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, 2019

or

☐ **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. **001-00100**

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.)
951 Yamato Road, Suite 220, Boca Raton, FL	**33431**
(Address of Principal Executive Offices)	(Zip Code)

561-961-1900
(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	TXMD	The Nasdaq Stock Market LLC

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, a 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 (Check one):

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 4, 2019 was 271,177,076.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
INDEX

PART I - FINANCIAL INFORMATION

Item. 1 Financial Statements

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash	$ 155,330,050	$ 161,613,077
Accounts receivable, net of allowance for doubtful accounts of $691,699 and $596,602, respectively	15,323,614	11,063,821
Inventory	10,532,844	3,267,670
Other current assets	10,578,260	10,834,693
Total current assets	191,764,768	186,779,261
Fixed assets, net	2,338,346	472,683
Other Assets:		
License rights, net	39,984,002	20,000,000
Intangible assets, net	4,942,151	4,092,679
Right of use asset	10,459,635	—
Other assets	473,009	639,301
Total other assets	55,858,797	24,731,980
Total assets	$ 249,961,911	$ 211,983,924
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 24,133,506	$ 22,743,841
Other current liabilities	43,196,032	18,334,948
Total current liabilities	67,329,538	41,078,789
Long-Term Liabilities:		
Long-term debt	194,361,169	73,381,014
Operating lease liability	9,500,133	—
Total liabilities	271,190,840	114,459,803
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: 241,277,076 and 240,462,439 issued and outstanding, respectively	241,277	240,463
Additional paid-in capital	624,515,559	616,559,938
Accumulated deficit	(645,985,765)	(519,276,280)
Total stockholders' (deficit) equity	(21,228,929)	97,524,121
Total liabilities and stockholders' equity	$ 249,961,911	$ 211,983,924

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,	
	2019	**2018**	**2019**	**2018**
Product revenue, net	$ 8,213,341	$ 3,473,535	$ 18,238,857	$ 11,009,937
License revenue	15,506,400	—	15,506,400	—
Total revenue, net	23,719,741	3,473,535	33,745,257	11,009,937
Cost of goods sold	1,444,308	699,118	3,455,995	1,786,902
Gross profit	22,275,433	2,774,417	30,289,262	9,223,035
Operating expenses:				
Sales, general, and administrative	45,126,986	30,354,072	121,378,519	80,578,079
Research and development	4,077,738	6,708,271	15,359,988	20,545,948
Depreciation and amortization	141,959	73,321	363,956	198,545
Total operating expenses	49,346,683	37,135,664	137,102,463	101,322,572
Operating loss	(27,071,250)	(34,361,247)	(106,813,201)	(92,099,537)
Other expense				
Loss on extinguishment of debt	—	—	(10,057,632)	—
Miscellaneous income	703,662	809,022	1,878,980	1,457,817
Interest expense	(5,599,005)	(2,053,077)	(11,717,632)	(2,584,459)
Total other expense	(4,895,343)	(1,244,055)	(19,896,284)	(1,126,642)
Loss before income taxes	(31,966,593)	(35,605,302)	(126,709,485)	(93,226,179)
Provision for income taxes	—	—	—	—
Net loss	$ (31,966,593)	$ (35,605,302)	$ (126,709,485)	$ (93,226,179)
Loss per share, basic and diluted:				
Net loss per share, basic and diluted	$ (0.13)	$ (0.16)	$ (0.53)	$ (0.42)
Weighted average number of common shares outstanding, basic and diluted	241,261,299	228,107,240	241,163,994	220,466,673

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Nine Months Ended September 30, 2019 and 2018

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2017	216,429,642	$ 216,430	$ 516,351,405	$ (386,659,120)	$ 129,908,715
Shares issued for exercise of options, net	154,632	154	43,902	—	44,056
Share-based compensation	—	—	1,751,358	—	1,751,358
Net loss	—	—	—	(24,401,829)	(24,401,829)
Balance, March 31, 2018	216,584,274	216,584	518,146,665	(411,060,949)	107,302,300
Shares issued for exercise of options, net	249,785	250	1,084,689	—	1,084,939
Share-based compensation	—	—	2,377,082	—	2,377,082
Net loss	—	—	—	(33,219,048)	(33,219,048)
Balance, June 30, 2018	216,834,059	216,834	521,608,436	(444,279,997)	77,545,273
Shares issued for exercise of options, net	1,052,300	1,053	106,265	—	107,318
Shares issued in offering, net	18,578,430	18,578	89,889,219	—	89,907,797
Share-based compensation	—	—	2,260,195	—	2,260,195
Net loss	—	—	—	(35,605,302)	(35,605,302)
Balance, September 30, 2018	236,464,789	$ 236,465	$ 613,864,115	$ (479,885,299)	$ 134,215,281
Balance, December 31, 2018	240,462,439	$ 240,463	$ 616,559,938	$ (519,276,280)	$ 97,524,121
Shares issued for exercise of options and warrants, net	759,401	759	99,348	—	100,107
Share-based compensation	—	—	2,575,369	—	2,575,369
Net loss	—	—	—	(39,506,375)	(39,506,375)
Balance, March 31, 2019	241,221,840	241,222	619,234,655	(558,782,655)	60,693,222
Share-based compensation	—	—	2,637,264	—	2,637,264
Net loss	—	—	—	(55,236,517)	(55,236,517)
Balance, June 30, 2019	241,221,840	$ 241,222	$ 621,871,919	$ (614,019,172)	$ 8,093,969
Shares issued for exercise of options, net	55,236	55	8,494	—	8,549
Share-based compensation			2,635,146	—	2,635,146
Net loss	—	—	—	(31,966,593)	(31,966,593)
Balance, September 30, 2019	241,277,076	$ 241,277	$ 624,515,559	$ (645,985,765)	$ (21,228,929)

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,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (126,709,485)	$ (93,226,179)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	223,750	121,423
Amortization of intangible assets	140,206	77,123
Write off of patent and trademark cost	78,864	—
Non-cash operating lease expense	711,836	—
Provision for doubtful accounts	95,097	231,475
Loss on extinguishment of debt	10,057,632	—
Share-based compensation	7,859,357	6,388,635
Amortization of intellectual property license fee	15,998	
Amortization of deferred financing fees	582,829	149,909
Changes in operating assets and liabilities:		
Accounts receivable	(4,354,890)	(8,705,325)
Inventory	(7,265,174)	(892,863)
Other current assets	(1,128,515)	1,233,482
Accounts payable	1,389,665	7,284,493
Accrued expenses and other liabilities	3,402,511	8,670,986
Net cash used in operating activities	(114,900,319)	(78,666,841)
CASH FLOWS FROM INVESTING ACTIVITIES		
Payment for intellectual property license	—	(20,000,000)
Patent costs	(1,068,542)	(748,906)
Purchase of fixed assets	(2,089,413)	(66,295)
Payment of security deposit	(20,420)	(11,485)
Net cash used in investing activities	(3,178,375)	(20,826,686)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from Financing Agreement	200,000,000	—
Proceeds from exercise of options and warrants	108,656	1,236,313
Proceeds from sale of common stock, net of costs	—	89,907,797
Proceeds from Credit Agreement	—	75,000,000
Payment of deferred financing fees	(6,652,270)	(3,786,918)
Repayment of Credit Agreement	(81,660,719)	—
Net cash provided by financing activities	111,795,667	162,357,192
(Decrease) increase in cash	(6,283,027)	62,863,665
Cash, beginning of period	161,613,077	127,135,628
Cash, end of period	$ 155,330,050	$ 189,999,293
Supplemental disclosure of cash flow information		
Interest paid	$ 12,446,792	$ 1,759,316
Non-cash investing activity		
Amount accrued for intellectual property license	$ 20,000,000	$ —

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." TherapeuticsMD®, vitaMedMD®, BocaGreenMD®, IMVEXXY® and BIJUVA® are registered trademarks of our company and ANNOVERA™ is a licensed trademark of our company.

Nature of Business

We are a women's healthcare company focused on creating and commercializing innovative products to support the lifespan of women and championing awareness of women's healthcare issues, specifically, for pregnancy prevention, pregnancy, childbirth, nursing, pre-menopause, and menopause. At TherapeuticsMD, we combine entrepreneurial spirit, clinical expertise, and business leadership to develop and commercialize health solutions that enable new standards of care for women. Our solutions range from advanced hormone therapy pharmaceutical products to patient-controlled, long-acting contraceptive. We also manufacture and distribute branded and generic prescription prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

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. Our commercialization plan allows us to efficiently leverage and grow our marketing and sales organization to commercialize our recently approved products. During 2018, the U.S. Food and Drug Administration, or FDA, approval of our drugs has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our drugs. In July 2018, we launched our 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. In April 2019, we launched our FDA-approved product BIJUVA, our hormone therapy combination of bio-identical 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus, which was approved by the FDA on October 28, 2018. In October 2019, we began a test and learn market introduction for our FDA-approved product ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive option for women, which was approved by the FDA on August 10, 2018. We expect the full commercial launch of ANNOVERA in the first quarter of 2020. On July 30, 2018, we entered into an exclusive license agreement, or the Population Council License Agreement, with the Population Council, Inc., or the Population Council, to commercialize ANNOVERA in the U.S. In addition, 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. On June 6, 2019, we entered into an exclusive license and supply agreement, or the License Agreement, with Theramex HQ UK Limited, or Theramex, to commercialize BIJUVA and IMVEXXY outside of the U.S., excluding Canada and Israel, or the Territory.

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, 2018, as filed with the Securities and Exchange Commission, or the SEC, from which we derived the accompanying consolidated balance sheet as of December 31, 2018. 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 the FASB, issued Accounting Standards Update, or ASU, 2018-13 which 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 ASC 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, the 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 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 adopted this standard on January 1, 2019 and the adoption of this standard did not have a material effect on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets while recognizing 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 was effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. In July 2018, the FASB amended the new leases standard and issued ASU 2018-11, Leases, (Topic 842): Targeted Improvements to give entities another option for transition and to provide lessors with a practical expedient. We adopted ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed for under ASU 2018-11 and we recorded a $ 3.8 million right of use asset and a $4.1 million liability related to adoption of this standard. In addition, upon commencement of additional lease space in the third quarter of 2019 (as disclosed in Note 15) we recorded an additional $7.4 million right of use asset and an additional $7.2 million liability related to our new lease space. Comparative financial information was not adjusted and will continue to be reported under ASC 840. We also elected the transition relief package of practical expedients and as a result we did not assess (1) whether existing or expired contracts contain leases, (2) lease classification for any existing or expired leases, and (3) whether lease origination costs qualified as initial direct costs. We elected the short-term lease practical expedient by establishing an accounting policy to exclude leases with a term of 12 months or less. We elected not to separate lease components from non-lease components for our specified asset classes. Additionally, the adoption of the new standard resulted in increased disclosure requirements in our quarterly and annual filings.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC did not, and are not expected to, have a material effect on our results of operations or financial position.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair Value of Financial Instruments

Our financial instruments consist primarily of cash, accounts receivable, accounts payable, 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. The carrying amount for long-term debt as of September 30, 2019 (as disclosed in Note 9), approximates fair value based on market activity for other debt instruments with similar characteristics and comparable risk (Level 2).

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 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, 2019 and 2018, 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 the company’s impairment test on an annual basis.

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 chargebacks and provide an allowance for doubtful accounts, which is based upon a review of outstanding receivables, historical collection information, and existing economic conditions. We evaluate trade accounts receivable aged more than 90 days for delinquency. 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.

Revenue Recognition

We adopted 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

As of September 30, 2019, our products consisted primarily of prescription vitamins and our FDA-approved products: IMVEXXY, which we began selling during the third quarter of 2018, BIJUVA, which we began selling in the second quarter of 2019, and ANNOVERA, which we began selling in the third quarter of 2019. We sell our name brand and generic prescription products primarily through wholesale distributors and retail pharmacies. 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 pharmacies, 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. 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 (when recognition of revenue is deferred due to the anticipated return). Return estimates are recorded in the accrued expenses and 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. Rebate and coupon estimates and distributor fees are recorded in accrued expenses and 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. Estimates related to distributors fees, rebates, coupons and returns are disclosed in Note 8. 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.

As part of commercial launches for our FDA-approved prescription products, we introduce a co-pay assistance program where eligible enrolled patients, out of pocket cost is reduced to a more affordable price. This allows patients to access the product at a reasonable cost and is in line with our responsible pricing approach. We reimburse pharmacies for this discount through third-party vendors. We consider certain 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, the estimated levels of inventory in the distribution channel and the current level of prescriptions covered by patients' insurance. Payers may change coverage levels for our prescription products 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 our prescription products is susceptible to such changes in coverage levels, which are outside the influence of the Company. As a result, we constrain revenue recognized for our prescription products to an amount that will not result in a significant revenue reversal in future periods. Our ability to estimate the net transaction price for our prescription products is constrained by our estimates of the amount to be paid for the co-pay assistance program which is directly related to the level of prescriptions paid for by insurance. As such, 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. We re-evaluate any constraint each reporting period.

License Revenue

License arrangements may consist of non-refundable upfront license fees, exclusive licensed rights to patented or patent pending technology, and various performance or sales milestones and future product royalty payments. Some of these arrangements are multiple element arrangements. Non-refundable up-front fees that are not contingent on any future performance by us, and do not require continuing involvement on our part, are recognized as revenue when the license term commences and the licensed data or technology is delivered.

Disaggregation of revenue

The following table provides information about disaggregated revenue by product mix for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Prescription vitamins	$ 2,550,330	$ 3,261,459	$ 7,309,174	$ 10,797,861
IMVEXXY	4,772,354	212,076	9,904,744	212,076
BIJUVA	490,705	—	624,987	—
ANNOVERA	399,952	—	399,952	—
License revenue	15,506,400	—	15,506,400	—
Net revenue	$ 23,719,741	$ 3,473,535	$ 33,745,257	$ 11,009,937

Cost of Sales

Cost of sales includes the cost of inventory, manufacturing, manufacturing overhead and supply chain costs, and product shipping and handling costs. Certain license agreements require the payment of royalties based on the sale of future products. Such royalties are recorded as a component of cost of sales. Additionally, the amortization of license fees or milestone payments related to licensed products are classified as components of cost of sales to the extent such payments become due in the future.

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 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. 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 and in 2019 we started using only our own stock price in the volatility calculation. 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, 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. We recognize the compensation expense for 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. Effective January 1, 2017, we account for forfeitures when they occur.

On January 1, 2019, we adopted ASU 2018-07 which simplified 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 expanded the scope of 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 superseded the guidance in ASC 505-50. Prior to January 1, 2019, equity instruments issued to non-employees were recorded on a fair value basis, as required by ASC 505, Equity - Based Payments to Non-Employees.

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 other 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. These consulting 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 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, 2019	December 31, 2018
Finished product	$ 5,011,192	$ 2,908,958
Work in process	1,005,575	339,312
Raw material	4,516,077	19,400
TOTAL INVENTORY	$ 10,532,844	$ 3,267,670

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	September 30, 2019	December 31, 2018
Prepaid sales and marketing costs	$ 1,313,192	$ 5,148,789
Deferred financing fees (Note 9)	550,757	1,898,074
Prepaid insurance	2,542,008	790,465
Other prepaid costs	6,172,303	2,997,365
TOTAL OTHER CURRENT ASSETS	$ 10,578,260	$ 10,834,693

NOTE 6 – FIXED ASSETS, NET

Fixed assets, net consist of the following:

	September 30, 2019	December 31, 2018
Accounting system	$ 301,096	$ 301,096
Equipment	1,371,390	490,576
Furniture and fixtures	1,294,241	116,542
Computer hardware	80,211	80,211
Leasehold improvements	68,788	37,888
	3,115,726	1,026,313
Accumulated depreciation	(777,380)	(553,630)
TOTAL FIXED ASSETS, NET	$ 2,338,346	$ 472,683

Depreciation expense for the three months ended September 30, 2019 and 2018 was $90,700 and $42,221, respectively, and $223,750 and $121,423 for the nine months ended September 30, 2019 and 2018, respectively.

NOTE 7 – INTANGIBLE ASSETS

The following table sets forth the gross carrying amount, accumulated amortization and net carrying amount of our intangible assets as of September 30, 2019 and December 31, 2018:

	September 30, 2019			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
Approved hormone therapy drug candidate patents	3,138,308	(421,694)	2,716,614	13.25 years
Hormone therapy drug candidate patent (pending)	1,937,691	—	1,937,691	n/a
Non-amortizable intangible assets:				
Multiple trademarks	287,846	—	287,846	indefinite
TOTAL	$ 5,363,845	$ (421,694)	$ 4,942,151	

	December 31, 2018			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizable intangible assets:				
OPERA® software patent	$ 31,951	$ (10,484)	$ 21,467	10.75 years
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	2,234,129	(282,485)	1,951,644	14 years
Hormone therapy drug candidate patents (pending)	1,855,279	—	1,855,279	n/a
Non-amortizable intangible assets:				
Multiple trademarks	264,289	—	264,289	indefinite
TOTAL	$ 4,477,391	$ (384,712)	$ 4,092,679	

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 nine months ended September 30, 2019, we wrote off $78,864 in costs related to trademarks and patents, including the net carrying amount of the OPERA patent.

As of September 30, 2019, we had 26 issued domestic, or U.S., patents and 28 issued foreign patents, including:

- 12 domestic patents and six foreign patents that relate to BIJUVA as well as three domestic patents that relate to estradiol and progesterone product candidates. These patents establish an important intellectual property foundation for BIJUVA and are owned by us. The domestic patents will expire in 2032. The foreign patents will expire no earlier than 2032. In addition, we have pending patent applications relating to BIJUVA in the U.S., Argentina, Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea;
- Five domestic patents (four utility and one design) and 13 foreign patents (three utility and ten design) that relate to IMVEXXY. These patents establish an important intellectual property foundation for IMVEXXY and are owned by us. The domestic patents will expire in 2032 or 2033. The foreign utility patents will expire no earlier than 2033. The foreign design patents provide protection expiring no earlier than 2025. In certain jurisdictions, the foreign design patents provide protection through at least 2037. 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 topical-cream candidates, which is owned by us. The domestic patent will expire in 2035. We have pending patent applications with respect to our topical-cream candidates in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, Russia, South Africa, and South Korea;
- One domestic utility patent and five foreign patents that relate to our transdermal-patch candidates, which are owned by us. The domestic utility patent will expire in 2032. The foreign patents will expire no earlier than 2033. We have pending patent applications with respect to our transdermal-patch candidates in the U.S., Brazil, Canada, Europe, Mexico, and South Africa;
- One domestic utility patent that relates to our OPERA information-technology platform, which is owned by us and will expire in 2031;
- One domestic utility patent that relates to a product candidate containing d-limonene, which is owned by us and will expire in 2036; and
- Two domestic utility patents that relate to TX-009HR, a progesterone and estradiol product candidate, which are owned by us and will expire in 2037. We have pending patent applications with respect to TX-009HR in the U.S., Argentina, Australia, Brazil, Canada, Europe, Israel, Japan, Mexico, New Zealand, Russia, South Africa, and South Korea.

Amortization expense was $51,259 and $31,100 for the three months ended September 30, 2019 and 2018, respectively, and $140,206 and $77,123 for the nine months ended September 30, 2019 and 2018, respectively.

Estimated amortization expense for the next five years for the patent costs currently being amortized is as follows:

Year Ending December 31,	Estimated Amortization
2019 (3 months)	$ 51,259
2020	$ 205,035
2021	$ 205,035
2022	$ 205,035
2023	$ 205,035

License Agreement with the Population Council

On July 30, 2018, we entered into the Council License Agreement to commercialize ANNOVERA in the U.S. ANNOVERA became commercially available in the third quarter of 2019 and we expect the full commercial launch in the first quarter of 2020.

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. The first commercial batch of ANNOVERA was released during the third quarter of 2019 and we are required to pay the Population Council $20,000,000 as a result of the commercial batch release. Both milestone payments of $20,000,000 were recorded as finite-lived intangible asset in the consolidated balance sheet as of September 30, 2019. We started amortizing the intangible asset in the third quarter of 2019 once ANNOVERA became commercially available for use. The cost is amortized over the remaining useful life over which an intangible asset will contribute directly or indirectly to our cash flows. During both the three and nine months ended September 30, 2019, we recorded $15,998 in amortization expense related to the license fee which was recorded as a component of cost of sales.

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. 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. 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 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 purchased 3,921,568 shares of our Common Stock concurrent with the closing of the underwritten public offering of Common Stock at a price of $5.10, for proceeds of $20,000,000, on August 6, 2018.

License Agreement with Theramex

On June 6, 2019, we entered into an exclusive license and supply agreement, or the License Agreement, with Theramex, a leading, global specialty pharmaceutical company dedicated to women's health, to commercialize BIJUVA and IMVEXXY outside of the U.S., excluding Canada and Israel, or the Territory. Under the terms of the License Agreement, Theramex paid us EUR 14 million in cash as an upfront fee on August 5, 2019. Within thirty days of signing the License Agreement, we provided Theramex the regulatory materials and clinical data that were necessary for Theramex to obtain marketing authorizations and other applicable regulatory approvals for commercializing BIJUVA and IMVEXXY. We recognized the revenue related to the upfront fee, which was a non-refundable payment, during the third quarter of 2019, at a point in time when Theramex was able to use and benefit from the license which was when the knowledge transfer of regulatory documents occurred. We are eligible to receive additional milestone payments comprised of (i) up to an aggregate of EUR 2 million in regulatory milestone payments based on regulatory approvals for BIJUVA and IMVEXXY in certain specified markets and (ii) up to an aggregate of EUR 27.5 million in sales milestone payments to be paid in escalating tranches based on Theramex first attaining certain aggregate annual net sales milestones of BIJUVA and IMVEXXY in the Territory ranging from EUR 25 million to EUR 100 million. We are also entitled to receive quarterly royalty payments on net sales of BIJUVA and IMVEXXY in the Territory. Theramex will be responsible for all regulatory and commercial activities for BIJUVA and IMVEXXY in the Territory. Theramex may sublicense its rights to commercialize BIJUVA and IMVEXXY in the Territory, except for certain specified markets. We may terminate the License Agreement if Theramex does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize BIJUVA and IMVEXXY within certain specified time periods. We also may terminate the License Agreement if Theramex challenges our patents. Either party may terminate the 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.

NOTE 8 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	September 30, 2019	December 31, 2018
Accrued payroll, bonuses and commission costs	$ 4,536,358	$ 6,854,002
Accrued intellectual license fee	20,000,000	—
Allowance for coupons and returns	7,079,005	5,294,120
Accrued sales and marketing costs	1,560,257	2,288,028
Accrued compensated absences	1,551,042	1,178,110
Allowance for wholesale distributor fees	2,375,894	792,891
Accrued legal and accounting expense	469,446	385,824
Accrued research and development	1,226,160	388,675
Operating lease liability	1,242,290	—
Accrued rent	—	365,155
Accrued rebates	2,543,456	412,570
Other accrued expenses	612,124	375,573
TOTAL OTHER CURRENT LIABILITIES	$ 43,196,032	$ 18,334,948

NOTE 9 – DEBT

On April 24, 2019, we entered into a Financing Agreement, or the Financing Agreement, with TPG Specialty Lending, Inc., as administrative agent, or the Administrative Agent, various lenders from time to time party thereto, and certain of the Company's subsidiaries party thereto from time to time as guarantors, which provides us with a $300,000,000 first lien secured term loan credit facility, or the Facility. The Facility provides for availability to us in three tranches: (i) $200,000,000 was drawn upon entering into the Financing Agreement; (ii) $50,000,000 will be available to us upon the designation of our ANNOVERA product as a new category of birth control by the FDA on or prior to December 31, 2019 and satisfaction (or waiver) of other customary conditions precedent; and (iii) $50,000,000 will be available to us upon our achieving $11,000,000 in net revenues, as defined in the Financing Agreement, from our IMVEXXY, BIJUVA and ANNOVERA products for the fourth quarter of 2019 and satisfaction (or waiver) of other customary conditions precedent. Borrowings under the Facility accrue interest at either (i) 3-month LIBOR plus 7.75%, subject to a LIBOR floor of 2.70% or (ii) the prime rate plus 6.75%, subject to a prime rate floor of 5.2% as selected by us. Interest on amounts borrowed under the Facility will be payable quarterly. The outstanding principal amount of the Facility is payable in four equal quarterly installments beginning on June 30, 2023, with the Facility maturing on March 31, 2024. We have the right to prepay borrowings under the Facility in whole or in part at any time, subject to a prepayment fee on the principal amount being prepaid of (i) 30.0% for the first two years following the initial funding date of the applicable borrowing, (ii) 5.0% for the third year following the initial funding date of the applicable borrowing, (iii) 3.0% for the fourth year following the initial funding date of the applicable borrowing and (iv) 1.0% for the fifth year following the initial funding date of the applicable borrowing but prior to March 31, 2024. In connection with the initial borrowing under the Facility, we paid, for the benefit of the lenders, a facility fee equal to 2.5% of the initial amount borrowed and will be required to pay such a facility fee in connection with any subsequent borrowings under the Facility. We are also required to pay the Administrative Agent and the lenders an annual administrative fee in addition to other fees and expenses. The Financing Agreement contains customary mandatory prepayments, restrictions and covenants applicable to us that are customary for financings of this type. Among other requirements, we are required to (i) maintain a minimum unrestricted cash balance of $50,000,000, which will increase to $60,000,000 if we draw either the second or third tranche of the Facility, and (ii) achieve certain minimum consolidated net revenue amounts attributable to commercial sales of our IMVEXXY, BIJUVA and ANNOVERA products beginning with the fiscal quarter ending December 31, 2020. The Financing Agreement also includes other representations, warranties, indemnities and events of default that are customary for financings of this type, including an event of default relating to a change of control of the Company. Upon or after an event of default, the Administrative Agent and the lenders may declare all or a portion of our obligations under the Financing Agreement to be immediately due and payable and exercise other rights and remedies provided for under the Financing Agreement. The obligations of our company and its subsidiaries under the Financing Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a first priority perfected security interest in all existing and after-acquired assets of our company and its subsidiaries. The obligations under the Financing Agreement will be guaranteed by each of our future direct and indirect subsidiaries, subject to certain exceptions.

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), as amended. The Credit Agreement provided 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 was available to be made in three separate tranches, with each tranche to be made available to us, at our option, upon our achievement of certain milestones. Amounts borrowed under the Term Loan bore 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.

On April 24, 2019, we terminated the Credit Agreement. A portion of the initial tranche of borrowing under the Financing Agreement in the amount of approximately $81,661,000 was used to repay all amounts outstanding under the Credit Agreement, which included a prepayment fee of 4%, a repayment fee of 4% and other fees and expenses payable to the lenders under the Credit Agreement. As a result of the termination of the Credit Agreement, we recorded $10,057,632 in loss on extinguishment of debt in the accompanying unaudited consolidated financial statements. Interest on amounts borrowed under the Term Loan was due and payable monthly in arrears. Interest expense for the nine months ending September 30, 2019 related to the Credit Agreement was $1,816,747. During the nine months ended September 30, 2019, and prior to the repayment of the Credit Agreement, we amortized $120,146 of deferred financing fees as interest expense in the accompanying unaudited consolidated financial statements.

As of September 30, 2019, we had $200,000,000 in borrowings outstanding under the Financing Agreement, which are classified as long-term debt in the accompanying unaudited consolidated financial statements. We incurred $6,652,270 in deferred financing fees related to the Financing Agreement. Deferred financing fees related to the entire Financing Agreement have been allocated pro rata between the funded and unfunded portions of each tranche. Allocated deferred financing fees related to Tranche 1 of $6,101,513 have been reflected as a debt discount and are accreted to interest expense using the effective interest method. Deferred financing fees associated with unfunded tranches were deferred as assets until the Tranche 2 and Tranche 3 milestones have been met. As of September 30, 2019, deferred financing fees related to Tranche 2 and Tranche 3 were included in other current assets in the accompanying consolidated financial statements. During the three and nine months ended September 30, 2019, we amortized $265,949 and $462,683, respectively, of deferred financing fees related to Tranche 1 as interest expense in the accompanying unaudited consolidated financial statements. Interest on amounts borrowed under the Financing Agreement is due and payable quarterly in arrears. Interest expense for the three and nine months ended September 30, 2019 was $5,333,056 and $9,318,056, respectively. The overall effective interest rate under the Financing Agreement was approximately 11% as of September 30, 2019.

As of September 30, 2019 and December 31, 2018, the carrying value of debt consisted of the following:

	September 30, 2019	December 31, 2018
Financing Agreement	$ 200,000,000	$ —
Credit Agreement	—	75,000,000
Debt discount and financing fees	(5,638,831)	(1,618,986)
TOTAL LONG-TERM DEBT	$ 194,361,169	$ 73,381,014

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, par value $0.001 per share, or 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, warrants and restricted stock awards and were excluded from the calculation of diluted EPS because their effect would have been antidilutive 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, 2019	**September 30, 2018**
Stock options	24,849,984	24,837,349
Warrants	1,832,571	3,007,571
Restricted stock awards	1,240,000	—
TOTAL	27,922,555	27,844,920

NOTE 11 – STOCKHOLDERS' EQUITY

Preferred Stock

At September 30, 2019, we had 10,000,000 shares of preferred stock, par value $0.001 per share, authorized for issuance, of which no shares of preferred stock were issued or outstanding.

Common Stock

At September 30, 2019, we had 350,000,000 shares of Common Stock authorized for issuance, of which 241,277,076 shares of Common Stock were issued and outstanding.

Issuances During the Three and Nine Months Ended September 30, 2019

During the three months ended September 30, 2019, certain individuals exercised stock options to purchase 55,236 shares of Common Stock for $8,549 in cash. During the nine months ended September 30, 2019, certain individuals exercised stock options to purchase 331,619 shares of Common Stock for $108,656 in cash. Also, during the same period, stock options to purchase 12,097 shares of Common Stock were exercised pursuant to the options' cashless exercise provisions, wherein 11,834 shares of Common Stock were issued.

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.

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.

Warrants to Purchase Common Stock

As of September 30, 2019, we had warrants outstanding to purchase an aggregate of 1,832,571 shares of Common Stock with a weighted-average contractual remaining life of approximately 2.2 years, and exercise prices ranging from $0.24 to $8.20 per share, resulting in a weighted average exercise price of $2.62 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, 2019, we granted warrants to purchase75,000 shares of Common Stock to outside consultants at an exercise price of $5.63. 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 60.8%; risk free rate of 2.52%; and dividend yield of 0%. The grant date fair value of the warrants was $3.00 per share. The warrants are vesting ratably over a 12 month period and have an expiration date of February 12, 2024. 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 three months ended September 30, 2019 and 2018, we recorded $56,418 and $150,977, respectively, and during the nine months ended September 30, 2019 and 2018, we recorded $198,306 and $407,292, respectively, as share based compensation expense in the accompanying consolidated financial statements related to warrants. As of September 30, 2019, total unrecognized estimated compensation expense related to the unvested portion of these warrants was approximately $83,000, which is expected to be recognized over a weighted-average period of 0.4 years.

During the nine months ended September 30, 2019, warrants to purchase 1,250,000 shares of Common Stock were exercised pursuant to the warrants' cashless exercise provisions, wherein 471,184 shares of Common Stock were issued. During the nine months ended September 30, 2018,no warrants were exercised.

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. 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, 2019, there were non-qualified stock options to purchase 15,028,509 shares of Common Stock outstanding under the 2009 Plan. Effective upon our adoption of the TherapeuticsMD, Inc. 2019 Stock Incentive Plan, or the 2019 Plan, on June 20, 2019, no future awards may be made under the 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. As of September 30, 2019, there were non-qualified stock options to purchase 6,316,474 shares of Common Stock outstanding and 1,040,000 restricted stock awards under the 2012 Plan. Effective upon our adoption of the 2019 Plan, no future awards may be made under the 2012 Plan.

On June 20, 2019, we adopted the 2019 Plan 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 2019 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 2019 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. As of September 30, 2019, there were 13,779,632 shares of Common Stock available for issuance thereunder, consisting of (i) 11,294,999 new shares, (ii) 2,395,333 unallocated shares previously available for issuance under the 2012 Plan that were not then subject to outstanding "Awards" (as defined in the 2012 Plan), and (iii) 89,300 unallocated shares previously available for issuance under the 2009 Plan that were not then subject to outstanding "Awards" (as defined in the 2009 Plan). Any shares subject to outstanding options or other equity "Awards" under the 2019 Plan, the 2012 Plan and the 2009 Plan that are forfeited, expire or otherwise terminate without issuance of the underlying shares, or if any such Award is settled for cash or otherwise does not result in the issuance of all or a portion of the shares subject to such Award (other than shares tendered or withheld in connection with the exercise of an Award or the satisfaction of withholding tax liabilities), the shares to which those Awards were subject, shall, to the extent of such forfeiture, expiration, termination, cash settlement or non-issuance, again be available for delivery with respect to Awards under the 2019 Plan. As of September 30, 2019, there were non-qualified stock options to purchase 3,505,001 shares of Common Stock outstanding and 200,000 restricted stock awards outstanding under the 2019 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, 2019 and 2018 are set forth in the table below.

	Nine months ended September 30,	
	2019	**2018**
Risk-free interest rate	1.83-2.54%	2.78-2.82%
Volatility	61.25-64.49%	61.8-63.34%
Term (in years)	5.5-6.5	5.5-6.25
Dividend yield	0.00%	0.00%

A summary of activity under the 2009, 2012 and 2019 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, 2018	20,872,824	$ 4.93	5.94 years	$ 12,239,876
Granted	4,419,501	$ 3.13		
Exercised	(343,716)	$ 0.32		$ 1,426,828
Expired/Forfeited	(98,625)	$ 5.63		
Balance at September 30, 2019	24,849,984	$ 4.67	6.05 years	$ 13,761,778
Vested and Exercisable at September 30, 2019	17,601,027	$ 4.85	4.81 years	$ 9,745,527
Unvested at September 30, 2019	7,248,957	$ 4.22	9.06 years	$ 4,016,251

At September 30, 2019, our outstanding stock options had exercise prices ranging from $0.19 to $8.92 per share. The weighted average grant date fair value per share of options granted was $1.84 and $3.27 during the nine months ended September 30, 2019 and 2018, respectively. Share-based compensation expense for options recognized in our results of operations for the three months ended September 30, 2019 and 2018 ($2,194,667 and $2,109,218, respectively) and for the nine months ended September 30, 2019 and 2018 ($6,568,736 and $5,981,343, respectively) is based on vested awards. At September 30, 2019, total unrecognized estimated compensation expense related to unvested options granted prior to that date was approximately $13,468,000 which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.4 years. No tax benefit was realized due to a continued pattern of operating losses.

Restricted Stock Awards

Restricted stock awards granted under our 2009, 2012 and 2019 Plans entitle the holder to receive, at the end of vesting period, a specified number of shares of our Common Stock. Share-based compensation expense is measured by the market value of our Common Stock on the day of the grant. The shares vest ratably over the period specified in the grant. There is no partial vesting and any unvested portion is forfeited.

On December 13, 2018, we granted 1,040,000 restricted stock units to certain executive employees which will vest at the end of the third year. The grant date fair value was $4.06 per unit. On July 30, 2019, we granted 200,000 restricted stock units to certain executive employees which will vest on January 31, 2022. The grant date fair value was $2.18 per unit. During the three and nine months ended September 30, 2019, we recorded $384,061 and $1,080,738, respectively, in share-based compensation expense related to restricted stock units. At September 30, 2019, total unrecognized estimated compensation expense related to unvested restricted stock units was approximately $3,505,000, which may be adjusted for future changes in forfeitures. This cost is expected to be recognized over a weighted-average period of 2.2 years. At September 30, 2019, we had 1,240,000 restricted stock awards outstanding.

Cash-Settled Stock Appreciation Rights (SARs)

On July 1, 2018, we issued cash-settled SARs to certain consultants and employees. The SARs plan year began on July 1, 2018 and ended on or immediately following June 30, 2019. SARs were 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 provided 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 were recorded in our consolidated balance sheets as a liability until the date of exercise. The fair value of each SAR award was estimated using the Black-Scholes valuation model. In accordance with ASC Topic 718, "Stock Compensation," the fair value of each SAR award was 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 June 30, 2019, the fair market value of our Common Stock was lower than the grant price of SARs and, as a result, the recorded liability was reversed and no cash payment was made.

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 2019 as a result of (i) the losses recorded during the nine months ended September 30, 2019, (ii) additional losses expected for the remainder of 2019, 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, 2019, 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, 2019 and 2018, we were billed by Catalent approximately $2,196,000 and $830,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. During the nine months ended September 30, 2019 and 2018, we were billed by Catalent approximately $4,118,000 and $2,774,000, respectively, for manufacturing activities related to our clinical trials, scale-up, registration batches, stability and validation testing. As of September 30, 2019 and December 31, 2018, there were amounts due to Catalent of approximately $425,000 and $88,000, respectively.

NOTE 14 – BUSINESS CONCENTRATIONS

We purchase our prescription products from several suppliers with approximately 36%, 28%, and 26% of our purchases supplied by three vendors each, respectively, during the nine months ended September 30, 2019. Approximately 100% of our products were manufactured by one vendor related to each of IMVEXXY and prenatal vitamins during the nine months ended September 30, 2018.

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 the nine months ended September 30, 2019, four customers each generated more than 10% of our total prescription revenues. During the nine months ended September 30, 2018, four customers each generated more than 10% of our total prescription revenues. Prescription revenue generated from the four customers combined accounted for approximately 68% of our prescription revenue for the nine months ended September 30, 2019, and prescription revenue generated from the four customers combined accounted for approximately 71% of our prescription revenue for the nine months ended September 30, 2018.

During the nine months ended September 30, 2019, PI Services accounted for approximately $1,935,000 of our prescription revenue, Pillpack, Inc. accounted for approximately $6,397,000 of our prescription revenue, AmerisourceBergen accounted for approximately $2,226,000 of our prescription revenue and Cardinal Health accounted for approximately $1,863,000 of our prescription revenue. During the nine months ended September 30, 2018, PI Services accounted for approximately $1,559,000 of our prescription revenue, Pillpack, Inc. accounted for approximately $3,057,000 of our prescription revenue, AmerisourceBergen accounted for approximately $1,834,000 of our prescription revenue and Cardinal Health accounted for approximately $1,399,000 of our prescription revenue.

NOTE 15 – COMMITMENTS AND CONTINGENCIES

We adopted ASC 842 effective January 1, 2019. Substantially all our operating lease right-of-use assets and operating lease liabilities represent leases for office space used to conduct our business. Upon adoption, we have recognized a right-of-use asset and a lease liability for all leases that have commenced as of January 1, 2019. The right-of-use assets represent the right to use the leased asset for the lease term. The lease liabilities represent the present value of the lease payments under the lease. The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial direct costs incurred, less any lease incentives received. All right-of-use assets are reviewed for impairment. The lease liability is initially measured at the present value of the lease payments, discounted using our secured incremental borrowing rate for the same term as the underlying lease because the rates are not implicit in the leases. Some of our leases contain variable lease payments, including payments based on an index or rate. Variable lease payments based on an index or rate are initially measured using the index or rate in effect at lease commencement. Additional payments based on the change in an index or rate, or payments based on a change in our portion of the operating expenses are recorded as a period expense when incurred. Lease modifications result in remeasurement of the lease liability. Included in lease expense are any variable lease payments incurred in the period that were not included in the initial lease liability.

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.

In October 2018, we entered into a lease for new corporate offices in Boca Raton, Florida. The lease includes 56,212 rentable square feet, or the full premises, of which lease on 7,561 square feet commenced in 2018 and the lease on the remaining 48,651 square feet commenced in August 2019, or the full premises commencement date. The lease will expire 11 years after full premises commencement date, unless terminated earlier in accordance with the terms of the lease. We have the option to extend the term of the lease for two additional consecutive periods of 5 years. The extension option is not included in the determination of the lease term as it is not reasonably certain to be exercised. The term of the lease includes escalating rent and free rent periods. We are also responsible for certain other operating costs under the lease, including electricity and utility expenses. In June 2019, we entered into an agreement with the same lessors to lease additional 6,536 square feet of administrative office space in the same location, pursuant to an addendum to such lease, which is expected to commence as soon as the fourth quarter of 2019.

Supplemental lease information at September 30, 2019		
Right-of-use asset	$	10,459,635
Short-term operating lease liability (included in Other current liabilities)	$	1,242,290
Long-term operating lease liability	$	9,500,133
Weighted average remaining term		9 Years
Weighted average discount rate		8.25%

Supplemental cash flow information for nine months ended September 30, 2019		
Cash paid for amounts included in the measurement of lease liabilities for operating lease	$	849,440
Right-of-use assets obtained in exchange for lease obligation	$	11,171,471

The following table reconciles the undiscounted cash flows for all operating leases at September 30, 2019 to the operating lease liabilities recorded on the balance sheet:

Years Ending December 31,		
2019 (3 months)	$	314,670
2020		1,566,617
2021		2,198,541
2022		1,262,302
2023		1,293,859
Thereafter		9,363,136
Total undiscounted lease payments		15,999,125
Less: imputed interest		(5,256,702)
Present value of lease payments	$	10,742,423

During the three and nine months ended September 30, 2019, operating lease expense related to our real estate leases was approximately $458,000 and $1,062,000, respectively, and variable lease expense was insignificant for the three and nine months ended September 30, 2019. Rent expense totaled $257,000 and $772,000 during the three and nine months ended September 30, 2018, respectively.

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 number of softgels during the first contract year and a higher number of 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

On October 24, 2019, we entered into an underwriting agreement with J.P. Morgan Securities LLC, as representative of the underwriters, relating to an underwritten public offering of 26,000,000 shares of our Common Stock at a public offering price of $2.75 per share. We granted the underwriters an option, exercisable for a period of 30 days, to purchase up to 3,900,000 additional shares of Common Stock, which was exercised in full. The net proceeds from the offering were approximately $77.0 million, after deducting the underwriting discount and offering expenses payable by us. The offering closed on October 29, 2019.

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 unaudited 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, 2018 filed with the Securities and Exchange Commission, or the SEC, on February 27, 2019, or our 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 facility, including the conditions to draw additional tranches thereunder; 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.

This Quarterly Report on Form 10-Q includes our trademarks, trade names and service marks, such as vitaMedMD®, BocaGreenMD®, IMVEXXY®, BIJUVA® and ANNOVERA™ which are protected under applicable intellectual property laws and are the property of, or licensed to, our company. This Quarterly Report on Form 10-Q also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this quarterly report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

Overview

We are a women's healthcare company focused on creating and commercializing innovative products to support the lifespan of women and championing awareness of women's healthcare issues, specifically, for pregnancy prevention, pregnancy, childbirth, nursing, pre-menopause, and menopause. At TherapeuticsMD, we combine entrepreneurial spirit, clinical expertise, and business leadership to develop and commercialize health solutions that enable new standards of care for women. Our solutions range from advanced hormone therapy pharmaceutical products to patient-controlled, long-acting contraceptive. We also manufacture and distribute branded and generic prescription prenatal vitamins under the vitaMedMD® and BocaGreenMD® brands.

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. Our commercialization plan allows us to efficiently leverage and grow our marketing and sales organization to commercialize our recently approved products. During 2018, the U.S. Food and Drug Administration, or FDA, approval of our drugs has transitioned our company from predominately focused on conducting research and development to one focused on commercializing our drugs. In July 2018, we launched our 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. In April 2019, we launched our FDA-approved product BIJUVA, our hormone therapy combination of bio-identical 17ß-estradiol and bio-identical progesterone in a single, oral softgel capsule, for the treatment of moderate-to-severe vasomotor symptoms, or VMS, due to menopause in women with a uterus, which was approved by the FDA on October 28, 2018. In October 2019, we began a "test and learn" market introduction phase of launch for our licensed FDA-approved product ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only long-lasting, patient-controlled, procedure-free, reversible prescription contraceptive option for women, which was approved by the FDA on August 10, 2018. We expect the full commercial launch of ANNOVERA in the first quarter of 2020. On July 30, 2018, we entered into an exclusive license agreement, or the Population Council License Agreement, with the Population Council, Inc., or the Population Council, to commercialize ANNOVERA in the U.S. In addition, 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. On June 6, 2019, we entered into an exclusive license and supply agreement, or the License Agreement, with Theramex HQ UK Limited, or Theramex, to commercialize BIJUVA and IMVEXXY outside of the U.S., excluding Canada and Israel, or the Territory.

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 as well as various product websites. 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

On May 30, 2018, we announced that the FDA had approved the 4-µg and 10-µg 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-µg formulation of IMVEXXY represents the lowest FDA-approved dose of vaginal estradiol available.

On July 9, 2018, we launched IMVEXXY 10-µg with our early experience program to a targeted sample of healthcare providers, or HCPs, throughout the U.S. The national launch of the 10-µg dose of IMVEXXY began in August 2018, and the 4-µg dose of IMVEXXY launched on September 13, 2018. Since FDA approval of our NDA for IMVEXXY, we have been focused on executing our launch plan. The key objectives of our launch plan include: (i) providing broad commercial access at the retail level and with commercial payers, (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, medical affairs, information technology, data analytics, pharmacovigilance capacity and compliance) to support our commercial-stage company. We have made progress in each of these key strategic areas:

Commercial Access:

- Both the 4-µg and 10-µg doses of IMVEXXY are broadly available in major pharmacy chains in the U.S., as well as with our BIO-IGNITE™ partners, via our third-party logistics and our distribution partners.
- We have obtained the majority of commercial payer coverage and continue to seek unrestricted coverage from the remaining commercial insurance plans that we have not yet contracted with to provide affordable access for patients.
- Through September 30, 2019, we achieved unrestricted coverage with eight of the top ten commercial payers of VVA products by commercial payer lives and we continue to sign new agreements with payers to cover IMVEXXY. In addition, as of September 30, 2019, two of the top six Medicare Part D payers of VVA products were adjudicating IMVEXXY, with additional decisions for other Medicare Part D payers expected during the fourth quarter of 2019.
- Beginning at launch, we instituted a patient education and affordability program that allows all eligible patients who enroll to receive IMVEXXY at a reasonable cost. When a product is not covered, the patient is responsible to pay the full price for the medication, which can significantly limit a patient's ability to pay and subsequent utilization of the product. Prior to October 1, 2019, enrolled patients did not pay more than $35 for a prescription of IMVEXXY. Starting October 1, 2019, enrolled patients pay as little as $35 for a prescription of IMVEXXY with commercial insurance coverage and pay as little as $50 for a prescription of IMVEXXY without commercial insurance coverage.
- We have designed initiatives to drive starter pack volume and target competitors using clinical data, which are expected to begin in the first quarter of 2020. We have also begun a distribution optimization process that we expect will result in improvement over current distribution costs by the third quarter of 2020, including improved fees and new retail partnerships.

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 most of the active writing HCPs within the VVA category with IMVEXXY branded messages. The focus of our interactions with HCPs included: (i) introducing IMVEXXY and highlighting the unmet medical need 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. As of September 30, 2019, approximately 15,600 HCPs had sent an IMVEXXY prescription to a pharmacy for at least one patient.

Patient Awareness, Affordability and Adherence Programs:

- We believe the patient affordability and adherence 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. We launched our patient affordability and adherence program for IMVEXXY to help patients manage out-of-pocket costs and improve education regarding VVA and IMVEXXY with the goal of increasing patient adherence and compliance for an improved treatment experience. As of September 30, 2019, approximately 92% of our total IMVEXXY fills have utilized the patient savings programs. We launched print, social, point of care and digital direct-to-consumer marketing for IMVEXXY in the third quarter of 2019. As of September 30, 2019, we had approximately 95,300 patients who have received at least one paid IMVEXXY prescription filled at a pharmacy.

Customer Model:

- As of September 30, 2019, we had a sales force that covers approximately 200 territories throughout the U.S. Within these territories there are approximately 40,000 HCPs that represent the majority of the volume of FDA-approved prescriptions for these product categories. The sales representatives target a subset of these specific HCPs based on product and messaging objectives for a particular quarter. Our sales force is deploying a hybrid sales model that combines an internal sales leadership team with a fully dedicated contract sales force to call on our 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 we have launched our Key Account Managers (KAMs) to engage with our BIO-IGNITE partners. BIO-IGNITE is a program focused on supporting the synergistic relationships between community pharmacies and HCPs so that offering BIJUVA and IMVEXXY as appropriate treatment alternatives is economically practical for the pharmacy.

Infrastructure:

- We continue to expand our internal capabilities to support the continued launch of IMVEXXY. We have launched KAMs 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 KAMs. Our KAMs have national coverage and target over 1,900 community pharmacies that have a focus on compounded bio-identical hormones and the over 2,000 additional HCPs that are affiliated with these pharmacies. The KAM role is a dual role in delivering a trade message at the pharmacy level and a commercial message at the HCP level.

Regulatory:

- 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. The FDA has also asked the sponsors of other vaginal estrogen products to also participate in the observational study. In connection with the observational study, we will be required to provide progress reports to the FDA on an annual basis. The development of this method is underway, and we do not believe that the costs will be material. In addition, the FDA asked for post-approval information with respect to certain characteristics related to the product's specifications, which we submitted to FDA, fully completing this request.

BIJUVA

On October 28, 2018, the FDA approved BIJUVA (estradiol and progesterone) capsules, 1 mg/100 mg, the first and only FDA-approved bioidentical 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. The estrogen and progesterone in BIJUVA have the same chemical and molecular structure as the hormones that are naturally produced in a woman's body. Following meetings with the FDA, we plan to submit a New Drug Application (NDA) efficacy supplement for the 0.5/100 mg dose of BIJUVA to the FDA in the fourth quarter of 2019 for review and potential approval using existing data from our Phase 3 REPLENISH trial for BIJUVA, for which we announced results in December 2016, together with additional information and analyses. We do not anticipate that the FDA will require any new clinical trials in connection with our submission of the NDA efficacy supplement. If accepted for review by the FDA, we expect that the NDA efficacy supplement will be reviewed, under current Prescription Drug User Fee Act timeline goals, within ten months of receipt by the FDA.

We launched BIJUVA on April 17, 2019 with a similar model to IMVEXXY. The key objectives of our launch plan include: (i) broad commercial access at the retail level and with commercial payers, (ii) increasing awareness and appreciation of the clinical and patient features of BIJUVA amongst HCPs, (iii) expanding and leveraging our existing customer facing model, and (iv) leverage our internal capabilities (for example, in the areas of finance, human resources, information technology, data analytics and compliance) to support the launch of BIJUVA.

Our initial focus has been on key OB/GYN targets, particularly those that already adopted IMVEXXY, to deliver the core clinical messages as well as provide information on our patient affordability and adherence programs. In support of BIJUVA, our field force expanded to approximately 200 territories in April 2019. In addition, we will continue to deploy our BIO-IGNITE program with a fuller expansion towards the end of 2019 into 2020 when we have achieved coverage for the majority of commercial insurance plans that is beyond the six month payer block.

We launched our patient affordability and adherence program for BIJUVA, similar to IMVEXXY, to help patients manage out-of-pocket costs and improve patient education with the goal of increasing patient adherence and compliance for an improved treatment experience. As of September 30, 2019, approximately 88% of our total BIJUVA fills have utilized the patient savings programs. Prior to October 1, 2019, enrolled patients did not pay more than $35 for a prescription of BIJUVA. Starting October 1, 2019, enrolled patients pay as little as $35 for a prescription of BIJUVA with commercial insurance coverage and pay as little as $50 for a prescription of BIJUVA without commercial insurance coverage. As of September 30, 2019, we have approximately 9,100 patients who have received at least one paid BIJUVA prescription filled at a pharmacy.

We believe that the successful launch of IMVEXXY allows us to leverage existing contracts with our third-party logistics partner and our distribution partners. We anticipate similar timing regarding commercial payer coverage as we experienced with IMVEXXY as many commercial payers employ "new-to-market blocks" for newly launched brands while they make their decision on coverage. However, our ability to leverage existing payer contracts by amending to include BIJUVA, along with our recent experience with the payers may simplify and accelerate the process. Through September 30, 2019, we achieved unrestricted coverage with five of the top ten commercial payers of VMS products by commercial payer lives and we continue to sign new agreements with payers to cover BIJUVA. Although Medicare is a small percentage of the VMS market, as of September 30, 2019, two of the top six Medicare Part D payers of VMS products was adjudicating BIJUVA.

With the approval of BIJUVA, the FDA 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 and validation were completed and submitted to the FDA as required in our approval.

ANNOVERA

On July 30, 2018, we entered into an exclusive license agreement with the Population Council to commercialize in the U.S. ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system), the first and only patient-controlled, procedure-free, reversible prescription contraceptive that can prevent pregnancy for up to a full year, which was approved by the FDA on August 10, 2018.

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. ANNOVERA is a one-year ring-shaped contraceptive vaginal system, or CVS. ANNOVERA, which is made with a silicone elastomer, contains segesterone acetate, a 19-nor progesterone derivative also known as Nestorone ®, or NES, and ethinyl estradiol, or EE. EE is an approved active ingredient in many marketed hormonal contraceptive products. Segesterone acetate, a new chemical entity, is a potent progestin. Segestrone acetate also does not bind to the androgen or estrogen receptors and has no glucocorticoid effects at contraceptive doses. NES has been evaluated in 51 clinical studies across these delivery systems with more than 26,794 cycles of exposure.

ANNOVERA can be inserted and removed by the woman herself without the aid of a healthcare provider and, unlike oral contraceptives, or OCs, ANNOVERA does not require daily administration to obtain the contraceptive effect. After 21 days of use, the woman removes ANNOVERA for seven days, thereby providing a regular bleeding pattern (i.e., withdrawal/scheduled bleeding). The same CVS is then re-inserted for additional 21/7-days in/out, for up to a total of 13 cycles (one year). ANNOVERA releases daily vaginal doses of both active ingredients (NES and EE). The claimed release rate of 150 µg/day NES and 13/day µg EE is supported by the calculated average release rate from an ex vivo analysis of ANNOVERA used for 13 cycles and is also supported by data from 13 cycles of in vitro release.

We launched ANNOVERA in the third quarter of 2019 with limited sales and a full-scale launch expected in the first quarter of 2020. In October 2019, we began a "test and learn" market introduction phase of launch for ANNOVERA, with 36 of our existing sales representatives currently promoting ANNOVERA in addition to our other products, and our 23 regional sales managers and 12 compounding KAMs introducing ANNOVERA to top targeted healthcare practitioners outside of these 36 territories.

We believe that the strong initial commercial net revenue per unit of ANNOVERA and rapid commercial insurance adoption provide us with an opportunity to deploy additional financial resources to maximize ANNOVERA's consumer-focused commercialization strategy and leverage the ability of doctor/patient choice of contraceptive to override insurance company formularies when a generic equivalent has not been established. As part of this strategy, we are pursuing distribution opportunities for ANNOVERA with multiple direct-to-consumer contraceptive platforms that are both low cost to TXMD and offer an attractive return to the platforms.

We continue to dialogue with the FDA regarding the potential inclusion of ANNOVERA as a new class of contraception for women in the FDA's Birth Control Guide, which would require private health plans to cover ANNOVERA with no patient out-of-pocket costs as part of the Affordable Care Act. Eight states require insurance coverage of prescription contraception with co-pay regardless of inclusion in the FDA's Birth Control Guide and 11 states, plus Washington D.C., require coverage of prescription contraception with no co-pay regardless of inclusion in the FDA's Birth Control Guide. We believe that a recent reorganization of the FDA's Division of Bone Reproductive and Urologic Products (DBRUP) may delay a decision regarding the inclusion of ANNOVERA as a new class of contraception for women in the FDA's Birth Control Guide beyond the fourth quarter of this year, which could affect our ability to borrow an additional tranche of $50 million under our financing agreement, or the Financing Agreement, with TPG Specialty Lending, Inc., as administrative agent, or the Administrative Agent. Given the strong initial commercial net revenue per unit of ANNOVERA and rapid commercial insurance adoption during our "test and learn" market introduction phase of launch, as well as the potential for the FDA's decision regarding the inclusion of ANNOVERA as a new class of contraception to come after the fourth quarter of this year, we have begun discussions with the Administrative Agent about revising the draw trigger for this $50 million tranche in order to take into account the positive ANNOVERA launch trends that we are experiencing. The Administrative Agent has informed us that it is open to considering a revision to the terms and timing of this draw trigger, although there is no assurance that we and the Administrative Agent will agree on any such revisions.

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 draft protocol submission for the study was submitted 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 Population Council License Agreement. Given the observational nature of the study, we do not believe that the costs of the study will be material on an annual basis.

As of September 30, 2019, we had 28 issued foreign patents and 26 issued domestic or, U.S., patents, which included 12 domestic utility patents that relate to BIJUVA, three domestic patents that relate to estradiol and progesterone product candidates, five domestic 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 topical-cream candidates, one domestic utility patent that relates to a product candidate containing d-limonene, one domestic utility patent that relates to our OPERA® information technology platform that we wrote off in the second quarter of 2019, and two domestic utility patents that relate to TX-009HR, our progesterone and estradiol drug candidate.

Research and Development Expenses

A 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 research and development. Our research and development expenses consist primarily of expenses incurred under agreements with contract research organizations, or CROs, and consultants that conduct 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 Investigational New Drug application approval from the FDA.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(000s)		(000s)	
TX 001-HR (BIJUVA)	$ 454	$ 3,017	$ 2,869	$ 8,432
TX 004-HR(IMVEXXY)	527	764	1,869	3,922
ANNOVERA	396	—	2,109	—
Other research and development	2,701	2,927	8,513	8,192
Total	$ 4,078	$ 6,708	$ 15,360	$ 20,546

Research and development expenditures will continue to be incurred as we develop our drug pipeline, continue stability testing and validation on our drugs, develop and validate secondary manufacturers, 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 a variety of factors. 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. For a discussion of the nature of efforts, steps and costs necessary to complete these projects, see "Item 1. Business — Research and Development" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Research and Development Expenses" contained in our Annual Report.

Results of Operations

Three months ended September 30, 2019 compared with three months ended September 30, 2018

	Three Months Ended September 30,		
	2019	2018	Change
	(000s)		
Product revenue, net	$ 8,213	$ 3,474	$ 4,739
License revenue	15,506	—	15,506
Cost of goods sold	1,444	699	745
Operating expenses	49,347	37,136	12,211
Operating loss	(27,072)	(34,361)	(7,289)
Other expense, net	(4,895)	(1,244)	3,651
Net loss	$ (31,967)	$ (35,605)	$ (3,638)

Revenues and Cost of Goods Sold

Product revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. Product revenue for the three months ended September 30, 2019 increased approximately $4,739,000, or 136%, to approximately $8,213,000, compared with approximately $3,474,000 for the three months ended September 30, 2018. Product revenue increased primarily due to an increase in sales of approximately $4,560,000 of IMVEXXY in the current period, partially offset by a decrease in prenatal vitamin sales of approximately $711,000. Product revenue for the three months ended September 30, 2019 also included sales of BIJUVA of approximately $490,000 and sales of ANNOVERA of approximately $400,000. The revenue decrease related to our prenatal vitamins was primarily affected by lower number of units sold as compared to the prior year period, partially offset by increased revenue per unit. We launched IMVEXXY in the third quarter of 2018, BIJUVA in the second quarter of 2019 and ANNOVERA in the third quarter of 2019. Since the launches, revenues related to IMVEXXY and BIJUVA have been greatly affected by the co-pay assistance programs that we introduced to launch these products, which allows eligible enrolled patients to access the products at a reasonable cost regardless of insurance coverage. We expect our product revenues to improve as commercial and Medicare payer coverage increases, and plans complete the process needed to adjudicate IMVEXXY, BIJUVA and ANNOVERA prescriptions at pharmacies. In addition to our product revenue, during the three months ended September 30, 2019, we recognized license revenue of approximately $15,506,000 from the upfront fee, which was a non-refundable payment, payable to us by Theramex under the terms of the License Agreement, which we recognized at the point in time when Theramex was able to use and benefit from the license, which was when the knowledge transfer of regulatory documents occurred.

Cost of goods sold increased approximately $745,000, or 107%, to approximately $1,444,000 for the three months ended September 30, 2019, compared with approximately $699,000 for the three months ended September 30, 2018. Our gross margin related to prescription products was approximately 82% and 80% for the three-month periods ended September 30, 2019 and 2018, respectively. The change in our gross margin is primarily related to the change in product mix between the two periods.

Operating Expenses

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

	Three Months Ended September 30,	
	2019	2018
Sales and marketing costs, excluding human resources costs	45.7%	44.6%
Human resources related costs, including salaries, benefits and taxes	27.4%	24.0%
Product research and development costs	8.3%	18.1%
Professional fees and consulting costs	8.3%	4.4%
Other operating expenses	10.3%	8.9%

Operating expenses increased by approximately $12,211,000, or 33%, to approximately $49,347,000 for the three months ended September 30, 2019, from approximately $37,136,000 for the three months ended September 30, 2018 as a result of the following items:

	Three Months Ended September 30,		
	2019	2018	Change
	(000s)		
Sales and marketing, excluding human resources costs	$ 22,547	$ 16,577	$ 5,970
Human resources related costs	13,507	8,911	4,596
Product research and development costs	4,078	6,708	(2,630)
Professional fees and consulting costs	4,100	1,650	2,450
Other operating expenses	5,115	3,290	1,825
Total operating expenses	$ 49,347	$ 37,136	$ 12,211

Sales and marketing costs for the three months ended September 30, 2019 increased by approximately $5,970,000, or 36%, to approximately $22,547,000, compared with approximately $16,577,000 for the three months ended September 30, 2018, primarily as a result of increased expenses associated with sales and marketing efforts to support launch and commercialization of our prescription products, including costs related to outsourced sales personnel and their related expenses, physician education, advertising and travel expenses related to product commercialization. We expect sales and marketing expenses to continue to increase as we continue the launch of BIJUVA and ANNOVERA and continue to support our growing business and commercialization of our products.

Human resources costs, including salaries, benefits and taxes, for the three months ended September 30, 2019 increased by approximately $4,596,000, or 52%, to approximately $13,507,000, compared with approximately $8,911,000 for the three months ended September 30, 2018, primarily as a result of an increase of approximately $4,259,000 in personnel costs in sales, marketing and regulatory areas to support commercialization of our prescription products and an increase of approximately $337,000 in non-cash compensation expense included in this category related to employee stock-based compensation during 2019 as compared to 2018.

Research and development costs for the three months ended September 30, 2019 decreased by approximately $2,630,000, or 39%, to approximately $4,078,000, compared with approximately $6,708,000 for the three months ended September 30, 2018. Research and development costs include costs related to manufacturing validation and early development trials, as well as salaries, wages, non-cash compensation and benefits of personnel involved in research and development activities. Research and development costs decreased primarily as a result of certain employees and activities that were previously classified as research and development being transferred to operations as they began to support commercial and launch efforts after the FDA approvals of IMVEXXY and BIJUVA.

- Since the project's inception in February 2013, we have incurred approximately $130,056,000 in research and development costs with respect to BIJUVA.
- Since the project's inception in August 2014, we have incurred approximately $47,608,000 in research and development costs with respect to IMVEXXY.

For a discussion of the nature of efforts, steps and costs related to our research and development projects, see "Item 1. Business — Research and Development" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Research and Development Expenses" contained in our Annual Report.

Professional fees and consulting costs for the three months ended September 30, 2019 increased by approximately $2,450,000, or 148%, to approximately $4,100,000, compared with approximately $1,650,000 for the three months ended September 30, 2018, primarily as a result of increased recruiting and consulting fees.

All other operating expense for the three months ended September 30, 2019 increased by approximately $1,825,000, or 55%, to approximately $5,115,000, compared with approximately $3,290,000 for the three months ended September 30, 2018, as a result of increased information technology, travel, dues and subscriptions, allowance for bad debt expense, insurance and other office expenses primarily to support commercialization of our new drugs.

Operating Loss

As a result of the foregoing, our operating loss decreased approximately $7,289,000, or 21%, to approximately $27,072,000 for the three months ended September 30, 2019, compared with approximately $34,361,000 for the three months ended September 30, 2018, primarily as a result of increased total net revenue, partially offset by an increase in total operating expenses.

We anticipate that we will continue to have operating losses for the near future until we successfully commercialize IMVEXXY, BIJUVA and ANNOVERA, although there is no assurance that any commercialization of IMVEXXY, BIJUVA and ANNOVERA will be successful.

Other expense, net

Other non-operating expense, net increased by approximately $3,651,000, or 293%, to an expense of approximately $4,895,000 for the three months ended September 30, 2019, compared with an expense of approximately $1,244,000 for the three months ended September 30, 2018, primarily as a result of loss on extinguishment of debt and increased interest expense related to our Financing Agreement. For more information regarding our Financing Agreement, see "Liquidity and Capital Resources" below.

Net Loss

Because of the net effects of the foregoing, net loss decreased approximately $3,638,000, or 10%, to approximately $31,967,000 for the three months ended September 30, 2019, compared with approximately $35,605,000 for the three months ended September 30, 2018. Net loss per share of Common Stock, basic and diluted, was ($0.13) and ($0.16) for the three months ended September 30, 2019 and 2018, respectively.

Nine months ended September 30, 2019 compared with nine months ended September 30, 2018

	Nine Months Ended September 30,		
	2019	2018	Change
		(000s)	
Product revenue, net	$ 18,239	$ 11,010	$ 7,229
License revenue	15,506	—	15,506
Cost of goods sold	3,456	1,787	1,669
Operating expenses	137,102	101,323	35,779
Operating loss	(106,813)	(92,100)	(14,713)
Other expense, net	(19,896)	(1,126)	(18,770)
Net loss	$ (126,709)	$ (93,226)	$ (33,483)

Revenues and Cost of Goods Sold

Product revenue is recorded net of sales discounts, chargebacks, wholesaler fees, customer rebates, coupons and estimated returns. Product revenue for the nine months ended September 30, 2019 increased approximately $7,229,000, or 66%, to approximately $18,239,000, compared with approximately $11,010,000 for the nine months ended September 30, 2018. Product revenue increased primarily due to an increase in sales of approximately $9,693,000 of IMVEXXY in the current period partially offset by a decrease in prenatal vitamin sales of approximately $3,489,000. Product revenue during the nine months ended September 30, 2019 also included sales of BIJUVA of approximately $625,000 and sales of ANNOVERA of approximately $400,000. The revenue decrease related to our prenatal vitamins was primarily affected by lower number of units sold as compared to the prior year period. We launched IMVEXXY in the third quarter of 2018, BIJUVA in the second quarter of 2019 and ANNOVERA in the third quarter of 2019. Since the launches, revenues related to IMVEXXY and BIJUVA have been greatly affected by the co-pay assistance programs that we introduced to launch these products, which allows eligible enrolled patients to access the products at a reasonable cost regardless of insurance coverage. We expect our product revenues to improve as commercial and Medicare payer coverage increases, and plans complete the process needed to adjudicate IMVEXXY, BIJUVA and ANNOVERA prescriptions at pharmacies. In addition to our product revenue, during the nine months ended September 30, 2019, we recognized license revenue of approximately $15,506,000 from the upfront fee, which was a non-refundable payment, payable to us by Theramex under the terms of the License Agreement, which we recognized at the point in time when Theramex was able to use and benefit from the license, which was when the knowledge transfer of regulatory documents occurred.

Cost of goods sold increased approximately $1,669,000, or 93%, to approximately $3,456,000 for the nine months ended September 30, 2019, compared with approximately $1,787,000 for the nine months ended September 30, 2018, primarily due to an increased number of units sold. Our gross margin for our prescription products was approximately 81% and 84% for the nine months ended September 30, 2019 and 2018, respectively. The change in our gross margin is primarily related to the change in product mix between the two periods.

Operating Expenses

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

	Nine Months Ended September 30,	
	2019	2018
Sales and marketing costs, excluding human resources costs	44.2%	43.1%
Human resources related costs, including salaries, benefits and taxes	27.1%	23.0%
Product research and development costs	11.2%	20.3%
Professional fees and consulting costs	7.3%	5.3%
Other operating expenses	10.2%	8.3%

Operating expenses increased by approximately $35,779,000, or 35%, to approximately $137,102,000 for the nine months ended September 30, 2019, from approximately $101,323,000 for the nine months ended September 30, 2018 as a result of the following items:

	Nine Months Ended September 30,		
	2019	2018	Change
		(000s)	
Sales and marketing, excluding human resources costs	$ 60,537	$ 43,695	$ 16,842
Human resources related costs	37,162	23,296	13,866
Product research and development costs	15,360	20,546	(5,186)
Professional fees and consulting costs	10,025	5,411	4,614
Other operating expenses	14,018	8,375	5,643
Total operating expenses	$ 137,102	$ 101,323	$ 35,779

Sales and marketing costs for the nine months ended September 30, 2019 increased by approximately $16,842,000, or 39%, to approximately $60,537,000, compared with approximately $43,695,000 for the nine months ended September 30, 2018, primarily as a result of increased expenses associated with sales and marketing efforts to support launch and commercialization of our prescription products, including costs related to outsourced sales personnel and their related expenses, physician education and product samples, advertising and travel expenses related to product commercialization. We expect sales and marketing expenses to continue to increase as we continue the launch of BIJUVA and ANNOVERA, and continue to support our growing business and commercialization of our products.

Human resources costs, including salaries, benefits and taxes, for the nine months ended September 30, 2019 increased by approximately $13,866,000, or 60%, to approximately $37,162,000, compared with approximately $23,296,000 for the nine months ended September 30, 2018, as a result of an increase of approximately $12,278,000 in personnel costs in sales, marketing and regulatory areas to support commercialization of our prescription products and an increase of approximately $1,588,000 in non-cash compensation expense included in this category related to employee stock-based compensation during 2019 as compared to 2018.

Research and development costs for the nine months ended September 30, 2019 decreased by approximately $5,186,000, or 25%, to approximately $15,360,000, compared with approximately $20,546,000 for the nine months ended September 30, 2018. Research and development costs included costs related to on-going stability and laboratory testing, early development trials, as well as salaries, wages, non-cash compensation and benefits of personnel involved in research and development activities. Research and development costs decreased for the nine months ended September 30, 2019 as compared to the prior period primarily as a result of lower costs related to scale-up and manufacturing activities as well as decreased pre-clinical work to support our product pipeline. Research and development costs also decreased as a result of certain employees and activities that were previously classified as research and development being transferred to operations as they began to support commercial and launch efforts after the FDA approvals of IMVEXXY and BIJUVA.

For a discussion of the nature of efforts, steps and costs related to our research and development projects, see “Item 1. Business — Research and Development” and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Research and Development Expenses” contained in our Annual Report.

Professional fees and consulting costs for the nine months ended September 30, 2019 increased by approximately $4,614,000, or 85%, to approximately $10,025,000, compared with approximately $5,411,000 for the nine months ended September 30, 2018, primarily as a result of increased recruiting and consulting fees, partially offset by lower legal fees.

All other operating expense for the nine months ended September 30, 2019 increased by approximately $5,643,000, or 67%, to approximately $14,018,000, compared with approximately $8,375,000 for the nine months ended September 30, 2018, as a result of increased information technology, travel, allowance for bad debt expense, insurance and other office expenses primarily to support commercialization of our new drugs.

Operating Loss

As a result of the foregoing, our operating loss increased approximately $14,713,000, or 16%, to approximately $106,813,000 for the nine months ended September 30, 2019, compared with approximately $92,100,000 for the nine months ended September 30, 2018, primarily as a result of increased personnel costs, sales and marketing expenses to support commercialization of our prescription products, including costs related to outsourced sales personnel and their related expenses, professional fees and other operating expenses, partially offset by a decrease in research and development costs and an increase in total net revenue.

We anticipate that we will continue to have operating losses for the near future until we successfully commercialize IMVEXXY, BIJUVA, and ANNOVERA, although there is no assurance that any commercialization of IMVEXXY, BIJUVA, and ANNOVERA will be successful.

Other Expense, net

Other non-operating expense increased by approximately $18,770,000 to an expense of approximately $19,896,000 for the nine months ended September 30, 2019 compared with an expense of approximately $1,126,000 for the nine months ended September 30, 2018, primarily as a result of loss on extinguishment of debt and increased interest expense related to our Financing Agreement. For more information regarding our Financing Agreement, see “Liquidity and Capital Resources” below.

Net Loss

Because of the net effects of the foregoing, net loss increased approximately $33,483,000, or 36%, to approximately $126,709,000 for the nine months ended September 30, 2019, compared with approximately $93,226,000 for the nine months ended September 30, 2018. Net loss per share of Common Stock, basic and diluted, was ($0.53) and ($0.42) for the nine months ended September 30, 2019 and 2018, respectively.

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 three years ended December 31, 2018, we received approximately $293,344,000 in net proceeds from the issuance of shares of our Common Stock. As of September 30, 2019, we had cash and cash equivalents totaling approximately $155,330,000, 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.

Our net days sales outstanding, or net DSO, is calculated by dividing gross accounts receivable less the reserve for doubtful accounts, chargebacks and payment discounts by the average daily net product revenues during the quarter. We also disclose gross DSO, which includes the calculation of gross accounts receivable divided by the average daily gross product revenues to distributors during the quarter. For the three months ended September 30, 2019, our gross DSO was 46 days compared to 77 days for the three months ended December 31, 2018 and our net DSO was 172 days for the three months ended September 30, 2019 compared to 200 days for the three months ended December 31, 2018. Our DSO decreased primarily due to more favorable arrangements with customers that we entered into in the second quarter of 2019. We anticipate that our DSO will fluctuate in the future based upon a variety of factors, including longer payment terms associated with the launch of IMVEXXY, BIJUVA and ANNOVERA and changes in the healthcare industry.

On October 29, 2019, we closed our underwritten public offering of 29,900,000 shares of our common stock at a price to the public of $2.75 per share, inclusive of the underwriters' option to purchase additional shares of common stock, which option was exercised in full. We received net proceeds from the offering of approximately $77.0 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

On April 24, 2019, we entered into the Financing Agreement with the Administrative Agent, various lenders from time to time party thereto, and certain of the Company's subsidiaries party thereto from time to time as guarantors, which provided us with a $300,000,000 first lien secured term loan credit facility, or the Facility. The Facility provides for availability to us in three tranches: (i) $200,000,000 was drawn upon entering into the Financing Agreement; (ii) $50,000,000 will be available to us upon the designation of ANNOVERA as a new category of birth control by the FDA on or prior to December 31, 2019 and satisfaction (or waiver) of other customary conditions precedent; and (iii) $50,000,000 will be available to us upon our achieving $11,000,000 in net revenues from our IMVEXXY, BIJUVA and ANNOVERA products for the fourth quarter of 2019 and satisfaction (or waiver) of other customary conditions precedent. A portion of the initial tranche of borrowing under the Facility in the amount of approximately $81,661,000 was used to repay all amounts outstanding under our prior financing agreement with MidCap Financial Trust, or the MidCap Agreement. As a result of the termination of the MidCap Agreement, we recorded $10,057,632 in loss on extinguishment of debt in our unaudited consolidated financial statements. We believe that our existing cash and availability under the Facility 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, or ANNOVERA is delayed, our existing cash and availability under the Facility, if we are able to access such funds, 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 Facility. 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 sell debt securities or obtain additional debt financing is restricted pursuant to the Financing Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, to the extent permitted under the Financing 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 Financing Agreement, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products, if permitted under the Financing Agreement. Additionally, we may have to grant licenses on terms that may not be favorable to us.

License Agreement with Theramex

On June 6, 2019, we entered into an exclusive license and supply agreement, or the License Agreement, with Theramex, a leading, global specialty pharmaceutical company dedicated to women's health, to commercialize BIJUVA and IMVEXXY outside of the U.S., excluding Canada and Israel, or the Territory. Under the terms of the License Agreement, Theramex paid us EUR 14 million in cash as an upfront fee on August 5, 2019. Within thirty days of signing the License Agreement, we provided Theramex the regulatory materials and clinical data that were necessary for Theramex to obtain marketing authorizations and other applicable regulatory approvals for commercializing BIJUVA and IMVEXXY. We recognized the revenue related to the upfront fee, which was a non-refundable payment, during the third quarter of 2019, at a point in time when Theramex was able to use and benefit from the license which was when the knowledge transfer of regulatory documents occurred. We are eligible to receive additional milestone payments comprised of (i) up to an aggregate of EUR 2 million in regulatory milestone payments based on regulatory approvals for BIJUVA and IMVEXXY in certain specified markets and (ii) up to an aggregate of EUR 27.5 million in sales milestone payments to be paid in escalating tranches based on Theramex first attaining certain aggregate annual net sales milestones of BIJUVA and IMVEXXY in the Territory ranging from EUR 25 million to EUR 100 million. We are also entitled to receive quarterly royalty payments on net sales of BIJUVA and IMVEXXY in the Territory. Theramex will be responsible for all regulatory and commercial activities for BIJUVA and IMVEXXY in the Territory. Theramex may sublicense its rights to commercialize BIJUVA and IMVEXXY in the Territory, except for certain specified markets. We may terminate the License Agreement if Theramex does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize BIJUVA and IMVEXXY within certain specified time periods. We also may terminate the License Agreement if Theramex challenges our patents. Either party may terminate the 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.

We need substantial amounts of cash to complete the launch and commercialization of our hormone therapy and contraceptive drugs. 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,	
	2019	2018
	(000s)	
Net cash used in operating activities	$ (114,900)	$ (78,667)
Net cash used in investing activities	$ (3,178)	$ (20,827)
Net cash provided by financing activities	$ 111,796	$ 162,357

Operating Activities

The principal use of cash in operating activities for the nine months ended September 30, 2019 was to fund our current expenses primarily related to supporting commercialization activities for IMVEXXY, BIJUVA, and ANNOVERA, sales, marketing, scale-up and manufacturing activities and clinical development, adjusted for non-cash items. The increase of approximately $36,233,000 in cash used in operating activities for the nine months ended September 30, 2019 compared with the comparable period in the prior year was due primarily to an increase in our net loss and changes in the components of working capital, partially offset by an increase in non-cash items.

Investing Activities

Investing activities for the nine months ended September 30, 2019 decreased primarily due to a $20,000,000 payment for an intellectual property license fee that occurred during the nine months ended September 30, 2018, partially offset by higher spending related to patent, trademark and fixed asset costs during the nine months ended September 30, 2019.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the nine months ended September 30, 2019 provided net cash of approximately $111,796,000 which consisted of the net funding from our Facility of approximately $193,348,000 and exercise of options and warrants to purchase Common Stock of approximately $109,000, partially offset by the repayment of our Credit Agreement of approximately $81,661,000. Our financing activities for the nine months ended September 30, 2018 provided net cash of approximately $162,357,000, which consisted of the net funding from our Credit Agreement of approximately $71,213,000 and the exercise of options to purchase Common Stock of approximately $1,236,000 and approximately $89,908,000 in proceeds from the sale of our Common Stock.

New Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, 2018-13 which 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 ASC 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, the 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 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 adopted this standard on January 1, 2019 and the adoption of this standard did not have a material effect on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires lessees to record most leases on their balance sheets while recognizing 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. In July 2018, the FASB amended the new leases standard and issued ASU 2018-11, Leases, (Topic 842): Targeted Improvements to give entities another option for transition and to provide lessors with a practical expedient. We adopted ASU 2016-02 on January 1, 2019 utilizing the alternative transition method allowed for under ASU 2018-11 and we recorded a $3.8 million right of use asset and a $4.1 million liability related to adoption of this standard. In addition, upon commencement of additional lease space in the third quarter of 2019, we recorded an additional $7.4 million right of use asset and an additional $7.2 million liability related to our new lease space. Comparative financial information was not adjusted and will continue to be reported under ASC 840. We also elected the transition relief package of practical expedients and as a result we did not assess (1) whether existing or expired contracts contain leases, (2) lease classification for any existing or expired leases, and (3) whether lease origination costs qualified as initial direct costs. We elected the short-term lease practical expedient by establishing an accounting policy to exclude leases with a term of 12 months or less. We elected not to separate lease components from non-lease components for our specified asset classes. Additionally, the adoption of the new standard resulted in increased disclosure requirements in our quarterly and annual filings.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC did not, and are not expected to, have a material effect on our results of operations or financial position.

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.

As of April 24, 2019, we repaid all amounts outstanding under the MidCap Agreement and became subject to market risk in connection with borrowings under the Financing Agreement. Amounts borrowed under the Financing Agreement will accrue interest at either (i) 3-month LIBOR plus 7.75%, subject to a LIBOR floor of 2.70% or (ii) the prime rate plus 6.75%, subject to a prime rate floor of 5.20%. Considering the total outstanding principal balance under the Financing Agreement of approximately $200,000,000 at September 30, 2019, a 1.0% change in interest rates would result in an impact to income before income taxes of approximately $2,000,000 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 management, including 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, 2019, 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

In August 2019, without admitting or denying the findings, we consented to an order issued by the Securities and Exchange Commission charging us with violations of Regulation FD in connection with communications during 2017 regarding TX-004HR and agreed to pay a $200,000 penalty.

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

There have been no material changes to the risk factors previously disclosed in our Annual Report.

Item 6. Exhibits

Exhibit	Date	Description
10.1*+	September 28, 2018	Commercial Supply Agreement by and between TherapeuticsMD, Inc. and QPharma AB.
10.2*+	October 5, 2018	Lease by and between 951 Yamato Acquisition Company, LLC and TherapeuticsMD, Inc.
31.1*	November 8, 2019	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	November 8, 2019	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1**	November 8, 2019	Section 1350 Certification of Chief Executive Officer
32.2**	November 8, 2019	Section 1350 Certification of Chief Financial Officer
101.INS*	n/a	XBRL Instance Document – the instance document does not appear in the Interactive Data file because its XBRL tags are embedded within the Inline XBRL 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
104*	n/a	Cover Page Interactive Data File (formatted as Inline XBRL and Contained in Exhibit 101)

* Filed herewith.
** Furnished herewith.
\+ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.

SIGNATURES

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

DATE: November 8, 2019

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

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement (the "**Agreement**") is made as of the 28th day of September, 2018, by and between TherapeuticsMD, Inc., a Nevada corporation, with a place of business at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487 ("**TXMD**"), and QPharma AB, a Sweden corporation, having a place of business at Agneslundsvagen 27, Malmo, Sweden ("**QPharma**").

Each of QPharma and TXMD is sometimes referred to herein as a "Party" and collectively as the "Parties".

RECITALS

A. TXMD is a company that develops, markets and sells pharmaceutical products;

B. QPharma is a developer and contract manufacturer of a variety of pharmaceutical products and medical devices including, but not limited to, intra-vaginal devices eluting pharmaceutical substances;

C. TXMD is the exclusive licensee of the Population Council to commercialize in the United States a certain intra-vaginal ring system eluting segesterone acetate and ethinyl estradiol;

D. QPharma is a qualified manufacturer of such intra-vaginal ring systems; and

E. TXMD desires to engage QPharma to manufacture and supply quantities of such intra-vaginal ring systems, and QPharma desires to manufacture and supply such quantities of intra-vaginal ring systems, all pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

The following terms have the following meanings in this Agreement:

1.1 "**Acknowledgement**" has the meaning set forth in Section 4.3.

1.2 "**Affiliate(s)**" means, with respect to a referenced party, whether TXMD, QPharma or a third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such referenced party. For the purposes of this definition, "**control**" means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest or possession of the right to control the management and policies of such entity.

1.3 "**Agreement**" has the meaning set forth in the introductory paragraph, and includes all its Attachments and other appendices agreed to by the parties (all of which are incorporated herein by reference) and any amendments to any of the foregoing made as provided herein or therein.

1.4 "**API(s)**" means the compounds segesterone acetate and ethinyl estradiol, as further described in the Specifications that either (i) have been procured and released by TXMD and provided to QPharma or (ii) have been procured and released by QPharma, in either case along with a certificate of analysis from the manufacturer of such compounds, as provided in this Agreement.

1.5 "**Applicable Laws**" means, with respect to TXMD, all laws, ordinances, rules and regulations of each jurisdiction in which an API or Product is produced, marketed, distributed, used or sold; and with respect to QPharma, all laws, treaties, or ordinances, rules, regulations, cGMP, guidances, interpretations, authorizations, judgments, directives, injunctions, or orders of any court of any international, national, regional, local, or other governmental body, agency, authority, or court, or arbitrator, that has jurisdiction over the location where QPharma performs services, handles or stores an API, Raw Materials or Product, and manufactures Product under this Agreement (and applicable cGMP), including, but not limited to, the Federal Food, Drug and Cosmetic Act and Good Laboratory Practices, in each of the foregoing cases as in effect from time-to-time.

1.6 "**Batch**" means a defined quantity of Product that has been or is being Processed in accordance with the Specifications in a single production run. At the date of this Agreement, the theoretical size of a commercial validated Batch is approximately [***] units of Product.

1.7 "**Components**" means the silicon ring system and other tangible elements incorporated into or packaged with the Product, but for the avoidance of doubt, excluding APIs.

1.8 "**cGMP**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to TXMD and QPharma, respectively). In the United States, this includes 21 C.F.R. Parts 210, 211 and 820, as amended from time-to-time, together with pertinent guidelines and guidance documents, and in the European Union, to the extent applicable to the manufacture, handling and storage of the Product in Sweden for shipment to, and sale in, the United States, 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD)(1990) and Council Directive 93/42/EEC on Medical Devices (MDD) (1993), as amended, supplemented and superseded from time-to-time, together with pertinent guidelines and guidance documents then in effect.

1.9 "**Commencement Date**" means the first day of the Initial Pricing Term as established pursuant to Section 7.1, provided such date follows approval by a Regulatory Authority of QPharma as a manufacturer of the Product.

1.10 "**Confidential Information**" has the meaning set forth in Section 10.1.

1.11 "**Contract Year**" means each consecutive twelve (12) month period beginning on the Commencement Date or anniversary thereof, as applicable.

1.12 "**Defective Product**" has the meaning set forth in Section 5.2.

1.13 "**Discloser**" has the meaning set forth in Section 10.1.

1.14 "**Effective Date**" means July 26, 2018, [***].

1.15 "**Exception Notice**" has the meaning set forth in Section 5.2.

1.16 "**Facility**" means QPharma's facility located in Malmo, Sweden, or such other facility as agreed by the parties in writing.

1.17 "**Initial Pricing Term**" has the meaning set forth in Section 7.1.

1.18 "**Initial Term**" means the period of time commencing as of July 26, 2018, and ending on July 26, 2024.

1.19 "**Index**" has the meaning set forth in Section 7.2.

1.20 "**Losses**" has the meaning set forth in Section 13.1.

1.21 "**Marks**" means trademarks, trade names, service marks, logos and symbols.

1.22 "**Process**" or "**Processing**" means the compounding, filling, manufacturing, producing, testing and packaging of APIs, TXMD-supplied Materials, if any, and Raw Materials into Product by QPharma, and their handling, storage and delivery in accordance with the Specifications and under the terms of this Agreement.

1.23 "**Processing Date**" means the day on which the first step of physical Processing is scheduled to occur, as identified in an Acknowledgement.

1.24 "**Process Know-How**" means all know-how provided by or on behalf of TXMD to QPharma and know-how to the extent it relates to the processing, manufacture, quality control, formulation, filling, finishing, testing and packaging of a Product, whether in bulk or final form, and regardless of container, including, without limitation, analytical tests methods for in-process and final Product, copies of manufacturing records, formulation recipes, designs and drawings, and formulae, used in the Processing for a Product to the extent it is in the possession, or under the control, of QPharma, its Affiliates and their respective subcontractors. For the avoidance of doubt, such Process Know-How includes the Know-How TXMD obtained from The Population Council by operation of TXMD's acquisition of the Product's New Drug Application under the License Agreement with The Population Council dated August 1, 2018.

1.25 "**Process Know-How Transfer**" means the commercially reasonable efforts of the parties undertaken pursuant to the Process Know-How Transfer Plan to transfer copies of all Process Know-How (together with relevant books and records) and the "Standards" (defined below) in QPharma's possession or under its control, to TXMD as set forth in greater detail in the Process Know-How Transfer Plan. As used herein "Standards" means data, information, or samples of validated or QPharma manufactured or partially manufactured Product or other indicia measured at various points during Processing, to the extent QPharma possesses such data, information, or samples.

1.26 "**Process Know-How Transfer Plan**" means that plan addressing orderly Process Know-How Transfer, to be prepared in writing and reasonably agreed to by the parties within the sixty (60) day period following notice from TXMD to QPharma of its intention to commence Process Know-How Transfer.

1.27 "**Product**" means a silicon-based removable intra-vaginal ring system eluting segesterone acetate and ethinyl estradiol meeting the Specifications.

1.28 "**Product Maintenance Services**" has the meaning set forth in Section 2.2.

1.29 "**Purchase Order**" has the meaning set forth in Section 4.3.

1.30 "**QPharma**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign. QPharma shall have the right to cause any of its Affiliates, upon prior written notice to and approval from TXMD, to perform any of its obligations hereunder, and TXMD upon its prior approval of the use of such an Affiliate, shall accept such performance as if it were performance by QPharma, but QPharma shall remain jointly and severally liable for the performance by any of its Affiliates under this Agreement.

1.31 "**QPharma Defective Processing**" has the meaning set forth in Section 5.2.

1.32 "**QPharma Indemnitees**" has the meaning set forth in Section 13.2.

1.33 **"Qualified Person (QP)"** means a company employee that fulfils the requirements as described in European Directive 2001/83(2)/EC. These requirements include personal qualities of integrity, maturity, open-mindedness, assertiveness, sound analytical skills and judgment as well as a level of education, combined with practical work experience within pharmaceutical development, manufacture, or Quality Assurance. The regulations specify that no batch of medicinal product can be released for sale or supply prior to certification by a QP that the batch is in accordance with the relevant requirements.

1.34 "**Quality Agreement**" has the meaning set forth in Section 9.7.

1.35 "**Raw Material(s)**" means any and all raw materials, supplies, Components and packaging necessary to manufacture and ship Product in accordance with the Specifications, but excluding the APIs and TXMD-supplied Materials, if any.

1.36 "**Recall**" has the meaning set forth in Section 9.5.

1.37 "**Recipient**" has the meaning set forth in Section 10.1.

1.38 "**Regulatory Approval**" means any approvals, permits, product and/or establishment licenses, registrations or authorizations, including approvals pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications, as applicable, of any Regulatory Authorities that are necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of APIs or Product in the Territory.

1.39 "**Regulatory Authority**" means the international, federal, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities in the Territory that are responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use including, but not limited to, their manufacture, handling and storage, or (B) health, safety or environmental matters generally. In the United States, this includes the United States Food and Drug Administration.

1.40 "**Representatives**" of an entity mean such entity's duly-authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.41 "**Review Period**" has the meaning set forth in Section 5.2.

1.42 "**Risk Mitigation Plan**" has the meaning set forth in Section 16.5(B).

1.43 "**Specifications**" means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment A, as modified from time to time in accordance with Article 8.

1.44 "**Term**" has the meaning set forth in Section 16.1.

1.45 "**Term Sheet**" means that certain Binding Pricing Term Sheet for Supply of Product entered into on [***], between TherapeuticsMD and QPharma.

1.46 "**Territory**" means the United States of America, its territories, insular possessions and commonwealths.

1.47 "**TXMD**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.48 "**TXMD Equipment**" means the equipment listed on Attachment B, together with all diagrams, schematics, operator's manuals, operating software and warranties.

1.49 "**TXMD Indemnitees**" has the meaning set forth in Section 13.1.

1.50 "**TXMD IP**" has the meaning set forth in the Development Agreement.

1.51 "**TXMD-supplied Materials**" means materials to be supplied by or on behalf of TXMD to QPharma, other than APIs, for Processing, if any.

1.52 "**Unit Pricing**" has the meaning set forth in Section 7.1(A).

1.53 "**Validation Plan**" has the meaning set forth in Section 7.7.

1.54 "**Vendor**" has the meaning set forth in Section 3.1(B).

ARTICLE 2
PROCESSING & RELATED SERVICES

2 . 1 Supply and Purchase of Product. QPharma shall Process Product and deliver the same to TXMD, its Affiliates and licensees in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2 . 2 Product Maintenance Services. TXMD will receive the following product maintenance services (the "**Product Maintenance Services**"): one annual audit (as further described in Section 9.5); regulatory audits (as further described in Section 9.4); one annual Product review (within the meaning of 21 CFR § 211.180); access to document library over and above the Quality Agreement, including additional copies of Batch paperwork or other Batch documentation; assistance in preparing Regulatory Approvals; Product document and sample storage relating to cGMP requirements; vendor re-qualification; and maintenance, updates and storage of master batch records and audit reports. For avoidance of doubt, the following services and items are not included in Product Maintenance Services: technology transfer; analytical work; stability; and process rework.

2 . 3 Other Related Services. QPharma shall provide such Product-related services, other than Processing or Product Maintenance Services, as agreed to in writing by the parties from time to time. Such writing shall include the scope and fees for any such services and be appended to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services.

2.4 Validation Services. QPharma operates a validated Process for the production of the Product, and will continue to do so.

ARTICLE 3
API, MATERIALS & EQUIPMENT

3.1 The APIs and Raw Materials.

A. TXMD shall be responsible for establishing a source of supply of the APIs. TXMD, at its option, shall enable QPharma to place orders for the API's from such source of supply. QPharma shall be responsible for inspecting and releasing adequate quantities of the APIs and Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed to by the parties in writing. QPharma shall not be liable for any delay in delivery of Product if (i) TXMD is unable to obtain, in a timely manner, a particular API or (ii) QPharma is unable to obtain, in a timely manner, a particular API through its placement of orders therefor from TXMD's source of supply or Raw Material necessary for Processing and (iii) QPharma placed orders for such API or Raw Material promptly following receipt of TXMD's Firm Commitment. In the event that any API or Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the parties will negotiate in good faith an appropriate amendment to this Agreement. TXMD shall reimburse to QPharma its cost for the APIs. QPharma shall provide a credit to TXMD in the amount of any credit received by QPharma from an API supplier resulting from a pricing agreement with such supplier, with such credits to be applied to the next invoice issued thereafter to TXMD and successive invoices until fully expended. In order to facilitate the ordering and delivery of initial supplies of APIs to QPharma, TXMD, in consultation with QPharma, may purchase supplies of APIs for delivery to QPharma. Further, in order to facilitate the timely manufacture of Product for the Firm Commitment, QPharma shall maintain a safety stock of APIs and Raw Materials. Such safety stock shall be in an amount mutually agreed to by the Parties. TXMD shall be responsible for payment of the purchase price of any such APIs so ordered by it for delivery to QPharma.

B. In certain instances, TXMD may require a specific supplier, manufacturer or vendor ("**Vendor**") to be used for a Raw Material. In such an event occurring after the date of this Agreement, such Vendor will be identified in the Specifications. If the cost of such Raw Material from any such Vendor is greater than QPharma's costs for the same Raw Material of equal quality from other vendors, QPharma shall add the difference between QPharma's cost of such Raw Material and the Vendor's cost of the Raw Material to the Unit Pricing. TXMD will be responsible for all costs associated with qualification of any Vendor specifically required to be used upon written instruction from TXMD, which Vendor has not been previously qualified by QPharma.

C. In the event of (i) a Specification change for any reason, (ii) obsolescence of any API or Raw Material or (iii) termination or expiration of this Agreement, TXMD shall bear the cost of any unused API or Raw Materials (including packaging), so long as QPharma purchased such API and Raw Materials in quantities consistent with TXMD's most recent Firm Commitment and the vendor's minimum purchase obligations. Such APIs and Raw Material shall be the property of TXMD upon payment therefor.

3.2 Supply of Materials.

A. TXMD shall supply to QPharma for Processing, at TXMD's cost, all TXMD-supplied Materials set forth on Attachment C, if any, in quantities sufficient to meet TXMD's requirements for Product. TXMD shall deliver such items and associated certificates of analysis to the Facility no later than [***] ([***]) days before the Processing Date. TXMD's failure to fulfill the foregoing obligations in this Section 3.2 shall not by itself give rise to a cause of action in QPharma or a right by it to terminate this Agreement. However, QPharma shall not be held liable for a delayed Processing Date related to TXMD's own delay in delivering TXMD supplied Materials and associated certificates to the Facility. TXMD shall be responsible at its expense for securing any necessary DEA, export or import, similar clearances, permits or certifications required in respect of such supply. QPharma shall use such items solely for Processing. Prior to delivery of any such items, TXMD shall provide to QPharma a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any Regulatory certifications or authorizations that may be required under Applicable Laws with respect thereto, and shall promptly provide any updates thereto.

B. Following receipt of TXMD-supplied Materials, QPharma shall inspect, test and release such items employing such measures as are set forth in the Specifications. QPharma will receive, handle, store and use all TXMD-supplied Materials in compliance with all Applicable Laws and labeled storage requirements, or lacking labeled storage requirement, the written instructions of TXMD, as agreed to by QPharma, such agreement not to be unreasonably withheld. In the event that QPharma detects a nonconformity with Specifications, QPharma shall give TXMD prompt notice of such nonconformity. QPharma shall not be liable for any defects in TXMD-supplied Materials, or in Product resulting from defective TXMD-supplied Materials, unless QPharma failed to properly perform the foregoing obligations. QPharma shall follow TXMD's reasonable written instructions in respect of return or disposal of defective TXMD-supplied Materials, at TXMD's cost.

C. TXMD shall retain title to TXMD-supplied Materials at all times and shall bear the risk of loss thereof, except for losses to the extent due to the negligent acts or omissions of QPharma or QPharma's failure to follow storage and handling requirements or mutually agreed to written instructions of TXMD, in each case, subject to Article 14.

3.3 Artwork and Labeling. TXMD shall provide or approve, prior to the procurement of applicable Raw Materials, all artwork, advertising and labeling information necessary for Processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of TXMD, and TXMD shall be solely responsible for the content thereof. Hence, TXMD will be responsible for the artwork and labelling information communicated to QPharma for Processing and ensure itself that the latter comply with provided text and relevant applicable laws and regulations prevailing in the Territory. Such artwork, advertising and labeling information or any reproduction thereof may not be used by QPharma in any manner other than performing its obligations hereunder.

3.4 TXMD Equipment. QPharma hereby acknowledges that the TXMD Equipment is the sole and exclusive property of TXMD, and is in the possession of QPharma. During the Term, except as set forth below, QPharma shall be entitled to use the TXMD Equipment in the performance of its obligations to TXMD pursuant to this Agreement. QPharma (i) shall mark the TXMD Equipment so as to identify it as the property of TXMD, (ii) shall safeguard the TXMD Equipment with the same degree of care as it uses in connection with the safeguarding of its own equipment and (iii) shall be responsible for the proper operation, maintenance and repair of the TXMD Equipment. QPharma shall not sell, lease or lend the TXMD Equipment to any third party or relinquish possession or control of the TXMD Equipment. QPharma shall not move the TXMD Equipment from its current location without the advance written consent of TXMD. QPharma shall not grant a security interest in, use as collateral or otherwise encumber the TXMD Equipment in any way, or suffer the placement of a lien or other security device upon the TXMD Equipment. Upon request of TXMD, whether at the expiration of the Term or prior thereto, QPharma shall promptly make the TXMD Equipment ready for removal by TXMD or its designees, and shall grant access to TXMD and its designees to QPharma facilities for the purpose of such removal. During the Term, in the event, and to the extent, there exists capacity in the use of the TXMD Equipment in excess of its use to fulfill purchase orders of TXMD, QPharma may use the TXMD Equipment for its intended purpose in the performance of its manufacturing obligations for The Population Council, Inc. or its designee.

3.5 Additional Manufacturing Line. In order to plan for and meet potential demand for the Product in excess of QPharma's current capacity, the Parties will prepare and reasonably agree to a manufacturing capacity expansion plan within ninety (90) days of the date of this Agreement, such plan to address the actions to be taken, the equipment to be purchased and installed, and financial responsibility therefor, along with a timeline, headcount plan, budget and assignment of responsibilities in the implementation of a second manufacturing line and other capacity improvements, all as set forth in such plan. For the avoidance of doubt, the Additional Manufacturing Line will also be comprised of TXMD Equipment.

ARTICLE 4
PURCHASE ORDERS & RELATED MATTERS

4.1 Purchase Order Requirement. No purchase order shall be submitted for less than [***] commercial validated [***]. Purchase orders reflecting purchases in excess of [***] shall be submitted only in [***] Batch multiples.

4.2 Guidance. TXMD shall keep QPharma generally informed of its anticipated need for Product, including anticipated launch quantities, through delivery of a summary report every [***] ([***]) months. The parties shall cooperate in an effort to provide for an orderly process of purchase order submissions and deliveries of Product.

4.3 Purchase Orders.

A. As provided in this Section 4.3(A), TXMD shall submit to QPharma a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch ("**Purchase Order**").

B. Promptly following receipt of a Purchase Order, QPharma shall issue a written acknowledgement ("**Acknowledgement**") that it accepts or rejects such Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date, and shall include the Processing Date. QPharma may reject any Purchase Order not given in accordance with this Agreement; provided, however, QPharma shall accept any Purchase Order that meets the requirements of this Agreement.

C. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control. No Purchase Order, confirmation, shipping document, receipt or similar document shall amend any term set forth in this Agreement or set forth any term inconsistent with the terms and conditions contained in this Agreement.

4.4 QPharma's Cancellation of Purchase Orders. Notwithstanding Section 4.5, QPharma reserves the right to cancel all, or any part of, a Purchase Order upon written notice to TXMD, and QPharma shall have no further obligations or liability with respect to such Purchase Order, if TXMD refuses or fails to timely supply conforming TXMD-supplied Materials in accordance with Section 3.2. Any such cancellation of Purchase Orders shall not constitute a breach of this Agreement by QPharma. QPharma shall use reasonable efforts to re-schedule Processing reflected on such Purchase Order promptly after conforming TXMD-supplied Materials are delivered to QPharma.

4.5 TXMD's Modification or Cancellation of Purchase Orders. TXMD may modify the delivery date or quantity of Product in a Purchase Order only by submitting a written change order to QPharma at least [***] ([***]) days in advance of the earliest Processing Date covered by such change order. Such change order shall be effective and binding against QPharma only upon the written approval of QPharma. QPharma shall endeavor in good faith to mitigate the costs of such change order, but TXMD shall be responsible to QPharma for unavoidable costs, including those resulting from non-cancellable contracts entered into by QPharma in good faith.

4.6 Unplanned Delay or Elimination of Processing. QPharma shall use commercially reasonable efforts to meet the Purchase Orders, subject to the terms and conditions of this Agreement. QPharma shall provide TXMD with as much advance notice as practicable if QPharma determines that any Processing will be delayed or eliminated for any reason.

4.7 Observation of Processing. In addition to TXMD's audit right pursuant to Section 9.5, TXMD may send up to [***] ([***]) Representatives to the Facility to observe Processing. Provided that QPharma has given TXMD adequate notice of commencement of Processing, TXMD shall give QPharma written notice of its intention to observe processing at least [***] ([***]) days prior to the date of its visit. The foregoing limitations shall not apply to time spent by TXMD Representatives on site at the Facility to participate in or witness research and development activities or to witness Processing of validation Batches of Product. Such Representatives shall abide by all QPharma safety rules and other applicable employee policies and procedures, and TXMD shall be responsible for such compliance. TXMD shall indemnify and hold harmless QPharma for any action, omission or other activity of such Representatives while on QPharma's premises. TXMD's Representatives who are not employees of TXMD shall be required to sign QPharma's standard visitor confidentiality agreement prior to being allowed access to the Facility. QPharma shall not be required to accommodate any observation request or activity that would violate GMP or Swedish law. TXMD acknowledges that space constraints at QPharma's facilities also may limit its ability to observe.

ARTICLE 5
TESTING; RELEASE

5.1 Batch Release. After QPharma completes Processing of a Batch, QPharma shall also provide TXMD or its designee with QPharma's certificate of analysis, certificate of compliance and Qualified Person release for such Batch. Issuance of a certificate of analysis, executed batch records and a certificate of compliance by QPharma constitutes release of the Batch by QPharma to TXMD. TXMD shall be responsible for final release of Product to the market.

5.2 Testing; Rejection. No later than [***] days after receipt of the Batch ("**Review Period**"), TXMD or its designee shall notify QPharma whether the Batch conforms to Specifications. Upon receipt of notice from TXMD that a Batch meets Specifications, or upon failure of TXMD to respond by the end of the Review Period, the Batch shall be deemed accepted by TXMD and TXMD shall have no right to reject such Batch other than for defects which existed at the time of delivery and were not discovered or discoverable in the exercise of reasonable care ("**Latent Defects**"). For the avoidance of doubt, (i) Batches failing to meet Specifications at the time of delivery due to Latent Defects may be rejected, if at all, only upon notice to QPharma within [***] ([***]) days following the date on which such Latent Defect was discovered or should have been discovered in the exercise of reasonable care and (ii) in no event may TXMD reject Product after such Product's expiration date. If TXMD or its designee timely notifies QPharma in writing (an "**Exception Notice**") that a Batch does not conform to the Specifications or otherwise does not meet the warranty set forth in Section 12.1(A), whether due to a Latent Defect or otherwise ("**Defective Product**"), and provides a sample of the alleged Defective Product, QPharma shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with TXMD that Product is Defective Product and to determine the cause of any nonconformity. If QPharma agrees that Product is Defective Product and determines that the cause of nonconformity is attributable to QPharma's failure to perform the Processing in accordance with the Specifications ("**QPharma Defective Processing**"), then Section 5.4 shall apply. For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned, it shall be deemed not QPharma Defective Processing. For the avoidance of doubt, the Processing of any Batch that does not proceed to completion or any Batch that does not pass release testing by QPharma shall be treated as Defective Product resulting from QPharma Defective Processing. In such case, the remedies set forth in Section 5.4 shall apply.

5 . 3 Discrepant Results. If the parties disagree as to whether Product is Defective Product and/or whether the cause of the nonconformity is QPharma Defective Processing, and this is not resolved within [***] days of the Exception Notice date, the parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including TXMD-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed to by the parties in writing, the costs associated with such testing and review shall be borne by QPharma if Product is Defective Product attributable to QPharma Defective Processing, and by TXMD in all other circumstances. TXMD will be apprised in writing of all Defective Product investigations executed by QPharma on TXMD's materials/products, including Product and TXMD-supplied Materials, as well as final investigation outcome and conclusion(s).

5 . 4 Defective Processing. QPharma shall, at TXMD's option, either (A) replace at its cost another Batch of Product (as a replacement for any Batch of Defective Product attributable to QPharma Defective Processing) using TXMD-supplied Materials provided at QPharma's cost, if any such items are required or (B) credit any payments made by TXMD for such Batch. THE OBLIGATION OF QPHARMA TO REPLACE QPHARMA DEFECTIVE PROCESSING IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT PAYMENTS MADE BY TXMD FOR DEFECTIVE PRODUCT ATTRIBUTABLE TO QPHARMA DEFECTIVE PROCESSING SHALL BE TXMD'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT (APART FROM RECALL COSTS SET FORTH IN SECTION 9.6, AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED).

ARTICLE 6
DELIVERY

6.1 Delivery. QPharma shall deliver Product ExWorks (Incoterms 2010) at the Facility promptly following TXMD's approval and notification to QPharma's to release the Product; provided, however, QPharma shall be responsible for loading the Product on the carrier's vehicle using due care. QPharma shall segregate and store all Product until tender of delivery. Title to Product shall transfer to TXMD upon such delivery. TXMD shall qualify at least [***] ([***]) carriers to ship Product and then designate the priority of such qualified carriers to QPharma.

6 . 2 Storage. Any items temporarily stored at QPharma shall be stored in compliance with requirements set forth in the Specification, or if no such storage Specification exists for such item, QPharma shall store such items using due care taking into account the identity of such item.

6.3 Subcontracting. QPharma may utilize third parties to provide any part of the Processing only with the prior written approval of TXMD, provided that the foregoing will not apply to generally available goods and services or to subcontracting to QPharma Affiliates. If TXMD approves a subcontractor, then QPharma shall enter a written agreement with such subcontractor that enables QPharma to comply with its obligations under this Agreement and places such subcontractors under obligations of confidentiality, non-use and intellectual property ownership no less burdensome than those set forth herein and applicable to QPharma. QPharma will oversee all services performed by any subcontractor, and will be responsible for such services as if such services were performed by QPharma. QPharma shall remain liable for the performance of its subcontractors under this Agreement. The use of subcontractors shall not relieve QPharma of any responsibility under this Agreement.

ARTICLE 7
PAYMENTS

7.1 Fees. In consideration for QPharma performing services hereunder:

A. TXMD shall pay QPharma the unit pricing for Product set forth on Attachment D ("**Unit Pricing**"), which shall be in effect for the period ending on (i) the third anniversary of delivery by QPharma of the first commercial Batch of Product to or for TXMD; provided launch occurs on or before [***], or (ii) [***], if there is no such launch on or before [***] (the "**Initial Pricing Term**"). QPharma shall sell and deliver Product in final dosage form, packaged for end user use. QPharma shall submit an invoice to TXMD for such fees upon tender of delivery of Product as provided in Section 6.1.

B . Other Fees. TXMD shall pay QPharma for all other fees and expenses of QPharma owing in accordance with the terms of this Agreement, including pursuant to Sections 2.3 and 4.1. QPharma shall submit an invoice to TXMD for such fees as and when appropriate.

7 . 2 Unit Pricing Increase. After the Initial Pricing Period, the Unit Pricing may be adjusted on an annual basis, effective on each July 1st (with the first possible price adjustment to be effective on July 1, 2021), upon [***] days' prior written notice from QPharma to TXMD, to reflect increases in labor, utilities and overhead and shall be in an amount equal to the change in the Producer Price Index (the "**Index**"), "Pharmaceutical Preparation Manufacturing" (Series ID: PCU325412325412), not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Labor Statistics. The initial base period for comparison shall be the twelve (12) month period ending on June 30 immediately preceding the expiration of the Initial Pricing Period. For the avoidance of doubt, if launch of the Product occurs on or after [***], but before [***], QPharma shall be entitled to adjust Unit Pricing for the Initial Pricing Period based upon the difference in the Index on [***] and on [***], but not to exceed [***] percent ([***]%). For the further avoidance of doubt, Unit Pricing Increases after the Initial Pricing Period shall not exceed [***] percent ([***]%) in the aggregate for the Index. In addition, price increases (or decreases) for APIs and Raw Materials shall be passed through at cost to TXMD and not included in the Index-based price adjustment described above.

7.3 Payment Terms. All QPharma invoices shall be due [***] ([***]) days after the date of receipt of invoice. No invoice shall be issued to TXMD for Processing until the Batch so Processed has been released pursuant to Section 5.1; provided, however, with respect to purchase orders for the initial [***] ([***]) Batches ordered by TXMD pursuant to this Agreement (the "**Initial Batches**"), QPharma shall be entitled to issue invoices to TXMD upon receipt of such purchase orders in a non-refundable pre-paid amount equal to [***] percent ([***]%) of the price of each such purchase order. Purchase orders for the Initial Batches shall be placed only for even numbers of Batches to be Processed. Under a given purchase order covering some or all of the Initial Batches, TXMD shall pay for all Batches released pursuant to Section 5.1, but shall first receive a credit in the amount of the pre-payment made pursuant to such purchase order. If more than [***] percent ([***]%) the Batches Processed pursuant to a given purchase order for the Initial Batches fail release pursuant to Section 5.1, QPharma nevertheless shall be entitled to retain the pre-payment made in respect of such purchase order. TXMD shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. If any payment is not received by QPharma by its due date, then QPharma may, in addition to any other remedies available at equity or in law, charge interest on the outstanding sum from the due date (both before and after any judgment) at [***]% per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws).

7.4 Advance Payment. Notwithstanding any other provision of this Agreement, if at any time TXMD is in arrears in paying amounts due under this Agreement, QPharma may require payment in advance before performing any further services or making any further shipment of Product. If TXMD shall fail, within a reasonable time, to make such payment in advance, or if TXMD shall fail to make any payment when due, QPharma shall have the right, at its option, to suspend any further performance hereunder until such default is corrected, without thereby releasing TXMD from its obligations under this Agreement.

7.5 Taxes. All taxes, duties and other amounts assessed (excluding tax based on net income and franchise taxes) on TXMD-supplied Materials, services or Product prior to or upon provision or sale to QPharma or TXMD, as the case may be, are the responsibility of TXMD, and TXMD shall reimburse QPharma for all such taxes, duties or other expenses paid by QPharma or such sums will be added to invoices directed at TXMD, where applicable.

7.6 TXMD and Third Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, TXMD shall be responsible for 100% of its own and all third-party expenses associated with the development, Regulatory Approvals and commercialization of Product, including regulatory filings and post-approval marketing studies. The preceding sentence shall not be construed in derogation of QPharma's obligations pursuant to Section 9.2 herein.

7.7 Capital Equipment; Process Development and Validation. QPharma shall develop and implement a plan for the acquisition and installation of certain required capital equipment, and for the validation of the manufacturing process for the Product at the facilities where it is to be Processed, pursuant to a written plan to be agreed to by the Parties within sixty (60) days following the Effective Date (the "**Validation Plan**"). The Validation Plan shall set forth the obligations of QPharma with regard to equipment procurement and installation, process and facility validation activities, and the headcount, the budget (on a not-to-exceed basis) and the timeline for the accomplishment of such activities. Validation costs and expenses, including stability testing, will not exceed $[***]. Capital equipment procurement and installation costs and expenses will not exceed $[***]. The elements of the foregoing costs and expenses shall be set forth in the Validation Plan.

7.8 Manufacturing and Cost Improvement. Promptly following execution and delivery of this Agreement, the parties shall confer, as advisable, to formulate and put in place a plan for continuous improvement in manufacturing after considering appropriate means by which to increase efficiency, yield and process improvement with a view toward lowing the Unit Pricing for Product.

ARTICLE 8
CHANGES TO SPECIFICATIONS

8.1 All Specifications and any changes thereto agreed to by the parties from time to time shall be in writing, dated and signed by the parties. No change in the Specifications shall be implemented by QPharma, whether requested by TXMD or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing). QPharma shall respond promptly to any request made by TXMD for a change in the Specifications, and both parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. As soon as possible after a request is made for any change in Specifications, QPharma shall notify TXMD of the costs associated with such change and shall provide such supporting documentation as TXMD may reasonably require. TXMD shall pay all costs associated with such agreed upon changes. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. QPharma reserves the right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the required written amendment.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. QPharma shall maintain complete and accurate Batch, laboratory data, reports and other technical records relating to Processing in accordance with QPharma standard operating procedures. Such information shall be maintained for a period of at least [***] ([***]) years from the relevant finished Product expiration date or longer if required under Applicable Laws or the Quality Agreement. QPharma will retain samples required by cGMP and such samples shall be stored at the Facility pursuant to QPharma's standard operating procedures. Prior to the destruction of any such Product specific items, QPharma shall notify TXMD of the impending destruction and provide TXMD a reasonable opportunity to receive any or all such items.

9.2 Regulatory Compliance. QPharma shall obtain and maintain, at its cost and expense, all permits and licenses with respect to general Facility operations required by any Regulatory Authority in the jurisdiction where QPharma Processes Product and by any Regulatory Authority in the Territory. QPharma acknowledges that the Product is a hormonal product and as such is subject to specialized regulations relating to its manufacture. QPharma's Facility presently complies with such regulations and QPharma shall maintain the Facility's compliance with such regulations. TXMD shall obtain and maintain, at its cost and expense, all other Regulatory Approvals, authorizations and certificates, including those necessary for QPharma to commence Processing for the Territory. Upon reasonable written request, TXMD shall provide QPharma with a copy of applicable Regulatory Approvals required to distribute, market and sell Product in the Territory. If TXMD is unable to provide such information, QPharma shall have no obligation to deliver Product to TXMD, notwithstanding anything to the contrary in this Agreement. During the Term, QPharma will assist TXMD with all regulatory matters relating to Processing and review the Common Technical Document pertaining to the Product and make such corrections as are necessary to accurately reflect the Product, in each case at TXMD's request and reasonable expense; provided, however, QPharma shall review and correct such documents as they relate to QPharma activities at no charge to TXMD. The parties intend and commit to cooperate to allow each party to satisfy its obligations under Applicable Laws relating to Processing under this Agreement.

9.3 Regulatory Communications.

A. Each party may communicate with any governmental agency, including, but not limited to, governmental agencies responsible for granting regulatory approval for the Products, regarding such Products if in the opinion of that party's counsel, such communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Law; provided, however, that unless in the reasonable opinion of its counsel there is a legal prohibition against doing so, such party will permit the other party to review and take part in any communications with the applicable agency, and to receive copies of all such communications from that agency.

B. QPharma will notify TXMD promptly if QPharma receives any warning letters from or on behalf of a governmental agency directly related to the Product or systems utilized in Processing the Product including, without limitation, any Form FDA-483. QPharma will provide TXMD copies of any written communication from a governmental agency relating to a TXMD Product within [***] ([***]) Swedish business days of its receipt.

C. QPharma will promptly notify TXMD upon receipt of a notice from a Regulatory Authority for an inspection of any Facility where the Processing is being performed due to an issue related to the Product or a system used in the performance of such services, or, in the event of an unannounced inspection, QPharma will provide such prior notice as is possible and permissible. If not prohibited by the Regulatory Authority, TXMD will have the right to be present at the Facility and participate in and any wrap-up meeting with such Regulatory Authority as it applies to the Product. If QPharma receives any request by a Regulatory Authority with respect to the Product, including, but not limited to, a notice of deficiency or FDA-483 that requires a written response regarding TXMD-supplied Materials, project, or protocol, QPharma will provide a copy to TXMD of the deficiency notice within [***] ([***]) [***] of QPharma's receipt of the notice. QPharma will provide TXMD a draft of the response prior to the response being submitted to the Regulatory Authority so as to provide TXMD with reasonable time to review and comment on the response, which comments QPharma, in good faith, will consider incorporating into the response.

9.4 Governmental Inspections and Requests. QPharma shall promptly advise TXMD if an authorized agent of any Regulatory Authority notifies QPharma that it intends to or does visit a Facility or any other site for the purpose of reviewing the Processing or testing. Upon request, QPharma shall provide TXMD with a copy of any report issued by such Regulatory Authority received by QPharma following such visit, redacted as appropriate to protect any confidential information of QPharma and QPharma's other customers. TXMD acknowledges that it may not direct the manner in which QPharma fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities, but such acknowledgement shall not be construed to vitiate QPharma's obligations to TXMD pursuant to this Agreement. TXMD will not be required to pay costs to mitigate any deficiencies cited in a Form 483 or QPharma's Facility deficiencies.

9.5 TXMD Facility Audits. During the Term, TXMD's Representatives shall be granted access upon at least [***] ([***]) business days' prior notice, at reasonable times during regular business hours, to (A) the portion of the Facility where QPharma performs Processing, (B) relevant personnel involved in Processing and (C) Processing records described in Section 9.2, in each case solely for the purpose of verifying that QPharma is Processing in accordance with cGMPs, Applicable Laws, the Specifications and the Product master Batch records. TXMD may not conduct an audit under this Section more than once during any [***]-month period; provided, that additional unlimited inspections may be conducted by or on behalf of TXMD as deemed appropriate by TXMD in the event there is a material quality or compliance issue concerning Product or its Processing or to measure remediation following an audit by either TXMD or a Regulatory Authority that resulted in a finding of deficiency. TXMD's Quality Assurance Manager will arrange TXMD audits with QPharma Quality Management. Audits shall be designed to minimize disruption of operations at the Facility. TXMD's Representatives who are not employees of TXMD shall be required to sign QPharma's standard visitor confidentiality agreement prior to being allowed access to the Facility. Such Representatives shall comply with the Facility's rules and regulations which are made known in advance to TXMD. TXMD shall indemnify and hold harmless QPharma for any action or activity of such Representatives while on QPharma's premises. QPharma shall not be required to accommodate any activity that would violate GMP or Swedish law.

9.6 Recall. If a Regulatory Authority orders or requires the recall of any Product supplied hereunder or if either QPharma or TXMD believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly notify the other party in writing. With respect to any Recall, QPharma shall provide all necessary cooperation and assistance to TXMD. TXMD shall provide QPharma with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, and shall consider in good faith any comments from QPharma. The cost of any Recall shall be borne by TXMD, and TXMD shall reimburse QPharma for expenses incurred in connection with any Recall, in each case except to the extent such Recall is caused by QPharma's breach of its Processing obligations under this Agreement or QPharma's violation of Applicable Laws, then such cost shall be borne by QPharma in proportion to QPharma's contribution to the cause of the Recall, limited to an amount equal to the aggregate price for all Product subject to Recall plus the price for all Product sold to TXMD during the [***] ([***]) [***] period prior to Recall. For purposes hereof, such QPharma cost shall be limited to reasonable, actual and documented administrative costs incurred by TXMD for such Recall and if applicable, replacement of the Product subject to Recall both in accordance with Article 5.

9.7 Quality Agreement. The parties shall negotiate in good faith and enter into a quality agreement on QPharma's standard template or such other template agreed to by the parties (the "**Quality Agreement**"). If the parties have not entered into a Quality Agreement by the first to occur of (i) [***] ([***]) days following the date execution by the last party signing this Agreement or (ii) commencement of manufacturing of Product for human use, TXMD shall be entitled to terminate this Agreement on [***] ([***]) days' written notice to QPharma, without cost or expense; provided, however, TXMD shall reimburse QPharma for any (i) equipment acquired by QPharma upon written authorization of TXMD and (ii) Raw Materials procured upon written authorization by TXMD, which unused Raw Materials, at the election of TXMD, and such equipment shall become the property of TXMD upon payment pursuant to this Section. The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth therein. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

9.8 Audit of Suppliers. QPharma shall be responsible for the audit of suppliers in accordance with its standard auditing plans and practices. TXMD hereby agrees to conduct audits on behalf of QPharma of suppliers with locations in the United States, currently only [***], and of certain contract laboratories to be agreed to by QPharma and TXMD. QPharma will reimburse to TXMD its out-of-pocket costs in conducting such audits. TXMD is responsible for API audits. QPharma can audit other relevant suppliers, including [***] and [***].

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term "**Confidential Information**" includes all information furnished by or on behalf of QPharma or TXMD, their respective Affiliates or any of its or their respective Representatives (the "**Discloser**"), to the other party (the "**Recipient**"), its Affiliates or any of its or their respective Representatives, whether furnished before, on or after the date of this Agreement, and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, data, regulatory submission Information, compilations, business or technical information, strategies, or plan, samples, and other materials prepared or possessed by either party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any information furnished by the Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence of this Agreement and its terms. The manufacturing process parameters which are being provided to QPharma from TXMD, the Specifications and data resulting from performance of this Agreement by QPharma shall be considered TXMD's Confidential Information. Items and information for which ownership has been allocated to TXMD under the Development Agreement shall be deemed to be the Confidential Information of TXMD under this Agreement.

10.2 Exclusions. Notwithstanding Section 10.1, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by the Recipient at the time of disclosure as evidenced by the Recipient's written records created in the ordinary course of business, (C) becomes available to the Recipient on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for the Recipient without reference to the Confidential Information of the Discloser as evidenced by the Recipient's contemporaneously created written records (E) is required to be disclosed by a court or judicial or governmental authority of competent jurisdiction, and in such event, only after the party required to disclose the other party's Confidential Information provides prompt written notice to that party so as to enable that party to resist any such required disclosure and/or to obtain suitable protection regarding such required disclosure as is described in provision 10.4 below

10.3 Mutual Obligation. The Recipient agrees that it will not use the Discloser's Confidential Information except in connection with the performance of its obligations or the exercise of its rights under this Agreement, and will not disclose, without the prior written consent of the Discloser, Confidential Information of the Discloser to any third party, except that the Recipient may disclose the Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives and subcontractors for which consent has been given pursuant to Section 6.3 and who have obligations of confidentiality and non-use at least as rigorous as those terms herein, in each case, that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this Article and (C) are bound to the Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives or any person receiving Confidential Information directly or indirectly from or through the Recipient. The Recipient also may disclose any information to The Population Council, as may be required by any written contract now in existence.

10.4 Permitted Disclosure. The Recipient may disclose the Discloser's Confidential Information to the extent required by law or regulation; *provided*, that prior to making any such legally required disclosure, the Recipient shall give the Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Any such disclosure, however, shall not relieve the Recipient of its obligations contained herein.

10.5 No Implied License. Except as expressly set forth in Section 10.1, the Recipient will obtain no right of any kind or license under any Confidential Information of the Discloser, including any patent application or patent, by reason of this Agreement. All Confidential Information will remain the sole property of the Discloser, subject to Article 11.

10.6 Return of Confidential Information. Upon expiration or termination of this Agreement, the Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within thirty (30) days either return or destroy (and certify as to such destruction) all Confidential Information of the Discloser, including any copies thereof, except for a single copy which may be retained for the sole purpose of ensuring compliance with its continuing obligations under this Agreement.

10.7 Survival. The obligations of this Article will terminate with respect to items of Confidential Information upon the entry thereof into general knowledge in the public domain, other than due to breach of this Agreement by the Recipient thereof or by a person receiving such Confidential Information from or through the Recipient, but in no event earlier than [***] ([***]) years from the expiration or earlier termination of this Agreement.

10.8 Reverse Engineering. Unless otherwise consented to by the Discloser in writing or provided for in a separate agreement between the parties, the Recipient will not analyze for chemical composition any samples or materials that are the Confidential Information of Discloser, nor to allow or cause any such samples or materials that are the Confidential Information of Discloser to be released to third parties for analysis; provided, however, (i) this Section 10.8 shall not be construed to prevent TXMD from testing Product or items related to Product itself or through third parties, as it sees fit in its sole and absolute discretion; and (ii) this Section 10.8 shall not be construed to prevent QPharma from analyzing for chemical composition samples or materials that are commercially available.

ARTICLE 11
INTELLECTUAL PROPERTY

11.1 The parties hereby acknowledge that it is neither their intention nor the purpose of this Agreement to engage in inventive steps in the conception, reduction to practice or development of intellectual property. Nevertheless, in the event, and to the extent, that intellectual property is conceived, reduced to practice, developed or otherwise created by or on behalf of either or both of the parties in connection with this Agreement, the ownership of such intellectual property, as between the parties, shall be with TXMD with respect to such intellectual property that relates to the Product and its Processing. Otherwise ownership shall be with QPharma.

11.2 Transfer. Following notice given by TXMD to QPharma, QPharma will provide reasonable assistance to effect the timely and orderly transfer of the Process Know-How, and pertinent books and records (or copies thereof, as the case may be) pursuant to the Process Know-How Transfer Plan to TXMD pursuant to this Section 11.2 and the Process Know-How Transfer Plan whether to establish a second source during the term of this Agreement or at or about the time of termination or expiration of this Agreement. QPharma shall only be obligated to use its commercially reasonable efforts in the implementation of the Process Know-How Transfer Plan. QPharma will be reimbursed at a reasonable rate for the time of its personnel for such technology transfer.

11.3 Books and Records. Where any document, or books and records contain Process Know-How together with other information of QPharma, its Affiliates or their respective subcontractors, or other QPharma customers, QPharma shall only be required to provide to TXMD a copy of that portion of that document or books and records that discloses the Process Know-How that pertains to the Product. When transferred to TXMD, such copies will be the property of TXMD. QPharma may retain the original books and records and any documents required by Applicable Laws to be retained by QPharma, which disclose the Process Know-How. After completion of performance of the Process Know-How Transfer Plan, before destroying any documents, or books and records which contain material disclosures of Process Know-How that have not been previously been provided to TXMD (whether in the same form or some other form), QPharma will notify TXMD of such intended destruction and provide TXMD with [***] ([***]) days to notify QPharma in writing whether TXMD wishes to obtain the same to the extent it is entitled to under this Agreement, in which case QPharma will deliver the requested document or books and records (or copies of all or a portion thereof, as the case may be) to TXMD at TXMD's sole cost and expense.

11.4 TXMD Marks. QPharma will not use TXMD's Marks without prior written authorization from TXMD. The Marks are, and will remain, TXMD's sole and exclusive property, and QPharma has not acquired, and will not acquire (by operation of law, this Agreement, or otherwise), any right, title, or interest in any of TXMD's Marks other than as explicitly provided in writing by TXMD. Any and all goodwill and rights that arise under trademark and copyright law, and all other intellectual property rights that arise in favor of TXMD's Marks as a result of this Agreement or otherwise, will inure to the sole and exclusive benefit of TXMD. Subject to the next sentence, during the Term of this Agreement, QPharma will not attack, dispute, or challenge TXMD's right, title, and interest in and to TXMD's Marks or assist others in so doing. QPharma reserves the right to attack, dispute, or challenge TXMD's right, title, and interest in and/or to TXMD's Marks or assist others in so doing, if QPharma believes in good faith that TXMD's Mark infringes a Mark owned by or licensed to QPharma or one of its Affiliates.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES AND COMPLIANCE

12.1 QPharma. QPharma represents, warrants and undertakes to TXMD that:

A. at the time of delivery by QPharma as provided in Section 6.1, Product shall have been Processed in accordance with this Agreement and with Applicable Laws and in conformance with the Specifications and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided*, that QPharma shall not be liable for defects attributable to TXMD-supplied Materials (including artwork, advertising and labeling);

B. all personnel, employees, and agents of QPharma and its Affiliates and their respective subcontractors who perform services, are and will continue to be qualified and to have sufficient technical expertise to perform QPharma's obligations under this Agreement;

C. QPharma has the full power and authority to execute and deliver this Agreement and perform its covenants, duties, and obligations described in this Agreement, and once executed, this Agreement will be a valid, legal, and binding obligation upon QPharma;

D. QPharma is not now, nor will it be, a party to any agreement, whether with The Population Council or others, which would prevent QPharma from fulfilling its obligations under this Agreement, and that during the Term of this Agreement will not enter into any agreement with any other party that would in any way prevent QPharma from performing its obligations under this Agreement;

E. QPharma's Facility complies with and QPharma will maintain its compliance with the regulations for the manufacture of hormonal products;

F. QPharma will maintain all records and reports as required under this Agreement, and as required to comply with Applicable Laws;

G. QPharma will not in the performance of its obligations under this Agreement use those services prohibited to be provided by any person debarred or suspended (or subject to debarment or suspension) under 21 U.S.C. §335(a) or (b) or otherwise disqualified by Applicable Law;

H. (i) QPharma is not nor has it ever been, and (ii) QPharma has not used, and will not use, the services of any person excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs, and has not used, and will not use, those services prohibited to be provided by any person listed on the HHS/OIG List of Excluded Individuals/Entities (http://www.oig.hhs.gov), the GSA's List of Parties Excluded from Federal Programs (http://www.epls.gov), or the FDA Debarment List (http://www.fda.gov/ora/compliance_ref/debar/default.htm), as amended or replaced from time to time, in connection with any of the services performed under this Agreement. QPharma further certifies that it, and, to its knowledge, any other person or entity used by QPharma in performing any of the services under this Agreement, has not been convicted of a criminal offense that falls within the ambit of 42 U.S.C. §1320a-7(a). QPharma agrees to notify TXMD promptly in the event QPharma, or any person used by QPharma in connection with this Agreement, ever becomes excluded, debarred, suspended, or, otherwise to its knowledge, ineligible to participate in Federal health care programs or in Federal procurement or non-procurement programs. This certification applies to QPharma and its respective officers, agents, and employees as well as subcontractors performing on behalf of QPharma under this Agreement;

I. QPharma has all necessary authority to use the QPharma technology utilized with the Product and as contemplated by this Agreement; there are no patents owned by others related to the QPharma IP utilized with the Product that would be infringed or misused by QPharma's performance of the Agreement; and, to its knowledge, no trade secrets or other proprietary rights of others related to the QPharma IP utilized with the Product that would be infringed or misused by QPharma's performance of this Agreement;

J. QPharma will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications; and

K. no transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.

12.2 TXMD. TXMD represents, warrants and undertakes to QPharma that:

A. all TXMD-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

B. the content of all artwork provided to QPharma shall comply with all Applicable Laws;

C. all Product delivered to TXMD by QPharma shall be held, used and disposed of by or on behalf of the TXMD in accordance with all Applicable Laws, and TXMD will otherwise comply with all laws, rules, regulations and guidelines applicable to TXMD's performance under this Agreement;

D. TXMD will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if TXMD does not hold all necessary Regulatory Approvals to market and sell the Product;

E. TXMD has all necessary authority to use and to permit QPharma to use pursuant to this Agreement all intellectual property related to Product or TXMD-supplied Materials (including artwork), and the Processing by QPharma of the foregoing, including any copyrights, trademarks, trade secrets, patents, inventions and developments; to TXMD's knowledge there are no patents owned by others related to the TXMD IP utilized with the Product that would be infringed or misused by TXMD's performance of the Agreement; and, to its knowledge, no trade secrets or other proprietary rights of others related to the TXMD IP utilized with the Product that would be infringed or misused by TXMD's performance of this Agreement;

F. To TXMD's knowledge the services to be performed by QPharma under this Agreement will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other intellectual property or other right held by any person or entity; provided that TXMD makes no representation with respect to the QPharma IP;

G. TXMD has the full power and authority to execute and deliver this Agreement and perform its covenants, duties, and obligations described in this Agreement, and once executed, this Agreement will be a valid, legal, and binding obligation upon TXMD; and

H. no transactions or dealings under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States.

1 2 . 3 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE INCLUDING, WITHOUT LIMITATION, ANY REPRESENTATION OR WARRANTY BY TXMD WITH REGARD TO THE TXMD EQUIPMENT, WHICH IS PROVIDED "AS IS."

12.4 Compliance with Anti-Corruption Laws.

Each Party agrees that, in the performance of its obligations under this Agreement, it will not: (i) provide or promise to provide, directly or indirectly, any unlawful contribution, gift, entertainment, or other unlawful payment to any foreign or domestic government employee relating to political activity; (ii) take any action, directly or indirectly, that violates Foreign Corrupt Practices Act ("FCPA"), or any other applicable anti-corruption law of any foreign jurisdiction, including, without limitation, "use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value" to any "foreign official" (as is defined in the FCPA), any foreign political party or official thereof, or any candidate for foreign political office, to influence their acts or decisions in their official capacity, to induce them to do or omit from doing any act in violation of their lawful duty, or to secure any improper advantage in order to assist in obtaining business, or retaining business, or directing business to any person; and (iii) make or propose to make any bribe, payoff, influence payment, kickback, unlawful rebate, or other similar unlawful payment of any nature, including to healthcare providers or those employed by any governmental institutions.

12.5 Covenant of QPharma. QPharma hereby covenants and agrees that it shall neither directly or indirectly, on behalf of itself or a third party, engage in or assist a third party, in developing, manufacturing or commercializing a generic product of the Product in the Territory during the Term of this Agreement, and during the [***] ([***]) month period thereafter. [***].

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by QPharma. QPharma shall indemnify, defend and hold harmless TXMD, its Affiliates, and their respective shareholders, directors, officers and employees ("**TXMD Indemnitees**") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees and reasonable investigative costs) in connection with any suit, demand or action brought by any third party ("**Losses**") directly or indirectly arising out of or resulting from (a) any breach of its representations, warranties or obligations set forth in this Agreement; (b) any negligence or willful misconduct by QPharma, its Affiliates, subcontractors, employees or agents; (c) any misrepresentation made by QPharma in this Agreement; (d) a violation of, or non-compliance with any Applicable Law by QPharma, its Affiliates, subcontractors, employees or agents in the performance of this Agreement; (e) the infringement or alleged infringement of any trade secrets, copyrights, trademarks, trade names, or other proprietary or contractual rights of any third party arising from QPharma's performance of services under this Agreement (except to the extent arising from the making or using of TXMD-supplied Materials) or (f) the use of the TXMD Equipment on behalf of any third party, and the storage, handling and use of any items manufactured with the use of the TXMD Equipment, in each case of clauses (a) through (e) above, except to the extent that TXMD is obligated to indemnify any of the QPharma Indemnitees pursuant to Section 13.2 for such events.

13.2 Indemnification by TXMD. TXMD shall indemnify, defend and hold harmless QPharma, its Affiliates, and their respective shareholders, directors, officers and employees ("**QPharma Indemnitees**") from and against any and all Losses directly or indirectly arising out of or resulting from (a) any promotion, distribution, sale or use of or exposure to the Product or TXMD-supplied Materials, or APIs, other than claims by QPharma employees and contractors arising from Processing under this Agreement; (b) any negligence or willful misconduct of TXMD, its Affiliates, subcontractors, employees or agents, (c) any breach of TXMD's representations, warranties or obligations set forth in this Agreement; (d) the content of TXMD's instructions to the extent they are followed by QPharma and violate Applicable Laws; (e) the conduct of any clinical trials by or on behalf of TXMD utilizing Product or APIs; (f) any actual or alleged infringement or violation of any third party patent, trade secret, copyright, trademark or other proprietary right by the use, as authorized, of intellectual property or other information provided by TXMD to QPharma, including TXMD-supplied Material; in each case of clauses (a) through (f) above, except to the extent that QPharma is obligated to indemnify any of the TXMD Indemnitees pursuant to Section 13.1 for such events.

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified party (a) promptly notifying the indemnifying party of any claim or liability of which the indemnified party becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is prejudiced by such failure, (b) allowing the indemnifying party to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense), (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 15
INSURANCE

For so long as each Party has any indemnity obligations hereunder to the other Party, each Party shall obtain and maintain such type and amounts of liability insurance as are normal and customary for the activities contemplated by this Agreement. Each Party shall upon request provide the other Party with written proof of insurance. Notwithstanding the foregoing, QPharma hereby represents and warrants to TXMD that it has and shall maintain at all times during the term of this Agreement product liability insurance, professional negligence insurance and general commercial liability insurance in a minimum in aggregate of [***] Euros (€[***]). QPharma shall name TXMD as an additional named insured under such policies.

ARTICLE 16
TERM AND TERMINATION

16.1 Term. The term of this Agreement shall commence as of the Effective Date and shall expire at the end of the Initial Term; provided, however, TXMD shall have the right to renew the Agreement thereafter for successive one-year terms upon giving at least [***] ([***]) days' written notice of such renewal prior to the expiration of the Initial Term or any annual renewal thereafter.

16.2 Termination. This Agreement may be terminated Immediately upon written notice without further action:

A. By either Party if the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within thirty (30) days, or takes any equivalent or similar action in consequence of debt in any jurisdiction; or

B. By TXMD upon [***] ([***]) days prior written notice to QPharma in the event TXMD ceases pursuit of Regulatory Approval for, or to offer for sale or to sell, Product, due to material regulatory, patient health, or intellectual property issues.

C. By either Party due to an uncured breach of this Agreement following [***] ([***]) days' written notice, the elements of such breach being described in such notice in reasonable detail.

D. By TXMD for convenience upon [***] ([***]) months' written notice, or by QPharma after the first anniversary of this Agreement upon [***] ([***]) months' written notice due to the failure of QPharma to produce Product at a profit based upon the then existing supply projections by TXMD or for other demonstrated economic hardship. Upon notice from QPharma of the exercise of its rights under this Section 16.2(D) to terminate the Agreement, TXMD shall have the right exercisable in the [***] ([***]) day period following such notice to require QPharma to re-negotiate the price of Products in good faith for a period of up to [***] ([***]) days. The Parties shall not be obligated to reach agreement regarding a revised price of Products.

16.3 Effects of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either party prior to such expiration or termination. In the event of a termination of this Agreement:

A. QPharma shall promptly return to TXMD, at TXMD's expense and direction, any remaining inventory of Product or TXMD-supplied Materials; *provided*, that all outstanding invoices have been paid in full;

B. TXMD shall pay QPharma all invoiced amounts outstanding hereunder, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) except following a termination by TXMD pursuant to Section 16.2(A) or (B), all Product in process of being Processed pursuant to Purchase Orders (or, alternatively, TXMD may instruct QPharma to complete such work in process, and the resulting completed Product shall be governed by clause (ii)); and

16.4 Except as otherwise set forth in this Agreement, in the event that this Agreement is terminated for any reason other than by TXMD pursuant to Section 16.2(A) or (B), TXMD shall pay QPharma for all costs and expenses incurred, and all non-cancellable commitments made, in connection with QPharma's performance of this Agreement, so long as such costs, expenses or commitments were made by QPharma consistent with TXMD's most recent ordering history, and have not otherwise been paid pursuant to Section 16.3(B). At TXMD's discretion, such transfer shall not be considered complete until such third party transferee has successfully Processed and released for human use [***] ([***]) successive Batches of Product. If QPharma terminates this Agreement pursuant to Section 16.2(D), it shall provide to TXMD reasonable person-hours as TXMD shall require, at QPharma's then standard published rates, to effectuate a transfer of Processing to a third party of TXMD's choice. QPharma shall provide reasonable assistance, as requested by TXMD, to identify third parties capable and willing to provide Processing of Product promptly.

16.5 Interruption of Supply; Safety Stock.

A. In the event QPharma fails to timely deliver the quantities of Product ordered that comply with the requirements of this Agreement on [***] ([***]) consecutive occasions or on any [***] ([***]) occasions during any [***] ([***]) [***] period, TXMD shall be entitled to cause QPharma to conduct Process Know-How Transfer along with pertinent books and records to TXMD or its designee, pursuant to the Process Know-How Transfer Plan in order to allow the Processing of Product by a third party for TXMD, its Affiliates and their respective licensees. QPharma will be reimbursed at a reasonable rate for the time of its personnel for such technology transfer.

B. To mitigate the risk of TXMD going out of stock, QPharma shall maintain such safety stocks of APIs, Raw Materials, Components and Product as would be reasonably prudent in the combination drug-device product industry under relevant circumstances, particularly in light of those APIs, Raw Materials and Components that are procured from single sources of supply. QPharma shall use reasonable efforts to put in place a written risk mitigation plan with the consultation of TXMD to address such issues, and shall reasonably endeavor to secure multiple sources of supply for all critical APIs, Raw Materials and Components (the "**Risk Mitigation Plan**").

1 6 . 6 Survival. The rights and obligations of the parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 7.3 (Payment Terms), 7.5 (Taxes), 7.6 (TXMD and Third Party Expenses), 9.1 (Recordkeeping), 9.6 (Recall), 12.3 (Limitations on Warranties), 16.3 (Effect of Termination) and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

ARTICLE 17
NOTICE

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (C) when delivered, if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

To TXMD:	TherapeuticsMD, Inc. 6800 Broken Sound Parkway NW, Third Floor Boca Raton, Florida 33487 Attn: President
With a copy to:	Legal Department at the above address
To QPharma:	QPharma AB Agneslundsvagen 27 Malmo, Sweden Attn: Managing Director

ARTICLE 18
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, the Quality Agreement, and the Validation Costs and Expenses; Capital Equipment Procurement and Installation Costs and Expenses (referenced as Exhibit B to the Term Sheet) constitute the entire understanding between the Parties, and supersede any contracts, agreements or understandings (oral or written) of the Parties, with respect to the subject matter hereof including the Term Sheet, other than Exhibit B thereto. For the avoidance of doubt, this Agreement does not supersede any existing generally applicable confidentiality agreement between the Parties as it relates to time periods prior to the date hereof or to business dealings not covered by this Agreement. No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular shall include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (E) the word “or” shall be deemed to include the word “and” (e.g., “and/or”) and (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and neither party will incur any debts or make any commitments for the other party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint ventures, co-partners, employer/employee or principal and agent. Neither party shall have any responsibility for the hiring, termination or compensation of the other party's employees or contractors or for any employee benefits of any such employee or contractor.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party's consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning party or the assigning party's business unit responsible for performance under this Agreement.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person or entity other than the parties named herein and their respective successors and permitted assigns.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of England and Wales, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Dispute Resolution. Any dispute that arises between the parties in connection with this Agreement shall first be presented to the senior executives of the Parties for consideration and resolution. If such executives cannot reach a resolution of the dispute within a reasonable time, then the parties may seek remedies in a court of law.

18.11 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.12 Right to Dispose and Settle. If QPharma requests in writing from TXMD direction with respect to disposal of any inventories of Product, TXMD-supplied Materials, equipment, samples or other items belonging to TXMD and is unable to obtain a response from TXMD within a reasonable time period after making reasonable efforts to do so, QPharma shall be entitled in its sole discretion to (A) dispose of all such items and (B) set-off any and all amounts due to QPharma or any of its Affiliates from TXMD against any credits TXMD may hold with QPharma or any of its Affiliates.

18.13 Force Majeure. Except as to payments required under this Agreement, neither party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such party's performance hereunder if such default or delay is caused by events beyond such party's reasonable control, including but not limited to acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, vendors, public utilities or common carriers; *provided*, that the party seeking relief under this Section shall immediately notify the other party of such cause(s) beyond such party's reasonable control. The party that may invoke this Section shall use commercially reasonable efforts to reinstate its ongoing obligations to the other party as soon as practicable. If the cause(s) shall continue unabated for three (3) consecutive months, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.14 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused their respective duly authorized Representatives to execute this Agreement effective as of the date first written above.

QPHARMA PHARMA AB	THERAPEUTICSMD, INC.
By: /s/ David Segerberg	By: /s/ Dan Cartwright
Name: David Segerberg	Name: Dan Cartwright
Title: Managing Director	Title: CFO

ATTACHMENT A

SPECIFICATIONS

ATTACHMENT B

TXMD EQUIPMENT (as of 12/18/18)

Purchased Assets
Equipment used for production and analysis of NES/EE CVR

Description (swe)	Description (eng)	Equipment No	Process step	QPharma Building
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

ATTACHMENT C

TXMD-SUPPLIED MATERIALS (as of 12/18/18)

[***]

ATTACHMENT D

UNIT PRICING

During the Initial Pricing Period, QPharma shall sell Product in final dosage form, packaged for end user use, to TXMD at the prices set forth below. [***]

[***]

Purchase Per Contract Year	Prices Not to Exceed (low yield)
[***] – [***] units of Product	$[***] per unit
[***] – [***] units of Product	$[***] per unit
[***] – [***] units of Product	$[***] per unit
[***] – [***] units of Product	$[***] per unit
[***] – [***] units of Product	$[***] per unit
More than [***] units of Product	$[***] per unit

Purchase Per Contract Year	Prices Not to Exceed (anticipated yield)
[***] – [***] units of Product	$[***] per unit
[***] – [***] units of Product	$[***] per unit
[***] – [***] units of Product	$[***] per unit
[***] – [***] units of Product	$[***] per unit
[***] – [***] units of Product	$[***] per unit
More than [***] units of Product	To be determined

The foregoing prices include a recovery for depreciation expenses of Facility improvements made by QPharma. Recovery of these depreciation expenses will end upon expiration of the depreciation recovery schedule. TXMD will purchase a minimum of [***] units of Product per Contract Year.

The foregoing prices include the purchase by, and payment for, both of the Product's APIs by QPharma. If TXMD supplies one or both of the Product's APIs to QPharma at no cost, or QPharma procures one or both APIs and passes the cost through to TXMD, the foregoing prices will be adjusted downward, as reasonably agreed to by QPharma and TXMD.

These prices will be applied to cumulative purchased by TXMD together with its Affiliates and licensees, if any. The unit price for which QPharma will sell Product to TXMD, its Affiliates and their licensees during the Initial Pricing Period will be as set forth in the table above in accordance with the cumulative quantities ordered by and on behalf of such parties during each Contract Year. Within [***] ([***]) days following (i) the end of each Contract Year or (ii) the expiration or termination of the Agreement, as the case may be, QPharma shall determine the total quantity of Product ordered by or on behalf of TXMD, its Affiliates and their respective licensees during the prior Contract Year (or portion of a Contract Year in the event of a termination) and issue a credit memo or refund to TXMD, at its option, in such amount as may be necessary to true up amounts actually paid by TXMD with the prices to which TXMD, its Affiliates and their respective licensees were entitled during such Contract Year based on their actual cumulative orders.

TXMD and QPharma will revisit this yield-based pricing scheme after the first commercial Batch of Product as defined in Section 7.1A.

Exhibit 10.2

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

LEASE

BY AND BETWEEN

951 YAMATO ACQUISITION COMPANY, LLC
("Landlord")

and

TherapeuticsMD, Inc.
("Tenant")

TABLE OF CONTENTS

1. TERMS. Each reference in this Lease to any of the following subjects shall be construed to incorporate the data stated for that subject in this Section 1:

Effective Date:	October 5, 2018
Name of Tenant:	TherapeuticsMD, Inc., a Nevada corporation
Notice Address of Tenant: (a) Prior to possession:	6800 Broken Sound Parkway NW 3rd Floor Boca Raton, Florida 33487
(b) Following the Full Premises Commencement Date:	951 Yamato Road Suite 160 Boca Raton, Florida 33431
Name of Landlord:	951 Yamato Acquisition Company, LLC
Notice Address of Landlord:	138 Conant Street Beverly, MA 01915 Attention: Director of Asset Management
with a copy to:	Michael C. Wilde, Esq. BAKER & HOSTETLER LLP SunTrust Center, Suite 2300 200 South Orange Avenue Orlando, Florida 32801
Landlord's Remittance Address:	951 Yamato Acquisition Company P.O. Box 864885 Orlando, FL 32886-4885
Building:	The building located at 951 Yamato Road, Boca Raton, Florida
Property:	The Building and the real property on which the Building is located and any other buildings and improvements located thereon as shown on the site plan attached hereto as **Exhibit A-1**. For all purposes under this Lease, the Property shall include all related site land, property, improvements, parking facilities, common areas, driveways, sidewalks and landscaping which form a part of the project located at 951 Yamato Road, Boca Raton, Florida 33431 and commonly known as 951 Yamato Road.

Premises:	Approximately 56,212 rentable square feet of space located on the first and second floors of the south wing of the Building and comprised of: (i) Suite 150 containing approximately 27,321 rentable square feet ("Suite 150"), (ii) Suite 220 containing approximately 21,330 rentable square feet ("Suite 220") and (iii) Suite 160 on the first floor of the west wing containing approximately 7,561 rentable square footage ("Suite 160"), as shown by the floor plans attached hereto as **Exhibit A**. The "rentable square footage" of the Premises shall be deemed to be 56,212 square feet for all purposes under this lease. The usable square footage of the Premises has been measured in accordance with the American National Standard Method of Measuring Floor Area in Office Buildings of the Building Owners and Managers Association International (ANSI Z65.1-2010), provided the load factor is not calculated per BOMA.
Permitted Use:	General office use, and no other use or purpose.
Term:	The period of time beginning on the Suite 160 Commencement Date and ending at 11:59 P.M. on the Expiration Date.
Suite 160 Commencement Date:	Subject to the terms of Section 3 of the Lease, the earlier to occur of (i) October 27, 2018 or (ii) the date Tenant commences operation of its business in Suite 160. Tenant shall confirm the Suite 160 Commencement Date pursuant to the terms herein.
Full Premises Commencement Date:	Subject to the terms of Section 3 of the Lease, the Full Premises Commencement Date shall be the earlier to occur of (i) "Substantial Completion" of the "Tenant Improvements" (as said terms are defined in the Work Letter attached as **Exhibit F**) but no earlier than June 1, 2019 or (ii) the date Tenant commences operation of its business in either Suite 150 or Suite 220. Tenant shall confirm the Full Premises Commencement Date pursuant to the terms herein.
Expiration Date:	That certain date which is the last day of the one hundred thirty second (132nd) complete calendar month following the Full Premises Commencement Date.
Tenant's Percentage:	[***]%, being the ratio of rentable square footage of the Premises to the total rentable square footage of the Building (currently [***] rentable square feet), provided that until the occurrence of the Full Premises Commencement Date the Tenant's Percentage shall be [***]% (based on Suite 160).

Prepaid Rent:	$[***] (to be applied, pursuant to the terms herein), representing the amounts estimated for the first month in which rent is payable for the entire Premises (estimated to be $[***]) and the last month in which rent is payable for the entire Premises (estimated to be $[***]). Provided that (i) Tenant has paid all amounts due and has otherwise performed all obligations hereunder, (ii) there exists no Event of Default hereunder, and (iii) this Lease is then in full force and effect, the Landlord shall credit the remaining portion of the Prepaid Rent (after deducting the amount for the first month's rent) to the Rent payable for the month of January 2024, with such credit to be conditioned on (i), (ii), and (iii) above. In the event the conditions above are not satisfied as of December 31, 2023, the remaining portion of the Prepaid Rent shall be held and credited to the last month of the Term.
Security Deposit:	$[***].
Exhibits:	Exhibit A-1 Site Plan of the Building Exhibit A-2 Location of Parking Spaces Exhibit A-3 Building Lot and Shared Lot Exhibit A The Premises Exhibit B Rules and Regulations Exhibit C Commencement Letter Exhibit D Additional Stipulations Exhibit E Suite 160 Work Letter Exhibit F Landlord Work Letter Exhibit G Intentionally Deleted Exhibit H Current Lender Form SNDA Exhibit I Assumed Rent Table Exhibit J Landlord's Agreement All of the Exhibits listed above are incorporated into and made part of this Lease.

Rent:	Base Rent and all Additional Rent, plus all applicable sales tax thereon.
Additional Rent:	All amounts required to be paid by Tenant to Landlord pursuant to this Lease other than Base Rent, including, without limitation, Tenant's Percentage of Operating Expenses and Taxes.
Base Rent:	Base Rent is at the initial rate of $[***] per rentable square foot, plus all applicable sales tax thereon, escalating annually at the rate of [***]% on each anniversary of the Suite 160 Commencement Date (as to the Base Rent for Suite 160) and each anniversary of the Full Premises Commencement Date (as to the Base Rent for Suite 150 and Suite 220) with the Term to expire at the end of the 132nd full month from the Full Premises Commencement Date.

Notwithstanding the foregoing, Base Rent and Tenant's Percentage of Operating Expenses and Taxes for Suite 160 (7,561 rentable square feet) shall be abated for the first [***] ([***]) [***] period of the Term commencing on the Suite 160 Commencement Date (the "Suite 160 Rent Abatement Period"). The Base Rent and Tenant's Percentage of Operating Expenses and Taxes for Suite 160 due for any partial calendar month immediately following the Suite 160 Rent Abatement Period shall be prorated based on the number of days in that month. Notwithstanding anything herein to the contrary, during the Suite 160 Rent Abatement Period, Tenant shall pay the Tenant's Percentage of electricity for Suite 160 and Tenant's Percentage of janitorial services for Suite 160 which is estimated to be $[***] psf, provided that Tenant's Percentage of electricity and janitorial services shall be subject to reconciliation based upon the actual cost of the electricity and janitorial services, but in no event shall the cost exceed $[***] per rsf for calendar year 2018.

Further, notwithstanding the foregoing, Base Rent and Tenant's Percentage of Operating Expenses and Taxes for the Suite 150 (27,321 rentable square feet) and Suite 220 (21,330 rentable square feet) shall be abated for the [***] ([***]) [***] period commencing on the Full Premises Commencement Date (the "Suites 150 & 220 Rent Abatement Period"). The Base Rent and Tenant's Percentage of Operating Expenses and Taxes for Suites 150 & 220 due for any partial calendar month immediately following the Suites 150 & 220 Rent Abatement Period shall be prorated based on the number of days in that month. Tenant shall pay the Tenant's Percentage of electricity for Suite 150 and Suite 220 and Tenant's Percentage of janitorial services for Suite 150 and Suite 220, which shall be based on 2019 budgets, provided that Tenant's Percentage of electricity and janitorial services shall be subject to reconciliation based upon the actual cost of the electricity and janitorial services, but in no event shall the cost exceed $[***] per rsf for calendar year 2019.

2. THE PREMISES. Landlord leases to Tenant, and Tenant leases from Landlord, upon and subject to the terms and conditions of this Lease, the Premises together with certain rights to the Common Areas as hereinafter specified, it being acknowledged and agreed that the commencement dates for the respective suites of the Premises shall be staggered in accordance with the terms herein. The term "Common Areas" is defined as all areas and facilities outside the Premises and within the exterior boundary line of the Property that are designated by Landlord from time to time for the general non-exclusive use of Landlord, Tenant and the other tenants of the Building and their respective employees, suppliers, customers and invitees, including, but not limited to, common entrances, lobbies, corridors, stairwells, public restrooms, conference rooms, elevators, parking areas, loading and unloading areas, roadways and sidewalks.

3. **TERM**. The Premises, or applicable portion thereof as they case may be, are leased for the Term. If for any reason Landlord is unable to deliver possession of the Suite 160 Premises to Tenant on or prior to October 7, 2018 (subject to a day-for-day extension due to Force Majeure), in addition to any other free rent periods as provided for in this Lease, Tenant shall receive one day of free rent for each day in the period commencing on October 7, 2018 (subject to a day-for-day extension due to Force Majeure) and ending on the date that Landlord delivers the Suite 160 Premises to Tenant. If Landlord has not completed the Phase 2 portion of the Landlord's Suite 160 Work (as defined in **Exhibit E**) on or before December 15, 2018 (subject to a day-for-day extension due to Force Majeure or Tenant Delay), in addition to any other free rent periods as provided for in this Lease, Tenant shall receive one day of free rent for each day in the period commencing on December 15, 2018 (subject to a day-for-day extension due to Force Majeure or Tenant Delay) and ending on the date that Landlord completes the Phase 2 portion of the Landlord's Suite 160 Work. If for any reason Landlord is unable to deliver possession of the Suite 150 & Suite 220 portion of the Premises to Tenant on or prior to July 1, 2019 (subject to a day-for-day extension due to (i) Force Majeure, (ii) Tenant's failure to fully approve of the plans for Tenant Improvements by November 15, 2018, or (iii) Tenant Delay) in the condition required by the Work Letter, Tenant shall receive one day of free rent for each day in the period commencing on July 1, 2019 (subject to a day-for-day extension due to (i) Force Majeure, (ii) Tenant's failure to fully approve of the plans for Tenant Improvements by November 15, 2018, or (iii) Tenant Delay) and ending on the date that Landlord delivers the Suite 150 & Suite 220 portion of the Premises to Tenant in the condition required by the Work Letter.

If for any reason Landlord has not delivered the Suite 150 & Suite 220 portion of the Premises to Tenant on or prior to November 30, 2019 (subject to a day-for-day extension due to (i) Force Majeure, (ii) Tenant's failure to fully approve of the plans for Tenant Improvements by November 15, 2018, or (iii) Tenant Delay) in the condition required by the Work Letter, Tenant shall have the right to terminate this Lease by providing written notice of such termination to Landlord on or before December 10, 2019. Tenant shall have the option to extend the Term subject to the terms and conditions of **Exhibit D** attached hereto.

4. **CONDITION OF THE PREMISES**. Except as expressly set forth herein and in the Work Letter, the Premises are leased in an "as is" and "where is" condition without any warranty of suitability, habitability or fitness for use, occupation or any particular purpose express or implied, it being agreed that Tenant has had an opportunity to examine the condition of the Premises, that Landlord has made no representations or warranties of any kind with respect to such condition, and that except as expressly set forth herein and in the Work Letter, Landlord has no obligation to do or approve any work or make or approve any improvements to or with respect to the Premises to prepare the same for Tenant's occupancy except as expressly set forth herein and in the Work Letter. Landlord shall make improvements to the Suite 160 Premises and tender possession of the Suite 160 Premises in accordance with the terms of the Work Letter attached as **Exhibit E**. Landlord shall make improvements to Suite 150 and Suite 220 and tender possession of Suite 150 and Suite 220 as described in the Work Letter attached as **Exhibit F**.

5. **MONTHLY RENT**. Subject to the rent abatement periods provided herein, commencing on the Suite 160 Commencement Date and the Full Premises Commencement Date (respectively), Base Rent for the applicable portion of the Premises, plus applicable sales tax, shall be paid monthly in advance on or before the first day of each calendar month. The Base Rent shall not be adjusted or modified if the actual rentable square footage of the Premises varies from the rentable square footage set forth herein by [***]% or less. If the Suite 160 Commencement Date or the Full Premises Commencement Date (respectively) shall be on any day other than the first day of a calendar month, Base Rent, plus applicable sales tax, for the partial month shall be prorated based on the number of days in that month. Unless otherwise provided herein, commencing on the Suite 160 Commencement Date and the Full Premises Commencement Date (respectively), Additional Rent, plus applicable sales tax, shall also be paid monthly in advance on or before the first day of each calendar month. If the Suite 160 Commencement Date or the Full Premises Commencement Date (respectively) shall be on any day other than the first day of a calendar month, Additional Rent, plus applicable sales tax, for the partial month shall be prorated based on the number of days in that month. Rent shall be paid to Landlord, without notice or demand, and without deduction or offset, in lawful money of the United States of America, at Landlord's Remittance Address as set forth in Section 1 or to such other address as Landlord may from time to time designate in writing. Tenant acknowledges that the late payment of Rent or other sums due hereunder shall cause Landlord to incur costs not contemplated by this Lease, the exact amount of which shall be extremely difficult to ascertain. Such costs include, but are not limited to, processing and accounting charges, and late charges which may be imposed on Landlord by the terms of any mortgage or trust deed covering the Property. Accordingly, if any installment of Rent or any other sums due from Tenant shall not be received by Landlord within [***] ([***]) days of when due, Tenant shall pay to Landlord a late charge equal to [***] percent ([***]%) of such overdue amount. In addition, any amount due to Landlord, if not paid within [***] ([***]) days of when due, shall bear interest from the date due until paid at the lesser of: (i) the Prime Rate (as hereinafter defined) plus [***] percent ([***]%) per annum, or (ii) the highest rate permitted by law (the "Default Rate"). The term "Prime Rate" shall mean the Prime Rate as published in The Wall Street Journal from time to time. The parties agree that such late charges represent a fair and reasonable estimate of the costs Landlord shall incur by reason of late payment by Tenant. The acceptance of such late charges by Landlord shall in no event constitute a waiver of Tenant's default with respect to the overdue amount or prevent Landlord from exercising any of the other rights and remedies granted hereunder. Notwithstanding anything to the contrary in this Lease, Tenant shall pay the Prepaid Rent simultaneously with Tenant's execution and delivery of this Lease. Notwithstanding the foregoing, Landlord shall not charge Tenant interest or late charges for the first late payment in any [***] ([***]) month period provided that Tenant pays any all sums due within [***] ([***]) days of the date due, with any subsequent late payment to incur fees and interest without any additional grace period.

Notwithstanding anything to the contrary, at the expiration of any rent abatement period, Landlord shall apply the portion of the Prepaid Rent (as apportioned to Suite 160 after the expiration of the Suite 160 Rent Abatement Period and to Suites 150 and 220 after expiration of the Suites 150 and 220 Rent Abatement Period) applicable to the first month in which Rent is payable to Landlord, and Tenant shall not be obligated to pay Rent for that month, unless the amount of the Prepaid Rent is insufficient to cover the entire amount of the actual Rent due in which case Tenant will be obligated to pay the additional amount owed upon the same terms and at the same time such payment would otherwise be due. The remaining amount of any Prepaid Rent shall be credited or applied as set forth above.

6. **TAXES**. Tenant shall pay monthly, as Additional Rent, one-twelfth (1/12) of Tenant's Percentage of annual Taxes based on estimates provided by Landlord from time to time and subject to reconciliation as provided in Section 8 below. "Taxes" means all taxes, assessments and fees levied upon the Property by any governmental entity based upon the ownership, leasing, renting or operation of the Property. Taxes shall not include any federal, state or local net income, capital stock, succession, transfer, replacement, gift, estate or inheritance taxes; provided, however, if at any time during the Term, a tax or excise on income is levied or assessed by any governmental entity in lieu of or as a substitute for, in whole or in part, real estate taxes or other ad valorem taxes, such tax shall constitute and be included in Taxes. In addition to the foregoing, Tenant shall pay Landlord, as Additional Rent, for any use, rent or sales tax, service tax, value added tax, franchise tax or any other tax on Rent however designated as well as for any taxes which are reasonably attributable to the cost or value of Tenant's equipment, furniture, fixtures and other personal property located in the Premises or the cost or value of any leasehold improvements made in or to the Premises by or for Tenant. All expenses, including attorneys' fees and disbursements, experts' and other witnesses' fees, incurred in contesting the validity or amount of any Taxes or in obtaining a refund of Taxes shall be considered as part of the Taxes for the year in which the expenses are incurred. For property tax purposes, to the extent allowed by Law, Tenant waives all rights to protest or appeal the appraised value of the Premises, as well as the Property, and all rights to receive notices of reappraisement.

Landlord may, in Landlord's commercially reasonable opinion, contest the real property Taxes assessed against the Building on an annual basis and, upon Tenant's request, Landlord and Tenant shall meet to discuss such contest and Landlord shall share such information that Landlord may have obtained relative to any recommendation from a tax consultant. All costs incurred by Landlord in seeking to obtain a real property Tax reduction shall be considered an Operating Expense.

7. OPERATING EXPENSES. Tenant shall pay monthly, as Additional Rent, one-twelfth (1/12) of Tenant's Percentage of annual Operating Expenses based on commercially reasonable estimates provided by Landlord on or about each January 1 during the term of this Lease and subject to reconciliation as provided in Section 8 below. "Operating Expenses" means and includes, but is not limited to: (a) all expenses paid or incurred by Landlord for ownership, maintaining, operating and repairing the Property, and all other systems and components of the Building, its parking areas, the curbs, sidewalks and plazas adjoining the same, including, but not limited to, the cost of painting, cleaning, refurbishing, re-carpeting, redecorating, gardening, planting, seeding and maintenance of landscaped areas, trash removal, drain maintenance, assessments, expenses and contributions in connection with the City of Boca Raton's Transportation Demand Management Programs, security guard service and Building security access, exterior maintenance of the improvements, window cleaning, janitorial service, uniforms, management fees, supplies and sundries; (b) utility expenses incurred by Landlord in furnishing utility services for the Property, including the cost of electricity, gas or other fuel, heating, lighting, air conditioning, sewer and waste water service and general surface drainage; (c) those expenses paid or incurred by Landlord for insurance, including, but not limited to, fire, extended coverage, liability, workers compensation, elevator, or any other insurance carried in good faith by Landlord and applicable to the Property; (d) the cost of rental of all supplies, tools, materials and equipment, including expenses paid or incurred by Landlord for sales or use taxes on supplies or services; (e) the cost of wages and salaries of all persons engaged in the operation, maintenance and repair of the Property, and so-called fringe benefits, including social security taxes, unemployment insurance taxes, cost for providing coverage for disability benefits, cost of any pensions, hospitalization, welfare or retirement plans, or any other similar or like expenses incurred under the provisions of any collective bargaining agreement, or any other cost of expense which Landlord pays or incurs to provide benefits for employees so engaged in the operation, maintenance and repair of the Property; (f) the charges of any independent contractor who, under contract with Landlord or its representatives, does any of the work of operating, maintaining or repairing the Property, including without limitation, the charges for services, materials and supplies furnished in connection with the operation, maintenance or repair of any part of the Building or the heating, air conditioning, ventilating, plumbing, roofing, electrical, elevator, escalators, fire detection systems (including sprinklers) and other systems of the Building; (g) depreciation of hand tools and other moveable equipment used in the repair, maintenance or operation of the Property; (h) legal, accounting, and other professional expenses incurred in connection with the operation, maintenance and management of the Property, including, but not limited to, such expenses as relate to seeking refunds of or obtaining reductions in the taxes; (i) the costs of any capital improvement or alteration, together with any financing charges incurred in connection therewith, made to the Property which is either required by a change in or enactment of any new law (or governmental regulation) after the Effective Date or intended by Landlord to reduce operating costs or expenses, it being understood that such costs shall be amortized over their useful life as reasonable determined by Landlord; and (j) the cost of any other service provided by Landlord or any cost that is elsewhere stated in this Lease to be an "Operating Expense". Landlord may allocate any item of Operating Expenses among different portions or occupants of the Building or Property based on use or other considerations as determined by Landlord in Landlord's reasonable discretion. If during any calendar year, any rentable space in the Building shall be vacant or unoccupied, at Landlord's option, the Operating Expense for such calendar year which vary with occupancy shall be adjusted to reflect the expenses that would have been incurred if such space had been occupied. If any Operating Expense, though paid in one (1) year, relates to more than one (1) calendar year, at the option of the Landlord such expense may be proportionately allocated among such related calendar years.

Notwithstanding the foregoing, Operating Expenses shall not include:

(i) Ground lease rental payments;

(ii) Costs incurred by Landlord for the repair of damage to the Building to the extent that Landlord is reimbursed by insurance proceeds;

(iii) Costs, including permit, license and inspection costs, incurred with respect to the installation of tenant improvements made for tenants or other occupants in the Building or incurred in renovating or otherwise improving, decorating, painting or redecorating vacant space for tenants or other occupants of the Building;

(iv) Marketing costs including leasing commissions, attorneys' fees in connection with the negotiation and preparation of letters, deal memos, letters of intent, leases, subleases and/or assignments, space planning costs, and other costs and expenses incurred in connection with lease, sublease and/or assignment negotiations and transactions or the enforcement of the terms of any leases or subleases with present or prospective tenants or other occupants of the Building;

(v) Expenses in connection with services or other benefits which are not offered to Tenant or for which Tenant is charged for directly but which are provided to another tenant or occupant of the Building;

(vi) Overhead and profit increment paid to Landlord or to subsidiaries or affiliates of Landlord for goods and/or services in the Building to the extent the same exceeds the costs of such goods and/or services rendered by unaffiliated third parties on a competitive basis;

(vii) Interest, principal, points and fees on debts or amortization on any mortgage or mortgages or any other debt instrument encumbering the Building;

(viii) Landlord's general corporate overhead and general and administrative expenses;

(ix) Any compensation paid to clerks, attendants or other persons in commercial concessions operated by Landlord;

(x) Advertising and promotional expenditures, and costs of signs in or on the building identifying the owner of the Building or other tenants' signs, other than directional signs, the building directory and maintenance of the Building's monument sign;

(xi) Property management fees in excess of the rates then customarily charged for building management by property managers with equal or better qualifications for buildings of like class and character;

(xii) Penalties for the late payment of any taxes (provided that Tenant is not the cause of such late payment);

(xiii) Wages, cost, and salaries associated with home office, off-site employees of Landlord and wages, cost and salaries attributable to persons above the level of "General Manager";

(xiv) The cost of separate metering and/or tap in charges for utilities for other tenants of Building;

(xv) The cost of correcting defects in the design or construction of or latent defects in the Premises or the Building, including repair or replacement of any item actually paid for or completed under a warranty, except that conditions (not occasioned by construction defects) resulting from ordinary wear and tear will not be deemed defects for the purpose of this category;

(xvi) Except as specifically permitted under this Lease, the cost of any repairs, alterations, additions, changes, replacements, and other items which under generally accepted accounting principles are properly classified as capital expenditures or capital improvements;

(xvii) The cost of tools and equipment used initially in the construction, of the Building;

(xviii) The cost of removal, abatement, or treatment of asbestos or any other hazardous substance, including any amounts expended by Landlord as environmental response costs for removal, enclosure, encapsulation, clean-up, remediation or other activities regarding Landlord's compliance with federal, state, municipal or local hazardous waste and environmental laws, regulations or ordinances;

(xix) Charitable and political contributions of Landlord; and

(xx) Cost and maintenance of paintings, sculptures or other art work leased and/or purchased for display at the Building.

Notwithstanding anything to the contrary contained in this Section 7, Tenant's total Operating Expense payment obligations for all Operating Expenses other than security costs, insurance premiums, utilities, uninsured costs related to weather related events (but in no event more than $[***] per year), and real property taxes shall not increase by more than [***] percent ([***]%) (on a cumulative and compounded basis) over the sum paid by Tenant in the immediately preceding full calendar year. In the event that the immediately preceding calendar year is not a full calendar year, the Operating Expenses shall be equitably estimated so as to approximate the cost for a full calendar year. Any increases in Operating Expenses not recovered by Landlord due to the foregoing limitation may be carried forward into all succeeding calendar years during the Term (on a cumulative and compounded basis) until fully recouped by Landlord.

8. RECONCILIATION. Landlord shall deliver to Tenant within one hundred twenty (120) days after the expiration of each calendar year a reasonably detailed statement (the "Statement") showing Tenant's Percentage of the actual Operating Expenses incurred during such year. Except as otherwise set forth below, Landlord's failure to deliver the Statement to Tenant within said period shall not constitute Landlord's waiver of its right to collect said amounts or otherwise prejudice Landlord's rights hereunder. If Tenant's payments under this Section 8 during said year exceed Tenant's Percentage of Operating Expenses as indicated on the Statement (the "Operating Expense Overstatement"), Landlord shall credit the amount of such overpayment against such payment of Rent next falling due, or, if the Term will expire before the overpayment is fully credited, Landlord shall pay such difference to Tenant within [***] ([***]) days of the determination of such Operating Expense Overstatement. If Tenant's payments under this Section 7 during said year were less than Tenant's Percentage as indicated on the Statement, Tenant shall pay to Landlord the amount of the deficiency within [***] ([***]) days after delivery by Landlord to Tenant of the Statement. Landlord and Tenant shall forthwith adjust between them by cash payment any balance determined to exist with respect to that portion of the last year of the Lease Term for which Tenant is responsible for Operating Expenses, notwithstanding that the Lease Term may have terminated before the end of such year. The obligations set forth in this subsection shall survive the expiration, or earlier termination, of this Lease.

Provided Tenant is not then in default beyond applicable notice and cure periods and has paid the Operating Expenses shown on the Statement, if Tenant disputes the amount set forth in the Statement, Tenant shall have the right, at Tenant's sole expense, not later than [***] ([***]) days following receipt of such Statement, to cause Landlord's books and records with respect to the calendar year which is the subject of the Statement to be audited by a certified public accountant mutually acceptable to Landlord and Tenant); provided, however, Landlord's approval shall not be unreasonably withheld, and the [***] ([***]) day period shall be tolled for the period during which Landlord is determining whether to approve such certified public accountant. The audit shall take place at the offices of Landlord where its books and records are located at a mutually convenient time during Landlord's regular business hours in Palm Beach County, Florida. The accountant conducting the audit shall be compensated on an hourly basis and shall not be compensated based upon a percentage of overcharges it discovers. If Tenant gives Landlord notice of its intention to audit Operating Expenses, it must commence such audit within [***] ([***]) days after such notice is delivered to Landlord, and the audit must be completed within [***] ([***]) days after such notice is delivered to Landlord. If Tenant does not commence and complete the audit within such periods, the Statement that Tenant elected to audit shall be deemed final and binding upon Tenant and shall, as between the parties, be conclusively deemed correct. Tenant will use good faith commercially reasonable efforts to keep the results of any Operating Expense audit confidential. Upon Landlord's receipt of a timely objection notice from Tenant, Landlord and Tenant shall work together in good faith to resolve the discrepancy between Landlord's statement and Tenant's review. If Landlord and Tenant determine that Operating Expenses for the year in question are less than reported in Landlord's statement, Landlord shall provide Tenant with a credit against future Rent in the amount of any overpayment by Tenant. Likewise, if Landlord and Tenant determine that Operating Expenses for the year in question are greater than reported in Landlord's statement, Tenant shall forthwith pay to Landlord the amount of underpayment by Tenant. If after Landlord and Tenant agree on the results of any audit of Landlord's books and records indicates that Landlord has made an error in Landlord's favor for more than [***] percent ([***]%) of the amount of Operating Expenses for any calendar year, Landlord shall reimburse Tenant for Tenant's reasonable costs of conducting the audit up to a maximum of $[***]. In addition, Landlord shall pay to Tenant an amount equal to such overstated amounts, which sums shall be paid within [***] ([***]) days of Tenant's demand therefore. If such payment is not received by Tenant prior to the expiration of such [***] ([***]) day period, Tenant may withold such amount from future payments of Rent until such amount is reduced to 0.00.

Notwithstanding any provision in this Lease to the contrary, Landlord shall not be entitled to collect any charge or expense for Operating Expenses if Landlord has not presented Tenant with a billing within [***] ([***]) years after the date such charge or expense was incurred.

9. INSURANCE.

(A) Tenant shall maintain the following insurance in force from the date upon which Tenant first enters the Premises and throughout the Term and thereafter for so long as Tenant is in occupancy of any part of the Premises:

(i) Commercial General Liability insurance with limits of at least $[***] per occurrence, $[***] general aggregate, and, if the Tenant manufacturers or produces a product, $[***] products completed operations aggregate or such larger amounts as Landlord may reasonably require from time to time, covering bodily injury and property damage arising out of the use of the Premises, as well as products/completed operations, blanket contractual liability, personal injury and advertising liability;

(ii) Worker's Compensation insurance as required by the state in which the Premises is located covering occupational injuries or disease to all employees of Tenant and to any contractors, subcontractors or other agents used by Tenant for work or other activities on or about the Premises. If such insurance is not required by the state in which the Premises is located, then, and in any event, Tenant shall maintain such insurance with Employer's Liability limits of at least $[***] each accident, $[***] each employee, and $[***] disease;

(iii) Business Automobile Liability insurance for all owned (Symbol 1), non-owned (Symbol 9) hired, rented and/or borrowed (Symbol 8) vehicles used by the Tenant, its employees or agents. Such policy shall include a combined single limit of liability of at least $[***] per claim for bodily injury and property damage;

(iv) Excess or Umbrella Liability insurance with a limit of at least $[***] providing additional limits of insurance over the primary per occurrence and aggregate limits of the Commercial General Liability (including bodily injury, property damage, products/completed operations, personal/advertising injury and blanket contractual liability); and

(v) Property insurance covering "all risk" of physical damage to Tenant's personal property.

(B) Tenant's Commercial General Liability, Property, and Excess Liability/Umbrella Liability policies shall name Landlord and Landlord's managing agent and any mortgagee that Landlord has provided the name of to Tenant, as Additional Insureds and the Commercial General Liability and Excess Liability/Umbrella Liability shall be primary and non-contributory insurance as to any insurance carried by the parties designated as Additional Insureds. All policies purchased and maintained by Tenant to satisfy the requirements in this Lease must be purchased from an insurance company with a minimum rating of "A- X" or its equivalent from one of the major rating agencies (AM Best, Moodys, Standard & Poors, Fitch) that is admitted or eligible to do business in the state where the Premises is located.

(C) Tenant shall provide Landlord with a certificate of insurance for each policy simultaneously with the delivery of an executed counterpart of this Lease and at least [***] ([***]) days prior to each renewal of such insurance. Such certificates of insurance shall be on an ACORD Form 25 or ISO Form 2026 or their equivalent, shall certify that such policy has been or shall be issued and that it provides the coverage and limits required above, and shall provide that the insurance shall not be canceled or materially changed unless [***] ([***]) days prior written notice shall have been given to Landlord. Tenant shall notify Landlord in writing at least [***] ([***]) days in advance if Tenant intends to or receives a notice that its insurance company intends to cancel or non-renew such insurance for any reason, or if the required coverage or limits are to be materially changed from the initial requirements in this Lease. In the event that the applicable statutory time period is less than [***] ([***]) days, then Tenant shall notify Landlord within [***] ([***]) business days of receipt of any cancellation or non-renew notice. In the event that Tenant fails to obtain or maintain the insurance required above or fails to provide the Certificates of Insurance required, Landlord may, at its option, after providing Tenant with written notice and a reasonable opportunity to cure, obtain such insurance on behalf of Tenant. Tenant shall pay, as Additional Rent within [***] ([***]) days after Landlord's written demand, the reasonable cost of such insurance. Landlord's failure to obtain such coverage on behalf of Tenant shall not limit Tenant's liability in the event of an uncovered loss.

(D) Landlord shall carry or cause to be carried property insurance for full replacement cost and commercial general liability insurance in amounts and with deductibles as a reasonably prudent owner of a building similar to the Building in the geographic vicinity of the Building ("Comparable Building") would purchase and maintain with respect to the Property. Tenant shall pay Tenant's Percentage of Landlord's insurance premiums ("Insurance Premiums") during the Term of the Lease as a part of Operating Expenses. If Tenant does conduct any activity within or about the Premises that result in an increase to the cost of Landlord's insurance Tenant shall reimburse Landlord for the entire amount of such additional premiums or surcharges within [***] ([***]) days after Landlord's written demand.

(E) The limits of insurance required by this Lease, or as carried by Tenant, will not limit the liability of Tenant or relieve Tenant of any obligation hereunder, except to the extent provided for under Section 10 below (Subrogation). Any deductibles selected by Tenant will be the sole responsibility of Tenant.

(F) Landlord may, at its sole discretion, change the insurance policy limits and forms which are required to be provided by Tenant; such changes will be made to conform with common insurance requirements for Comparable Buildings if commercially reasonably available.

10. WAIVER OF SUBROGATION. All provisions of this Lease to the contrary notwithstanding, Landlord waives any and all rights of recovery against Tenant, Tenant's employees, agents and contractors for or arising out of damage to, or destruction of the Building, the Premises or Landlord's personal property to the extent that such damage or destruction is covered by Landlord's insurance policies then in effect or the insurance policies Landlord is required to obtain by Section 9 (whether or not the insurance Landlord is required to obtain by Section 9 is then in force and effect), whichever is broader. Landlord's waiver shall not be limited by the amount of insurance then carried by Landlord. All provisions of this Lease to the contrary notwithstanding, Tenant waives any and all rights of recovery against Landlord, Landlord's employees, agents and contractors for loss or damage to the Premises and Tenant's personal property to the extent such liability or damage is covered by Tenant's insurance policies then in force or the insurance policies Tenant is required to obtain by Section 9 (whether or not the insurance Tenant is required to obtain by Section 9 is then in force and effect), whichever is broader. Tenant's waiver shall not be limited by the amount of insurance then carried by Tenant. Each party shall cause the property insurance policies it obtains in accordance with Section 9 to provide that the insurance company waives all right of recovery by subrogation against the other party in connection with any liability or damage covered by such insurance policies. If necessary to effect the foregoing waivers, Landlord and Tenant hereby agree to cause an endorsement to be issued to their respective insurance policies (including any contents, fire and casualty insurance) recognizing this waiver of subrogation; provided, however, that failure to obtain such endorsements shall not affect the releases hereinabove given.

11. SECURITY DEPOSIT. Upon execution of this Lease, Tenant shall deposit with Landlord the amount of the Security Deposit specified in Section 1 of this Lease. Provided that Tenant has paid all amounts due and has otherwise performed all obligations hereunder, the Security Deposit shall be returned to Tenant without interest within [***] ([***]) days of the expiration of the Term, further provided that Landlord may deduct from the Security Deposit prior to returning it any amounts owed by Tenant to Landlord. If Tenant defaults under any provision of this Lease, Landlord may, but shall not be obligated to, apply all or any part of the Security Deposit to cure the default. In the event Landlord elects to apply the Security Deposit as provided for above, Tenant shall, within [***] ([***]) business days after Landlord's demand, restore the Security Deposit to the original amount. Landlord may, at its discretion, commingle the Security Deposit with its other funds. Upon any sale or other conveyance of the Building, Landlord may transfer the Security Deposit (or any amount of the Security Deposit remaining) to a successor owner, and upon such successor's actual receipt of the Security Deposit (or any amount of the Security Deposit remaining) Tenant agrees to look solely to the successor owner for repayment of the same. The Security Deposit shall not operate as a limitation on any recovery to which Landlord may be entitled.

12. USE. The Premises shall be used for the Permitted Use and for no other purposes whatsoever. Tenant shall not do or permit to be done in or about the Premises, Building or Property anything which is prohibited by any ordinance, order, rule, regulation, certificate of occupancy, or other governmental requirement, now in force or which may hereafter be enacted, including, without limitation, the Americans with Disabilities Act of 1990, as amended (collectively, "Applicable Law"). Tenant shall comply with all Applicable Law that applies to Tenant's use or occupation of the Premises and common areas of the Property. Tenant shall use and cause all contractors, agents, employees, invitees and visitors of Tenant to use the Premises and any common area of the Property in such a manner as to prevent waste, nuisance and any disruption of other occupants. Tenant shall not place a load upon any floor in the Premises exceeding the floor load per square foot of area which such floor was designed to carry or which is allowed by law. The judgment of any court of competent jurisdiction or the admission by Tenant in any action or proceeding against Tenant, whether Landlord is a party thereto or not, that Tenant has violated any Applicable Law in the use or occupancy of the Premises, Building or Property shall be conclusive of that fact as between Landlord and Tenant.

13. MAINTENANCE; SERVICES. Excepting only those obligations for which Landlord is expressly responsible pursuant to this section, Tenant will, throughout the Term and at its sole cost, keep and maintain the interior of the Premises and all fixtures and equipment located therein, including, without limitation, carpeting, wall-covering, doors, plumbing and other fixtures, and any alterations performed for the benefit of the Premises, clean safe and in good working order, condition and repair and make all necessary repairs and replacements thereto, including, without limitation, replacing all interior broken glass with glass of the same size and quality as that broken and maintain all systems or portions of systems exclusively serving the Premises including, without limitation, electrical, mechanical, plumbing and heating, ventilating and air conditioning systems. All repairs and replacements required of Tenant in connection herewith shall be of a quality and class at least equal to the minimum building standards established by Landlord and shall be done in a good and workmanlike manner in compliance with all applicable laws and the terms and conditions of this Lease. If Tenant fails to maintain the Premises in compliance with the terms hereof, Landlord shall have the right after written notice to do such acts and expend such funds at the expense of Tenant as are reasonably required and Tenant shall reimburse Landlord for the cost thereof as Additional Rent within [***] ([***]) business days after written demand. In the event Tenant shall request that it be allowed to consume, or actually does consume electrical services in excess of that so determined by Landlord to be reasonable for office use, Landlord may require that upgraded supply facilities, panels and/or sub-meters be installed at Tenant's expense. Tenant agrees not to connect with water pipes any apparatus using water without consent of Landlord. Tenant shall not be permitted to install any equipment causing a floor load in excess of eighty (80) pounds per square foot. Landlord's may, in its reasonable discretion, grant Tenant the right to exceed the floor loading capacity stated above in certain portions of the Building.

Should Tenant require any additional service not provided by Landlord pursuant to this Lease, Landlord shall reasonably cooperate with Tenant to obtain such additional service and Tenant agrees to pay Landlord's charges therefor, including a reasonable administrative fee, any taxes imposed thereon, and, where appropriate, a reasonable allowance for depreciation of any systems being used to provide such service, as Additional Rent within [***] ([***]) days after Landlord's written demand. Landlord will provide afterhours HVAC upon Tenant's request subject to limitations due to reasonable maintenance and repair on such systems and Force Majeure. The current charge for after-hours HVAC usage is $[***] per hour, subject to adjustment from time to time by Landlord but not more than [***]% per year, on a cumulative and compounded basis.

If there is a tenant in the Building that will consume electricity materially beyond that of a typical office tenant, Landlord shall equitably allocate the total cost of electricity for the Building to all tenants and shall require the tenant that is consuming electricity materially beyond that of a typical office tenant to pay an increase in its electricity costs.

If the Premises contains supplemental HVAC equipment which is sub metered, Tenant shall be responsible to pay the cost for the same. During the Term, Tenant shall be solely responsible for maintaining any supplemental HVAC equipment in good condition and repair at Tenant's sole cost and expense, and Tenant shall reimburse Landlord for all electricity consumed by the supplemental HVAC equipment, as Additional Rent, within [***] ([***]) days after Tenant's receipt of Landlord's invoice for same.

Landlord shall maintain the roof, foundation, exterior walls, structural portions of the Building, elevators, if any, any Common Areas and electrical, plumbing, mechanical and fire protection systems (subject to systems exclusive to the Premises such as dishwashers) of the Building, the cost of which shall be included as a part of Operating Expenses, provided that Landlord shall have no obligation to make any repairs unless Landlord has first received written notice of the need for such repairs from Tenant. Notwithstanding the foregoing and subject to the terms herein, any damage to the Property occasioned by the negligence or willful act of Tenant or any person claiming under Tenant, or contractors, agents, employees, invitees or visitors of Tenant or any such person, shall be repaired by and at the sole expense of Tenant, except that Landlord shall have the right, at its sole option, to make such repairs and to charge Tenant for all costs and expenses incurred in connection therewith and Tenant shall pay the cost therefor as Additional Rent within [***] ([***]) days after Landlord's written demand. Landlord shall not be responsible to maintain any additional air conditioning equipment particular to the Premises, such as air conditioning units located in a computer room or other utility area, or for any plumbing particular to the Premises, such as a break room or restroom located within the Premises.

In addition to the foregoing, during normal hours of operation of the Building throughout the Term, Landlord shall provide: (i) reasonable quantities of electricity for the common areas; (ii) electricity for Tenant's normal office use; (iii) heating, ventilation and air conditioning as required in Landlord's reasonable judgment for the comfortable use and occupancy of the Premises during the normal hours of operation of the Building; (iv) building standard window washing and janitorial services; (v) water for drinking, cleaning and restroom purposes only, and (vi) such other services as Landlord reasonably determines are necessary or appropriate. The normal hours of operation of the Building shall be 8:00 a.m. to 6:00 p.m. on Monday through Friday (except holidays) and 9:00 a.m. to 1:00 p.m. on Saturday (except holidays). Upon Tenant's request, Landlord shall replace Building standard bulbs and ballasts in the Premises (to be included in Operating Expenses).

14. SUBLEASE; ASSIGNMENT. Tenant shall not mortgage, pledge, hypothecate or otherwise encumber its interest in this Lease without Landlord's consent, which will not be unreasonably withheld, conditional or delayed. Except in connection with a Permitted Transfer (as hereinafter defined), Tenant shall not allow the Premises to be occupied, in whole or in part, by any other party and shall neither sublet the Premises, in whole or in part, nor assign this Lease, nor amend any sublease or assignment to which Landlord has consented, without in each case obtaining the prior written consent of Landlord. Any sublease or assignment, or amendment to any sublease or assignment, without Landlord's prior written consent shall, at Landlord's option, be null, void and of no effect, and shall, at Landlord's option, constitute an Event of Default. Except in connection with a Permitted Transfer, the provisions of this section shall apply to a transfer, by one or more transfers, of all, or substantially all, of the business or assets of Tenant, of a majority of the stock, partnership or membership interests, or other evidences of ownership, of Tenant, and of any shares, voting rights or ownership interests of Tenant which results in a change in the identity of the entity or entities which exercise, or may exercise, effective control of Tenant as if such transfers were an assignment of this Lease. Tenant must request Landlord's consent to any assignment or sublease at least [***] ([***]) days prior to the proposed effective date of the assignment or sublease. At the time of its request, Tenant shall provide Landlord in writing: (a) the name and address of the proposed assignee or subtenant, (b) a complete copy of the proposed assignment or sublease, (c) reasonably satisfactory information about the nature, business, and business history of the proposed assignee or subtenant and its proposed use of the Premises, and (d) banking, financial or other credit information about the proposed assignee or subtenant sufficient to enable Landlord to determine its financial condition and operating performance. Concurrently with such request, Tenant shall pay to Landlord a fee of $[***] to defray Landlord's expenses in reviewing such request. Landlord shall not unreasonably withhold or delay its consent to Tenant's written request to sublease the Premises or assign this Lease which is made in compliance with the terms and conditions of this section. Without limiting the other instances in which it may be reasonable for Landlord to withhold its consent to an assignment or sublease, Landlord's refusal to consent to any proposed assignment or sublease shall not be unreasonable if: (a) the financial condition or operating performance of the proposed subtenant or assignee, determined in Landlord's reasonable discretion does not meet Landlord's then existing Leasing criteria, (b) Tenant is in default under any of the terms, covenants or conditions of this Lease beyond applicable notice and cure periods, (c) the proposed use of the Premises may result in increased wear and tear on the Premises or the Building, (d) the proposed subtenant or assignee is a governmental agency, (e) Landlord has comparable space available elsewhere in the Building which can accommodate the needs of the proposed subtenant or assignee or the proposed subtenant and the assignee is a prospect to whom Landlord has made a proposal for the lease of space within the Building within the prior [***] ([***]) months, (f) the proposed subtenant or assignee would cause Landlord to be in violation of any covenant or restriction contained in another lease or other agreement, or (h) Landlord's lender, if any, does not consent to the proposed sublease or assignment.

No subletting or assignment shall release Tenant from Tenant's obligations under this Lease or alter the primary liability of Tenant to pay the Rent and to perform all other obligations to be performed by Tenant hereunder. Any subtenant shall, at Landlord's election, attorn to Landlord following any early termination of this Lease and any assignee shall be jointly and severally liable for the full performance of all of Tenant's obligations hereunder. Landlord may require, as a condition to granting Landlord's consent with respect to the provisions of this section, that the proposed subtenant or assignee enter into a written agreement with Landlord confirming the obligations of such subtenant or assignee under this Lease. If Tenant receives rent or other payments under any assignment or sublease in excess of the payments made by Tenant to Landlord under this Lease (as such amounts are adjusted on a per square foot basis if less than all of the Premises is transferred), then Tenant shall pay Landlord [***] ([***]%) of such excess after first deducing the reasonable and customary third party costs incurred by Tenant to effectuate the transfer. Landlord's consent to one assignment or sublease shall not be deemed a waiver of the requirement of Landlord's consent to any subsequent assignment or sublease.

Notwithstanding anything to the contrary contained in this Section 14, provided Tenant is not in default beyond applicable notice and cure periods, Tenant may assign this Lease or sublet the Premises (or a portion thereof) in connection with any of the following without the prior written consent of Landlord (and without being required to pay any excess rents to Landlord), each a "Permitted Transfer" to an entity (each a "Permitted Transferee") in connection with: (i) a sale of all or substantially all of Tenant's assets or stock to an unrelated entity, (ii) any merger, consolidation, reorganization or similar transaction, (iii) any assignment or sublease to an Affiliate, or (iv) any transfer of stock whenever Tenant is a corporation, the outstanding stock of which is listed on a recognized national stock exchange. The term "Affiliate" as used in this Section 14, shall mean any person or entity that is, directly or indirectly, controlled by, under common control with, or controlling, another person or entity. Tenant acknowledges and agrees that any such assignment or sublease shall not release Tenant from Tenant's obligations hereunder or alter the primary liability of Tenant to pay the Rent and other sums due Landlord hereunder and to perform all other obligations to be performed by Tenant hereunder. In such event, Tenant must give Landlord at least [***] ([***]) days prior written notice with respect to any such Permitted Transfer.

15. INDEMNITY; NON-LIABILITY OF LANDLORD.

(A) Subject to the terms of Section 10 hereof, and except to the extent caused by the negligence or willful misconduct of an Indemnified Party, Tenant hereby agrees to indemnify, defend and hold harmless Landlord and its employees, partners, agents, members, managers, lenders and ground lessors (said persons and entities are hereinafter collectively referred to as the "Indemnified Parties") from and against any and all liability, loss, cost, damage, claims, loss of rents, liens, judgments, penalties, fines, settlement costs, investigation costs, the reasonable cost of consultants and experts, reasonable attorneys' fees, court costs and other legal expenses, insurance policy deductibles and other reasonable expenses (hereinafter collectively referred to as "Damages") arising out of or related to an "Indemnified Matter" (as defined below). For purposes of this Section 15, an "Indemnified Matter" shall mean any matter for which one or more of the Indemnified Parties incurs liability or Damages if the liability or Damages are caused by (a) any negligent act or omission or willful misconduct of Tenant or its employees, agents, assignees, subtenants, licensees, contractors or invitees (all of said persons or entities are hereinafter collectively referred to as "Tenant Parties"), (b) Tenant's failure to perform any of its obligations under the Lease (which failure continues after the passage of any applicable notice and cure period under the Lease), (c) the use or occupancy of the Premises by Tenant or any person claiming under Tenant, and/or (d) any other matters for which Tenant has agreed to indemnify Landlord pursuant to any other provision of this Lease. Tenant's obligations hereunder shall include, but shall not be limited to, compensating the Indemnified Parties for Damages arising out of Indemnified Matters within [***] ([***]) days after written demand from an Indemnified Party plus a reasonable period of time for Tenant's investigation of the claim. Tenant shall also defend, with counsel reasonably satisfactory to the Indemnified Party, at Tenant's sole expense, within [***] ([***]) days after written demand from the Indemnified Party, plus a reasonable period of time for Tenant's investigation of the claim, any claims, action or proceeding arising out of or relating to an Indemnified Matter whether or not litigated or reduced to judgment and whether or not well founded. This indemnity is intended to apply to the fullest extent permitted by applicable law. Tenant's obligations under this Section shall survive the expiration or termination of this Lease unless specifically waived in writing by Landlord after said expiration or termination. Except in connection with liabilities, obligations, and claims pursuant to Sections 17 and 28 herein, Landlord hereby waives its right to recover consequential, special, indirect, exemplary or punitive damages (including but not limited to, lost profits) arising out of an Indemnified Matter.

(B) Subject to the terms of Section 10, and except to the extent caused by the negligence or willful misconduct of a Tenant Indemnified Party, Landlord hereby agrees to indemnify, defend and hold harmless Tenant and its employees, affiliates and agents (said persons and entities are hereinafter collectively referred to as the "Tenant Indemnified Parties") from and against any and all Damages that result from (i) the negligence or intentional misconduct of Landlord its employees and its authorized representatives (ii) Landlord's failure to perform any of its obligations under the Lease (which failure continues after the passage of any applicable notice and cure period under the Lease), and (iii) any other matters for which Landlord has agreed to indemnify Tenant pursuant to any other provision of this Lease (a "Tenant Indemnified Matter"). Landlord's obligations hereunder shall include, but shall not be limited to (a) compensating the Tenant Indemnified Parties for Damages arising out of Tenant Indemnified Matters within [***] ([***]) days after written demand from a Tenant Indemnified Party plus a reasonable period of time for Landlord's investigation of the claim and (b) providing a defense, with counsel reasonably satisfactory to the Tenant Indemnified Party, at Landlord's sole expense, within [***] ([***]) days after written demand from the Tenant Indemnified Party plus a reasonable period of time for Landlord's investigation of the claim, of any claims, action or proceeding arising out of or relating to an Tenant Indemnified Matter. This indemnity is intended to apply to the fullest extent permitted by applicable law. Landlord's obligations under this section shall survive the expiration or termination of this Lease unless specifically waived in writing by Tenant after said expiration or termination. Tenant hereby waives its right to recover consequential, special, indirect, exemplary or punitive damages (including but not limited to, lost profits) arising out of a Tenant Indemnified Matter.

16. UTILITIES. Tenant shall contract directly with public utility providers for all utilities which are separately metered to the Premises and shall pay such utility providers directly and promptly when due. If any utility is not separately metered to the Premises, the cost of such utility consumed on the Premises, as reasonably determined by Landlord, shall be paid by Tenant as a part of Operating Expenses. Tenant's obligation to pay for utilities provided to the Premises during the Term shall survive the expiration or earlier termination of the Lease. Tenant shall not utilize an alternative provider for a utility service other than the public utility provider servicing the Property unless Tenant shall first obtain the written consent of Landlord. Landlord shall not be liable or responsible for any loss, damage, or expense that Tenant may sustain or incur by reason of any change, failure, interruption, or defect in the supply or character of the electric energy furnished to the Premises or Building by the applicable utility provider. To ensure the proper functioning and protection of all utilities, Tenant agrees to abide by all reasonable regulations and requirements which Landlord may prescribe and to allow Landlord and its utility providers' access to all electric lines, feeders, risers, and wiring within the Premises.

Notwithstanding the provisions of this Section 16, in the event the Building experiences an interruption of electrical, telephone, HVAC or water service, which in any such case prevents Tenant from utilizing the Premises (or portion thereof) to conduct its business (a "Service Failure") which Service Failure is due to Landlord's actions (i.e. not as a result of the inability of Landlord to obtain the applicable utility service through no fault of Landlord (a "Controllable Service Failure"), Landlord shall commence and diligently pursue the curative action within a commercially reasonable amount of time after written notice from Tenant of a Controllable Service Failure. Notwithstanding the foregoing, if Tenant does not conduct business in the Premises (or portion thereof) as a result of a Controllable Service Failure, Tenant shall be entitled to an equitable abatement of Rent (in proportion to the portion of the Premises subject to the Service Failure) with respect to a Controllable Service Failure commencing with the [***] ([***]) consecutive business day after Tenant's notice to Landlord of the Controllable Service Failure until such time as the services are restored and/or the applicable repair is made, as the case may be.

17. HOLDING OVER. If Tenant or any party claiming by or under Tenant remains in occupancy of the Premises or any part thereof beyond the expiration or earlier termination of this Lease, such holding over shall be without right and a tenancy at sufferance, and Tenant shall be liable to Landlord for any actual loss or damage incurred by Landlord as a result thereof, including consequential damages, provided that in the case of consequential damages Landlord has first provided Tenant with at least [***] ([***]) days prior written notice that Landlord is obligated to deliver the space to a bona fide new tenant and that Landlord's failure to deliver the space to such new tenant could result in consequential damages. In addition, for each month or any part thereof that such holding over continues, Tenant shall pay to Landlord a monthly fee for the use and occupancy of the Premises equal to [***] percent ([***]%) of the Base Rent payable for the month immediately preceding such hold over, plus all Additional Rent due hereunder and there shall be no adjustment or abatement for any partial month. The provisions of this section shall not be deemed to limit or exclude any of Landlord's rights of re-entry or any other right granted to Landlord hereunder, at law or in equity.

18. NO RENT DEDUCTION OR SET OFF. Tenant's covenant to pay Rent is and shall be independent of each and every other covenant of this Lease. Tenant agrees that any claim by Tenant against Landlord shall not be deducted from Rent nor set off against any claim for Rent in any action except as expressly permitted under this Lease. No payment by Tenant or receipt by Landlord of a lesser amount than the Rent herein stipulated shall be deemed to be other than on account of the earliest stipulated Rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as Rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or pursue any remedy provided in this Lease or at law. In connection with the foregoing, Landlord shall have the absolute right in its sole discretion to apply any payment received from Tenant to any account or other payment of Tenant then not current and due or delinquent.

19. CASUALTY. If the Premises or any part thereof are damaged by fire or other casualty, Tenant shall give prompt notice thereof to Landlord. If the Premises or the Building are totally or partially damaged or destroyed by fire or other casualty, thereby rendering the Premises totally or partially inaccessible or unusable, Landlord shall diligently restore and repair the Premises and the Building to substantially the same condition they were in prior to such damage. Until the repair and restoration of the Premises is completed, Rent shall be abated for that part of the Premises that Tenant is unable to use and is not occupied while repairs are being made, based on the ratio that the amount of unusable rentable area bears to the total rentable area of the Premises. Landlord shall bear the costs and expenses of repairing and restoring the Premises and the Building, provided, however, that Landlord shall not be obligated to spend more than the net proceeds of insurance proceeds made available for such repair and restoration nor shall Landlord be obligated to repair or restore, or to pay for the repair or restoration of, any furnishings, equipment or personal property belonging to Tenant. It shall be Tenant's sole responsibility to repair and restore all such items.

Notwithstanding the foregoing, (a) if there is a destruction of the Building that exceeds [***] percent ([***]%) of the replacement value of the Building from any risk, whether or not the Premises are damaged or destroyed, or (b) if Landlord reasonably believes that the repairs and restoration cannot be completed despite reasonable efforts within [***] ([***]) days after the occurrence of such damage, or (c) if Landlord reasonably believes that there shall be less than [***] ([***]) year remaining in the Term (exclusive of any extension options) upon the substantial completion of such repairs and restoration, or (d) if any mortgagee or lender fails or refuses to make sufficient insurance proceeds available for repairs and restoration, or (e) if zoning or other applicable laws or regulations do not permit such repairs and restoration, Landlord shall have the right, at its sole option, to terminate this Lease by giving written notice of termination to Tenant within [***] ([***]) days after the occurrence of such damage. If this Lease is terminated pursuant to the preceding sentence, all Rent payable hereunder shall be apportioned and paid to the date Tenant was unable to occupy and ceased operations in the Premises.

Notwithstanding the foregoing, (a) if there is a destruction of the Building that exceeds [***] percent ([***]%) of the replacement value of the Building from any risk, and Tenant's use of the Premises or the Common Areas are materially adversely impacted, or (b) if Landlord reasonably believes that the repairs and restoration cannot be completed despite reasonable efforts within [***] ([***]) days after the occurrence of such damage, and Tenant's use of the Premises or the Common Areas are materially adversely impacted, or (c) if Landlord reasonably believes that there shall be less than [***] remaining in the Term (exclusive of any extension options) upon the substantial completion of such repairs and restoration, and Tenant's use of the Premises or the Common Areas are materially adversely impacted, or (d) if the Premises or Common Areas are damaged or destroyed and any mortgagee or lender fails or refuses to make sufficient insurance proceeds available for repairs and restoration, or (e) if zoning or other applicable laws or regulations do not permit such repairs and restoration, then Tenant shall have the right, at its sole option, to terminate this Lease by giving written notice of termination to Landlord within [***] ([***]) days after the occurrence of such damage. If this Lease is terminated pursuant to the preceding sentence, all Rent payable hereunder shall be apportioned and paid to the date Tenant was unable to occupy and ceased operations in the Premises.

If neither party elects to terminate this Lease and Landlord commences to restore the Building but does not substantially complete the repair and restoration of the Building within [***] ([***]) days following the date of casualty, then Tenant may terminate this Lease upon written notice to Landlord as of the end of such [***] ([***]) day period by providing written notice to Landlord, such termination to be effective [***] ([***]) days after notice from Tenant is received by Landlord, unless Landlord substantially completes the repairs within such [***] ([***]) day period upon which the Tenant's termination shall be vitiated and the Lease shall continue in full force and effect.

In the event of any damage or destruction to the Building or Premises, it shall be Tenant's responsibility to secure the Premises and, upon notice from Landlord, to remove forthwith, at its sole cost and expense, property belonging to Tenant or its licensees from such portion of the Premises as Landlord shall request.

20. SUBORDINATION; ESTOPPEL LETTERS. This Lease is expressly subject and subordinate to any current or future mortgage or mortgages placed on the Property and to all other documents executed in connection with any such mortgage. Tenant agrees that from time to time it shall deliver to Landlord or Landlord's mortgagee or designee within ten (10) business days of the date of Landlord's or Landlord's mortgagees or such other designee's request, a statement, in writing, certifying (i) that this Lease is unmodified and in full force and effect, if this is so, or if there have been modifications, that the Lease, as modified, is in full force and effect; (ii) the dates to which Rent and other charges have been paid; (iii) that Landlord is not in default under any provisions of this Lease or, if in default, the nature thereof in detail; and (iv) such other true statements as Landlord or Landlord's mortgagee or designee may reasonable require. Tenant's failure to execute and deliver such statements within the time required shall, at Landlord's election, be an Event of Default and shall also be conclusive upon Tenant that (a) this Lease is in full force and effect and has not been modified except as represented by Landlord; (b) that Landlord is not in default under any provisions of this Lease and that Tenant has no right of offset, counterclaim or deduction against Rent.

Notwitstanding the foregoing, Landlord will obtain a subordination, non-disturbance and attornment agreement in the form attached hereto as **Exhibit H** (the "SNDA") executed by Landlord and the current mortgagee, and Tenant shall execute and deliver such SNDA concurrently with Tenant's execution and delivery of this Lease and until the Full Premises Commencement Date, Landlord shall obtain a subordination/non-disturbance and attornment agreement from any future mortgagee on such mortgagee's standard form, subject to Tenant's reasonable comments. After the occurrence of the Full Premises Commencement Date and upon Tenant's request, Landlord agrees to use reasonable efforts to have any mortgagee of the Property enter into its usual subordination, non-disturbance agreement with Tenant provided that Tenant is not then in default under this Lease.

21. ALTERATIONS; RESTORATION.

(A) Tenant shall not make or permit to be made any alterations, additions, or improvements in or to the Premises ("Alterations") without first obtaining the prior written consent of Landlord which consent shall not be unreasonably withheld, conditioned or delayed, provided any Alterations that may impact the structural portions of the Building or any mechanical systems shall be in Landlord's sole discretion. All Alterations (i) must comply with all applicable laws, (ii) must be compatible with the Building and its mechanical, electrical, heating, ventilating, air-conditioning and life safety systems; (iii) must not interfere with the use and occupancy of any other portion of the Building by any other tenant or their invitees; and (iv) must not affect the integrity of the structural portions of the Building. In addition, Landlord may impose as a condition to such consent such additional requirements as Landlord in its sole discretion deems necessary or desirable, including, without limitation: (a) Tenant's submission to Landlord, for Landlord's prior written approval, of all plans and specifications relating to the Alterations; (b) Landlord's prior written approval of the time or times when the Alterations are to be performed; (c) Landlord's prior written approval of the contractors and subcontractors performing work in connection with the Alterations; (d) Tenant's receipt of all necessary permits and approvals from all governmental authorities having jurisdiction over the Premises prior to the construction of the Alterations; (e) Tenant's delivery to Landlord of such bonds and insurance as Landlord customarily requires; (f) Tenant's payment to Landlord of a commercially reasonable fee for Landlord's supervision of any Alterations; (g) Tenant's and Tenant's contractor's compliance with such construction rules and regulations and building standards as Landlord promulgates from time to time; and (h) Tenant's delivery to Landlord of "as built" drawings of the Alterations in such form or medium as Landlord may reasonably require. All direct and indirect costs relating to any modifications, alterations or improvements of Building, whether outside or inside of the Premises, required by any governmental agency or by law as a condition or as the result of any Alteration requested or effected by Tenant shall be borne by Tenant. Tenant shall not permit any mechanic's lien or other liens to be placed upon the Premises or the Building as a result of any materials, services or labor ordered by or provided to Tenant or any of Tenant's agents, officers, or employees. Without waiving any other rights or remedies under this Lease, Landlord may bond or insure or otherwise discharge any such lien and Tenant shall reimburse Landlord for any amount paid by Landlord in connection therewith as Additional Rent within [***] ([***]) days after Landlord's written demand.

(B) Upon the expiration or earlier termination of the Lease, Tenant shall surrender the Premises in good working order and condition, reasonable wear and tear and damage by casualty or condemnation excepted. Tenant shall remove any trade fixtures, equipment, data/telecommunications cabling and wiring installed by or on behalf of Tenant and furniture from the Premises and Tenant shall fully repair any damage, including any structural damage, occasioned by the removal of the same. Notwithstanding the foregoing, Landlord may require that Tenant not remove any or all Alterations and any such Alteration or Alterations shall become a part of the realty and shall belong to Landlord without compensation, and title thereto shall pass to Landlord under this Lease as by a bill of sale. At the time Tenant requests approval for an Alteration, Tenant may request that Landlord also provide consent for such Alteration to remain upon expiration of the Term, with Landlord not to unreasonably withhold consent thereto, and if Landlord consents (i) to the Alteration, and (ii) for the Alteration to remain, Tenant shall not be required to remove the Alteration in accordance with the terms of the Lease upon expiration of the Term. At Landlord's election, all Alterations, trade fixtures, equipment, wire and cable, furniture, fixtures, other personal property not removed shall conclusively be deemed to have been abandoned by Tenant and may be appropriated, sold, stored, destroyed or otherwise disposed of by Landlord without notice to Tenant or to any other person and without obligation to account for them. Tenant shall pay Landlord all reasonable expenses incurred in connection with Landlord's disposition of such property, including without limitation the cost of repairing any damage to the Building or the Premises caused by removal of such property, and shall hold Landlord harmless from loss, liability, or expense arising from the claims of third parties such as Tenant's lenders whose loans are secured by such property. Tenant's obligations under this section shall survive the end of this Lease.

(C) The interest of Landlord in the Premises shall not be subject in any way to any liens, including construction liens, for improvements to or other work performed in the Premises by or on behalf of Tenant. Tenant shall have no power or authority to create any lien or permit any lien to attach to the present estate, reversion, or other estate of Landlord in the Premises or in the Property and all mechanics, materialmen, contractors, artisans, and other parties contracting with Tenant or its representatives or privies as to the Premises or any part of the Premises are charged with notice that they must look to Tenant to secure payment of any bill for work done or material furnished or for any other purpose during the Lease term. These provisions are made with express reference to Section 713.10, Florida Statutes. Landlord and Tenant acknowledge and agree that there is no requirement under this Lease that Tenant make any alterations or improvements to the Premises. Tenant shall notify every contractor making improvements to the Premises that the interest of Landlord in the Premises shall not be subject to liens for improvements to or other work performed in the Premises by or on behalf of Tenant. In the event that a construction claim of lien is filed against the Property in connection with any work performed by or on behalf of Tenant, Tenant shall satisfy such claim, or shall transfer same to security, within [***] ([***]) business days from the date that Tenant becomes aware of the same. In the event that Tenant fails to satisfy or transfer such claim within said [***] ([***]) business day period, Landlord may do so and thereafter charge Tenant, as Additional Rent, all costs incurred by Landlord in connection with the satisfaction or transfer of such claim, including attorneys' fees. Further, Tenant agrees to indemnify, defend and save Landlord harmless from and against any damage or loss incurred by Landlord as a result of any such claim or lien.

If so requested by Landlord, Tenant shall execute a short form or memorandum of this Lease, which may, in Landlord's discretion be recorded in the Public Records for the purpose or protecting Landlord's estate from construction claims of lien, as provided in Florida Statutes, Chapter 713.10. No other memorandum of this Lease, nor this Lease itself shall be recordable in the public records of any county within the State of Florida without Landlord's written consent and joinder, which may be arbitrarily withheld by Landlord in its sole discretion. In the event such short form of Memorandum of Lease is executed, Tenant shall simultaneously execute and deliver to Landlord an instrument terminating Tenant's interest in the real property upon which the Premises are located, which instrument may be recorded by Landlord at the expiration of the term of this Lease, or such earlier termination hereof. The Security Deposit paid by Tenant may be used by Landlord for the transfer of any claim of lien, as provided in this Section. This Section shall survive the termination of this Lease.

Notwithstanding the foregoing to the contrary, during the Term of this Lease, Tenant shall be permitted, with prior written notice to Landlord, but without Landlord's prior written consent, to make non-structural interior alterations to the Premises costing in the aggregate not more than [***] Dollars ($[***]) in any [***] ([***]) month period, provided that such alterations (i) are not structural, (ii) do not affect the use or proper strengthening of any utilities, building systems, or other tenant spaces, (iii) are not visible from outside the Premises, (iv) do not include the penetration of the roof, and/or (v) do not require building permits.

22. DEFAULT; REMEDIES.

(A) In addition to any other acts or omissions designated in this Lease as Events of Default, each of the following shall constitute an Event of Default by Tenant hereunder: (i) the failure to make any payment of Rent, Additional Rent or any installment thereof or to pay any other sum required to be paid by Tenant under this Lease within [***] ([***]) days after written notice for Landlord that such sum is due; (ii) the use or occupancy of the Premises for any purpose other than the Permitted Use without Landlord's prior written consent or the conduct of any activity in the Premises which constitutes a violation of law; (iii) if the interest of Tenant or any part thereof under this Lease shall be levied on under execution or other legal process and said interest shall not have been cleared by said levy or execution within [***] ([***]) days from the date thereof; (iv) if any voluntary or involuntary petition in bankruptcy or for corporate reorganization or any similar relief shall be filed by or against Tenant or any guarantor of the Lease or if a receiver shall be appointed for Tenant or any guarantor or any of the property of Tenant or guarantor; (v) if Tenant or any guarantor of the Lease shall make an assignment for the benefit of creditors or if Tenant shall admit in writing its inability to meet Tenant's debts as they mature; (vi) if any insurance required to be maintained by Tenant pursuant to this Lease shall be cancelled or terminated or shall expire or shall be reduced or materially changed, except, in each case, as permitted in this Lease, or mutually agreed to in writing by the parties; (vii) if Tenant shall fail to discharge or bond over any lien placed upon the Premises as a result of Tenant's actions in violation of this Lease; (viii) if any Letter of Credit required to be maintained by Tenant pursuant to this Lease shall be cancelled or terminated or shall expire or shall be reduced or materially changed, except, in each case, as permitted in this Lease, or mutually agreed to in writing by the parties; (ix) if Tenant shall abandon or vacate the Premises during the Term and otherwise fail to comply with the terms of the Lease; (x) if Tenant shall fail to execute and deliver an estoppel certificate or subordination agreement as required hereunder; or (xi) the failure to observe or perform any of the other covenants or conditions in this Lease which Tenant is required to observe and perform and which Tenant has not corrected within [***] ([***]) days after written notice thereof to Tenant, provided, however, that if the nature of Tenant's non-performance is such that more than [***] ([***]) days are reasonably required for its cure, then Tenant shall not be deemed to be in default if Tenant commences such cure within said [***] ([***]) day period and thereafter diligently and continuously pursues such cure to completion.

(B) Upon the occurrence of an Event of Default by Tenant, Landlord may, at its option, with or without notice or demand of any kind to Tenant or any other person, exercise any one or more of the following described remedies, in addition to all other rights and remedies provided at law, in equity or elsewhere herein, and such rights and remedies shall be cumulative and none shall exclude any other right allowed by law:

(i) Upon [***] ([***]) days written notice to Tenant, Landlord may terminate this Lease, repossess and re-let the Premises in accordance with Florida law, as the agent and for the account of Tenant upon such terms and conditions as Landlord may deem advisable or satisfactory, in which case Landlord shall be entitled to recover as damages (in addition to any other sums or damages for which Tenant may be liable to Landlord) a lump sum equal to the amount by which the present value of the excess Rent remaining to be paid by Tenant for the balance of the Term of the Lease exceeds the fair market rental value of the Premises, after deduction of all anticipated expenses of reletting. For the purpose of determining present value, Landlord and Tenant agree that the interest rate shall be the rate applicable to the then-current yield on obligations of the U.S. Treasury having a maturity date on or about the Expiration Date. Should the fair market rental value of the Premises for the balance of the Term (after deduction of all anticipated expenses of reletting) exceed the value of the Rent to be paid by Tenant for the balance of the Term, Landlord shall have no obligation to pay to or otherwise credit Tenant for any such excess amount;

(ii) Landlord may, without terminating the Lease, terminate Tenant's right of possession, repossess the Premises including, without limitation, removing all or any part of Tenant's personal property in the Premises and to place such personal property in storage or a public warehouse at the expense and risk of Tenant, and relet the same for the account of Tenant for such rent and upon such terms as shall be satisfactory to Landlord. For the purpose of such reletting, Landlord is authorized to decorate, repair, remodel or alter the Premises. Tenant shall pay to Landlord as damages a sum equal to all Rent under this Lease for the balance of the Term unless and until the Premises are relet. If the Premises are relet, Tenant shall be responsible for payment within [***] ([***]) days after Landlord's written demand of any deficiency between the Rent as relet and the Rent for the balance of this Lease, all costs and expenses of reletting, and all reasonable decoration, repairs, remodeling, alterations, additions and collection of the rent accruing therefrom. Tenant shall not be entitled to any rents received by Landlord in excess of the rent provided for in this Lease. No re-entry or taking possession of the Premises by Landlord shall be construed as an election to terminate this Lease unless a written notice of such intention be given to Tenant or unless the termination thereof be decreed by a court of competent jurisdiction. Notwithstanding any reletting without termination, Landlord may at any time thereafter elect to terminate this Lease for any breach, and in addition to the other remedies it may have, recover as damages (in addition to any other sums or damages for which Tenant may be liable to Landlord) a lump sum equal to the amount by which the present value of the excess Rent remaining to be paid by Tenant for the balance of the Term of the Lease exceeds the fair market rental value of the Premises, after deduction of all anticipated expenses of reletting. In the event Landlord repossesses the Premises as provided above, Landlord may remove all persons and property from the Premises and store any such property at the cost of Tenant, and Tenant hereby waives any and all claims against Landlord for loss, destruction and/or damage or injury which may be occasioned by any of the aforesaid acts; and

(iii) Landlord may, but shall not be obligated to, and without waiving or releasing Tenant from any obligations of Tenant hereunder, make any payment or perform such other act on Tenant's part to be made or performed as provided in this Lease. All sums so paid by Landlord and all necessary incidental costs shall be payable to Landlord as Additional Rent within [***] ([***]) days after Landlord's written demand and Tenant covenants to pay such sums.

(C) Tenant agrees that Landlord may file suit to recover any sums falling due under the terms of this section from time to time and that no suit or recovery of any portion due Landlord hereunder shall be any defense to any subsequent action brought for any amount not theretofore reduced to judgment in favor of Landlord.

(D) Tenant shall promptly pay upon notice, as Additional Rent, all reasonable costs, charges and expenses incurred by Landlord (including, without limitation, reasonable fees and out-of-pocket expenses of legal counsel, collection agents, and other third parties retained by Landlord) together with interest thereon at the rate set forth in Section 5 of this Lease, in collecting any amount due from Tenant, enforcing any obligation of Tenant hereunder, or preserving any rights or remedies of Landlord.

(E) No waiver of any provision of this Lease shall be implied by any failure of Landlord to enforce any remedy on account of the violation of such provision, even if such violation be continued or repeated subsequently, and no express waiver by Landlord shall be valid unless in writing and shall not affect any provision other than the one specified in such written waiver and that provision only for the time and in the manner specifically stated in the waiver. No receipt of monies by Landlord from Tenant after the termination of this Lease shall in any way alter the length of the Term or Tenant's right of possession hereunder or after the giving of any notice shall reinstate, continue or extend the Term or affect any notice given Tenant prior to the receipt of such monies, it being agreed that after the service of notice or the commencement of a suit or after final judgment for possession of the Premises, Landlord may receive and collect any Rent due, and the payment of Rent shall not waive or affect said notice, suit or judgment. Landlord shall not be required to serve Tenant with any notices or demands as a prerequisite to its exercise of any of its rights or remedies under this Lease, other than those notices and demands specifically required under this Lease.

(F) In the event of a breach or threatened breach by Tenant of any of the covenants or provisions hereof, Landlord shall have the right of injunction and the right to invoke any remedy allowed at law or in equity as if re-entry, summary proceedings and other remedies were not herein provided for. Mention in this Lease of any particular remedy shall not preclude Landlord from any other remedy, in law or in equity. Tenant hereby expressly waives any and all rights of redemption granted by or under any present or future laws in the event of Tenant being evicted or dispossessed for any cause, or in the event of Landlord obtaining possession of Premises by reason of the violation by Tenant of any of the covenants and conditions of this Lease, or otherwise.

23. LANDLORD'S DEFAULT. Landlord shall not be in default under this Lease unless Landlord fails to perform obligations required of Landlord within [***] ([***]) days after written notice by Tenant to Landlord and to the holder of any mortgage or deed of trust encumbering the Building whose name and address shall have theretofore been furnished to Tenant in writing, specifying wherein Landlord has failed to perform such obligation; provided, however, that if the nature of Landlord's obligation is such that more than [***] ([***]) days are required for its cure, then Landlord shall not be in default if Landlord commences performance within such [***] ([***]) day period and thereafter diligently pursues the same to completion. In the event Landlord shall be in default under this Lease, Tenant may exercise any rights and remedies as provided for at law or in equity.

If Landlord fails to commence to cure any default by Landlord within the period provided in the paragraph above and if, as a result, Tenant is incapable despite commercially reasonable efforts to continue operations within the Premises, Tenant may give Landlord an additional written notice confirming that the default has not been cured and that Tenant intends to cure such default, and, if Landlord fails to cure such default within [***] ([***]) days after such notice, Tenant may take such steps within the confines of its Premises as are reasonably appropriate to cure the default and deduct the reasonable cost of such cure from the rent next coming due. Tenant shall have no right to perform any obligation of Landlord in lieu of Landlord to the extent the same involves or may impact any base building system or any area of the Building outside of the Premises, including, without limitation, common areas or the premises of any other tenant or occupant of the Building. Landlord's liability to keep, maintain, and repair shall be limited to the cost of making such repair or accomplishing such maintenance or repair and Landlord shall in no case be liable for consequential or any indirect damages. The provisions of this paragraph are subject to the provisions of Section 19 Casualty, Section 25 Eminent Domain, and Section 31(G) Force Majeure.

24. NOTICES. All notices permitted or required hereunder shall be in writing and (i) delivered personally, (ii) sent by U.S. certified mail, postage prepaid, with return receipt requested, or (iii) sent overnight by nationally recognized overnight courier and sent to the respective parties at the Notice Addresses provided in Section 1 of this Lease. If sent by U.S. certified mail, such notice shall be considered received by the addressee upon receipt. If sent by nationally recognized overnight courier, such notice shall be considered received by the addressee upon receipt. Notices may be given by an agent on behalf of Landlord or Tenant.

25. EMINENT DOMAIN. If during the Term (a) the whole of the Premises or the Building shall be taken by any governmental or other authority having powers of eminent domain or conveyed to such entity under threat of the exercise of such power or (b) any part of the Premises or the Building including parking or access to the Building shall be so taken or conveyed and as a result, the remainder of the Premises or the Building has been rendered impractical, in Landlord's and Tenant's mutual reasonable judgment, for the operation of Tenant's business, this Lease shall terminate on the date of the taking or conveyance, and Rent shall be apportioned to the date thereof. Any award for the taking of all or any part of the Premises or the Building under the power of eminent domain or any payment made under threat of the exercise of such power shall be the property of Landlord, whether such award shall be made as compensation for diminution in value of the leasehold, for good will, for the taking of the fee, as severance damages, or as damages for tenant improvements; provided, however, that Tenant shall be entitled to any separate award for loss of or damage to Tenant's removable personal property and for moving expenses, provided it does not reduce the amount payable to Landlord. In the event that this Lease is not terminated by reason of such condemnation, Landlord shall to the extent of severance damages received by Landlord in connection with such condemnation, repair any damage to the Building caused by such condemnation except to the extent that Tenant has been reimbursed therefor by the condemning authority.

26. QUIET ENJOYMENT. Landlord represents and warrants that it has full right and authority to enter into this Lease and that Tenant, while paying the rental and performing its other covenants and agreements contained in this Lease, shall peaceably and quietly have, hold and enjoy the Premises for the Term without hindrance or molestation from Landlord subject to the terms and provisions of this Lease.

27. RULES AND REGULATIONS. Tenant agrees to comply with (and cause its agents, contractors, employees and invitees to comply with) the rules and regulations attached hereto as Exhibit B and with such reasonable modifications thereof and additions thereto as Landlord may from time to time make and deliver to Tenant in writing. Landlord agrees to enforce the rules and regulations uniformly against all tenants of the Property. Landlord shall not be liable, however, for any violation of said rules and regulations by other tenants or occupants of the Building or Property.

28. ENVIRONMENTAL. "Environmental Laws" shall mean all federal, state, including but not limited to the Florida Department of Environmental Regulation or the Florida Department of Health, and local laws (including, without limitation, case and common law), statutes, regulations, rules, ordinances, guidance, permits, licenses, grants, orders, decrees and judgments relating to the environment, human health and safety. "Hazardous Substances" shall mean all explosive materials, radioactive materials, hazardous or toxic materials, wastes, chemicals or substances, petroleum, petroleum by-products and petroleum products (including, without limitation, crude oil or any fraction thereof), asbestos and asbestos-containing materials, radon, lead, polychlorinated biphenyls, mold, urea-formaldehyde, and all materials, wastes, chemicals and substances that are regulated by any Environmental Law. "Release" shall mean any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing of Hazardous Substances into the environment. Tenant shall not (i) manufacture, generate, utilize, store, handle, treat, process, or Release any Hazardous Substances at, in, under, from or on the Premises or Property or (ii) suffer or permit to occur any violation of Environmental Laws with respect to the Premises or Property. Tenant shall indemnify, defend (with counsel reasonably acceptable to Landlord and at Tenant's sole cost) and hold harmless Landlord and its partners, managers, members, officers, directors, employees, agents, successors, grantees, assigns and mortgagees from any and all claims, demands, liabilities, damages, expenses, fees, costs, fines, penalties, suits, proceedings, actions, causes of action and losses of any and every kind and nature, including, without limitation, diminution in value of the Property, damages for the loss or restriction on use of the rentable or usable space or of any amenity, natural resource damages, damages arising from any adverse impact on leasing space on the Premises or Property, and sums paid in settlement of claims and for attorney's fees, consultant's fees and expert's fees that may arise during or after the Term or any extension of the Term as a result of Tenant's or Tenant's agents, employees, contractors, assignees, subtenants, guests, invitees, or representatives introduction of any Hazard Substance to the property. For purposes of this section, the term "costs" includes, without limitation, costs, expenses and consultant's fees, expert's fees and attorney's fees incurred in connection with any investigation of site conditions or any cleanup, remedial, removal, restoration, monitoring or maintenance work. This covenant of indemnity shall survive the termination of this Lease. Notwithstanding the foregoing, the prohibition contained herein shall not apply to ordinary office products that may contain de minimis quantities of Hazardous Substances, provided such products are used in compliance with Environmental Laws; however, Tenant's indemnification obligations are not diminished with respect to the presence of such products. Tenant shall notify Landlord of any Release or threatened Release at, in, under, from, to or on the Premises or Property, promptly after Tenant become aware of the same.

To Landlord's actual knowledge, as of the Effective Date, there are no Hazardous Substances in the Premises or the Building in violation of applicable law. Notwithstanding anything contained in this Section 28 to the contrary, Tenant shall have no obligation under this Lease arising from or related to Hazardous Substances, unless such Hazardous Substances were introduced to the Premises or the Building by Tenant or Tenant's agents, employees, contractors, assignees, subtenants, guests, invitees, or representatives.

29. INTENTIONALLY OMITTED.

30. BROKERS. Tenant and Landlord each represent and warrant to the other that neither has had any dealings or entered into any agreements with any person, entity, broker or finder in connection with the negotiation of this Lease other than NAI Merin Hunter Codman, Inc., representing the Landlord, and Butters Realty and Management, representing the Tenant (the "Disclosed Brokers"). No other broker, person, or entity is entitled to any commission or finder's fee in connection with the negotiation of this Lease, and the party against whom a claim is made agrees to indemnify, defend and hold the other harmless from and against any claims, damages, costs, expenses, attorneys' fees or liability for compensation or charges which may be claimed by any such unnamed broker, finder or other similar party by reason of any dealings, actions or agreements of the indemnifying party. Landlord shall pay the Disclosed Brokers pursuant to the terms of a separate agreement.

31. MISCELLANEOUS.

(A) Time is of the essence of this Lease and each of its provisions.

(B) This Lease and all covenants and agreements herein contained shall be binding upon, apply, and inure to the respective heirs, executors, successors, administrators and assigns of all parties to this Lease.

(C) This Lease contains the entire agreement of the parties, all other and prior representations, negotiations and agreements having been merged herein and extinguished hereby. No modification, waiver or amendment of this Lease or of any of its conditions or provisions shall be binding upon either party hereto unless in writing signed by both parties.

(D) The captions of sections and subsections of this Lease are for convenience only and shall not be deemed to limit, construe, affect or alter the meaning of such sections or subsections.

(E) Interpretation of this Lease shall be governed by the laws of the state or commonwealth in which the Premises is located, without regard to conflict of laws. The parties irrevocably submits to the nonexclusive jurisdiction of the courts of said state or commonwealth and agrees that all suits, actions, claims or proceedings may be heard and determined in such courts. The parties waive any objection which it may have at any time to the laying of venue of any suit, action, claim or proceeding arising out of or relating to this Lease.

(F) This Lease is and shall be deemed and construed to be the joint and collective work product of Landlord and Tenant and, as such, this Lease shall not be construed against either party, as the otherwise purported drafter of same, by any court of competent jurisdiction in order to resolve any inconsistency, ambiguity, vagueness or conflict, if any, in the terms or provisions contained herein.

(G) In the event that either party thereto shall be delayed or hindered in or prevented from the performance of any act required hereunder by reason of strikes, lock-outs, labor troubles, inability to procure labor, inability to procure materials or equipment or reasonable substitutes therefore, failure of power, fire or other casualty, restrictive government laws or regulations, judicial orders, enemy or hostile government actions, riots, insurrection or other civil commotions, war or other reason of a like nature not the fault of the party delayed in performing any act as required under the terms of this Lease ("Force Majeure"), then performance of such act shall be excused for the period of delay and the period for the performance of any such act shall be extended for a period equivalent to the period of such delay. Force Majeure shall not operate to excuse either party from the prompt payment of Rent or any other payments required under the terms of this Lease.

(H) Tenant shall reimburse Landlord as Additional Rent within [***] ([***]) days after Landlord's written demand for all reasonable out-of-pocket expenses, including without limitation legal, engineering or other professional services or expenses incurred by Landlord in connection with any requests by Tenant for consents or approvals hereunder.

(I) A final determination by a court of competent jurisdiction that any provision of this Lease is invalid shall not affect the validity of any other provision, and any provision so determined to be invalid shall, to the extent possible, be construed to accomplish its intended effect.

(J) If more than one person or entity shall ever be Tenant, the liability of each such person and entity shall be joint and several.

(K) Each individual executing this Lease on behalf of Tenant, represents and warrants that such individual is duly authorized to execute and deliver this Lease on behalf of Tenant, that Tenant is duly authorized to enter into this Lease, and that this Lease is enforceable against Tenant in accordance with its terms. Each individual executing this Lease on behalf of Landlord, represents and warrants that such individual is duly authorized to execute and deliver this Lease on behalf of Landlord, that Landlord is duly authorized to enter into this Lease, and that this Lease is enforceable against Landlord in accordance with its terms.

(L) The submission of this Lease to Tenant is not an offer to lease the Premises, or an agreement by Landlord to reserve the Premises for Tenant. Landlord shall not be bound to Tenant until Tenant has duly executed and delivered an original Lease to Landlord and Landlord has duly executed and delivered an original Lease to Tenant. Notwithstanding the Suite 160 Commencement Date or Full Premises Commencement Date contemplated in Section 1 hereof, this Lease shall take effect and be binding upon the parties hereto as of its execution and delivery.

(M) This Lease may be executed in any number of counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Any signature to this Lease transmitted via PDF or electronic signature shall be deemed an original signature and be binding upon the parties hereto.

(N) Each party represents and warrants that neither such party nor any of its members, shareholders or other equity owners, is a person or entity with whom U.S. persons or entities are restricted from doing business under regulations of the Office of Foreign Asset Control ("OFAC") of the Department of the Treasury (including those named on OFAC's Specially Designated and Blocked Persons List) or under any statute, executive order (including the September 24, 2001, Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism), or other governmental action.

32. SOUTH FLORIDA COMMUTER SERVICE PROGRAMS. The Property participates in programs promoted by regional commuter service and other similar organizations designed and intended to maximize the people-moving capability of the transportation system, encourage mass transit and manage transportation demand. Information relating to such programs, including contact information for the Employee Transportation Coordinator, is available at the main security desk as well as the mailroom/vending area of the Property.

33. CITY APPLICATION.

(A) Prior to Tenant's submission to the City of Boca Raton (the "City") of an application (the "City Application") for a business tax receipt, certificate of use or any other item which requires any statement as to the use of the Premises (the "Proposed Use"), Tenant shall deliver to Landlord a copy of the proposed City Application for Landlord's prior review to ensure the Proposed Use complies with the City's zoning and other laws and regulations pertaining to the Premises. Landlord shall have the right to require Tenant to modify, amend or adjust the City Application prior to Tenant's submission of the City Application to the City. Landlord's approval of a City Application does not create any liability on the part of Landlord and is merely being provided by Landlord to help ensure the City Application is properly submitted.

(B) Each year during the Term, Tenant shall provide Landlord with evidence that Tenant has timely and properly renewed its business tax receipt, certificate of use or other item relating to the Proposed Use, within [***] ([***]) days of such renewal. In connection with such renewal, Tenant agrees not to modify, amend or adjust the Proposed Use in any manner.

(C) Tenant's failure to comply with the terms and provisions of this paragraph shall be an Event of Default and Landlord shall have any and all rights and remedies set forth in Section 22 (Default; Remedies) hereof on account of such Event of Default.

34. RADON GAS. Radon is a naturally occurring radioactive gas that, when it has accumulated in a building in sufficient quantities, may present health risks to persons who are exposed to it over time. Levels of radon that exceed federal and state guidelines have been found in buildings in Florida. Additional information regarding radon and radon testing may be obtained from your county public health unit.

35. MOLD. Mold is a naturally occurring substance. Mold is found both indoors and outdoors. The presence of mold may cause property damage or health problems. Tenant acknowledges that it shall be Tenant's responsibility to undertake necessary measures to retard and prevent mold from accumulating within the Premises, including, but not limited to, the following: (i) maintaining appropriate climate control within the Premises; (ii) maintaining the cleanliness of the Premises; (iii) removing visible moisture accumulations on windows, window sills, walls, floors, ceilings and other surfaces as soon as reasonably possible; and (iv) not blocking or covering any heating, ventilating or air conditioning ducts within the Premises. Tenant shall report in writing to Landlord any evidence of mold or of a water leak or excessive moisture within the Premises, promptly after Tenant becomes aware of same. Should Tenant desire a mold inspection or additional information about mold, Tenant should contact a professional in this field.

36. PARKING. At all times during the Term (with the allocation of such spaces to be staggered based on the Suite 160 Commencement Date and the Full Premsies Commencement Date), Tenant shall be entitled to the non-exclusive use of 281 parking spaces in the Building's parking lot or the shared lot (as shown on **Exhibit A-3**) (37 spaces as of the Suite 160 Commencement Date, and the remaining 244 spaces as of the Full Premises Commencement Date). As part of the overall parking allocation (with the allocation of such spaces to be staggered based on the Suite 160 Commencement Date and the Full Premsies Commencement Date) provided to Tenant herein (with the following parking to count towards Tenant's 281 parking spaces), Landlord shall provide forty-eight (48) covered spaces (6 covered spaces as of the Suite 160 Commencement Date, and the remaining 42 covered spaces as of the Full Premises Commencement Date) at the locations identified on **Exhibit A-1**, at the initial rate of $[***] per space, per month, with such rate to increase at the same time and at the same percentage increase as Base Rent. Landlord reserves the right to control the method, manner and time of parking in all parking spaces. Tenant shall not use any parking space designated by Landlord as visitor parking or as exclusive to other parties. Tenant shall insure that its employees, customers, clients, guests, invitees and licensees comply with the provision of this Section 36. If Tenant uses parking in excess of that provided for herein, and if such excess use occurs on a regular basis, and if Tenant fails, after written notice from Landlord of any one violation, to reduce its excess use of the parking areas, then Landlord may assess a charge of [***] Dollars ($[***]) against the Tenant for each violation, which shall be payable as Additional Rent. Further, Landlord reserves the right to post a notice of violation on any offending vehicle and to tow the offending vehicle regardless of whether the vehicle is owned by a Tenant or any other party, including any employee, customer, client, invitee or licensee of a Tenant, and to charge the expense thereof to owner of the vehicle.

37. SIGNAGE. Tenant shall be entitled to Building standard suite entry and directory signage. Landlord may specify that the design of such signage be similar to, or consistent with, the design and location of other signs identifying tenants in the Building. Such signage shall be subject to all applicable laws and ordinances.

38. RIGHT OF ENTRY. Except in the event of an emergency, Landlord shall only have the right to enter the Premises after first providing Tenant with at least twenty-four (24) hours prior advance notice (which may be verbal) to Tenant. Such entry shall only be permitted for purposes of allowing Landlord to perform those acts required of or permitted to Landlord herein, including, without limitation, (i) the right to make any repairs or replacements Landlord reasonably deems necessary, (ii) the right to show the Premises to prospective purchasers and mortgagees, (iii) during the last twelve (12) months of the Term, the right to show the Premises to prospective tenants. Notwithstanding anything to the contrary contained in this Lease, no entry by Landlord or its agents or representatives shall be made into or upon the Premises without the presence of an authorized employee of Tenant, except in a bona fide emergency not permitting prior notification to Tenant. Tenant shall make an authorized employee available at reasonable hours to allow Landlord to exercise its right to enter the Premises in accordance with the terms of this Section 38. It is understood that entry is being restricted because of the nature of the business of Tenant requiring special security. In addition to the foregoing, except in the event of a bona fide emergency or a specific request to acess such secure area in connection with an inspection by a governmental authority, and provided that an authorized employee of Tenant accompanies the party entering into the secure area during such emergency or governmental inspection, Tenant may prohibit Landlord from entering certain secure areas of the Premises as reasonably determined by Tenant. During any entry on to the Premises as permitted under this Section 38, Landlord and Landlord's agents and representatives shall comply with Tenant's customary security procedures and shall use good faith efforts to minimize any interference with Tenant's operations at the Premises.

39. CERTAIN RIGHTS RESERVED TO LANDLORD. Landlord reserves the following rights, and the exercise of any such rights shall not be deemed to constitute an eviction or disturbance of Tenant's use or possession of the Premises and shall not give rise to any claim for set-off or abatement of Rent or any other claim provided that such rights do not adversely interfere with Tenant's use of and operations at the Property: (a) to enter the Premises for the purposes of examining the same or to make repairs or alterations or to provide any service; (b) to change the arrangement and/or locations of entrances, or passageways, doors and doorways, and corridors, windows, elevators, stairs, parking areas and any other common areas, (c) to change the name or street address of the Building or the suite number of the Premises; (d) to install, affix and maintain any and all signs on the exterior or interior of the Building; (e) to make repairs, decorations, alterations, additions or improvements, whether structural or otherwise, in, about and to the Building or common areas and for such purposes temporarily close doors, corridors and other areas of the Building and interrupt or temporarily suspend services or use of common areas; (f) to retain at all times, and to use in appropriate instances, keys to all doors within and into the Premises; (g) to grant to any person or to reserve unto itself the exclusive right to conduct any business or render any service in the Building; (h) if the Premises have been permanently vacated or abandoned by Tenant, to prepare the Premises for re-occupancy; (i) to install, use and maintain in and through the Premises pipes, conduits, wires and ducts serving the Building; (j) to approve the weight, size and location of safes or other heavy equipment or other articles which may be located in the Premises and to determine the time and manner in which such articles may be moved in, about or out of the Building or Premises; and (k) to take any other action which Landlord deems reasonable in connection with the operation, maintenance, marketing or preservation of the Premises or Building. The reduction or elimination of Tenant's light, air or view shall not affect Tenant's liability under this Lease, nor shall it create any liability of Landlord to Tenant.

40. LEASE COMMENCEMENT/ACCEPTANCE OF PREMISES. At Landlord's request, Landlord and Tenant shall enter into a commencement letter agreement (the "Commencement Letter") in form substantially similar to that attached hereto as **Exhibit C** once the Suite 160 Commencement Date has occurred and once the Full Premises Commencement Date has occurred in accordance with the terms of **Exhibit F**. Tenant's failure to execute and return the Commencement Letter, or to provide written objection to the statements contained in the Commencement Letter, within [***] ([***]) days shall be deemed an approval by Tenant of the statements contained therein.

41. WAIVER OF RIGHT TO JURY TRIAL. LANDLORD AND TENANT WAIVE THEIR RESPECTIVE RIGHTS TO A TRIAL BY JURY OF ANY CLAIM, ACTION, PROCEEDING OR COUNTERCLAIM BY EITHER PARTY AGAINST THE OTHER ON ANY MATTERS ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT, AND/OR TENANT'S USE OR OCCUPANCY OF THE PREMISES OR BUILDING (INCLUDING ANY CLAIM OF INJURY OR DAMAGE OR THE ENFORCEMENT OF ANY REMEDY UNDER ANY CURRENT OR FUTURE LAWS, STATUTES, REGULATIONS, CODES OR ORDINANCES).

42. RECORDING. Tenant shall not record this Lease without the prior written consent of Landlord. Tenant, upon the request of Landlord, shall execute and acknowledge a short form memorandum of this Lease for recording purposes.

43. SUBORDINATION OF LANDLORD'S LIEN. Landlord hereby agrees to subordinate (on the form of agreement attached hereto as **Exhibit J**) any rights to a lien (including statutory rights) on any of Tenant's personal property located within the Premises to any purchase money lender.

44. NO RELOCATION. Landlord waives any right to relocate Tenant to any other space in the Building without first obtaining Tenant's prior written consent, which consent may be withheld by Tenant in its sole discretion.

[signatures on following page]

IN WITNESS WHEREOF, the parties hereto have executed this Lease.

LANDLORD:

951 YAMATO ACQUISITION COMPANY, LLC, a Florida limited liability company

By: BROOKWOOD YAMATO INVESTORS, LLC, a Delaware limited liability company, its Sole Member

By: BROOKWOOD YAMATO CO., LLC, a Delaware limited liability company, its Manager

By: /s/ Kurt M. Zernich
Name: Kurt M. Zernich
Its: Authorized Signer

TENANT:

TherapeuticsMD, Inc., a Nevada corporation

By: /s/ Daniel Cartwright
Name: Daniel Cartwright
Its: CFO

WITNESS: (2 witnesses required)

/s/ Jennifer Johnson
Witness #1 Signature

Jennifer Johnson
Witness #1 Print Name

/s/ Nicole Reeves
Witness #2 Signature

Nicole Reeves
Witness #2 Print Name

WITNESS: (2 witnesses required)

/s/ John Milligan
Witness #1 Signature

John Milligan
Witness #1 Print Name

/s/ Lisa Maxwell
Witness #2 Signature

Lisa Maxwell
Witness #2 Print Name

EXHIBIT A

THE PREMISES

[***]

EXHIBIT A-1

[Site Plan for the Building]

[***]

EXHIBIT A-2

[Location of Parking Spaces]

[***]

EXHIBIT A-3

[Building Lot and Shared Lot]

[***]

EXHIBIT B

RULES AND REGULATIONS

[***]

EXHIBIT C

FORM OF COMMENCEMENT LETTER

[***]

EXHIBIT D

ADDITIONAL STIPULATIONS

[***]

Schedule D-1

Tenant's Exterior Building Signage

[***]

Schedule D-2

Tenant's Monument Signage

[***]

EXHIBIT E

SUITE 160 WORK LETTER

[***]

Schedule E-1

[Space Plan for Suite 160 Work]

[***]

EXHIBIT F

TENANT IMPROVEMENTS LETTER

[***]

Schedule F-1

[Suite 150 Space Plan]

[***]

Schedule F-1

[Suite 220 Space Plan]

[***]

EXHIBIT H

FORM SNDA

[***]

EXHIBIT I

ASSUMED RENT TABLE

[***]

EXHIBIT J

LANDLORD'S AGREEMENT

[***]

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, 2019

/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, 2019

/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, 2019 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, 2019

/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, 2019 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, 2019

/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.