restrictions described in this Section 10.2.1 shall not apply to such Third Party as long as LICENSEE takes reasonable steps to ensure that no Council Technology or Program Improvements are used in the development, Manufacturing or Commercialization of such Competing Product including as follows: (i) by limiting the access of Council Technology or Program Improvements by LICENSEE personnel that are working on such Competing Product to those such LICENSEE personnel that have a need-to-know such information for the performance of LICENSEE's obligations under this Agreement; and (ii) by conducting the research or Development activities required under this Agreement separately from any research or development activities directed to such Competing Product, including by the maintenance of separate lab notebooks and records (password-protected to the extent kept on a computer network) (except that this requirement shall not apply to personnel who have senior research management roles and not project level research roles, provided such personnel in senior research management roles are not directly involved in the day-to-day activities under such Competing Program).

(d) LICENSEE shall have the right to engage Third Party manufacturers that are manufacturing Competing Products, provided such Third Party manufacturer is not manufacturing a Competing Product on behalf of LICENSEE during the Exclusivity Term and does not use Council Technology for the manufacture of such Competing Product.

10.2.2 Subject to this Section 10.2.2 (including the exclusive option described herein), LICENSEE acknowledges that, in furtherance of Council's goals, Council will continue to sponsor the development of contraceptive and other products which may, from time to time, compete with the Licensed Product, and that Council may receive compensation from licensees of such competing products in respect of sales thereof:

(a) Council hereby grants LICENSEE an exclusive option ("Option") to negotiate an exclusive license under which LICENSEE would have the exclusive right to develop, Commercialize, manufacture, make, have made, use, import, export, offer to sell, sell, have sold and distribute New Products in the Territory ("New License"). LICENSEE will have the right to exercise the Option at any time beginning on the Effective Date and ending on December 31, 2019 (the "Option Period") by delivery of written notice to Council specifying the category or categories ((i) or (ii) set forth in the definition of New Product) for which LICENSEE is exercising the Option ("Option Exercise Notice"). Upon delivery of the Option Exercise Notice by LICENSEE in accordance with this Section 10.2.2(a) and for the remainder of the Option Period (such time period, the "Negotiation Period", as may be extended by the Parties by mutual agreement), the Parties will negotiate in good faith a definitive written agreement for the New License, (such definitive agreement, the "License Agreement"), provided that the reasonableness and good faith of any position taken by a Party during such negotiation shall not be determined based on the presence or absence of any term or condition contained in this Agreement. During the Negotiation Period, Council will provide to LICENSEE such reasonable additional information in Council's possession and Control regarding the New Product as LICENSEE may reasonably request in writing to assist LICENSEE to make a reasonably informed decision with respect to the execution of the License Agreement, provided that in the event that the Parties do not enter into a License Agreement by the end of the Option Period, LICENSEE shall return to Council all such additional information (and all copies thereof) promptly upon expiration of the Option Period. With respect to each category (i) and (ii) set forth in the definition of New Product, upon the expiration of the Option Period for such category without the Parties' having entered into a License Agreement for such category of New Product, Council will have the right to assign, transfer, convey, license, or otherwise encumber its rights with respect to such category of New Product and any product falling within such category with any Third Party or multiple Third Parties without owing any duty or obligation to LICENSEE with respect thereto. LICENSEE acknowledges and agrees that in the event it does not exercise the Option or the Parties fail to enter in to the License Agreement for one or both of the categories of New Products, that, subject to Council fulfilling its obligations under Section 10.2.2(c) and 10.2.2(d), any development or Commercialization of one or more products within any such category of New Product by or on behalf of Council or a licensee of Council with respect thereto in the Territory may compete with the Licensed Product hereunder.

(b) "New Product" means (i) any vaginal ring product developed by the Council after the Effective Date that contains both and only Nestorone and estradiol as Active Pharmaceutical Ingredients, and (ii) any vaginal ring product that contains both Nestorone and ethinyl estradiol as Active Pharmaceutical Ingredients.

(c) During the Option Period, the Council will not assign, transfer, convey, license, or otherwise encumber its right, title and interest in the any New Product in any manner that would prevent it from entering into and granting the rights to LICENSEE contemplated under this Section 10.2.2 upon agreement by the Parties, if any, as to the form and substance of the License Agreement and execution thereof.

(d) Council agrees not to license intellectual property rights encompassing or claiming any New Product to any Third Party in a manner that grants rights to market such New Product in the United States prior to the sixth (6^{th}) anniversary of the Effective Date.

XI. CONFIDENTIAL INFORMATION

11.1 Confidentiality.

11.1.1 During the Product Term and at all times thereafter, each Party will use commercially reasonable efforts to keep, and cause its Affiliates and permitted sublicensees, if any, to keep confidential all Confidential Information of the other Party, and neither Party nor any of its Affiliates or sublicensees, if any, will use or disclose the Confidential Information of the other Party except as expressly permitted in this Agreement. The Parties acknowledge that Confidential Information may have been disclosed by either Party or its Affiliates to the other Party or its Affiliates pursuant to the Confidentiality Agreement. All information disclosed pursuant to the Confidentiality Agreement will be deemed Confidential Information of the disclosing Party within the meaning of this Agreement and subject to the terms hereof.

11.1.2 The fact that a particular item of information is not or has ceased to be Confidential Information by virtue of one or more of the exclusions specified in the definition of Confidential Information set forth in Section 1.12 (the "Excluded Item") will not relieve the Party who obtained or received the Excluded Item from that Party's obligation of confidentiality and non-use (a) as to any other item of Confidential Information of the other Party or (b) as to the relationship of the Excluded Item to any other item of Confidential Information of the other Party.

11.1.3 Each Party hereby acknowledges that the Confidential Information of the other Party is highly valuable, proprietary, and confidential and that any disclosure to any officer, director, employee, trustee, or agent of such Party or any of its Affiliates will be made only to the extent necessary to carry out its responsibilities under this Agreement and only if such officer, director, employee, trustee, or agent is informed of the confidential nature thereof and will have agreed to hold such information in confidence under confidentiality provisions at least as stringent as those provided in this Agreement.

11.1.4 The Parties agree that the obligations of this Section 11.1 are necessary and reasonable in order to protect the Parties' respective businesses, and that monetary damages alone may be inadequate to compensate a Party for any breach by the other Party of its covenants and agreements set forth herein. The Parties agree that any breach or threatened breach of this Section 11.1 may cause irreparable injury to the injured Party for which Damages may not be an adequate remedy and that, in addition to any other remedies that may be available, in law and equity or otherwise, such Party will be entitled to seek equitable relief against the breach or threatened breach of the provisions of this Section 11.1.

11.1.5 Following termination of the License for any reason and at the request of the other, each Party will destroy all physical records or embodiments of Confidential Information of the other Party or return such information to the other Party, at the returning Party's expense, and a senior officer of such Party will certify to the other Party that all such items have been so returned or destroyed; provided, however, that each Party will be entitled to maintain one copy of the Confidential Information of the other Party solely for the purpose of monitoring its continuing obligations hereunder.

11.2 Disclosure to Investors; Public Announcements. Prior to making any public announcement or other disclosure regarding this Agreement, the Parties will agree in writing on an initial press release of the transaction contemplated by this Agreement (the "Initial Press Release"). The Initial Press Release may be issued or used by any Party individually or by the Parties jointly on or after the Effective Date. Other than the Initial Press Release and any information described therein, neither Party will disclose the specific terms described in this Agreement without the prior written approval of the other Party, except such announcements or disclosures, as in the opinion of the counsel for the Party making such announcement or disclosure, are required by law or regulation (including, without limitation, the regulations or rules of any stock exchange or similar self-governing body) If a Party decides to make an announcement or disclosure it believes to be required by law or regulation with respect to this Agreement or the subject matter hereof, it will give the other Party such notice as is reasonably practicable and the Parties will work together in good faith to attempt to agree on the content of the disclosure; provided, however, that if such announcement or disclosure is required to be made immediately pursuant to any applicable law or regulation, then no such agreement will be required, and provided further that the Party deciding to make such an announcement shall have the final decision making authority with respect to the form, content and timing of such disclosure.

11.3 Required Disclosure. The receiving Party will be entitled to disclose Confidential Information where such disclosure is reasonably necessary to enforce its rights pursuant to this Agreement or where demand for such disclosure is made on the receiving Party pursuant to: (i) a valid order of a court or other governmental body or (ii) any other applicable law or regulation; provided that if the receiving Party intends to make such disclosure or receives such demand, the receiving Party will give the disclosing Party prompt notice of such fact to enable the disclosing Party to seek a protective order or other appropriate remedy concerning any such disclosure. The receiving Party will fully co-operate with the disclosing Party at the disclosing Party's expense in connection with the disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, the receiving Party will make such disclosure only to the extent that such disclosure is legally required.

11.4 Use of Council's Name. LICENSEE will not use or refer to Council's name, in writing or otherwise, except (1) with the approval of Council in accordance with the following sentence of this clause, (ii) by disseminating informational materials furnished by Council or (iii) in order to comply with any requirement of the FDA or any other requirement of applicable law. Prior to each proposed use of Council's name (other than pursuant to clause (ii) above), LICENSEE will submit to Council a sample of such proposed use. Not later than the tenth Business Day (the "Notice Deadline") after the date of its receipt of such sample, Council will notify LICENSEE in writing (the "Use Notice") whether it approves such proposed use, which approval will not be unreasonably withheld. If Council does not deliver the Use Notice on or before the Notice Deadline, Council will be deemed to have approved such use. When using Council's name in any promotional and other materials or public information generated by LICENSEE relating to the Licensed Product, LICENSEE will credit Council for its role in inventing and developing the Licensed Product.

XII. TERM AND TERMINATION

12.1 Term. The "Term" of this Agreement will commence on, and this Agreement will remain in full force and effect from, the Effective Date and will continue until the later of (a) the expiration of the last-to-expire of the Council Patent Rights in the Territory, or (b) the date following such expiration that follows a continuous period of six (6) months during which LICENSEE or any of its Affiliates or sublicensees have made no commercial sales of Licensed Product in the Territory, unless earlier terminated as specified in this Article XII.

12.2 Termination by Council.

12.2.1 Subject to this Section 12.2.1, Council may terminate this Agreement upon written notice as follows:

(a) in the event of a material breach by LICENSEE of this Agreement (other than a failure to pay an undisputed material amount or a disputed material amount due under Section 3.1.1 or 3.1.2).

(b) if LICENSEE shall have failed to pay an undisputed material amount, or

(c) if LICENSEE shall have failed to pay a disputed material amount due under Section 3.1.1 or 3.1.2 within seven (7) days of the date payment was due, immediately upon expiration of the foregoing seven (7) day period;

provided that in the case of 12.2.1(a) and 12.2.1(b) above, LICENSEE has received written notice from Council of such breach, specifying in reasonable detail the particulars of the alleged breach, and such breach in the case of (a) above, if curable, has not been cured within sixty (60) calendar days of the date of notice or such longer period as may reasonably be required to cure such breach, or in the case of (b) above within seven (7) Business Days, after the date of the relevant notice.

12.2.2 Notwithstanding the foregoing Section 12.2.1:

(a) other than with respect to a disputed material payment amount, if LICENSEE in good faith disputes a purported material breach referred to in 12.2.1(a) , or the failure to cure or remedy such material breach and elects by written notice to Council within seven (7) Business Days after notice to LICENSEE of such breach to resolve the dispute in accordance with the dispute resolution provisions in Section 14.3, then Council may not terminate this Agreement until the date on which it has been, determined under Section 14.3that LICENSEE is in material breach of this Agreement;

(b) if LICENSEE elects by written notice given within seven (7) Business Days of the payment date therefore to resolve a dispute regarding a material payment due under Section 3.1.1 or 3.1.2 pursuant to Section 14.3 and has made payment of such disputed amount to Council within such seven (7) Business Day period as provided above, then Council may not terminate this Agreement on account of failure to make such payment and LICENSEE will be entitled to recover from Council all or such portion of such payment as may be determined to be owing to it pursuant to Section 14.3; and

(c) for a disputed material payment amount, either Party may submit such dispute to an audit procedure as set forth in Section 3.2.4 upon written notice to the other Party, with the Party whose position in the applicable dispute is farthest away from what the auditors determine to bear the costs of such audit, and any such dispute so resolved shall not be subject to further dispute resolution pursuant to Section 14.3.

12.2.3 If Council terminates this Agreement pursuant to Section 12.2.1, the License granted to LICENSEE and any permitted sublicensees, and any other rights granted by Council hereunder (including any license to any trademarks), will automatically terminate and the following obligations will apply (the "Program Transfer Provisions"):

(a) LICENSEE and all permitted sublicensees whose sublicenses are terminated will promptly provide to Council complete documentation of all clinical data and all regulatory data, in each case regarding the Licensed Product and generated by or on behalf of LICENSEE and solely to the extent owned or Controlled by LICENSEE.

(b) LICENSEE and all permitted sublicensees whose sublicenses are terminated will promptly provide to Council reasonably detailed disclosure of all Program Improvements and any other know-how or information other than the Program Improvements set forth in Section 12.2.2(a) and that are Controlled by LICENSEE or its Affiliates.

(c) Where any Third Party rights have been obtained by LICENSEE, or any permitted sublicensee whose sublicense is terminated, for purposes of the Program, LICENSEE and all such permitted sublicensees will use all reasonable efforts to promptly assign (or failing assignment, to sublicense) to Council or its designee such Third Party rights.

(d) LICENSEE and all permitted sublicensees whose sublicenses are terminated will transfer to Council or its designee the ownership of all regulatory submissions and filings related to the Licensed Product that are owned or Controlled by LICENSEE or such sublicensees, including the NDA for the Licensed Product.

(e) LICENSEE and all permitted sublicensees whose sublicenses are terminated will promptly transfer to Council or its designee, at LICENSEE's expense, any inventory and supplies of Licensed Product and any other inventories or supplies obtained by LICENSEE or its Affiliates for purposes of the Program, and will grant to Council or its designee a fully-paid-up license to use any LICENSEE trademarks on such inventory and supplies on customary terms solely for the purpose of selling such remaining inventory and supplies.

(f) LICENSEE and all permitted sublicensees whose sublicenses are terminated will make personnel (as well as the personnel of its Affiliates) reasonably available to Council or its designee to effect an orderly transition to Council or its designee of the information and rights contemplated above in this Section 12.2.2 for a period of up to ninety (90) days following the effective date of termination.

(g) The exclusivity provisions of Section 10.2.1 as applied to LICENSEE and all permitted sublicensees whose sublicenses provided for Commercialization of the Licensed Product and are terminated will survive such termination for the lesser of (i) a period of three (3) years following the effective date of such termination, or (ii) the remainder of the Exclusivity Term.

12.3 Termination by LICENSEE

12.3.1 LICENSEE may terminate this Agreement upon written notice to Council (a) for any reason, upon one-hundred eighty (180) days' written notice to Council, (b) in the event of a material breach by Council or its Affiliates of this Agreement, provided that Council has received written notice from LICENSEE of such breach, specifying in reasonable detail the particulars of the alleged breach, such breach is continuing for sixty (60) calendar days after such notice and such breach has not been cured within such sixty (60) day period (except that, in the event such breach is curable but may not reasonably be cured in sixty (60) calendar days, then such cure period will be extended for an additional period during which Council is making good faith attempts to cure such breach); (c) immediately in the event (i) that Council becomes insolvent or is unable to pay its debts when due; (ii) Council files a petition in bankruptcy, reorganization or similar proceeding, or, if such a petition is filed against Council, such petition is not dismissed within ninety (90) days; (iii) Council discontinues its business; or (iv) a receiver is appointed or there is an assignment for the benefit of Council's creditors, and (d) on fifteen (15) days written notice following the NDA Response Date if the FDA indicates that the Licensed Product does not qualify as employing an NCE that is entitled to five years regulatory exclusivity in the United States.

12.3.2 If LICENSEE terminates this Agreement pursuant to Section 12.3.1(a), the Program Transfer Provisions will apply.

(a) For the avoidance of doubt, upon LICENSEE's termination of this Agreement pursuant to Section 12.3.1(a), LICENSEE's rights included in the relevant licenses granted by Council to LICENSEE under this Agreement will immediately and automatically revert to Council; provided, however, that LICENSEE will have ninety (90) days from LICENSEE's termination of the Agreement to complete the sale of any Licensed Product then in inventory, subject to payment of royalties and milestone payments pursuant to Article III.

12.3.3 If LICENSEE terminates the Agreement pursuant to Section 12.3.1(b) or (c), then (i) Council's License grant to LICENSEE will convert to an irrevocable exclusive License, with the right to sublicense, and will survive termination, and (ii) the obligations of the Parties under Article III will also survive such termination.

12.4 Automatic Termination. This Agreement will terminate automatically, without notice or opportunity to cure, upon the occurrence of any of the following events:

12.4.1 LICENSEE being authorized (whether by its board of directors or such other Person having authority to direct LICENSEE) to commence or institute any bankruptcy, receivership, insolvency, reorganization or other similar proceedings under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code (as may be amended, the "Bankruptcy Code") or under any similar laws or statutes of the United States or any state thereof or of any jurisdiction (whether or not in the United States) having authority or jurisdiction over the assets of LICENSEE or in which LICENSEE may operate or have assets;

12.4.2 the commencement or institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against LICENSEE under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the Bankruptcy Code or under any similar laws or statutes of the United States or any state thereof or of any jurisdiction (whether or not in the United States) having authority or jurisdiction over the assets of LICENSEE or in which LICENSEE may operate or have assets; and

12.4.3 the appointment of a receiver, trustee, or similar party with respect to any material asset of LICENSEE.

12.5 Rights and Duties Upon Termination or Expiration. Upon the termination or expiration of this Agreement, each Party will have the right to retain all payments from the other Party properly made pursuant to this Agreement, and each Party will pay to the other all sums accrued hereunder which are then due.

XIII. INDEMNIFICATION AND LIMITATION OF LIABILITY

13.1 In order to allocate between themselves the responsibility for claims arising out of this Agreement, and except as otherwise specifically provided for herein, from and after the Effective Date, the parties will indemnify each other as provided in this Article XIII.

13.1.1 Indemnification Obligations of LICENSEE. From and after the Effective Date, LICENSEE will defend, indemnify and hold Council, its Affiliates, and each of their respective officers, directors, agents, employees and shareholders (collectively, "Council Indemnitees"), harmless from and against any and all Damages which Council Indemnitees may incur or suffer, or with which any of them may be faced arising out of or in connection with:

(a) The development or Commercialization of the Licensed Product (including with respect to product liability, death, personal injury, pregnancy, or otherwise);

(b) The breach by LICENSEE of this Agreement including any breach of its representations, warranties, covenants or obligations under this Agreement;

(c) LICENSEE's violation of any applicable Laws; and

(d) LICENSEE's willful misconduct; and

(e) Any suit against Council related directly or indirectly to the Licensed Product and brought by any investor or holder of equity or other interest in, or lender to, LICENSEE or any sublicensee hereunder;

provided, however, that, in each such case, LICENSEE will not be liable hereunder to the extent such Damages arise from the willful misconduct of, or a violation of any applicable laws by or from the breach of the provisions of this Agreement by Council, its Affiliates, agents, employees or contractors.

13.1.2 Indemnification Obligations of Council. From and after the Effective Date, Council will defend, indemnify and hold LICENSEE, its Affiliates, and each of' their respective officers, directors, agents, employees, shareholders or members (collectively, "LICENSEE Indemnitees") harmless from and against any and all Damages which LICENSEE Indemnitees may incur, or suffer, or with which any of them may be faced arising out of:

(a) The breach by Council of this Agreement including any breach of its representations, warranties, covenants or obligations under this Agreement;

(b) Council's violation of any applicable Laws;

(c) Claims made by subjects in the Council-sponsored clinical trials to the extent they make a claim based on their participation in those trials;

(d) Claims made by Watson Pharma Inc. and/or its successor in interest with respect to the Watson License or by WomanCare Global Trading CIC and/or its successor in interest with respect to the WCG Agreement; and

(e) Council's willful misconduct;

provided, however, that, in each such case, Council will not be liable hereunder to the extent such Damages arise from willful misconduct of, or a violation of any applicable laws or from the breach of the provisions of this Agreement LICENSEE, its Affiliates, agents, employees or contractors.

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITS THE INFORMATION SUBJECT TO THE CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED AS [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

13.2 Conditions of Indemnification of Third-Party Claims. The obligations and liabilities of an indemnifying Party under Section 13.1 and hereof with respect to Damages resulting from Claims made by Third Parties will be subject to the following terms and conditions:

13.2.1 Promptly after the delivery of a notice seeking indemnification in respect of a Claim and subject to Section 13.2.3, the indemnifying Party may elect, by written notice to the indemnified Party, to undertake the defense thereof, at the sole cost and expense of the indemnifying Party, provided that an indemnified Party's failure or delay to provide notice to the indemnifying party will not constitute a waiver of the indemnifying Party's indemnification obligations unless, and then only to the extent that, an indemnifying Party is actually and damaged thereby. If the indemnifying Party chooses to defend any Claim, the indemnified Party will cooperate with all reasonable requests of the indemnifying Party and will make available to the indemnifying Party any books, records or other documents within its control that are necessary or appropriate for such defense.

13.2.2 In the event that the indemnifying Party, within a reasonable time after receipt of a notice seeking indemnification, does not so elect to defend such Claim, the indemnified Party will have the right (upon further notice to the indemnifying Party) to undertake the defense, compromise or settlement of such Claim for the account of the indemnifying Party, subject to the right of the indemnifying Party to assume the defense of such Claim pursuant to the terms of Section 13.2.1 at any time prior to settlement, compromise or final determination thereof, provided, that the indemnifying Party reimburses in full all costs of the indemnified Party (including reasonable attorney's fees and expenses) incurred by it in connection with such defense prior to such assumption.

13.2.3 Notwithstanding anything in this Section 13.2 to the contrary, if the indemnifying Party assumes the defense of any Claim, any indemnified Party will be entitled to participate in the defense, compromise or settlement of such Claim with counsel of its own choice at its own expense.

13.3 Insurance. In addition to its duty to indemnify, beginning on the date of the first commercial sale of a Licensed Product and during the Term and for a period of [***], LICENSEE will, at its expense, maintain with insurers rated A-7 or higher by A.M. Best a comprehensive general liability insurance policy or policies, including coverage exclusively for the Licensed Product for product liability of least [***], provided that LICENSEE will, on no less than an annual basis have the applicable policies reviewed by a reputable licensed insurance broker in the applicable market with reference to Licensed Product sales in the prior period, projected sales and other relevant factors to determine an appropriate level of insurance for the Licensed Product, will increase the foregoing exclusive coverage as so advised by such broker, and will promptly notify the Council in writing regarding any such increased coverage. Such insurance policy or policies will name Council as an additional insured and will provide that at least 30 days' prior written notice of cancellation or material change in coverage under such policy or policies will be given to Council. LICENSEE will furnish copies of such policy or policies to Council as promptly as reasonably practicable after the Effective Date, and will provide documentation evidencing that such policy or a similar policy is in force each year during the Term.

13.4 Settlements. No Person who has undertaken to defend a Claim under Sections 13.2.1 or 13.2.2 will, without written consent of all indemnified Parties, settle or compromise any Claim or consent to entry of any judgment, provided, however, that such consent will not be required if such settlement, compromise or judgment (i) includes as an unconditional term thereof the release by the claimant or the plaintiff of all indemnified Parties from all liability arising from events which allegedly gave rise to such Claim and (ii) contains no restriction, limitation or prohibition of any kind on the manner in which any indemnified Party conducts its business. Any payment made by a Party to settle a Claim against it without obtaining consent of the indemnifying Party will be at its own cost and expense. Notwithstanding the foregoing, the indemnifying Party will be liable under this Article XIII for any settlement effected without its consent if the indemnifying Party has refused to acknowledge liability for indemnification hereunder and/or declines to defend the indemnified Party in any such Claim, action or proceeding and it is determined that the indemnifying Party was liable to the indemnified Party for indemnification related to such settlement.

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITS THE INFORMATION SUBJECT TO THE CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED AS [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

13.5 Disclaimer of Consequential Damages. IN NO EVENT WILL EITHER COUNCIL OR LICENSEE BE LIABLE TO THE OTHER FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, INCIDENTAL, OR PUNITIVE DAMAGES ARISING UNDER OR AS A RESULT OF THIS AGREEMENT (OR THE TERMINATION HEREOF) INCLUDING, BUT NOT LIMITED TO, THE LOSS OF PROSPECTIVE PROFITS OR ANTICIPATED SALES, OR ON ACCOUNT OF EXPENSES, INVESTMENTS, OR COMMITMENTS IN CONNECTION WITH THE BUSINESS OR GOODWILL OF LICENSEE OR COUNCIL OR OTHERWISE, EXCEPT TO THE EXTENT ANY SUCH DAMAGES RESULT FROM SUCH OTHER PARTY'S BREACH OF ARTICLE XI HEREOF, WILLFUL MISCONDUCT OR ARE PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM.

XIV. MISCELLANEOUS

14.1 Certain Events.

(a) It is the intention of LICENSEE and Council that LICENSEE's rights under this Agreement will remain in place if Council files a petition in bankruptcy, is adjudicated as bankrupt or files a petition or otherwise seeks relief under any bankruptcy, insolvency or reorganization statue or proceeding, or a petition in bankruptcy is filed against it or is not dismissed within 60 days, or it becomes insolvent or makes an assignment for the benefit of creditors or a custodian, receiver or trustee is appointed for it or a substantial portion of its business or assets or it admits in writing its inability to pay its debts as they become due (each a "Bankruptcy Event"). It is the intention of LICENSEE and Council that LICENSEE's exclusive rights and licenses to Commercialize and market the Licensed Product in the Territory continue, without impairment, if and after any Bankruptcy Event. All rights and licenses granted under this Agreement by Council to LICENSEE are, and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses or other rights to "intellectual property" as defined under Section 101(52) of the Bankruptcy Code. Council and LICENSEE agree that LICENSEE, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

14.2 Governing Law. For all matters other than the scope and validity of patents, this Agreement will be deemed to have been made in the State of New York and its form, execution, validity, construction and effect will be determined in accordance with the laws of the State of New York, without giving effect to the principles of conflicts of law thereof and the Parties agree to the personal jurisdiction of and venue in any federal court located in the Southern District of New York or state court located in New York County, New York. The application of the United Nations Convention for Contracts for the International Sales of Goods is hereby expressly excluded.

14.3 Dispute Resolution. If a dispute arises between the Parties under or with respect to this Agreement (a "Dispute"), it will first be submitted to the respective chief executive officers of the Parties for resolution by good-faith negotiation. Any Dispute not resolved by such good-faith negotiation after thirty (30) days from the first notification by one Party to the other Party of the existence of such Dispute may be submitted thereafter by one or both Parties to Arbitration in accordance with this Section 14.3. Any Dispute not settled by negotiation between the Parties will be finally resolved by, arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then in effect (the "Rules"), except as modified herein. The place of arbitration will be New York, New York. If the amount in controversy is $4 million or less (including all claims and counterclaims) there will be one (1) neutral and impartial arbitrator who will be agreed upon by the Parties within twenty (20) days of receipt by respondent of a copy of the demand for arbitration. If the amount in controversy is more than $4 million (including all claims and counterclaims) there will be three (3) neutral and impartial arbitrators, of whom each Party will appoint one (1) within thirty (30) days of the receipt by the respondent of the demand for arbitration. The two (2) arbitrators so appointed will select the chair of the arbitral tribunal within thirty (30) days of the appointment of the second arbitrator. If any arbitrator is not appointed within the time limit provided herein, such arbitrator will be appointed by the AAA in accordance with the listing, striking, and ranking procedures in the Rules. Any arbitrator appointed by the AAA will be a retired judge or a practicing attorney with no less than fifteen (15) years of experience with commercial cases and an experienced arbitrator, who will if practicable, have substantial experience with transactions or disputes related to the field of pharmaceuticals and/or, if applicable, intellectual property. In rendering an award, the arbitral tribunal will be required to follow the laws of the state of New York. The arbitral tribunal is not empowered to award damages in excess of compensatory damages, and each party hereby irrevocably waives any right to recover punitive, exemplary, multiple or similar damages with respect to any Dispute. Any arbitration proceedings, decision, or award rendered hereunder and the validity, effect, and interpretation of this arbitration provision will be governed by the Federal Arbitration Act, 9 U.S.C. §1 et seq. The award will be in writing and will state the findings of fact and conclusions of law on which it is based. The award will be final and binding upon the Parties and will be the sole and exclusive remedy between the Parties regarding any claims, counterclaims, issues, or accounting presented to the arbitrator(s). Judgment upon the award may be entered in any court having jurisdiction. Any costs or fees (including attorneys' fees and expenses) incident to enforcing the award will be charged against the Party resisting such enforcement. By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment, or other order in aid of arbitration proceedings and the enforcement of any award. Without prejudice to such provisional remedies as may be available under the jurisdiction of a court, the arbitral tribunal will have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any temporary or preliminary relief issued by such court, and to award damages for the failure of a Party to respect the arbitral tribunal's orders to that effect. The Parties hereby submit to the exclusive jurisdiction of the federal and state courts located in New York County, New York, for the purpose of an order to compel arbitration, for preliminary relief in aid of arbitration, or for a preliminary injunction to maintain the status quo or prevent irreparable harm prior to the appointment of the arbitrators, and to the non-exclusive jurisdiction of such courts for the enforcement of any award issued hereunder. The Parties hereby agree to accept service of process pursuant to the notice provisions of this Agreement.

14.4 Assignment and Binding Effect.

14.4.1 This Agreement may not be assigned, by operation of law or otherwise, by either Party without the prior written consent of the other, such consent not to be unreasonably withheld; provided, however, that either party may assign this Agreement without the prior written consent of the other Party: (a) to any Affiliate of such Party, or (b) in connection with the sale of all or substantially all of the assets of such Party (whether by sale of assets, sale of stock or merger).

14.4.2 No assignment under this Section 14.4 will be effective unless the intended assignee executes and delivers to the Party which is not the assignor a writing whereby the assignee expressly undertakes to perform and comply with all of its assignor's obligations hereunder. Notwithstanding such undertaking, such assignor will continue to be primarily liable for such assignee's performance hereof and compliance herewith.

14.4.3 Any assignment in violation of this Section 14.4 will be void and of no effect.

14.4.4 This Agreement, and the rights and duties of the Parties therein contained, will be binding upon, and will inure to the benefit of, the Parties and their respective legal representatives, successors and permitted assigns.

14.5 Independent Contractor Status. The relationship of the Parties hereto is that of independent contractors. Nothing in this Agreement will be construed to constitute, create, give effect or otherwise imply a joint venture, agency, partnership or other formal business organization or any employer/employee relationship of any kind between the Parties.

14.6 Notices. All notices, requests and other communications required or permitted to be given hereunder or with respect hereto will be in writing, and may be given by (i) personal service, (ii) registered first-class United States mail, postage prepaid, return receipt requested, or (iii) overnight delivery service, charges prepaid, and in each case addressed to the other Party at the address for such Party as set forth below, and will be effective upon receipt in the case of clauses (i) or (iii) above, and five days after mailing in the case of clause (ii) above.

If to LICENSEE:

Therapeutics MD, Inc.
6800 Broken Sound Parkway, NW
3rd Floor
Boca Raton, FL 33487
Attention: Legal Department

With a copy to:

King & Spalding LLP
101 Second Street
Suite 2300
San Francisco, CA 94105
Attention: Stephen Abreu

If to Council:

Population Council
One Dag Hammarskjold Plaza
New York, NY 10017
Attention: General Counsel

The address of either Party set forth above may be changed from time to time by written notice in the manner prescribed herein from the Party requesting the change.

14.7 Waivers. The waiver by either Party of a default or a breach of any provision of this Agreement by the other Party will not operate or be construed to operate as a waiver of any subsequent default or breach. The continued performance by either Party with knowledge of the existence of a default or breach will not operate or be construed to operate as a waiver of any default or breach. Any waiver by a Party of a particular provision or right will be in writing, will be as to a particular matter and, if applicable, for a particular period of time and will be signed by such Party.

14.8 Entire Agreement. This Agreement (including the Exhibits hereto) constitutes the entire agreement between the Parties with respect to the subject matter hereof, superseding all prior agreements and negotiations, and may be modified only by written agreement executed by both Parties.

14.9 Severability. If any provision in this Agreement is deemed to be, or becomes, invalid, illegal, void or unenforceable under applicable laws, then: (i) it will be deleted and the validity, legality and enforceability of the remaining provisions of this Agreement will not be impaired or affected in any way, and (ii) the Parties will use Commercially Reasonable Efforts to substitute for the invalid, illegal or unenforceable provision a valid, legal and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

14.10 Counterparts. This Agreement may be executed in more than one counterpart, each of which will be deemed to be an original but all of which taken together will be deemed a single instrument. A facsimile transmission of the signed Agreement will be legal and binding on both Parties.

14.11 Force Majeure. Neither Party to this Agreement will be liable for failure or delay in the performance of any of its obligations hereunder (other than the failure to pay monies owed), if such failure or delay is due to acts of God, earthquakes, fires, strikes, acts of war (whether declared or not), civil unrest, or intervention of any governmental authority, but any such delay or failure will be remedied by such Party as soon as practicable after the removal of the cause of such failure or delay. Upon the occurrence of an event of force majeure, the Party failing or delaying performance will promptly notify the other Party in writing, setting forth the nature of the occurrence, its expected duration and how such Party's performance is affected. If any event of force majeure lasts for more than ninety (90) days, the Party failing or delaying performance will use its all reasonable efforts to mitigate any Damages suffered by the other Party as a result of the failure or delay. A force majeure event that lasts longer than one-hundred eighty (180) days will give the Party not failing in or delaying performance the option, in its sole discretion, to terminate this Agreement for material breach.

14.12 Interest on Late Payments. If any Party fails to pay in full on or before the date due any royalty, fee or other amount that is required to be paid to the other Party under this Agreement, the paying Party will also pay to the other Party (or its designee), on demand, interest compounded daily on any such amount beginning thirty (30) days after such due date at an annual rate equal to the lowest prime rate as published by The Wall Street Journal (or, if The Wall Street Journal is not then published, such other financial periodical of general circulation in the United States) on or nearest to such due date plus two percent (2%) to be assessed from the date payment of the amount in question first became due.

14.13 Cumulative Remedies. Unless expressly set forth in this Agreement, all rights and remedies of the Parties, including all rights to payment, rights of termination, rights to injunctive relief, and other rights provided under this Agreement, will be cumulative and in addition to all other remedies provided for in this Agreement, in law, and in equity.

14.14 Amendment. This Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by both Parties that specifically refers to this Agreement.

14.15 Headings and References. All section headings contained in this Agreement are for convenience of reference only and will not affect the meaning or interpretation of this Agreement.

14.16 No Strict Construction. This Agreement has been prepared jointly and will not be strictly construed against either Party.

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITS THE INFORMATION SUBJECT TO THE CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED AS [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

14.17 Survival. Upon expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement will cease, except as specifically provided in this Agreement to the contrary, including the rights and obligations in the following sections which will survive termination: Article I, Section 3.2.3(a) (solely with respect to reporting of Net Sales that occur prior to such termination), Section 3.2.4 (solely with respect to reporting of Net Sales that occur prior to such termination), Section 3.3(solely with respect to reporting of Net Sales that occur prior to such termination), Section 6.1, Article XI (for the time periods described therein), Section 12.2.2 (solely for the time periods necessary to perform the activities described therein), Section 12.2.3 (solely for the time periods necessary to perform the activities described therein), Section 12.3.3, Section 12.5, Section 13.1, Section 13.2, Section 13.4, Section 13.5, and Article XIV.

INTENTIONALLY LEFT BLANK

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IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

THE POPULATION COUNCIL, INC.

By: /s/ Julia Buntine
Name: Julia Buntine
Title: President

THERAPEUTICSMD, INC.

By: /s/ Dan Cartwright
Name: Dan Cartwright
Title: CFO

[SIGNATURE PAGE TO LICENSE AGREEMENT]

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EXHIBIT A

Council Patent Rights

Country Code	COUNTRY	Application No	Patent Number	Status
US	United States	[***]	[***]	[***]

[***]

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SCHEDULE 4.2.2(a),

1. A clinical drug-drug interaction study to evaluate the effects of strong CYP3A induction and inhibition on the pharmacokinetics of SA and EE from the SA/EE contraceptive vaginal system (CVS).

2. An open-label pharmacokinetic study to evaluate the effects of tampons on the pharmacokinetics of SA and EE from the SA/EE CVS.

3. Study to characterize the in vivo release rate.

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SCHEDULE 4.2.2(b),

A controlled, non-interventional, long term cohort study that follows a series of cohorts comprising new users of your ring [Segesterone Acetate (SA) and Ethinyl Estradiol (EE) contraceptive vaginal system], new users of other ring contraceptives, new users of any intrauterine system, and new users of combined oral contraceptives containing other progestins. The primary objective of the study is to assess the risk for venous thromboembolism (VTE) of short term and long-term use of your product in a study population representative of actual users of the product in the United States and other countries where your ring is prescribed.

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Schedule 2.3.1(a)

API Supply Agreement

[***]

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Schedule 2.3.1(b)

Letter Agreement

[***]

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Schedule 2.3.3

- ANNOVERA™

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Schedule 5.4.1

Outreach Plan

At least once per Quarter following Launch of the licensed Product and ending upon the first commercial sale of a Generic Equivalent in the Territory: LICENSEE will:

1. [***]
2. [***]
3. [***]
4. [***]

Exhibit 10.2

Execution Version

AMENDMENT NO. 1 TO CREDIT AND SECURITY AGREEMENT

This AMENDMENT NO. 1 TO CREDIT AND SECURITY AGREEMENT (this "**Agreement**") is made as of July 30, 2018, by and among THERAPEUTICSMD, INC., a Nevada corporation ("**TherapeuticsMD**"), each of its direct and indirect Subsidiaries set forth on the signature pages hereto, **MIDCAP FINANCIAL TRUST**, a Delaware statutory trust, as Agent (in such capacity, together with its successors and assigns, "**Agent**") and the other financial institutions or other entities from time to time parties to the Credit Agreement referenced below, each as a Lender.

RECITALS

A. Agent, Lenders and Borrowers have entered into that certain Credit and Security Agreement, dated as of May 1, 2018 (as amended, modified, supplemented and restated prior to the date hereof, the "**Original Credit Agreement**" and as the same is amended hereby and as it may be further amended, modified, supplemented and restated from time to time, the "**Credit Agreement**"), pursuant to which the Lenders have agreed to make certain advances of money and to extend certain financial accommodations to Borrowers in the amounts and manner set forth in the Credit Agreement.

B. Borrowers desire to consummate an Acquisition by entering into that certain License Agreement, dated on or about July 30, 2018 and attached hereto as Exhibit A (the "**Council License Agreement**" as the same may be amended, modified, supplemented and restated from time to time in accordance with the terms of the Financing Documents), with the Population Council, Inc. ("**Council**") including the exhibits and schedules thereto, and all other agreements, documents and instruments executed and delivered pursuant thereto or in connection therewith (together with the Council License Agreement, the "**Council License Agreement Documents**").

C. Pursuant to Section 5.7 of the Credit Agreement, no Borrower shall acquire any assets other than in the Ordinary Course of Business and other than Permitted Acquisitions.

D. Borrowers have requested, and Agent and Lenders constituting at least the Required Lenders have agreed, to amend certain provisions of the Original Credit Agreement to permit TherapeuticsMD's entry into the Council License Agreement, in each case, in accordance with the terms and subject to the conditions set forth herein and in the other Financing Documents.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, the terms and conditions set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Agent, Lenders and Borrowers hereby agree as follows:

1. **Recitals**. This Agreement shall constitute a Financing Document and the Recitals and each reference to the Credit Agreement, unless otherwise expressly noted, will be deemed to reference the Credit Agreement as amended hereby. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Credit Agreement (including those capitalized terms used in the Recitals hereto).

2. **Amendments to Original Credit Agreement**. Subject to the satisfaction of the conditions to effectiveness set forth in Section 5 below, the Original Credit Agreement is hereby amended as follows:

(a) Section 1.1 of the Original Credit Agreement is hereby amended by replacing the definition of "**Material Contracts**" in its entirety with the following definition:

"**Material Contracts**" means (a) the Operative Documents, (b) the agreements listed on Schedule 3.17, (c), the Council License Agreement and (d) each agreement or contract to which a Credit Party or its Subsidiaries is a party the termination of which could reasonably be expected to result in a Material Adverse Effect.

(b) Section 1.1 of the Original Credit Agreement is hereby amended by replacing clause (j) in the definition of "**Permitted Acquisition**" with the following:

"(j) the sum of all cash amounts paid or payable in connection with all Permitted Acquisitions (including all Debt, liabilities and Contingent Obligations (in each case to the extent otherwise permitted hereunder) incurred or assumed and the maximum amount of any earn-out or comparable payment obligation in connection therewith, regardless of when due or payable and whether or not reflected on a consolidated balance sheet of Borrowers) shall not exceed (i) $10,000,000 in the aggregate for any calendar year or (ii) $50,000,000 in the aggregate during the term of this Agreement; *provided* that the foregoing shall not prohibit or limit any Equity Interests of TherapeuticsMD (other than Disqualified Stock) issued by a Borrower as consideration; *provided further* that the caps set forth in each of clause (i) and (ii) shall not apply to amounts paid in connection with the Council Acquisition; and"

(c) Section 1.1 of the Original Credit Agreement is hereby amended by adding the following phrase to the beginning of clause (k) in the definition of "**Permitted Acquisition**":

"except with respect to the Council Acquisition,"

(d) The definition of "**Permitted Debt**" in Section 1.1 of the Original Credit Agreement is hereby amended by:

(i) adding the following new clause (l)

"(l) All Debt of TherapeuticsMD pursuant to terms of the Council License Agreement; and"; and

(ii) renumbering existing clause (l) as new clause (m).

(e) Section 1.1 of the Original Credit Agreement is hereby amended by adding the following definition in the appropriate alphabetical order therein:

"**Council Acquisition**" means the Acquisition made pursuant to and in accordance with the Council License Documents and in accordance with the terms of the Financing Documents.

"**Council License Agreement**" has the meaning given it the First Amendment.

"**Council License Agreement Documents**" has the meaning set forth in the First Amendment.

"**First Amendment**" means that certain Amendment No. 1 to Credit and Security Agreement, dated as of July 30, 2018, among Borrower, Agent and Lenders.

(f) Schedule 4.15 to the Credit Agreement is hereby supplemented by the supplement attached hereto as Exhibit B.

3. **Representations and Warranties; Reaffirmation of Security Interest.**

(a) Each Borrower hereby confirms that each of the representations and warranties set forth in the Credit Agreement is true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) with respect to such Borrower as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (without duplication of any materiality qualifier in the text of such representation or warranty). Each Borrower confirms and agrees that all security interests and Liens granted to Agent continue in full force and effect, and that all Collateral remains free and clear of any Liens, other than Permitted Liens. Nothing herein is intended to impair or limit the validity, priority or extent of Agent's security interests in and Liens on the Collateral. Each Borrower acknowledges and agrees that the Credit Agreement, the other Financing Documents and this Agreement constitute the legal, valid and binding obligation of such Borrower, and are enforceable against such Borrower in accordance with their terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws relating to the enforcement of creditors' rights generally and by general equitable principles.

(b) Each Borrower confirms and agrees that the Council License Agreement does not constitute Excluded Property.

4. **Collateral Assignment**.

(a) For the purpose of securing the Obligations, each Borrower hereby collaterally assigns and transfers to Agent, for its benefit and the benefit of the Lenders, and grants a security interest to Agent, for its benefit and the benefit of the Lenders (as collateral security for the performance and payment in full of all Obligations (other than contingent indemnification obligations for which no claim has been made)), in, all right, title and interest of such Borrower in, to and under: (a) each of the Council License Agreement Documents including but not limited to, any and all rights of enforcement with respect to any breach by any party to the License Agreement, including any rights of indemnification, reservations of rights, assignments of warranties, whenever arising or coming into existence, termination rights, and such Borrower's right to payments under and its right to receive payments or other amounts from any party pursuant to or in connection with the Council License Agreement Documents, and (b) all proceeds of the foregoing.

(b) Without limiting any right or remedy of Agent or Lenders under the Financing Documents or any applicable law or at equity, upon the occurrence and during the continuance of an Event of Default, Agent may enforce, either in its own name or in the name of any Borrower, all rights of such Borrower under the Council License Agreement Documents in accordance with the terms thereof, and may do any and all things necessary, convenient or proper to fully and completely effectuate the collateral assignment of the rights of such Borrower under the Council License Agreement Documents pursuant hereto.

(c) Notwithstanding the foregoing, each Borrower expressly agrees that it shall remain liable under the Council License Agreement Documents to perform all of the conditions and obligations provided therein to be observed and performed by it, and neither the assignment pursuant to this Section 5 nor any action taken hereunder, shall cause Agent or any of the Lenders to be under any obligation or liability in any respect to any party to the Council License Agreement Documents including, without limitation, such Borrower, for the performance or observance of any of the representations, warranties, conditions, covenants, agreements or terms of the Council License Agreement Documents.

5. **Conditions to Effectiveness.** This Agreement shall become effective as of the date on which each of the following conditions has been satisfied (or waived in writing by the Agent and the Lenders), as determined by Agent in its sole discretion:

(a) Borrowers and Lenders shall each have delivered to Agent this Agreement, executed by an authorized officer of each such Person;

(b) Agent shall have received a fully executed copy of the Council License Agreement and all other material Council License Agreement Documents executed on or prior to the date hereof;

(c) with respect to the Acquisition contemplated by the Council License Agreement Documents, all conditions set forth in the definition of "**Permitted Acquisition**" (as amended by this Agreement) of the Credit Agreement shall be satisfied in accordance with their terms;

(d) all representations and warranties of Borrowers contained herein shall be true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (without duplication of any materiality qualifier in the text of such representation or warranty) (and such parties' delivery of their respective signatures hereto shall be deemed to be its certification thereof);

(e) prior to and after giving effect to the agreements set forth herein, no Default or Event of Default shall exist under any of the Financing Documents; and

(f) Borrowers shall have delivered such other documents, information, certificates, records, permits, and filings as the Agent may reasonably request in connection with this Agreement, the Council License Agreement Documents and the transactions contemplated thereby.

6. **Post-Closing Covenant**. By the date that is thirty (30) days after the date of this Agreement, Borrower shall have provided Agent with evidence satisfactory to Agent that Borrower has received net cash proceeds of at least $75,000,000 (subject, in each case to no clawback, escrow or other terms limiting Borrower's ability to freely use such proceeds) from the issuance of Equity Interests (other than Disqualified Stock) of TherapeuticsMD following the date of this Agreement. Borrower's failure to complete the obligation set forth in the previous sentence on or before the date indicated above shall constitute an immediate and automatic Event of Default.

7. **Release**. In consideration of the agreements of Agent and Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Borrower, voluntarily, knowingly, unconditionally and irrevocably, with specific and express intent, for and on behalf of itself and all of its respective parents, subsidiaries, affiliates, members, managers, predecessors, successors, and assigns, and each of their respective current and former directors, officers, shareholders, agents, and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Releasing Parties**") does hereby fully and completely release, acquit and forever discharge each of Agent, Lenders, and each their respective parents, subsidiaries, affiliates, members, managers, shareholders, directors, officers and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Released Parties**"), of and from any and all actions, causes of action, suits, debts, disputes, damages, claims, obligations, liabilities, costs, expenses and demands of any kind whatsoever, at law or in equity, whether matured or unmatured, liquidated or unliquidated, vested or contingent, choate or inchoate, known or unknown that the Releasing Parties (or any of them) has against the Released Parties or any of them (whether directly or indirectly) based in whole or in part on facts, whether or not now known, existing on or before the date hereof. Each Borrower acknowledges that the foregoing release is a material inducement to Agent's and each Lender's decision to enter into this Agreement and agree to the modifications contemplated hereunder, and has been relied upon by Agent and Lenders in connection therewith.

8. **No Waiver or Novation.** The execution, delivery and effectiveness of this Agreement shall not, except as expressly provided in this Agreement, operate as a waiver of any right, power or remedy of Agent, nor constitute a waiver of any provision of the Credit Agreement, the Financing Documents or any other documents, instruments and agreements executed or delivered in connection with any of the foregoing. Nothing herein is intended or shall be construed as a waiver of any existing Defaults or Events of Default under the Credit Agreement or the other Financing Documents or any of Agent's rights and remedies in respect of such Defaults or Events of Default. This Agreement (together with any other document executed in connection herewith) is not intended to be, nor shall it be construed as, a novation of the Credit Agreement.

9 . **Affirmation.** Except as specifically amended pursuant to the terms hereof, each Borrower hereby acknowledges and agrees that the Credit Agreement and all other Financing Documents (and all covenants, terms, conditions and agreements therein) shall remain in full force and effect, and are hereby ratified and confirmed in all respects by such Borrower. Each Borrower covenants and agrees to comply with all of the terms, covenants and conditions of the Credit Agreement and the Financing Documents, notwithstanding any prior course of conduct, waivers, releases or other actions or inactions on Agent's or any Lender's part which might otherwise constitute or be construed as a waiver of or amendment to such terms, covenants and conditions.

10. **Miscellaneous**.

(a) Reference to the Effect on the Credit Agreement. Upon the effectiveness of this Agreement, each reference in the Credit Agreement to "this Agreement," "hereunder," "hereof," "herein," or words of similar import shall mean and be a reference to the Credit Agreement, as amended by this Agreement.

(b) Incorporation of Credit Agreement Provisions. The provisions contained in Section 11.6 (Indemnification) of the Credit Agreement are incorporated herein by reference to the same extent as if reproduced herein in their entirety.

(c) THIS AGREEMENT AND ALL DISPUTES AND OTHER MATTERS RELATING HERETO OR THERETO OR ARISING THEREFROM (WHETHER SOUNDING IN CONTRACT LAW, TORT LAW OR OTHERWISE), SHALL BE GOVERNED BY, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO CONFLICTS OF LAWS PRINCIPLES (OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW).

(d) EACH BORROWER HEREBY CONSENTS TO THE JURISDICTION OF ANY STATE OR FEDERAL COURT LOCATED IN THE STATE OF NEW YORK IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN AND IRREVOCABLY AGREES THAT, SUBJECT TO AGENT'S ELECTION, ALL ACTIONS OR PROCEEDINGS ARISING OUT OF OR RELATING TO THIS AGREEMENT SHALL BE LITIGATED IN SUCH COURTS. EACH BORROWER EXPRESSLY SUBMITS AND CONSENTS TO THE JURISDICTION OF THE AFORESAID COURTS AND WAIVES ANY DEFENSE OF FORUM NON CONVENIENS. EACH BORROWER HEREBY WAIVES PERSONAL SERVICE OF ANY AND ALL PROCESS AND AGREES THAT ALL SUCH SERVICE OF PROCESS MAY BE MADE UPON SUCH BORROWER BY CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED, ADDRESSED TO SUCH BORROWER AT THE ADDRESS SET FORTH IN THIS AGREEMENT AND SERVICE SO MADE SHALL BE COMPLETE TEN (10) DAYS AFTER THE SAME HAS BEEN POSTED.

(e) EACH BORROWER, AGENT AND THE LENDERS HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY AND AGREES THAT ANY SUCH ACTION OR PROCEEDING SHALL BE TRIED BEFORE A COURT AND NOT BEFORE A JURY. EACH BORROWER, AGENT AND EACH LENDER ACKNOWLEDGES THAT THIS WAIVER IS A MATERIAL INDUCEMENT TO ENTER INTO A BUSINESS RELATIONSHIP, THAT EACH HAS RELIED ON THE WAIVER IN ENTERING INTO THIS AGREEMENT, AND THAT EACH WILL CONTINUE TO RELY ON THIS WAIVER IN THEIR RELATED FUTURE DEALINGS. EACH BORROWER, AGENT AND EACH LENDER WARRANTS AND REPRESENTS THAT IT HAS HAD THE OPPORTUNITY OF REVIEWING THIS JURY WAIVER WITH LEGAL COUNSEL, AND THAT IT KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS.

(f) Headings. Section headings in this Agreement are included for convenience of reference only and shall not constitute a part of this Agreement for any other purpose.

(g) Counterparts. This Agreement may be signed in any number of counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same instrument. Delivery of an executed counterpart of this Agreement by facsimile or by electronic mail delivery of an electronic version (e.g., .pdf or .tif file) of an executed signature page shall be effective as delivery of an original executed counterpart hereof and shall bind the parties hereto.

(h) Entire Agreement. This Agreement constitutes the entire agreement and understanding among the parties hereto and supersedes any and all prior agreements and understandings, oral or written, relating to the subject matter hereof.

(i) Severability. In case any provision of or obligation under this Agreement shall be invalid, illegal or unenforceable in any applicable jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(j) Successors/Assigns. This Agreement shall bind, and the rights hereunder shall inure to, the respective successors and assigns of the parties hereto, subject to the provisions of the Credit Agreement and the other Financing Documents.

[SIGNATURES APPEAR ON FOLLOWING PAGES]

IN WITNESS WHEREOF, intending to be legally bound, the undersigned have executed this Agreement as of the day and year first hereinabove set forth.

AGENT:

MIDCAP FINANCIAL TRUST

By: Apollo Capital Management, L.P., its investment manager

By: Apollo Capital Management GP, LLC, its general partner

By: /s/ Maurice Amsellem
Name: Maurice Amsellem
Title: Authorized Signatory

LENDER:

MIDCAP FINANCIAL TRUST

By: Apollo Capital Management, L.P., its investment manager

By: Apollo Capital Management GP, LLC, its general partner

By: /s/ Maurice Amsellem
Name: Maurice Amsellem
Title: Authorized Signatory

LENDER:

MIDCAP FUNDING H TRUST

By: Apollo Capital Management, L.P., its investment manager

By: Apollo Capital Management GP, LLC, its general partner

By: /s/ Maurice Amsellem
Name: Maurice Amsellem
Title: Authorized Signatory

LENDER:

MIDCAP FUNDING XIII TRUST

By: Apollo Capital Management, L.P., its investment manager

By: Apollo Capital Management GP, LLC, its general partner

By: /s/ Maurice Amsellem
Name: Maurice Amsellem
Title: Authorized Signatory

LENDER:

ELM 2016-1 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By: /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

LENDER:

APOLLO INVESTMENT CORPORATION

By: Apollo Investment Management, L.P., as Advisor

By: ACC Management, LLC, as its General Partner

By: Trevor Powell
Name: Trevor Powell
Title: Authorized Signatory

LENDER:

CION INVESTMENT CORPORATION

By: /s/ Gregg Bresner
Name: Gregg Bresner
Title: Chief Investment Officer

LENDER:

33rd STREET FUNDING, LLC

By: /s/ Gregg Bresner
Name: Gregg Bresner
Title: Chief Investment Officer

LENDER:

FLEXPOINT MCLS SPV LLC

By: /s/ David Edelman
Name: David Edelman
Title: Vice President

BORROWERS:

THERAPEUTICSMD, INC.

By: /s/ Daniel Cartwright
Name: Daniel Cartwright
Title: Chief Financial Officer

VITAMEDMD LLC

By: /s/ Daniel Cartwright
Name: Daniel Cartwright
Title: Chief Financial Officer

BOCAGREENMD, INC.

By: /s/ Daniel Cartwright
Name: Daniel Cartwright
Title: Chief Financial Officer

VITACARE PRESCRIPTION SERVICES, INC.

By: /s/ Daniel Cartwright
Name: Daniel Cartwright
Title: Chief Financial Officer

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Robert G. Finizio, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of TherapeuticsMD, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 8, 2018

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Daniel A. Cartwright, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of TherapeuticsMD, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 8, 2018

/s/ Daniel A. Cartwright
Daniel A. Cartwright
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

SECTION 1350 CERTIFICATION OF CHIEF EXECUTIVE OFFICER

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert G. Finizio, Chief Executive Officer of the Company, certify, to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 78o(d)); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

November 8, 2018

/s/ Robert G. Finizio
Robert G. Finizio
Chief Executive Officer
(Principal Executive Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

SECTION 1350 CERTIFICATION OF CHIEF FINANCIAL OFFICER

In connection with the quarterly report of TherapeuticsMD, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel A. Cartwright, Chief Financial Officer of the Company, certify to my best knowledge and belief, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 78o(d)); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

November 8, 2018

/s/ Daniel A. Cartwright
Daniel A. Cartwright
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.