TherapeuticsMD, Inc.
Form 10-Q
November 07, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

¨ **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. **010-001000**

THERAPEUTICSMD, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

6800 Broken Sound Parkway NW, Third Floor, Boca Raton, FL 33487 **(561) 961-1900**
(Address of Principal Executive Offices) (Issuer's Telephone Number)

N/A

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes þ No ¨

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

Large accelerated filer ¨	Accelerated filer þ
Non-accelerated filer ¨	Smaller reporting company ¨
(Do not check if a smaller reporting company)	

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

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of November 4, 2014 was 156,030,476.

THERAPEUTICSMD, INC. AND SUBSIDIARIES
INDEX

		Page
PART I - FINANCIAL INFORMATION		
Item. 1	**Financial Statements**	
	Condensed Consolidated Balance Sheets as of September 30, 2014 (Unaudited) and December 31, 2013	3
	Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2014 (Unaudited) and 2013 (Unaudited)	4
	Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2014 (Unaudited) and 2013 (Unaudited)	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	**Management's Discussion and Analysis of Financial Condition and Results of Operations**	20
Item 3.	**Quantitative and Qualitative Disclosures about Market Risk**	29
Item 4.	**Controls and Procedures**	29
PART II - OTHER INFORMATION		
Item 1.	**Legal Proceedings**	30
Item 1A.	**Risk Factors**	30
Item 2.	**Unregistered Sales of Equity Securities and Use of Proceeds**	54
Item 6.	**Exhibits**	54

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

THERAPEUTICSMD,
INC. AND
SUBSIDIARIES
CONDENSED
CONSOLIDATED
BALANCE SHEETS

	September 30, 2014 (Unaudited)	December 31, 2013
ASSETS		
Current Assets:		
Cash	$66,999,114	$54,191,260
Accounts receivable, net of allowance for doubtful accounts of $29,149 and $26,555, respectively	2,148,724	1,690,753
Inventory	1,011,945	1,043,618
Other current assets	2,020,118	2,477,715
Total current assets	72,179,901	59,403,346
Fixed assets, net	69,567	61,318
Other Assets:		
Prepaid expense	1,392,264	1,750,455
Intangible assets	841,741	665,588
Security deposit	125,000	135,686
Total other assets	2,359,005	2,551,729
Total assets	$74,608,473	$62,016,393
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$5,648,679	$2,114,217
Deferred revenue	848,149	1,602,580
Other current liabilities	4,511,079	3,601,189
Total current liabilities	11,007,907	7,317,986
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock - par value $0.001; 10,000,000 shares authorized; no shares issued and outstanding	—	—

Common stock - par value $0.001; 250,000,000 shares authorized; 156,030,476 and 144,976,757 issued and outstanding, respectively	156,030	144,977
Additional paid-in capital	181,891,791	135,086,056
Accumulated deficit	(118,447,255)	(80,532,626)
Total stockholder' equity	63,600,566	54,698,407
Total liabilities and stockholders' equity	$74,608,473	$62,016,393

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014 (Unaudited)	2013 (Unaudited)	2014 (Unaudited)	2013 (Unaudited)
Revenues, net	$4,186,261	$2,294,720	$10,768,572	$5,912,800
Cost of goods sold	1,068,605	648,403	2,792,268	1,492,355
Gross profit	3,117,656	1,646,317	7,976,304	4,420,445
Operating expenses:				
Sales, general, and administration	6,043,354	4,752,062	16,610,015	14,455,839
Research and development	14,909,430	4,098,903	29,052,149	7,710,546
Depreciation and amortization	12,747	32,356	39,909	50,949
Total operating expense	20,965,531	8,883,321	45,702,073	22,217,334
Operating loss	(17,847,875)	(7,237,004)	(37,725,769)	(17,796,889)
Other income (expense):				
Miscellaneous income	6,260	11,965	43,411	15,444
Interest income	9,364	—	27,756	18,133
Interest expense	—	—	—	(1,165,981)
Financing costs	—	(447,969)	(260,027)	(1,107,937)
Loan guaranty costs	—	—	—	(2,944)
Total other income (expense)	15,624	(436,004)	(188,860)	(2,243,285)
Loss before taxes	(17,832,251)	(7,673,008)	(37,914,629)	(20,040,174)
Provision for income taxes	—	—	—	—
Net loss	$(17,832,251)	$(7,673,008)	$(37,914,629)	$(20,040,174)
Loss per share, basic and diluted:				
Net loss per share, basic and diluted	$(0.12)	$(0.06)	$(0.26)	$(0.16)
Weighted average number of common shares outstanding	152,200,455	131,212,706	147,594,810	121,701,292

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

4

THERAPEUTICSMD, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2014 (Unaudited)	2013 (Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(37,914,629)	$(20,040,174)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation	22,713	41,186
Amortization of intangible assets	17,196	9,764
Provision for doubtful accounts	2,594	48,355
Stock based compensation	3,226,241	1,926,992
Stock based expense for services	708,595	804,878
Amortization of deferred financing costs	260,027	1,055,948
Amortization of debt discount	—	1,102,680
Loan guaranty costs	—	2,944
Changes in operating assets and liabilities:		
Accounts receivable	(460,565)	(1,235,433)
Inventory	31,673	467,624
Other current assets	197,569	(1,927,156)
Other assets	(17,069)	(984,974)
Accounts payable	3,534,462	830,585
Deferred revenue	(754,431)	707,520
Accrued expenses and other current liabilities	909,890	1,190,178
Net cash flows used in operating activities	(30,235,734)	(15,999,083)
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent and trademark costs, net of abandoned costs	(193,349)	(257,633)
Purchase of property and equipment	(30,962)	(23,755)
Net cash flows used in investing activities	(224,311)	(281,388)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, net	42,771,353	78,984,960
Proceeds from exercise of options	315,546	6,231
Proceeds from exercise of warrants	181,000	—
Proceeds from line of credit	—	500,000
Repayment of line of credit	—	(500,000)
Repayment of notes payable	—	(4,691,847)
Net cash flows provided by financing activities	43,267,899	74,299,344
Increase in cash	12,807,854	58,018,873

Cash, beginning of period	54,191,260	1,553,474
Cash, end of period	66,999,114	59,572,347
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	$—	$212,853
Cash paid for income taxes	$—	$—
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING ACTIVITIES:		
Warrants issued for financing	$—	$1,711,956
Warrants issued for services	$—	$462,196

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

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – THE COMPANY

TherapeuticsMD, Inc., a Nevada corporation, or TherapeuticsMD or the Company, has two wholly owned subsidiaries, vitaMedMD, LLC, a Delaware limited liability company organized on May 13, 2008, or VitaMed, and BocaGreenMD, Inc., a Nevada corporation incorporated on January 10, 2012, or BocaGreen. Unless the context otherwise requires, TherapeuticsMD, VitaMed, and BocaGreen collectively are sometimes referred to as “our company,” “we,” “our,” or “us.”

Nature of Business

We are a women’s health care product company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of our advanced hormone therapy pharmaceutical products. The current drug candidates used in our clinical trials to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating equivalent clinical efficacy at lower doses, thereby enabling a side effect profile compared with competing products. Our drug candidates are created from a platform of hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, vitamins and cosmetics.

NOTE 2 – BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

Interim Financial Statements

The accompanying unaudited interim condensed 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, 2013, as filed with the Securities and Exchange Commission, or the SEC, from which we derived our balance sheet as of December 31, 2013. The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles, 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 financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying 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.

Recently Issued and Newly Adopted Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable) and, if so, disclose that fact. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS (Continued)

Recently Issued and Newly Adopted Accounting Pronouncements (continued)

for annual or interim reporting periods for which the financial statements have not previously been issued. We do not expect the adoption of the ASU 2014-15 to have a material effect on our condensed consolidated financial statements and disclosures.

In May 2014, the FASB and the International Accounting Standards Board (IASB) issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligations. ASU 2014-09 is effective for public business entities, certain not-for-profit entities and certain employee benefit plans, for annual periods beginning after December 15, 2016, including interim periods within that period. Early adoption is not permitted under GAAP. We are currently evaluating the impact of ASU 2014-09 on our condensed consolidated financial statements and disclosures.

In July 2013, the FASB issued ASU 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force), or ASU 2013-11. The amendments in ASU 2013-11 provide guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in ASU No. 2013-11 do not require new recurring disclosures. The amendments in ASU 2013-11 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments in ASU No. 2013-11 did not have a material impact on our condensed consolidated financial statements.

In December 2011, the FASB issued ASU No. 2011-11, Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities, or ASU 2011-11. ASU 2011-11 enhances current disclosures about financial instruments and derivative instruments that are either offset on the statement of financial position or subject to an enforceable master netting arrangement or similar agreement, irrespective of whether they are offset on the statement of financial position. Entities are required to provide both net and gross information for these assets and liabilities in order to facilitate comparability between financial statements prepared in conformity with GAAP and financial statements prepared on the basis of International Financial Reporting Standards. ASU 2011-11 is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those years. ASU 2011-11 did not have a material impact on our financial position or results of operations.

We do not believe there would have been a material effect on the accompanying condensed consolidated financial statements had any other recently issued, but not yet effective, accounting standards been adopted in the current period.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – BASIS OF PRESENTATION AND RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS (Continued)

Reclassifications

Certain 2013 amounts have been reclassified to conform to current year presentation.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

There have been no material changes to our significant accounting policies as summarized in *NOTE 2* of our Annual Report on Form 10-K for the year ended December 31, 2013.

Impairment of Long-Lived Assets

We review the carrying values of property and equipment and long-lived intangible assets for impairment whenever events or changes in circumstances indicate that their carrying values may not be recoverable. Such events or circumstances include the following:

- significant declines in an asset's market price;
- significant deterioration in an asset's physical condition;
- significant changes in the nature or extent of an asset's use or operation;
- significant adverse changes in the business climate that could impact an asset's value, including adverse actions or assessments by regulators;
- accumulation of costs significantly in excess of original expectations related to the acquisition or construction of an asset;
- current-period operating or cash flow losses combined with a history of such losses or a forecast that demonstrates continuing losses associated with an asset's use; and
-

expectations that it is more likely than not that an asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life.

If impairment indicators are present, we determine whether an impairment loss should be recognized by testing the applicable asset or asset group's carrying value for recoverability. This test requires long-lived assets to be grouped at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities, the determination of which requires judgment. We estimate the undiscounted future cash flows expected to be generated from the use and eventual disposal of the assets and compare that estimate to the respective carrying values in order to determine if such carrying values are recoverable. This assessment requires the exercise of judgment in assessing the future use of and projected value to be derived from the eventual disposal of the assets to be held and used. In our assessments, we also consider changes in asset utilization, including the temporary idling of capacity and the expected timing for placing this capacity back into production. If the carrying value of the assets is not recoverable, then we record a loss for the difference between the assets' fair value and respective carrying values. We determine the fair value of the assets using an "income approach" based upon a forecast of all the expected discounted future net cash flows associated with the subject assets. Some of the more significant estimates and assumptions include market size and growth, market share, projected selling prices, manufacturing cost, and discount rate. We base estimates upon historical experience, our commercial relationships, market conditions, and available external information about future trends. We believe our current assumptions and estimates are reasonable and appropriate. Unanticipated events and changes in market conditions, however, could affect such estimates, resulting in the need for an impairment charge in future periods. There was no impairment of intangibles or long-lived assets during the three or nine months ended September 30, 2014 and 2013.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Fair Value of Financial Instruments

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

We categorize our assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy as defined by Accounting Standards Codification, or ASC, 820, *Fair Value Measurements.* The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). Assets and liabilities recorded 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, 2014 and December 31, 2013, we had no assets or liabilities that were valued at fair value on a recurring basis.

NOTE 4 – INVENTORY

Inventory consists of the following:

	September 30, 2014	December 31, 2013
Finished product	$670,276	$621,679
Raw material	178,426	250,943
Deferred costs	163,243	170,996
TOTAL INVENTORY	$1,011,945	$1,043,618

NOTE 5 – OTHER CURRENT ASSETS

Other current assets consist of the following:

	September 30, 2014	December 31, 2013
Prepaid consulting	$514,596	$530,596
Prepaid insurance	503,064	145,722
Prepaid research and development costs	457,458	1,267,588
Other receivables-related party (Note 14)	249,981	249,981
Other prepaid costs	195,019	23,806
Other current assets	100,000	—
Deferred financing costs	—	260,022
TOTAL OTHER CURRENT ASSETS	$2,020,118	$2,477,715

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 6 – FIXED ASSETS

Fixed assets consist of the following:

	September 30, 2014	December 31, 2013
Equipment	$132,150	$108,458
Furniture and fixtures	53,895	46,625
	186,045	155,083
Accumulated depreciation	(116,478)	(93,765)
TOTAL FIXED ASSETS	$69,567	$61,318

Depreciation expense for the three months ended September 30, 2014 and 2013 was $7,122 and $29,103, respectively. Depreciation expense for the nine months ended September 30, 2014 and 2013 was $22,713 and $41,186, respectively.

NOTE 7 – PREPAID EXPENSE

Prepaid expense consisted of the following:

	September 30, 2014	December 31, 2013
Prepaid manufacturing costs	$899,000	$899,000
Prepaid research and development costs	438,274	824,221
Accreted prepaid costs	54,990	27,234
TOTAL PREPAID EXPENSE	$1,392,264	$1,750,455

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – INTANGIBLE ASSETS

The following table sets forth the gross carrying amount and accumulated amortization of our intangible assets as of September 30, 2014 and December 31, 2013:

	September 30, 2014			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizing intangible assets:				
OPERA® software patent	$31,951	$ (1,997)	$29,954	15
Development costs of corporate website	91,743	(91,743)	—	n/a
Approved hormone therapy drug candidate patents	387,806	(13,616)	374,190	18.25
Non-amortizing intangible assets:				
Hormone therapy drug candidate patents (pending)	340,059	—	340,059	n/a
Multiple trademarks for vitamins/supplements	97,538	—	97,538	n/a
Total	$949,097	$ (107,356)	$841,741	

	December 31, 2013			
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Weighted-Average Remaining Amortization Period (yrs.)
Amortizing intangible assets:				

OPERA® software patent	$31,951	$ (499)	$31,452	15.8
Development costs of corporate website	91,743	(89,661)	2,082	0.3
Non-amortizing intangible assets:				
Hormone therapy drug candidate patents (pending)	572,726	—	572,726	n/a
Multiple trademarks for vitamins/supplements	59,328	—	59,328	n/a
Total	$755,748	$ (90,160)	$665,588	

11

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – INTANGIBLE ASSETS (Continued)

We amortized the intangible asset related to development costs for corporate website over 36 months, which is the prescribed life for software and website development costs. We amortize the intangible asset related to OPERA® using the straight-line method over the estimated useful life of approximately 20 years, which is the life of the intellectual property patents. We amortize the approved hormone therapy drug candidate patents using straight-line method over the estimated useful life of approximately 20 years. During the three and nine months ended September 30, 2014 and 2013, there was no impairment recognized.

Amortization expense was $5,625 and $3,255 for the three months ended September 30, 2014 and 2013, respectively and $17,196 and $9,764 for the nine months ended September 30, 2014 and 2013, respectively. Estimated amortization expense for the next five years is as follows:

Year Ending December 31,	Estimated Amortization
2014 (3 months)	$5,625
2015	$22,500
2016	$22,500
2017	$22,500
2018	$22,500

NOTE 9 – OTHER CURRENT LIABILITIES

Other current liabilities consist of the following:

	September 30, 2014	December 31, 2013
Accrued clinical trial costs	$2,385,094	$665,782
Accrued payroll and commission costs	603,525	941,313
Accrued vacation costs	434,614	256,920

Other accrued expenses[1]	266,576	177,900
Allowance for wholesale distributor fees	245,232	306,303
Accrued legal and accounting expense	220,526	224,550
Accrued royalties	164,707	52,188
Allowance for coupons and returns	97,890	126,233
Accrued rent	92,915	—
Accrued financing costs	—	850,000
TOTAL OTHER CURRENT LIABILITIES	$4,511,079	$3,601,189

———————

[1] In June 2008, we declared and paid a special dividend of $0.40 per share of our common stock to all stockholders of record as of June 10, 2008, of which $41,359 remained unclaimed by certain shareholders at September 30, 2014 and December 31, 2013.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 – NOTES PAYABLE

Issuance and Payment of Multiple Advance Revolving Credit Note

On January 31, 2013, we entered into a business loan agreement with Plato and Associates, LLC, or Plato, for a Multiple Advance Revolving Credit Note, or the Revolving Credit Note. The Revolving Credit Note allowed us to draw down funding up to a $10,000,000 maximum principal amount, at a stated interest rate of 6% per annum. Plato was able to make advances to us from time to time under the Revolving Credit Note at our request, which advances were of a revolving nature and were able to be made, repaid, and made from time to time. Interest payments were due and payable on the tenth day following the end of each calendar quarter in which any interest was accrued and unpaid, commencing on April 10, 2013, and the principal balance outstanding under the Revolving Credit Note, together with all accrued interest and other amounts payable under the Revolving Credit Note, if any, was due and payable on February 24, 2014. The Revolving Credit Note was secured by substantially all of our assets. On each of February 25 and March 13, 2013, $200,000 was drawn against the Revolving Credit Note. On March 21, 2013, we repaid $401,085, which included accrued interest, and there was no balance outstanding under the Revolving Credit Note as of December 31, 2013 and February 24, 2014 when it expired. As additional consideration for the Revolving Credit Note, we granted to Plato a warrant to purchase 1,250,000 shares of our common stock at an exercise price of $3.20 per share (See Note 12).

NOTE 11 – NET LOSS PER SHARE

We calculate basic and diluted net loss per share allocable to common stockholders using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of our common stock outstanding subject to repurchase or forfeiture for the three or nine months ended September 30, 2014 and 2013.

Since we are in a net loss position, we have excluded outstanding stock options, all of which are subject to forfeiture, as well as warrants for the purchase of our common stock from our calculation of diluted net loss per share.

The table below presents the potentially dilutive securities that would have been included in our calculation of diluted net loss per share allocable to common stockholders if they were not antidilutive for the periods presented.

	As of September 30, 2014	2013
Stock options	16,851,943	14,780,793
Warrants	13,927,916	14,293,499
	30,779,859	29,074,292

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 – STOCKHOLDERS' EQUITY

Preferred Stock

At September 30, 2014, we had 10,000,000 shares of preferred stock, par value $0.001, authorized for issuance, of which no shares of preferred stock were issued or outstanding.

Common Stock

At September 30, 2014, we had 250,000,000 shares of common stock, $0.001 par value per share, authorized, of which 156,030,476 shares of common stock were issued and outstanding.

Issuances During the Nine Months Ended September 30, 2014

On July 29, 2014, we entered into an underwriting agreement with Goldman Sachs & Co, or Goldman Sachs, as the representative of the underwriters named therein, or the Goldman Sachs Underwriters, relating to an underwritten public offering of 8,565,310 shares of our common stock. The price to the public in the offering was $4.67 per share. Under the terms of the underwriting agreement, we granted the Goldman Sachs Underwriters a 30-day option to purchase up to an additional 1,284,796 shares of our common stock. On July 30, 2014, the Goldman Sachs Underwriters exercised their option to purchase the additional 1,284,796 shares of our common stock. Net proceeds from this offering were approximately $42.8 million, after deducting underwriting discounts and commissions and other offering expenses. The offering closed on August 4, 2014.

During the nine months ended September 30, 2014, certain individuals exercised stock options to purchase 793,800 shares of our common stock. Stock options to purchase shares of our common stock were exercised as follows: (i) 674,193 options for $315,546 in cash and (ii) 119,607 options, pursuant to the stock options' cashless provision,

wherein 113,837 common shares were issued. The Company granted 50,000 common shares to an employee upon the vesting of restricted stock units which were granted in December 2013.

During the nine months ended September 30, 2014, certain individuals exercised warrants to purchase 365,583 shares of our common stock for $181,000 in cash.

Issuances During the Year Ended December 31, 2013

On March 14, 2013, we entered into an underwriting agreement with Jefferies LLC, or Jefferies, as the representative of the underwriters named therein, or the Jefferies Underwriters, relating to the issuance and sale of 29,411,765 shares of our common stock. The price to the public in the offering was $1.70 per share, and the Jefferies Underwriters agreed to purchase the shares of our common stock from us pursuant to the underwriting agreement at a price of $1.58 per share. The net proceeds to us from this offering were approximately $45.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. In addition, under the terms of the underwriting agreement, we granted the Jefferies Underwriters a 30-day option to purchase up to an additional 4,411,765 shares of our common stock. The offering closed on March 20, 2013. On April 12, 2013, the Jefferies Underwriters exercised their option to purchase an additional 1,954,587 shares of our common stock. We issued these shares to the Jefferies Underwriters on April 18, 2013 and received proceeds of approximately $3.1 million, net of expenses.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 – STOCKHOLDERS' EQUITY (Continued)

Common Stock (continued)

Issuances During the Year Ended December 31, 2013 (continued)

On September 25, 2013, we entered into an underwriting agreement with Stifel, Nicolaus & Company, Incorporated, as the representative of the underwriters named therein, or the Stifel Underwriters, relating to the issuance and sale of 13,750,000 shares of our common stock. The price to the public in the offering was $2.40 per share, and the Stifel Underwriters agreed to purchase the shares of our common stock from us pursuant to the underwriting agreement at a price of $2.23 per share. The net proceeds to us from this offering were approximately $30.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. The offering closed on September 30, 2013.

During 2013 certain individuals exercised their right to purchase shares of our common stock. Stock options to purchase an aggregate of 75,423 shares of our common stock were exercised for approximately $31,000.

Warrants to Purchase Common Stock of the Company

As of September 30, 2014, we had warrants outstanding to purchase an aggregate of 13,927,916 shares of our common stock with a weighted-average contractual remaining life of 3.2 years, and exercise prices ranging from $0.24 to $3.20 per share, resulting in a weighted average exercise price of $1.82 per share.

The valuation methodology used to determine the fair value of our warrants is the Black-Scholes-Merton valuation model, or 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 term of the warrant.

Warrant Activity During the Nine Months Ended September 30, 2014

During the nine months ended September 30, 2014, we did not grant any warrants.

Warrant Activity During the Year Ended December 31, 2013

In January 2013, we granted warrants to purchase 1,250,000 shares of our common stock in connection with the issuance of the Revolving Credit Note, or the Plato Warrant (see NOTE 10 above for more details). The Plato Warrant has an exercise price of $3.20 per share. The Plato Warrant vested on October 31, 2013 and may be exercised prior to its expiration on January 31, 2019. The Plato Warrant, with a fair value of approximately $1,711,956, was valued on the date of the grant using a term of six years; a volatility of 44.29%; risk free rate of 0.88%; and a dividend yield of 0%. For the nine months ended September 30, 2014, $260,027 was recorded as financing costs in connection with the issuance of the Plato Warrant on the accompanying condensed consolidated financial statements. For the three and nine months ended September 30, 2013, $395,980 and $1,055,948, respectively, was recorded as financing costs on the accompanying condensed consolidated financial statements.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 – STOCKHOLDERS' EQUITY (Continued)

Warrants to Purchase Common Stock of the Company (continued)

Warrant Activity During the Year Ended December 31, 2013 (continued)

In May 2013, we entered into a consulting agreement with Sancilio & Company, Inc., or SCI, to develop drug platforms to be used in our hormone replacement drug candidates. These services include support of our efforts to successfully obtain U.S. Food and Drug Administration, or the FDA, approval for our drug candidates, including a vaginal capsule for the treatment of vulvar and vaginal atrophy, or VVA. In connection with the agreement, SCI agreed to forfeit its rights to receive warrants to purchase 833,000 shares of our common stock that were to be granted pursuant to the terms of a prior consulting agreement dated May 17, 2012. As consideration under the agreement, we agreed to grant to SCI a warrant to purchase 850,000 shares of our common stock at $2.01 per share that has vested or will vest, as applicable, as follows:

1. 283,333 shares were earned on May 11, 2013 upon acceptance of an Investigational New Drug application by the FDA for an estradiol-based drug candidate in a softgel vaginal capsule for the treatment of VVA; however, pursuant to the terms of the consulting agreement, the shares did not vest until June 30, 2013. The fair value of $405,066 for the shares vested on June 30, 2013 was determined by using the Black-Scholes Model on the date of vesting using a term of 5 years; a volatility of 45.89%; risk free rate of 1.12%; and a dividend yield of 0%. We recorded the entire $405,066 as non-cash compensation as of June 30, 2013;
2. 283,333 shares vested on June 30, 2013. The fair value of $462,196 for these shares was determined by using the Black-Scholes Model on the date of the vesting using a term of 5 years; a volatility of 45.84%; risk free rate of 1.41%; and a dividend yield of 0%. As of September 30, 2014, we recorded $154,068 as prepaid expense-short term and $115,543 as prepaid expense-long term in the accompanying condensed consolidated financial statements. During the three and nine months ended September 30, 2014, we recorded $38,517 and $115,551 as non-cash compensation in the accompanying condensed consolidated financial statements; and
3. 283,334 shares will vest upon the receipt by us of any final FDA approval of a drug candidate that SCI helped us design. It is anticipated that this event will not occur before December 2015.

As of September 30, 2014, unamortized costs associated with the SCI warrants totaled approximately $950,000.

Stock Options to Purchase Common Stock of the Company

On September 25, 2009, our board of directors approved the 2009 Long Term Incentive Compensation Plan, or the LTIP, to provide financial incentives to our employees, members of the board of directors, and our advisers and consultants who are able to contribute towards the creation of or who have created stockholder value by providing them stock options and other equity and cash incentives, or the Awards.

The Awards available under the LTIP consist of stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock, performance units, EVA awards, and other stock or cash awards as described in the LTIP. There are 25,000,000 shares authorized for issuance under the LTIP. Under the LTIP, non-qualified stock options for the purchase of an aggregate of 14,883,469 shares of our common stock were outstanding at September 30, 2014.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 – STOCKHOLDERS' EQUITY (Continued)

Stock Options to Purchase Common Stock of the Company (continued)

On February 23, 2012, our board of directors approved the 2012 Stock Incentive Plan, and on June 10, 2013, approved the Amended and Restated 2012 Stock Incentive Plan, or the 2012 SOP. The 2012 SOP was designed to serve as an incentive for retaining qualified and competent key employees, officers and directors, and certain consultants and advisors. There are 10,000,000 shares authorized for issuance under the 2012 SOP. Non-qualified stock options for the purchase of an aggregate of 1,968,474 shares of our common stock were outstanding at September 30, 2014.

The valuation methodology used to determine the fair value of the 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 during the nine months ended September 30, 2014 and 2013 are set forth in the table below.

	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Risk-free interest rate	1.68-1.77%	0.65-1.71%
Volatility	69.15-70.93%	33.35-45.76%
Term (in years)	5-6.25	5-6.25
Dividend yield	0.00%	0.00%

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 expected life. Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the term of an award. Our estimated volatility is an average of the historical volatility of the stock prices of our peer entities whose stock prices were publicly available. Our calculation

of estimated volatility is based on historical stock prices over a period equal to the term of the awards. We used the historical volatility of our peer entities due to the lack of sufficient historical data on our stock price. The average expected life is based on the contractual term of the stock option using the simplified method.

A summary of activity under the LTIP and 2012 SOP 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, 2013	15,632,742	$ 1.44	7.2	$58,878,132
Granted	2,013,500	$ 4.85		
Exercised	(788,030)			
Expired	(167)			
Cancelled	(6,102)			
Balance at September 30, 2014	16,851,943	$ 1.90	7.1	$46,835,281
Vested and Exercisable at September 30, 2014	12,075,621	$ 1.19	5.8	$41,687,931

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 12 – STOCKHOLDERS' EQUITY (Continued)

Stock Options to Purchase Common Stock of the Company (continued)

The Black-Scholes Model is used to calculate the fair value of individual stock option grants on their issue date. The weighted-average issue date fair value of stock options issued during the nine months ended September 30, 2014 was $3.03. Stock options issued under our plans have exercise prices ranging from $0.10 to $5.21 per share. Stock-based compensation expense for stock options recognized in our results of operations for the three and nine months ended September 30, 2014 were $1,047,493 and $3,341,604 respectively, and $793,426 and $1,962,673, respectively, for the same periods in 2013 (all based on awards vested and estimated without forfeitures). ASC 718-10 requires forfeitures to be estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from the estimates. At September 30, 2014, total unrecognized estimated compensation expense related to unvested stock options previously issued was approximately $6,826,000, which is expected to be recognized over a weighted-average period of 2.8 years. No tax benefit was realized due to a continued pattern of operating losses.

NOTE 13 – 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 2014 as a result of (i) the losses recorded during the nine months ended September 30, 2014, (ii) additional losses expected for the remainder of 2014, 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, 2014, 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 14 – RELATED PARTIES

On February 29, 2012, Cooper C. Collins, who was then the largest shareholder of Pernix Therapeutics, LLC, or Pernix, was elected to serve on our board of directors. On October 5, 2011, we closed a stock purchase agreement with Pernix. From time to time, we have entered into agreements with Pernix in the normal course of business. All such agreements are reviewed by independent directors or a committee consisting of independent directors. During the nine months ended September 30, 2014 and 2013, we did not engage in any transactions with Pernix. At September 30, 2014 and December 31, 2013, there were amounts due Pernix of approximately $46,000.

Additionally, there were amounts due to us from Pernix for legal fee reimbursement relating to a litigation matter stemming from a license and supply agreement in the amounts of $249,981 at both September 30, 2014 and December 31, 2013.

THERAPEUTICSMD, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 15 - BUSINESS CONCENTRATIONS

We purchase our products from several suppliers with approximately 77% and 98% of our purchases supplied from one vendor for the nine months ended September 30, 2014 and 2013, respectively.

We sell our prescription dietary supplement products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. Revenue generated from four major customers accounted for approximately 95% and 98% of our recognized revenue for the nine months ended September 30, 2014 and 2013, respectively.

For the nine months ended September 30, 2014 and 2013, approximately 79% and 78%, respectively, of our recognized revenue and 96% and 98%, respectively, of our deferred revenue was generated from sales to four major customers.

NOTE 16 – COMMITMENTS AND CONTINGENCIES

We lease administrative office space in Boca Raton, Florida pursuant to a 63 month non-cancelable operating lease that commenced on July 1, 2013 and expires on September 30, 2018. The lease stipulates, among other things, average base monthly rents of $30,149 (inclusive of estimated operating expenses) and sales tax, for total future minimum payments over the life of the lease of $1,899,414. The straight line rental expense related to our office lease totaled $90,448 for the three months ended September 30, 2014, partially offset by rent income of $5,993. The straight line rental expense related to our office lease totaled $271,345 for the nine months ended September 30, 2014, partially offset by rent income of $41,953. The rental expense for the nine months ended September 30, 2013 was approximately $150,000.

As of September 30, 2014, future minimum rental payments for our office lease are as follows:

Years Ending December 31,	
2014 (3 months)	$91,438
2015	371,240
2016	382,377
2017	393,848
2018	302,748
Total minimum lease payments	$1,541,651

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. This discussion should be read together with our condensed consolidated financial statements and the notes to the financial statements, which are included in this report. 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, 2013 filed with the Securities and Exchange Commission, or the Commission or the SEC, on March 5, 2014, 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 Management's Discussion and Analysis of Financial Condition and Results of Operations contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. 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, 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. 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 this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2013, and include the following: our ability to maintain or increase sales of our products; our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor; the length, cost and uncertain results of our clinical trials; the potential of adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; 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, and BocaGreenMD, Inc., a Nevada corporation, or BocaGreen.

Overview

We are a women's health care company focused on developing and commercializing products targeted exclusively for women. Currently, we are focused on conducting the clinical trials necessary for regulatory approval and commercialization of hormone therapy pharmaceutical products. The current drug candidates used in our clinical trials are being investigated to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis, and vaginal dryness. We are developing these investigational hormone therapy drug candidates, which contain estradiol and progesterone alone or in combination, with the aim of demonstrating equivalent clinical efficacy at lower doses, thereby enabling a side effect profile compared with competing products. Our drug candidates are created from a platform of hormone technology that enables the administration of hormones with high bioavailability alone or in combination. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter, or OTC, vitamins and cosmetics.

Our common stock is traded on the NYSE MKT under the symbol “TXMD”. We maintain the following websites at www.therapeuticsmd.com, www.vitamedmd.com, www.vitamedmdrx.com, and www.bocagreenmd.com.

Research and Development

Overview

We have obtained the U.S. Food and Drug Administration, or FDA, approval of our Investigational New Drug, or IND, applications to conduct clinical trials for four of our hormone therapy drug candidates: TX-001HR, our oral combination of progesterone and estradiol; TX-002HR, our oral progesterone alone; TX-003HR, our oral estradiol alone; and TX-004HR, our vaginal suppository estradiol alone.

We are currently conducting phase 3 clinical trials for TX-001HR and TX-004HR. In July 2014, we temporarily suspended enrollment in the phase 3 clinical trial for TX-002HR, and in October 2014 we temporarily stopped the trial in order to update the phase 3 protocol based on discussions with the FDA. We have no current plans to conduct clinical trials for TX-003HR.

TX-001HR, our combination estradiol and progesterone drug candidate, is undergoing clinical trials for the treatment of moderate to severe vasomotor symptoms due to menopause, including hot flashes, night sweats and sleep disturbances for post- menopausal women with an intact uterus. The hormone therapy drug candidate is chemically identical to the hormones that naturally occur in a woman’s body, namely estradiol and progesterone, and is being studied as a continuous-combined regimen, in which the combination of estrogen and progesterone are taken together in one product daily. If approved by the FDA, we believe this would represent the first time a combination product of estradiol and progesterone (biologically identical or bioidentical to the estradiol and progesterone produced by the ovaries), would be approved for use in a single combined product.

On September 5, 2013, we began enrollment of the REPLENISH trial, a multicenter, double-blind, placebo-controlled, phase 3 study of TX-001HR in postmenopausal women with an intact uterus. The study is designed to evaluate the efficacy of TX-001HR for the treatment of moderate to severe vasomotor symptoms due to menopause and the endometrial safety of TX-001HR. Patients are assigned to one of five treatment arms, four active and one placebo, and receive study medication for 12 months. The primary endpoint for the reduction of endometrial hyperplasia is an incidence of endometrial hyperplasia of less than 1% at 12 months, as determined by endometrial biopsy. The primary endpoint for the treatment of moderate to severe vasomotor symptoms is the mean change of frequency and severity of moderate to severe vasomotor symptoms at weeks four and 12 compared to placebo, as

measured by the number and severity of hot flushes. Only subjects experiencing a minimum daily frequency of seven moderate to severe hot flushes at screening are included in the vasomotor symptoms analysis, while all subjects are included in the endometrial hyperplasia analysis. The secondary endpoints include reduction in sleep disturbances and improvement in quality of life measures, night sweats and vaginal dryness, measured at 12 weeks, 6 months and 12 months. We intend to enroll approximately 1,750 patients at approximately 100 sites. We currently anticipate that enrollment in the REPLENISH Trial will be completed in the first-half of 2015 and that results of the trial will be reported in the first-half of 2016.

TX-002HR is a natural progesterone for the treatment of secondary amenorrhea without the potentially allergenic component of peanut oil. The product would be chemically identical to the hormone progesterone, which naturally occurs in a woman's body. In January 2014, we began recruitment of patients in the SPRY Trial, a phase 3 clinical trial designed to measure the safety and effectiveness of TX-002HR in the treatment of secondary amenorrhea. During the first two quarters of 2014, the SPRY Trial encountered enrollment challenges because of Institutional Review Board approved clinical trial protocols and FDA inclusion and exclusion criteria. In July 2014, we temporarily suspended enrollment and in October 2014 we stopped the SPRY Trial in order to update the phase 3 protocol based on discussions with the FDA. We intend to update the phase 3 protocol to, among other things, target only those women with secondary amenorrhea due to polycystic ovarian syndrome and to amend the primary endpoint of the trial. We believe that the updated phase 3 protocol, if approved by the FDA, will allow us to mitigate the enrollment challenges in, and shorten the duration of, the SPRY Trial. However, there can be no assurance that the FDA will approve the updated phase 3 protocol that we intend to propose.

TX-004HR is a vaginal suppository estradiol drug candidate for the treatment of dyspareunia, a symptom of vulvar and vaginal atrophy, or VVA, due to menopause. We believe that our drug candidate will be at least as effective as the traditional treatments for VVA because of an early onset of action with less systemic exposure inferring a greater probability of dose administration to the target tissue, and it will have an added advantage of being a simple, easier to use dosage form versus traditional VVA treatments. We initiated a multicenter, double-blind, placebo-controlled phase 3 clinical trial during the third quarter of 2014 to assess the safety and efficacy of TX-004HR for the treatment of moderate to severe dyspareunia, or painful intercourse, as a symptom of VVA due to menopause. We are conducting a single 12 week study, evaluating three different doses of estradiol: 4 mcg, 10 mcg and 25 mcg versus placebo. The FDA has to date noted that in order to approve a drug based on a single trial, the trial would need to show statistical significance at a 0.01 level. The study has been designed to include four primary endpoints: the reduction of vaginal pH levels to less than 5.0, an increase in superficial cells, a decrease in parabasal cells and the improvement of dyspareunia. If approved, the 4 mcg formulation would represent a lower effective dose than the currently available VVA therapies approved by the FDA. The trial is designed to enroll approximately 700 patients across approximately 100 sites.

Research and Development Expenses

A significant portion of our operating expenses to date have been incurred in research and development activities. Research and development expenses relate primarily to the discovery and development of our drug products. Our business model is dependent upon our company continuing to conduct a significant amount of research and development. Until one of our drug products receives IND approval from the FDA, products costs are listed as Other Research and Development costs in the accompanying condensed consolidated financial statements. Our research and development expenses consist primarily of expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies; employee-related expenses, which include salaries and benefits, and non-cash share-based compensation; the cost of developing our chemistry, manufacturing and controls capabilities, and acquiring clinical trial materials; and costs associated with other research activities and regulatory approvals.

We make payments to the CROs based on agreed upon terms that may include payments in advance of a study starting date. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Advance payments to be expensed in future research and development activities were $457,459 and $1,267,588, at September 30, 2014 and December 31, 2013, respectively.

The following table indicates our research and development expense by project/category for the periods indicated (in 000s):

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
TX 001HR	$11,518	$1,902	$20,320	$2,434
TX 002HR	85	99	1,381	312
TX 004HR	567	729	931	733
Other research and development	2,739	1,369	6,420	4,232
	$14,909	$4,099	$29,052	$7,711

Research and development expenditures will continue to be significant as we continue development of our drug candidates and advance the development of our proprietary pipeline of novel drug candidates. We expect to incur significant research and development costs as we develop our drug pipeline, complete the ongoing clinical trials of our drug candidates, conduct our planned phase 3 clinical trials, subject to receiving input from regulatory authorities, and prepare regulatory submissions.

The costs of clinical trials may vary significantly over the life of a project owing to factors that include but are not limited to the following: per patient trial costs, the number of patients that participate in the trials; the number of sites included in the trials; the length of time each patient is enrolled in the trial; the number of doses that patients receive; the drop-out or discontinuation rates of patients; the amount of time required to recruit patients for the trial, the duration of patient follow-up; and the efficacy and safety profile of the drug candidate.

We base our expenses related to clinical trials on estimates that are based on our experience and estimates from CROs and other third parties.

Results of Operations

The following information presents the results of operations for the three and nine month periods ended September 30, 2014 and 2013. The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements included herewith and our Annual Report on Form 10-K filed with the Commission on March 5, 2014. This discussion should not be construed to imply that the results discussed herein will necessarily continue into the future, or that any conclusion reached herein will necessarily be indicative of actual operating results in the future. Such discussion represents only our best present assessment. Our historical financial information presented is reported on a consolidated basis with our subsidiaries.

Three months ended September 30, 2014 compared with three months ended September 30, 2013

	Three Months Ended September 30,		
	2014	2013	Change
	(000s)		
Revenues, net	$4,186	$2,294	$1,892
Cost of goods sold	1,069	648	421
Operating expenses	20,965	8,883	12,082
Operating loss	(17,848)	(7,237)	(10,611)
Other income (expense)	16	(436)	452
Net loss	$(17,832)	$(7,673)	$(10,159)

Revenues and Cost of Goods Sold

Revenues for the three months ended September 30, 2014 increased approximately $1,892,000 or approximately 82%, from the three months ended September 30, 2013. This increase was directly attributable to (i) the increase in the number of physicians writing prescriptions for our products, (ii) the increased productivity of our sales force, and (iii) the increase in the average net sales price of our products. Approximately 19% of this increase was due to an increase in the number of units sold and approximately 81% of the increase was related to product mix and price change. Cost of goods sold increased approximately $421,000, or approximately 65%, for the three months ended September 30, 2014 compared with the three months ended September 30, 2013. Cost of goods sold as a percentage of revenue was approximately 26% and 28% for the three months ended September 30, 2014 and 2013, respectively.

Operating Expenses

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

	Three Months Ended September 30,	
	2014	2013*
Human resource costs, including salaries, commissions, benefits and taxes	14.4%	31.9%
Research and development costs	71.1%	46.1%
Sales and marketing, excluding human resource costs	6.4 %	10.7%
Professional fees for legal, accounting and consulting	3.5 %	5.7 %
Other operating expenses	4.6 %	5.6 %

*Prior year numbers have been reclassified to conform to current year's presentation.

Operating expenses increased by approximately $12,082,000, or approximately 136%, from the three months ended September 30, 2013 as a result of the following items:

	(000s)
Increase in research and development costs	$10,811
Increase in human resource costs, including salaries, commissions, benefits and taxes	188

Increase in other operating expenses	448
Increase in sales and marketing, excluding human resource costs	404
Increase in legal, accounting and consulting fees	231
	$12,082

Research and development costs increased as a direct result of the development of our hormone therapy candidates and related clinical trials.

Human resource costs, including salaries, commissions, benefits and taxes increased by approximately $188,000, primarily as a result of an increase in personnel costs (approximately $408,000), partially offset by a decrease in commissions (approximately $220,000).

Other operating expense increased primarily as a result of increases in data services, insurance, non-cash compensation and investor relations expenses.

Sales and marketing costs increased primarily as a result of increases in advertising costs for the launch of our VitaPearl and Prena1 Pearl products.

Professional fees increased as a result of higher legal and accounting expenses.

Other Expense

Other non-operating expense decreased by approximately $452,000 for the three months ended September 30, 2014 compared with the comparable period in 2013. This decrease was primarily a result of a reduction of financing costs for the three months ended September 30, 2014.

Nine months ended September 30, 2014 compared with nine months ended September 30, 2013

	Nine Months Ended September 30,		
	2014	2013	Change
	(000s)		
Revenues, net	$10,769	$5,913	$4,856
Cost of goods sold	2,792	1,492	1,300
Operating expenses	45,703	22,218	23,485
Operating loss	(37,726)	(17,797)	(19,929)
Other expense	(189)	(2,243)	2,054
Net loss	$(37,915)	$(20,040)	$(17,875)

Revenues and Cost of Goods Sold

Revenues for the nine months ended September 30, 2014 increased approximately $4,856,000 or approximately 82%, from the nine months ended September 30, 2013. This increase was directly attributable to (i) the increase in the number of physicians writing prescriptions for our products, (ii) the increased productivity of our sales force, and (iii) the increase in the average net sales price of our products. Approximately 30% of this increase was due to an increase in the number of units sold and approximately 70% of the increase was related to product mix and price change. Cost of goods sold increased approximately $1,300,000, or approximately 87%, for the nine months ended September 30, 2014 compared with the nine months ended September 30, 2013. Cost of goods sold as a percentage of revenue was 26% and 25% for the nine months ended September 30, 2014 and 2013, respectively.

Operating Expenses

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

	Nine Months Ended September 30,	
	2014	2013*
Human resource costs, including salaries, commissions, benefits and taxes	19.2%	37.9%
Research and development costs	63.6%	34.7%
Sales and marketing, excluding human resource costs	8.1 %	13.6%
Professional fees for legal, accounting and consulting	3.7 %	7.2 %
Other operating expenses	5.4 %	6.6 %

*Prior year numbers have been reclassified to conform to current year's presentation.

Operating expenses increased by approximately $23,485,000, or approximately 106%, from the nine months ended September 30, 2013 as a result of the following items:

	(000s)
Increase in research and development costs	$21,342
Increase in other operating expenses	987
Increase in sales and marketing, excluding human resource costs	692
Increase in human resource costs, including salaries, commissions, benefits and taxes	352
Decrease in legal, accounting and consulting fees	112
	$23,485

Research and development costs increased as a direct result of the development of our hormone therapy candidates and related clinical trials.

Other operating expense increased primarily as a result of increases in data services, insurance and investor relations expenses.

Sales and marketing costs increased primarily as a result of increases in advertising costs related to the launch of our VitaPearl and Prena1 Pearl products.

Human resource costs, including salaries, commissions, benefits and taxes increased by approximately $352,000, primarily as a result of an increase in personnel costs (approximately $550,000), partially offset by a decrease in commissions (approximately $198,000).

Professional fees increased as a result of higher consulting and accounting fees, partially offset by a decrease in legal expenses.

Other Expense

Other non-operating expense decreased by approximately $2,054,000 for the nine months ended September 30, 2014 compared with the comparable period in 2013. This decrease was primarily a result of reduction of financing costs

(approximately $848,000) and a reduction in amortization of debt discount (approximately $1,103,000) recorded between the periods.

Liquidity and Capital Resources

We have funded our operations primarily through the private placement of equity and debt securities and public offerings of our common stock. For the year ending December 31, 2013, we received approximately $79.0 million in net proceeds from the issuance of shares of our common stock. As of September 30, 2014, we had cash and cash equivalents totaling approximately $67.0 million, 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.

On July 29, 2014, we entered into an underwriting agreement with Goldman Sachs & Co, or Goldman Sachs, as the representative of the underwriters named therein, or the Goldman Sachs Underwriters, relating to an underwritten public offering of 8,565,310 shares of our common stock. The price to the public in the offering was $4.67 per share. Under the terms of the underwriting agreement, we granted the Goldman Sachs Underwriters a 30-day option to purchase up to an additional 1,284,796 shares of our common stock. On July 30, 2014, the Goldman Sachs Underwriters exercised their option to purchase the additional 1,284,796 shares of our common stock. Net proceeds from this offering was approximately $42.8 million, after deducting underwriting discounts and commissions and other offering expenses. The offering closed on August 4, 2014.

We believe that our existing cash and cash equivalents will allow us to fund our operations through at least the next 12 months. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing 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, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products. Additionally, we may have to grant licenses on terms that may not be favorable to us.

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

Summary of (Uses) and Sources of Cash

	Nine Months Ended September 30,	
	2014	2013
	(000)	
Net cash flows used in operating activities	(30,236)	(15,999)
Net cash flows used in investing activities	(224)	(281)
Net cash flows provided by financing activities	43,268	74,299

Operating Activities

The use of cash in both periods resulted primarily from our net loss adjusted for non-cash charges and changes in components of working capital. The increase of approximately $14.2 million in cash used in operating activities for the nine months ended September 30, 2014 compared with the comparable period in the prior year was due primarily to research and development, and sales, general, and administrative costs. These were partially offset by an increase of approximately $4.9 million in revenue over the same periods.

Investing Activities

The use of cash in both periods consisted of patent costs, security deposits, and purchase of property and equipment. There was a minor reduction in cash used in investing activities for the nine months ended September 30, 2014 compared with the comparable period in 2013 due to the capitalization of patent and trademark costs in our initial year of phase 3 clinical trials in 2013.

Financing Activities

Financing activities represent the principal source of our cash flow. Our financing activities for the nine months ended September 30, 2014 consisted of the underwritten public offering of our common stock and stock option and warrant exercises.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

There were no material changes in our commitments under contractual obligations during the nine months ended September 30, 2014

New Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable) and, if so, disclose that fact. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We do not expect the adoption of the ASU 2014-15 to have a material effect on our condensed consolidated financial statements and disclosures.

In May 2014, the FASB and the International Accounting Standards Board (IASB) issued ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligations. ASU 2014-09 is effective for public business entities, certain not-for-profit entities and certain employee benefit plans, for annual periods beginning after December 15, 2016, including interim periods within that period. Early adoption is not permitted under GAAP. We are currently evaluating the impact of ASU 2014-09 on our condensed consolidated financial statements and disclosures.

In July 2013, the FASB issued ASU 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force), or ASU 2013-11. The amendments in ASU 2013-11 provide guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in ASU No. 2013-11 do not require new recurring disclosures. The amendments in ASU 2013-11 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments in ASU No. 2013-11 did not have a material impact on our

condensed consolidated financial statements.

In December 2011, the FASB issued ASU No. 2011-11, Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities, or ASU 2011-11. ASU 2011-11 enhances current disclosures about financial instruments and derivative instruments that are either offset on the statement of financial position or subject to an enforceable master netting arrangement or similar agreement, irrespective of whether they are offset on the statement of financial position. Entities are required to provide both net and gross information for these assets and liabilities in order to facilitate comparability between financial statements prepared in conformity with GAAP and financial statements prepared on the basis of International Financial Reporting Standards. ASU 2011-11 is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those years. ASU 2011-11 did not have a material impact on our financial position or results of operations.

We do not believe there would have been a material effect on the accompanying condensed consolidated financial statements had any other recently issued, but not yet effective, accounting standards been adopted in the current period.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our market risk has not changed materially from the interest rate risk disclosed in Item 7A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

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 Exchange Act is recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms and is accumulated and communicated to our principal executive officer and principal financial officer, as appropriate, in order to allow timely decisions in connection with required disclosure.

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Internal Controls

During the three months ended September 30, 2014, there were no significant 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

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 adverse effect on our business or financial condition.

Item 1A. Risk Factors

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should carefully consider the risks described below and the risks described under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2013, together with the other information contained in our other filings with the SEC. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

Risks Related to Our Business

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We have incurred recurring net losses, including net losses of $28 million, $35 million, and $13 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of September 30, 2014, we had an accumulated deficit of approximately $118 million. We have generated limited revenue and have funded our operations to date primarily from public and private sales of equity and private sales of debt securities. We expect to incur substantial additional losses over the next several years as our research, development and clinical trial activities increase, especially those related to our hormone therapy drug candidates. As a result, we may never achieve or maintain profitability unless we successfully commercialize our products, in particular, our hormone therapy drug candidates. If we are unable to make required payments under any of our obligations for any reason, our creditors may take actions to collect their debts, including foreclosing on property that collateralizes our obligations. If we continue to incur substantial losses and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, refinance existing debt obligations on terms unfavorable to us, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

We currently derive all of our revenue from sales of our women's health care products and our failure to maintain or increase sales of these products would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We currently derive all of our revenue from sales of women's health care products, including prenatal and women's multi-vitamins, iron supplements, vitamin D supplements, natural menopause relief and scar reduction creams. While sales of our vitamin products grew from 2010 through 2013, we cannot assure you that such sales will continue to grow. In addition to other risks described herein, our ability to maintain or increase existing product sales is subject to a number of risks and uncertainties, including the following:

- the presence of new or existing competing products, including generic copies of our prescription dietary supplement products;
- any supply or distribution problems arising with any of our manufacturing and distribution strategic partners;

- changed or increased regulatory restrictions or regulatory actions by the FDA;
- changes in health care laws and policy, including changes in requirements for rebates, reimbursement, and coverage by federal health care programs;
- the impact or efficacy of any price increases we may implement in the future;
- changes to our label and labeling, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell our products; and
- acceptance of our products as safe and effective by physicians and patients.

If revenue from sales of our existing prescription and over-the-counter dietary supplements and cosmetics does not continue or increase, we may be required to reduce our operating expenses or to seek to raise additional funds, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects, or we may not be able to commence or continue clinical trials to seek approval for and commercialize our hormone therapy drug candidates or any other products we may choose to develop in the future.

If our products do not have the effects intended or cause undesirable side effects, our business may suffer.

Although many of the ingredients in our current dietary supplement products are vitamins, minerals and other substances for which there is a long history of human consumption, they also contain innovative ingredients or combinations of ingredients. Although we believe all of these products and the combinations of ingredients in them are safe when taken as directed, the products could have certain undesirable side effects if not taken as directed or if taken by a consumer who has certain medical conditions, such as the potential effect of high doses of folic acid masking pernicious anemia. In addition, these products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary restrictions. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or on an unforeseen cohort. If any of our products or products we develop or commercialize in the future is shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations and prospects would be harmed significantly.

Our future success will depend in large part on our ability to commercialize our hormone therapy drug candidates designed to alleviate the symptoms of and reduce the health risks resulting from menopause, including hot flashes, osteoporosis and vaginal dryness.

Our future success will depend in large part on our ability to successfully develop and commercialize our hormone therapy drug candidates designed to alleviate the symptoms of and reduce the health risks resulting from menopause, including hot flashes, osteoporosis and vaginal dryness. We have submitted IND applications for our four hormone therapy drug candidates, which the FDA has made effective and which permit us to conduct clinical testing on these proposed products. We currently intend to clinically test three of those drug candidates. However, we may not be able to complete the development of these drug candidates, the results of the clinical trials may not be sufficient to support a New Drug Application, or NDA, for any of them and even if we believe the results of our clinical trials are sufficient to support any NDA that we submit, the FDA may disagree and may not approve our NDA. In addition, even if the FDA approves one or more of our NDAs, it may do so with restrictions on the intended uses that may make

commercialization of the product or products financially untenable. The failure to commercialize or obtain necessary approval for any one or more of these products would substantially harm our prospects and our business.

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

We need substantial amounts of cash to complete the clinical development of our hormone therapy drug candidates. Our existing cash and cash equivalents will not be sufficient to fund these requirements. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate and we may need to spend more money than currently expected because of circumstances beyond our control. We do not currently have any committed external source of funds. We will attempt to raise additional capital from the issuance of equity or debt securities, collaborations with third parties, licensing of rights to these products, or other means, or a combination of any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to take one or more of the following actions:

- significantly delay, scale back, or discontinue our product development and commercialization efforts;
- seek collaborators for our hormone therapy drug candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be the case; and
- license, potentially on unfavorable terms, our rights to our hormone therapy drug candidates that we otherwise would seek to develop or commercialize ourselves.

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

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

We have no experience as a company in bringing a drug to regulatory approval.

We have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all of our planned NDAs for substantive review or may conclude, after review of our data, that our

applications are insufficient to obtain regulatory approval of any of our hormone therapy drug candidates. We have recently begun to conduct validation and scale-up of the manufacturing processes for our proposed combination estradiol and progesterone drug candidate and our proposed suppository estradiol VVA product. The FDA may also require that we conduct additional clinical or manufacturing validation studies, which may be costly and time-consuming, and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA required studies, approval of any NDA that we submit may be significantly delayed, possibly for years, or may require us to expend more resources than we have available or can secure. Any delay or inability in obtaining regulatory approvals would delay or prevent us from commercializing our hormone therapy drug candidates, generating revenue from these proposed products and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA we submit. If any of these outcomes occur, we may be forced to abandon our planned NDAs for one or more of our hormone therapy drug candidates, which would materially adversely affect our business and could potentially cause us to cease operations.

Clinical trials involve a lengthy and expensive process with an uncertain outcome and results of earlier studies and trials may not be predictive of future trial results.

Three hormone therapy drug candidates are currently in various stages of clinical testing. We have begun phase 3 clinical trial of our estradiol and progesterone combination drug candidate, our progesterone alone drug candidate and our vaginal suppository estradiol drug candidate. Clinic trials are expensive, can take many years to complete and have highly uncertain outcomes. For example, we recently temporarily suspended enrollment in and subsequently stopped the SPRY Trial in order to update the phase 3 protocol based on discussions with the FDA. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our future clinical trials may not be successful or may be more expensive or time-consuming than we currently expect. Prior to approving a new drug, the FDA generally requires that the safety and efficacy of the drug be demonstrated in two adequate and well-controlled clinical trials. In some situations the FDA approves drugs on the basis of a single well-controlled clinical trial. We believe we may be required to conduct only a single phase 3 clinical trial of each of our estradiol and progesterone combination drug candidate, our progesterone alone drug candidate and our vaginal suppository estradiol drug candidate for the treatment of VVA. However, in connection with our VVA drug candidate, the FDA has to date noted that in order to approve a drug based on a single trial, the trial would need to show statistical significance at a 0.01 level, and that a trial that is merely statistically significant may not provide sufficient evidence to support an NDA filing or approval of a drug candidate where the NDA relies on a single clinical trial. If clinical trials for any of our hormone therapy drug candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA will not approve that drug and we would not be able to commercialize it, which will have a material adverse effect on our business, financial condition, results of operations and prospects.

Delays in clinical trials are common for many reasons and any such delays could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales as currently contemplated.

We may experience delays in clinical trials for our hormone therapy drug candidates. Our planned clinical trials might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be redesigned; might not enroll a sufficient number of patients; or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- delays in obtaining regulatory approval to commence a trial;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;

- imposition of a clinical hold because of safety or efficacy concerns by a the FDA, a data safety monitoring board or committee, or DSMB, a clinical trial site's institutional review board, or IRB, or us;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required IRB approval at each site;

- delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new sites;
- delays in obtaining sufficient supplies of clinical trial materials, including suitable active pharmaceutical ingredients; or
- delays resulting from negative or equivocal findings of DSMB for a trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Any of these delays in completing our clinical trials could increase our costs, slow down our product development and approval process, and jeopardize our ability to commence product sales and generate revenue.

We may be required to suspend or discontinue clinical trials because of adverse side effects or other safety risks that could preclude approval of our hormone therapy drug candidates.

Our clinical trials may be suspended or terminated at any time for a number of reasons. A clinical trial may be suspended or terminated by us, our collaborators, the FDA, or other regulatory authorities because of a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or negative or equivocal findings of the DSMB or the IRB for a clinical trial. An IRB may also suspend or terminate our clinical trials for failure to protect patient safety or patient rights. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe the clinical trials are not being conducted in accordance with applicable regulatory requirements or present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any proposed product that we develop, the commercial prospects of such proposed product will be harmed and our ability to generate product revenue from any of these proposed products will be delayed or eliminated. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

We rely on third parties to conduct our research and development activities, including our clinical trials, and we may experience delays in obtaining or may be unsuccessful in obtaining regulatory approval for, or in commercializing, our hormone therapy drug candidates if these third parties do not successfully carry out their contractual duties or meet expected deadlines.

We do not have the resources to independently conduct research and development activities. Therefore, we have relied, and plan to continue to rely, on various third-party CROs to conduct our research and development activities and to recruit patients and monitor and manage data for our on-going clinical programs for our hormone therapy drug candidates, as well as for the execution of our clinical studies. Although we control only certain aspects of our CROs' activities, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We cannot assure you that the CROs will conduct the research properly or in a timely manner, or that the results will be reproducible. We and our CROs are required to comply with the FDA's current Good Clinical Practices, or cGCPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable or invalid and the FDA may require us to perform additional clinical trials before approving our proposed products. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, to evaluate the safety and effectiveness compared to placebo of our hormone therapy drug candidates to a statistically significant degree, our clinical trials will require an adequately large number of test subjects. Any clinical trial that a CRO conducts abroad on our behalf is subject to similar regulation. Accordingly, if our CROs fail to comply with these regulations or recruit a sufficient number of patients, we may be required to repeat clinical trials, which would delay the regulatory approval process.

In addition, we do not employ the personnel of our CROs, and, except for remedies available to us under our agreements with such organizations, we cannot control whether or not they will devote sufficient time and resources to our on-going clinical and pre-clinical programs. Our CROs may also have relationships with other commercial entities, including one or more of our competitors, for which they may also be conducting clinical studies or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised because of the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our hormone therapy drug candidates that we seek to develop. As a result, our financial results and the commercial prospects for our hormone therapy drug candidates that we seek to develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed or ended.

We typically engage one or more CROs on a project-by-project basis for each study or trial. While we have developed and plan to maintain our relationships with CROs that we have previously engaged, we also expect to enter into agreements with other CROs to obtain additional resources and expertise in an attempt to accelerate our progress with regard to on-going clinical programs and, specifically, the compilation of clinical trial data for submission with an NDA for each of our hormone therapy drug candidates. If any of our relationships with these third parties terminate,

we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or entering into new relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially affect our ability to meet our desired clinical development timelines and can increase our costs significantly. Although we try to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations, or prospects.

Future legislation, regulations and policies adopted by the FDA or other regulatory authorities may increase the time and cost required for us to conduct and complete clinical trials for our hormone therapy drug candidates.

The FDA has established regulations, guidelines and policies to govern the drug development and approval process, as have foreign regulatory authorities. Any change in regulatory requirements resulting from the adoption of new legislation, regulations, or policies may require us to amend existing clinical trial protocols or add new clinical trials to comply with these changes. Such amendments to existing protocols or clinical trial applications or the need for new ones, may significantly and adversely affect the cost, timing and completion of the clinical trials for our hormone therapy drug candidates.

In addition, the FDA's policies may change and additional government regulations may be issued that could prevent, limit, or delay regulatory approval of our drug candidates, or impose more stringent product labeling and post-marketing testing and other requirements. For example, in the past the FDA has indicated it would regulate prenatal vitamins containing greater than 0.8 mg of folic acid as a drug under the Federal Food, Drug, and Cosmetic Act. More recently the FDA indicated that there is no specified upper limit on the amount of folic acid permitted in a dietary supplement. If the FDA were to seek to regulate products with higher amounts of folic acid as drugs, it may require us to stop selling certain of our dietary supplement products and otherwise adversely affect our business. If we are slow or unable to adapt to any such changes, our business, prospects and ability to achieve or sustain profitability would be adversely affected.

Even if we obtain regulatory approval for our hormone therapy drug candidates, we will still face extensive, ongoing regulatory requirements and review and our products may face future development and regulatory difficulties.

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

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

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's cGMPs regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the drug, requiring that we conduct additional clinical trials, imposing new monitoring requirements, or requiring that we establish a REMS. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Healthcare Act of 1992. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party collaborators fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions:

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

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

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

We do not currently have nor do we plan to build the infrastructure or capability internally to manufacture our existing women's health care products. For example, we depend on Lang Pharma Nutrition, or Lang, a full-service, private label and corporate brand manufacturer specializing in premium health benefit driven products, including medical foods, nutritional supplements, beverages, bars and functional foods in the dietary supplement category, to supply approximately 98% of our vitaMedMD and BocaGreen products. In certain circumstances, including our failure to

satisfy our production forecasts to Lang, we may be obligated to reimburse Lang for the costs of excess raw materials purchased by Lang that it cannot use in another product category that it then sells. We also rely on third-party contract manufacturing organizations, or CMOs, to supply our hormone therapy drug candidates for use in the conduct of our clinical trials. We rely on these third parties to manufacture these products in accordance with our specifications and in compliance with applicable regulatory requirements. We do not have long-term contracts for the commercial supply of our products or our hormone therapy drug candidates. We intend to pursue long-term manufacturing agreements, but we may not be able to negotiate such agreements on acceptable terms, if at all.

In addition, regulatory requirements could pose barriers to the manufacture of our products, including our hormone therapy drug candidates. Our third-party manufacturers are required to comply with cGMP regulations. As a result, the facilities used by any of our current or future manufacturers must be approved by the FDA. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are responsible for manufacturing even though that manufacturing is conducted by a third-party CMO. All of our existing products are, and our hormone therapy drug candidates, if approved, will be, manufactured by CMOs. These CMOs are required by the terms of our contracts to manufacture our products in compliance with the applicable regulatory requirements. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for the commercial manufacture of our existing products or our hormone therapy drug candidates, we may need to find alternative manufacturing facilities, which would result in disruptions of our sales and significant delays of up to several years in obtaining approval for our hormone therapy drug candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMP regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts and criminal prosecutions, any of which could have a material adverse impact on our business, financial condition, results of operations and prospects. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products and proposed products or otherwise do not satisfactorily perform according to the terms of their agreements with us.

If any supplier of the product for our hormone therapy drug candidates experiences any significant difficulties in its respective manufacturing processes, does not comply with the terms of the agreement between us, or does not devote sufficient time, energy and care to providing our manufacturing needs, we could experience significant interruptions in the supply of our hormone therapy drug candidates, which could impair our ability to supply our hormone therapy drug candidates at the levels required for our clinical trials and commercialization and prevent or delay their successful development and commercialization.

The commercial success of our existing products and our hormone therapy drug candidates that we develop, if approved in the future, will depend upon gaining and retaining significant market acceptance of these products among physicians and payors.

Physicians may not prescribe our products, including any of our hormone therapy drug candidates, if approved by the appropriate regulatory authorities for marketing and sale, which would prevent us from generating revenue or becoming profitable. Market acceptance of our products, including our hormone therapy drug candidates, by physicians, patients and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- the clinical indications for which our hormone therapy drug candidates are approved, if at all;
- acceptance by physicians and payors of each product as safe and effective treatment;
- the cost of treatment in relation to alternative treatments, including numerous generic drug products;

- the relative convenience and ease of administration of our products in the treatment of the symptoms for which they are intended;
- the availability and efficacy of competitive drugs;
- the effectiveness of our sales force and marketing efforts;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;
- limitations or warnings contained in a product's FDA-approved labeling; and
- prevalence and severity of adverse side effects.

Even if the medical community accepts that our products are safe and efficacious for their approved indications, physicians may not immediately be receptive to the use or may be slow to adopt our products as an accepted treatment for the symptoms for which they are intended. We cannot assure you that any labeling approved by the FDA will permit us to promote our products as being superior to competing products. If our products, including, in particular our hormone therapy drug candidates, if approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products and we may not become profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

Our products, including our hormone therapy drug candidates if approved, face significant competition from branded and generic products and our operating results will suffer if we fail to compete effectively.

Development and awareness of our brand will depend largely upon our success in increasing our customer base. The dietary supplement and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our products, including any hormone therapy drug candidates that are approved, face intense competition, including from major multinational pharmaceutical and dietary supplement companies, established biotechnology companies, specialty pharmaceutical and generic drug companies. A new non-hormonal product, Brisdelle, produced by Noven Pharmaceuticals, was approved by the FDA for treatment of vasomotor symptoms in June 2013. Many of these companies have greater financial and other resources, such as larger research and development staffs and more experienced marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval more rapidly and may be more effective in selling and marketing their products. They also may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we sell or develop obsolete. As a result, our competitors may succeed in commercializing products before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. If we are unable to economically promote or maintain our brand, our business, results of operations and financial condition could be severely harmed. In addition, our efforts to provide an alternative to the non FDA-approved compound bioidentical market for estradiol and progesterone products sold by compounding pharmacies may not be successful.

Coverage and reimbursement may not be available for our products, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of our products, including any hormone therapy drug candidates, will depend on coverage and reimbursement policies and may be affected by health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. Third-party payors generally do not cover over-the-counter products and coverage for vitamins and dietary supplements varies. We cannot be sure that coverage and reimbursement will be available for our products, including any hormone therapy drug candidates, if approved. We also cannot be sure that the amount of reimbursement available, if any, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully compete through sales of our existing dietary supplement products or successfully commercialize our hormone therapy drug candidates.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain others and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of certain outpatient drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These and future cost-reduction initiatives could decrease the coverage and price that we receive for our products, including our hormone therapy drug candidates, if approved, and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates and any reduction in reimbursement under Medicare may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, became law in the United States. The goal of PPACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. Among other measures, PPACA imposes increased rebates on manufacturers for certain covered drug products reimbursed by state Medicaid programs. While we cannot predict the full effect PPACA will have on federal reimbursement policies in general or on our business specifically, the PPACA may result in downward pressure on drug reimbursement, which could negatively affect market acceptance of our products. In addition, we cannot predict whether new proposals will be made or adopted, when they may be adopted, or what impact they may have on us if they are adopted.

The availability of generic products at lower prices than branded products may also substantially reduce the likelihood of reimbursement for branded products, such as our hormone therapy drug candidates, if approved. We expect to experience pricing pressures in connection with the sale of our products generally due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative proposals. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

We face an inherent risk of product liability claims as a result of the marketing of our current products and the clinical testing of our hormone therapy drug candidates despite obtaining appropriate informed consents from our clinical trial participants and, in light of the history of product liability claims related to other hormone replacement therapy products, we will face an even greater risk if we obtain FDA approval and commercialize our hormone therapy drug candidates in the United States or other additional jurisdictions or if we engage in the clinical testing of proposed new products or commercialize any additional products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, failures to warn of dangers inherent in the product, negligence, strict liability, or breaches of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products or hormone therapy drug candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in any of the following:

- the inability to commercialize our products or hormone therapy drug candidates;
- difficulty recruiting subjects for clinical trials or withdrawal of these subjects before a trial is completed;
- labeling, marketing, or promotional restrictions;
- product recalls or withdrawals;
- decreased demand for our products or products that we may develop in the future;
- loss of revenue;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- exhaustion of any available insurance and our capital resources; and
- a decline in our stock price.

Although we maintain general liability insurance of up to $10 million in the aggregate and clinical trial liability insurance of $10 million in the aggregate for our hormone therapy drug candidates, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, financial condition, results of operations and prospects.

Our business may be affected by unfavorable publicity or lack of consumer acceptance.

We are highly dependent upon consumer acceptance of the safety and quality of our products, as well as similar products distributed by other companies. Consumer acceptance of a product can be significantly influenced by scientific research or findings, national media attention, and other publicity about product use. A product may be received favorably, resulting in high sales associated with that product that may not be sustainable as consumer preferences change. Future scientific research or publicity could be unfavorable to our industry or any of our particular products and may not be consistent with earlier favorable research or publicity. A future research report or publicity that is perceived by our consumers as less than favorable or that may question earlier favorable research or publicity could have a material adverse effect on our ability to generate revenue. Adverse publicity in the form of published scientific research, statements by regulatory authorities or otherwise, whether or not accurate, that associates consumption of our product or any other similar product with illness or other adverse effects, or that questions the benefits of our product or a similar product, or that claims that such products do not have the effect intended could have a material adverse effect on our business, reputation, financial condition, or results of operations.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations in the United States govern the use, manufacture, storage, handling, and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing, and disposing of these materials (all of which only occur at third-party sites operated by our contractors) comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. We also cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines and the liability could exceed our resources, and we do not carry liability insurance covering the use of hazardous materials. If we fail to comply with applicable requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs, or capital expenditures for control equipment or operational changes necessary to achieve or maintain compliance. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which adversely affect our business, financial condition, results of operations and prospects.

We are subject to extensive and costly government regulation.

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

Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling products. Our failure to comply with these regulations could result in, by way of example, significant fines, criminal and civil liability, product seizures, recalls, withdrawals, withdrawals of approvals and exclusion and debarment from government programs. Any of these actions, including the inability of our hormone therapy drug candidates to obtain and maintain regulatory approval, would have a materially adverse effect on our business, financial condition, results of operations and prospects.

We are subject to additional federal and state laws and regulations relating to our business and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

We are subject to additional health care regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following:

- the federal health care program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under government health care programs such as the Medicare and Medicaid programs;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity can now be found guilty of fraud or false claims under PPACA without actual knowledge of the statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

PPACA also imposes new reporting requirements on device and pharmaceutical manufacturers to make annual public disclosures of payments to health care providers and ownership of their stock by health care providers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for “knowing failures”), for all payments, transfers of value, or ownership or investment interests that are not reported. Manufacturers were required to begin data collection on August 1, 2013 and

were required to report such data to CMS by March 31, 2014.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceutical industry depends in large part on our ability to attract and retain highly qualified managerial, scientific, and medical personnel. In order to induce valuable employees to remain with us, we have, among other things, provided stock-based compensation that vests over time. The value to employees of stock-based compensation will be significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We do not have employment agreements with a number of our key employees. As a result, most employees are employed on an at-will basis, which means that any of these employees could leave our employment at any time, with or without notice, and may go to work for a competitor. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results and financial condition. Our success also depends on our ability to continue to attract, retain and motivate highly skilled scientific and medical personnel.

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

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

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

commercialize drug candidates will be limited.

Our success is tied to our distribution channels.

We sell our prescription dietary supplement products to wholesale distributors, specialty pharmacies, specialty distributors, and chain drug stores that generally sell products to retail pharmacies, hospitals, and other institutional customers. However, over 74.93% of our product shipments since inception were to only four customers. Our business would be harmed if any of these customers refused to distribute our products or refused to purchase our products on commercially favorable terms to us.

A failure to maintain optimal inventory levels to meet commercial demand for our products could harm our reputation and subject us to financial losses.

Our ability to maintain optimal inventory levels to meet commercial demand depends on the performance of third-party contract manufacturers. In some instances, our products have unique ingredients used under license arrangements. If our manufacturers are unsuccessful in obtaining raw materials, if we are unable to manufacture and release inventory on a timely and consistent basis, if we fail to maintain an adequate level of product inventory, if inventory is destroyed or damaged, or if our inventory reaches its expiration date, patients might not have access to our products, our reputation and brands could be harmed, and physicians may be less likely to recommend our products in the future, each of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our ability to utilize net operating loss carryforwards may be limited.

As of December 31, 2013, we had net operating loss carryforwards, or NOLs, of approximately $37 million available to offset future taxable income through 2033. These NOLs may be used to offset future taxable income, to the extent we generate any taxable income, and thereby reduce or eliminate our future federal income taxes otherwise payable. Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, imposes limitations on a corporation’s ability to utilize NOLs if it experiences an ownership change as defined in Section 382. In general terms, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50 percent over a three-year period. In the event that an ownership change has occurred, or were to occur, utilization of our NOLs would be subject to an annual limitation under Section 382 determined by multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate. Any unused annual limitation may be carried over to later years. We may be found to have experienced an ownership change under Section 382 as a result of events in the past or the issuance of shares of our common stock in the future. If so, the use of our NOLs, or a portion thereof, against our future taxable income may be subject to an annual limitation under Section 382, which may result in expiration of a portion of our NOLs before utilization.

Our success depends on how efficiently we respond to changing consumer preferences and demand.

Our success depends, in part, on our ability to anticipate and respond to changing consumer trends and preferences. We may not be able to respond in a timely or commercially appropriate manner to these changes. Our failure to accurately predict these trends could negatively impact our inventory levels, sales, and consumer opinion of us as a source for the latest product. The success of our new product offerings depends upon a number of factors, including our ability to achieve the following:

- accurately anticipate customer needs;
- innovate and develop new products;
- successfully commercialize new products in a timely manner;
- competitively price our products in the market;
- procure and maintain products in sufficient volumes and in a timely manner; and
- differentiate our product offerings from those of our competitors.

If we do not introduce new products, make enhancements to existing products, or maintain the appropriate inventory levels to meet customers' demand in a timely manner, our business, results of operations, and financial condition could be materially and adversely affected.

We may initiate product recalls or withdrawals, or may be subject to regulatory enforcement actions that could negatively affect our business.

We may be subject to product recalls, withdrawals, or seizures if any of the products we formulate, manufacture, or sell are believed to cause injury or illness or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale, or distribution of any of our products. A recall, withdrawal, or seizure of any of our products could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our products. In addition, a recall, withdrawal, or seizure of any of our products would require significant management attention, would likely result in substantial and unexpected expenditures, and could materially and adversely affect our business, financial condition and results of operations.

We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of September 30, 2014, we had 96 employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial, and other resources and, depending on our commercialization strategy, we may further expand our employee base for sales and marketing resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional drug candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to increase revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our hormone therapy drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth in our organization.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately, or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing

and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to our Intellectual Property

Another party could develop hormone therapy products and obtain FDA regulatory exclusivity in the United States before we do, potentially preventing our ability to commercialize our hormone therapy drug candidates and other products in development.

We plan to seek to obtain market exclusivity for our hormone therapy drug candidates and any other drug candidates we develop in the future. To the extent that patent protection is not available or has expired, FDA marketing exclusivity may be the only available form of exclusivity available for these proposed products. Marketing exclusivity can delay the submission or the approval of certain marketing applications. Potentially competitive products may also be seeking marketing exclusivity and may be in various stages of development, including some more advanced than us. We cannot predict with certainty the timing of FDA approval or whether FDA approval will be granted, nor can we predict with certainty the timing of FDA approval for competing products or whether such approval will be granted. It is possible that competing products may obtain FDA approval with marketing exclusivity before we do, which could delay our ability to submit a marketing application or obtain necessary regulatory approvals, result in lost market opportunities with respect to our hormone therapy drug candidates, and materially adversely affect our business, financial condition and results of operations.

If our efforts to protect the proprietary nature of the intellectual property covering our hormone therapy drug candidates and other products are not adequate, we may not be able to compete effectively in our market.

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent positions as well as our ability to maintain adequate protection of other intellectual property for our hormone therapy drug candidates and other products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The patent positions of pharmaceutical companies are highly uncertain. The legal principles applicable to patents are in transition due to changing court precedent and legislative action and we cannot be certain that the historical legal standards surrounding questions of validity will continue to be applied or that current defenses relating to issued patents in these fields will be sufficient in the future. Changes in patent laws in the United States, such as the America Invents Act of 2011, may affect the scope, strength, and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States and we may encounter significant problems in protecting our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets.

These risks include the possibility of the following:

- the patent applications that we have filed may fail to result in issued patents in the United States or in foreign countries;
- patents issued or licensed to us or our partners may be challenged or discovered to have been issued on the basis of insufficient, incomplete, or incorrect information, and thus held to be invalid or unenforceable;
- the scope of any patent protection may be too narrow to exclude competitors from developing or designing around these patents;
- we or our licensors were not the first to make the inventions covered by each of our issued patents and pending patent applications;
- we or our licensors were not the first inventors to file patent applications for these technologies in the United States or were not the first to file patent applications directed to these technologies abroad;
- we may fail to comply with procedural, documentary, fee payment, and other similar provisions during the patent application process, which can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights;
- future drug candidates may not be patentable;
- others will claim rights or ownership with regard to patents and other proprietary rights that we hold or license;

- delays in development, testing, clinical trials, and regulatory review may reduce the period of time during which we could market our drug candidates under patent protection; and
- we may fail to timely apply for patents on our technologies or products.

While we apply for patents covering our technologies and products, as we deem appropriate, many third parties may already have filed patent applications or have received patents in our areas of product development. These entities' applications, patents, and other intellectual property rights may conflict with patent applications to which we have rights and could prevent us from obtaining patents or could call into question the validity of any of our patents, if issued, or could otherwise adversely affect our ability to develop, manufacture, or commercialize our hormone therapy drug candidates. In addition, if third parties file patent applications in the technologies that also claim technology to which we have rights, we may have to participate in interference, derivation, or other proceedings with the U.S. Patent and Trademark Office, or the USPTO, or foreign patent regulatory authorities to determine our rights in the technologies, which may be time-consuming and expensive. Moreover, issued patents may be challenged during in the courts or in post-grant proceedings at the USPTO, or in similar proceedings in foreign countries. These proceedings may result in loss of patent claims or adverse changes to the scope of the claims.

If we, our licensors, or strategic partners fail to obtain and maintain patent protection for our products, or our proprietary technologies and their uses, companies may be dissuaded from collaborating with us. In such event, our ability to commercialize our hormone therapy drug candidates or future drug candidates, if approved, may be threatened, we could lose our competitive advantage, and the competition we face could increase, all of which could adversely affect our business, financial condition, results of operations and prospects.

In addition, mechanisms exist in much of the world permitting some form of challenge by generic drug marketers to our patents prior to, or immediately following, the expiration of any regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as "at risk" launches to challenge relevant patent rights.

Our business also may rely on unpatented proprietary technology, know-how, and trade secrets. If the confidentiality of this intellectual property is breached, it could adversely impact our business.

If we are sued for infringing intellectual property rights of third parties, litigation will be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends, in part, on our not infringing the patents and proprietary rights of other parties and not breaching any collaboration or other agreements we have entered into with regard to our technologies and products. We are aware of numerous third-party U.S. and non-U.S. issued patents and pending applications that exist in the areas of hormone therapy, including compounds, formulations, treatment methods and synthetic processes, which may be applied towards the synthesis of hormones. Patent applications are confidential when filed and remain confidential until publication, approximately 18 months after initial filing, while some patent applications remain

unpublished until issuance. As such, there may be other third-party patents and pending applications of which we are currently unaware with claims directed towards composition of matter, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products or drug candidates. Therefore, we cannot ever know with certainty the nature or existence of every third-party patent filing. We cannot provide assurances that we or our partners will be free to manufacture or market our drug candidates as planned or that we or our licensors' and partners' patents will not be opposed or litigated by third parties. If any third-party patent was held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, or methods of treatment related to the use or manufacture of any of our drug candidates, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. There can be no assurances that we will be able to obtain a license to such patent on favorable terms or at all. Failure to obtain such license may have a material adverse effect on our business.

There is a substantial amount of litigation involving intellectual property in the pharmaceutical industry generally. If a third party asserts that we infringe its patents or other proprietary rights, we could face a number of risks that could adversely affect our business, financial condition, results of operations, and prospects, including the following:

- infringement and other intellectual property claims, which would be costly and time-consuming to defend, whether or not we are ultimately successful, which in turn could delay the regulatory approval process, consume our capital, and divert management's attention from our business;
- substantial damages for past infringement, which we may have to pay if a court determines that our products or technologies infringe a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our technologies or future products unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties or lump sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license; or
- redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We are party from time to time to legal proceedings relating to our intellectual property, and third parties in the future may file claims asserting that our technologies, processes, or products infringe on their intellectual property. We cannot predict whether third parties will assert these claims against us or our strategic partners or against the licensors of technology licensed to us, or whether those claims will harm our business. In addition, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we or our partners were to face infringement claims or challenges by third parties relating to our drug candidates, an adverse outcome could subject us to significant liabilities to such third parties, and force us or our partners to curtail or cease the development of some or all of our drug candidates, which could adversely affect our business, financial condition, results of operations and prospects.

We intend to submit NDAs for our hormone therapy drug candidates, assuming that the clinical data justify submission, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the filing of an NDA when at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) NDA with respect to any patents for the approved product on which the application relies that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification.

49

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months beginning on the date the patent holder receives notice, or until a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. The court also has the ability to shorten or lengthen the 30 month period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the FDA may approve the Section 505(b)(2) application at any time.

If we cannot certify that all of the patents listed in the Orange Book for the approved products referenced in the NDAs for each of our hormone therapy drug candidates have expired, we will be compelled to include a Paragraph IV certification in the NDA for such drug candidate. Our inability to certify that all of the patents listed in the FDA's Orange Book for approved products referenced in the NDAs for each of our hormone therapy drug candidates could have a serious and significant adverse effect on the timing for obtaining approval of our hormone therapy drug candidates. For example, at least one approved product that may be referenced in our 505(b)(2) application as a reference product for our vaginal suppository estradiol product currently lists unexpired patents in the Orange Book.

We may be required to file lawsuits or take other actions to protect or enforce our patents or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents, or those of our licensors, do not cover the technology in question or on other grounds. An adverse result in any litigation or defense proceedings could put one or more of our patents, or those of our licensors, at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications, or those of our

licensors, at risk of not issuing. Moreover, we may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries in which the laws may not protect those rights as fully as in the United States or in those countries in which we do not file national phase patent applications. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, if securities analysts or investors perceive public announcements of the results of hearings, motions, or other interim proceedings or developments to be negative, the price of our common stock could be adversely affected. The occurrence of any of the above could adversely affect our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of certain information, the value of our products and technology could be materially adversely affected.

We also rely on trade secrets, know-how and continuing technological advancement to develop and maintain our competitive position. To protect this competitive position, we regularly enter into confidentiality and proprietary information agreements with third parties, including employees, independent contractors, suppliers and collaborators. We cannot, however, ensure that these protective arrangements will be honored by third parties and we may not have adequate remedies if these arrangements are breached. In addition, enforcement of claims that a third party has illegally obtained and is using trade secrets, know-how, or technological advancements is expensive, time-consuming, and uncertain. Non-U.S. courts are sometimes less willing than U.S. courts to protect this information. Moreover, our trade secrets, know-how and technological advancements may otherwise become known or be independently developed by competitors in a manner providing us with no practical recourse against the competing parties. If any such events were to occur, they could adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Such claims may lead to material costs for us, or an inability to protect or use valuable intellectual property rights, which could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and you could lose all or part of your investment.

The trading price of our common stock on NYSE MKT is likely to be volatile. This volatility may prevent you from being able to sell your shares at or above the price you paid for your shares. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include the following:

- any delay our phase 3 clinical trials for our hormone therapy drug candidates;

- adverse results or delays in clinical trials;
- any delay in filing our NDAs for our hormone therapy drug candidates and any adverse development or perceived adverse development with respect to the FDA's review of the NDAs, including the FDA's issuance of a "refusal to file" letter or a request for additional information;
- changes in laws or regulations applicable to our products or proposed products, including clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of our hormone therapy drug candidates;
- a decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- the inability to obtain adequate clinical supply for our hormone therapy drug candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;

- the introduction of new products or technologies offered by us or our competitors;
- the effectiveness of our or our potential strategic partners' commercialization efforts;
- developments concerning our sources of manufacturing supply and any commercialization strategic partners;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the inability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- the failure to meet or exceed the estimates and projections of the investment community;
- the overall performance of the U.S. equity markets and general political and economic conditions;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- additions or departures of key scientific or management personnel;
- adverse market reaction to any indebtedness we may incur or securities we may issue in the future;
- sales of our common stock by us or our stockholders in the future;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the trading volume of our common stock;
- increases in our common stock available for sale upon expiration of lock-up agreements;
- effects of natural or man-made catastrophic events or other business interruptions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

At March 31, 2014, our executive officers, directors, holders of 5% or more of our stock, and their affiliates beneficially owned approximately 71.3% of our common stock on an as converted basis. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. In addition, pursuant to a Securities Purchase Agreement dated September 26, 2012, we granted certain of our stockholders the right, expiring in October 2015, if they elect, to purchase on the same terms as in any offering of our common stock, a number of shares of common stock that is sufficient to maintain their respective pro rata ownership percentage of our common stock.

If we fail to maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required annually to deliver a report that assesses the effectiveness of our internal control over financial reporting and our independent registered public accounting firm is required annually to deliver an attestation report on the effectiveness of our internal control over financial reporting. If we are unable to maintain effective internal control over financial reporting or if our independent auditors are unwilling or unable to provide us with an attestation report on the effectiveness of internal control over financial reporting for future periods as required by Section 404 of the Sarbanes-Oxley Act, we may not be able to produce accurate financial statements and investors may therefore lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which might cause our stock price and trading volume to decline.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain any future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will be limited to the value of their stock.

Some provisions of our charter documents and Nevada law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our articles of incorporation and bylaws, as well as certain provisions of Nevada law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if an acquisition would benefit our stockholders and could also make it more difficult to remove our current management. These provisions in our articles of incorporation and bylaws include the following:

- authorizing the issuance of “blank check” preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and
- advance notice provisions in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

In addition, we are subject to Nevada's Combination with Interested Stockholders statute (Nevada Revised Statute Sections 78.411—78.444), which prohibits an "interested stockholder" from entering into a "combination" with a company, unless certain conditions are met. An "interested stockholder" is a person who, together with affiliates and associates, beneficially owns (or within the prior two years, did beneficially own) 10% or more of the corporation's capital stock entitled to vote.

Item 2. Unregistered Sale of Equity Securities and Use of Proceeds

On July 2, 2014, we issued 10,000 shares of our common stock upon the exercise of warrants previously issued to an outside service provider. We received proceeds of $13,000 in connection with this exercise. On August 19, 2014, we issued 35,000 shares, 61,711 shares and 87,500 shares of our common stock upon the exercise of warrants previously issued to outside service providers. We received proceeds of $24,000, $13,300 and $23,450, respectively, in connection with each of these three exercises. Proceeds from these transactions were used in working capital. The shares of common stock were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

Item 6. Exhibits

Exhibit	Date	Description
1.1	July 29, 2014	Underwriting Agreement, dated July 29, 2014, between the Company and Goldman, Sachs & Co., as the representative of the several underwriters named in Schedule I thereto (Filed as Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the Commission on August 4, 2014 and incorporated herein by reference).
31.1*	November 7, 2014	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	November 7, 2014	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1*	November 7, 2014	Section 1350 Certification of Chief Executive Officer
32.2*	November 7, 2014	Section 1350 Certification of Chief Financial Officer
101.INS*	n/a	XBRL Instance Document
101.SCH*	n/a	XBRL Taxonomy Extension Schema Document
101.CAL*	n/a	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	n/a	XBRL Taxonomy Extension Definition Linkbase Instance Document
101.LAB*	n/a	XBRL Taxonomy Extension Label Linkbase Instance Document
101.PRE*	n/a	XBRL Taxonomy Extension Presentation Linkbase Instance Document

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* Filed herewith.

SIGNATURES

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

DATE: November 7, 2014

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)