SIMULATIONS PLUS INC
Form 10-Q
April 13, 2011

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

x Quarterly Report Pursuant to Section 13 or 15(d) of the Security Exchange Act of 1934

For the quarterly period ended February 28, 2011

OR

o Transmission Report Pursuant to Section 13 or 15(d) of the Security Exchange Act of 1937

For the transition period from __________ to __________

Commission file number: 001-32046

Simulations Plus, Inc.
(Name of registrant as specified in its charter)

California	95-4595609
(State or other jurisdiction of Incorporation or Organization)	(I.R.S. Employer identification No.)

42505 10th Street West
Lancaster, CA 93534-7059
(Address of principal executive offices including zip code)

(661) 723-7723
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) 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 filings requirements for the past 90 days. Yes x No o

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 o No o

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):

o Large accelerated filer	o Accelerated filer
o Non-accelerated filer (Do not check if a smaller reporting company)	x 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 o No x

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of April 13, 2011 was 15,432,420 and no shares of preferred stock were outstanding.

Simulations Plus, Inc.
FORM 10-Q Quarterly Report
For the Quarterly Period Ended February 28, 2011

PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

SIMULATIONS PLUS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
at February 28, 2011 (unaudited) and August 31, 2010 (audited)

ASSETS	February 28, 2011	August 31, 2010
Current assets		
Cash and cash equivalents	$8,758,887	$9,631,762
Income tax refund receivable	259,434	225,510
Accounts receivable, net of allowance for doubtful accounts and estimated contractual discounts of $296,738 and $421,118	2,253,714	1,291,350
Contracts receivable	146,306	184,081
Inventory	502,505	554,867
Prepaid expenses and other current assets	174,314	138,163
Deferred income taxes	307,991	364,264
Total current assets	12,403,151	12,389,997
Capitalized computer software development costs, net of accumulated amortization of $4,837,424 and $4,487,757	2,287,724	2,186,419
Property and equipment, net (note 3)	70,337	55,984
Customer relationships, net of accumulated amortization of $120,935 and $118,442	4,987	9,600
Other assets	18,445	18,445
Total assets	$14,784,644	$14,660,445
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$446,795	$239,424
Accrued payroll and other expenses	445,756	511,106
Accrued bonuses to officer	60,000	60,000
Accrued income taxes	380,342	261,861
Accrued warranty and service costs	43,799	35,586
Deferred revenue	83,624	96,092
Total current liabilities	1,460,316	1,204,069
Long-term liabilities		
Deferred income taxes	669,545	410,523
Total liabilities	2,129,861	1,614,592
Commitments and contingencies (note 4)		
Shareholders' equity (note 5)		
Preferred stock, $0.001 par value 10,000,000 shares authorized no shares issued and outstanding	-	-
Common stock, $0.001 par value 50,000,000 shares authorized 15,341,820 and 15,833,006 shares issued and outstanding	3,813	4,304

Additional paid-in capital	4,025,716	5,891,268
Retained earnings	8,625,254	7,150,281
Total shareholders' equity	12,654,783	13,045,853
Total liabilities and shareholders' equity	$14,784,644	$14,660,445

SIMULATIONS PLUS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
for the three months and six months ended February 28, 2011 and 2010
(unaudited)

	Three months ended		Six months ended	
	2011	2010	2011	2010
Net sales	$ 3,349,387	$ 2,949,719	$ 6,160,673	$ 5,386,771
Cost of sales	748,821	700,475	1,489,804	1,307,364
Gross profit	2,600,566	2,249,244	4,670,869	4,079,407
Operating expenses				
Selling, general, and administrative	980,327	1,088,819	2,042,702	2,093,092
Research and development	254,642	252,098	462,681	513,423
Total operating expenses	1,234,969	1,340,917	2,505,383	2,606,515
Income from operations	1,365,597	908,327	2,165,486	1,472,892
Other income (expense)				
Interest income	20,317	23,560	44,958	46,046
Interest expense	-	(1)	(118)	(303)
Miscellaneous income	-	-	231	231
Gain on sales of property and equipment	240	-	240	1,024
Gain on currency exchange	8,341	41,962	8,341	115,194
Total other income	28,898	65,521	53,652	162,192
Income before provision for income taxes	1,394,495	973,848	2,219,138	1,635,084
Provision for income taxes	(487,015)	(332,985)	(744,165)	(564,418)
Net income	$ 907,480	$ 640,863	$ 1,474,973	$ 1,070,666
Basic earnings per share	$ 0.06	$ 0.04	$ 0.09	$ 0.07
Diluted earnings per share	$ 0.06	$ 0.04	$ 0.09	$ 0.06
Weighted-average common shares outstanding				
Basic	15,472,504	15,826,030	15,581,301	15,735,400
Diluted	16,217,573	16,558,423	16,322,845	16,479,033

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SIMULATIONS PLUS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
for the six months ended February 28, 2011 and 2010
(unaudited)

	2011	2010
Cash flows from operating activities		
Net income	$1,474,973	$1,070,666
Adjustments to reconcile net income to net cash provided by operating activities		
Depreciation and amortization of property and equipment	14,713	13,246
Amortization of customer relationships	4,613	7,605
Amortization of capitalized computer software development costs	349,667	316,304
Bad debts	-	70,283
Excess tax benefits from share-based arrangement	(24,081)	-
Stock-based compensation	80,408	32,285
Gain on sales of property and equipment	(240)	(1,024)
Deferred income taxes	315,295	70,907
(Increase) decrease in		
Accounts receivable and Contracts receivable	(924,589)	(107,200)
Income tax refundable	(33,924)	-
Inventory	52,362	(10,251)
Prepaid expenses and other assets	(36,151)	47,995
Increase (decrease) in		
Accounts payable	207,371	102,418
Accrued payroll and other expenses	(65,351)	61,491
Accrued income taxes	142,562	168,438
Accrued warranty and service costs	8,213	(12,566)
Deferred revenue	(12,468)	37,561
Net cash provided by operating activities	1,553,373	1,868,158
Cash flows from investing activities		
Purchases of property and equipment	(29,066)	(31,769)
Proceeds from sale of property and equipment	240	-
Capitalized computer software development costs	(450,971)	(456,082)
Net cash used in investing activities	(479,797)	(487,851)
Cash flows from financing activities		
Repurchase of common stock	(2,048,172)	(288,698)
Excess tax benefits from share-based arrangement	24,081	-
Proceeds from the exercise of stock options	77,640	76,195
Net cash used in financing activities	(1,946,451)	(212,503)
Net increase (decrease) in cash and cash equivalents	$(872,875)	$1,167,804
Cash and cash equivalents, beginning of year	9,631,762	7,473,485

Cash and cash equivalents, end of period	$8,758,887	$8,641,289
Supplemental disclosures of cash flow information		
Interest paid	$118	$302
Income taxes paid	$320,232	$260,464

Simulations Plus, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1: GENERAL

This report on Form 10-Q for the quarter ended February 28, 2011, should be read in conjunction with the Company's annual report on Form 10-K for the year ended August 31, 2010, filed with the Securities and Exchange Commission (“SEC”) on November 29, 2010. As contemplated by the SEC under Article 8 of Regulation S-X, the accompanying financial statements and footnotes have been condensed and therefore do not contain all disclosures required by generally accepted accounting principles. The interim financial data are unaudited; however, in the opinion of Simulations Plus, Inc. ("we", "our", "us"), the interim data includes all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the results for the interim periods. Results for interim periods are not necessarily indicative of those to be expected for the full year.

Note 2: SIGNIFICANT ACCOUNTING POLICIES

Estimates
Our condensed consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. These estimates and assumptions are affected by management’s application of accounting policies. Actual results could differ from those estimates. Significant accounting policies for us include revenue recognition, accounting for capitalized computer software development costs, valuation of stock options, and accounting for income taxes.

Principles of Consolidation
The condensed consolidated financial statements include the accounts of Simulations Plus, Inc. and its wholly owned subsidiary, Words+, Inc. All significant intercompany accounts and transactions are eliminated in consolidation.

Revenue Recognition
We recognize revenues related to software licenses and software maintenance in accordance with Accounting Standards Update (“ASU”) 2009-14, which amends FASB ASC Topic 985 to exclude tangible products containing software components and non-software components that function together to deliver the product’s essential functionality. Software products revenue is recorded when the following conditions are met: 1) evidence of arrangement exists, 2) delivery has been made, 3) the amount is fixed, and 4) collectability is probable. We do not have tangible products containing software components; however, in the event we provide such products in the future, we will recognize its portion of revenue when tangible products are delivered. Post-contract customer support ("PCS") obligations are insignificant; therefore, revenue for PCS is recognized at the same time as the licensing fee, and the costs of providing such support services are accrued and amortized over the obligation period. For Words+ products, the revenue is recorded at the time of shipment, net of estimated allowances and returns.

As a byproduct of ongoing improvements and upgrades for the new programs and new modules of software, some modifications are provided to customers who have already purchased software at no additional charge. Other software modifications result in new, additional cost modules that expand the functionality of the software. These are licensed separately. We consider the modifications that are provided without charge to be minimal, as they do not significantly change the basic functionality or utility of the software, but rather add convenience, such as being able to plot some additional variable on a graph in addition to the numerous variables that had been available before, or adding some additional calculations to supplement the information provided from running the software. Such software modifications for any single product have typically occurred once or twice per year, sometimes more, sometimes less. Thus, they are infrequent. We provide, for a fee, additional training and service calls to our customers and recognize revenue at the time the training or service call is provided.

We enter into one-year license agreements with most of our customers for the use of our pharmaceutical software products. However, from time to time, we enter into multi-year license agreements. We unlock and invoice software one year at a time for multi-year licenses. Therefore, revenue is recognized one year at a time.

We recognize contract study revenue either equally over the term of the contract or using the percentage of completion method, depending upon how the contract studies are engaged, in accordance with FASB ASC 605-35. To recognize revenue using the percentage of completion method, we must determine whether we meet the following criteria: 1) there is a long-term, legally enforceable contract, 2) it is possible to reasonably estimate the total project costs, and 3) it is possible to reasonably estimate the extent of progress toward completion.

Cash and Cash Equivalents
For purposes of the statements of cash flows, we consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents.

Accounts Receivable
We maintain an allowance for doubtful accounts for estimated losses that may arise if any of its customers are unable to make required payments. Management specifically analyzes the age of customer balances, historical bad debt experience, customer credit-worthiness, and changes in customer payment terms when making estimates of the collectability of the Company’s trade accounts receivable balances. If management determines that the financial conditions of any of its customers deteriorated, whether due to customer-specific or general economic issues, an increase in the allowance may be made. Accounts receivable are written off when all collection attempts have failed. We also estimate the contractual discount obligation for third-party funding such as Medicare, Medicaid, and private insurance companies. Those estimated discounts are reflected in the allowance for doubtful accounts and contractual discounts.

Inventory
Inventory is stated at the lower of cost (first-in, first-out basis) or market and consists primarily of computers and peripheral computer equipment.

Capitalized Computer Software Development Costs
Software development costs are capitalized in accordance with FASB ASC 985-20. Capitalization of software development costs begins upon the establishment of technological feasibility and is discontinued when the product is available for sale.

The establishment of technological feasibility and the ongoing assessment for recoverability of capitalized software development costs require considerable judgment by management with respect to certain external factors including, but not limited to, technological feasibility, anticipated future gross revenues, estimated economic life, and changes in software and hardware technologies. Capitalized software development costs are comprised primarily of salaries and direct payroll-related costs and the purchase of existing software to be used in our software products.

Amortization of capitalized software development costs is provided on a product-by-product basis on the straight-line method over the estimated economic life of the products (not to exceed five years). Amortization of software development costs amounted to $349,667 and $316,304 for the six months ended February 28, 2011 and 2010, respectively. We expect future amortization expense to vary due to increases in capitalized computer software development costs.

We test capitalized computer software costs for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Depreciation and amortization are provided using the straight-line method over the estimated useful lives as follows:

Equipment	5 years
Computer equipment	3 to 7 years
Furniture and fixtures	5 to 7 years
Leasehold improvements	Shorter of life of asset or lease

Maintenance and minor replacements are charged to expense as incurred. Gains and losses on disposals are included in the results of operations.

Fair Value of Financial Instruments

Assets and liabilities recorded at fair value in the Condensed Consolidated Balance Sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The categories, as defined by the standard are as follows:

Level Input:	Input Definition:
Level I	Inputs are unadjusted, quoted prices for identical assets or liabilities in active markets at the measurement date.
Level II	Inputs, other than quoted prices included in Level I, that are observable for the asset or liability through corroboration with market data at the measurement date.
Level III	Unobservable inputs that reflect management’s best estimate of what market participants would use in pricing the asset or liability at the measurement date.

The following table summarizes fair value measurements by level at February 28, 2011 for assets and liabilities measured at fair value on a recurring basis:

	Level I	Level II	Level III	Total
Cash and cash equivalents	$ 8,758,887	$ -	$ -	$ 8,758,887
Total	$ 8,758,887	$ -	$ -	$ 8,758,887

For certain of our financial instruments, including accounts receivable, accounts payable, accrued payroll and other expenses, accrued bonuses to officers, and accrued warranty and service costs, the amounts approximate fair value due to their short maturities.

Shipping and Handling
Shipping and handling costs, recorded as cost of sales, amounted to $39,207 and $54,715 for the six months ended February 28, 2011 and 2010, respectively.

Research and Development Costs
Research and development costs are charged to expense as incurred until technological feasibility has been established. These costs consist primarily of salaries and direct payroll-related costs. It also includes purchased software which was developed by other companies and incorporated into, or used in the development of, our final products.

Income Taxes
We utilize FASB ASC 740-10 which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns.

Under this method, deferred income taxes are recognized for the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The provision for income taxes represents the tax payable for the period and the change during the period in deferred tax assets and liabilities.

We are currently being audited by the California Franchise Tax Board for the fiscal years ended August 31, 2007 and 2008. The outcome of this audit may result in changes to the tax liability for those tax years.

Customer relationships
We purchased customer relationships as a part of the acquisition of certain assets of Bioreason, Inc. in November 2005. Customer relationships was recorded at a cost of $128,042, and is being amortized over 78 months under the sum-of-the-years'-digits method. Amortization expense for the six months ended February 28, 2011 and 2010 amounted to $4,613 and $7,605, respectively. Accumulated amortization as of February 28, 2011 and 2010 was $123,055 and $112,333, respectively.

Earnings per Share

We report earnings per share in accordance with FASB ASC 260-10. Basic earnings per share is computed by dividing income available to common shareholders by the weighted-average number of common shares available. Diluted earnings per share is computed similar to basic earnings per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. The components of basic and diluted earnings per share for the six months ended February 28, 2011 and 2010 were as follows:

	02/28/2011	02/28/2010
Numerator		
Net income attributable to common shareholder	$1,474,973	$1,070,666
Denominator		
Weighted-average number of common shares outstanding during the year	15,581,301	15,735,400
Dilutive effect of stock options	741,544	743,633
Common stock and common stock equivalents used for diluted earning per share	16,322,845	16,479,033

Stock-Based Compensation

Compensation costs related to stock options are determined in accordance with FASB ASC 718-10 using the modified prospective method. Under this method, compensation cost includes: (1) compensation cost for all share-based payments granted prior to, but not yet vested as of September 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123 amortized over the options' vesting period, and (2) compensation cost for all share-based payments granted subsequent to September 1, 2006, based on the grant-date fair value estimated in accordance FASB ASC 718-10, amortized on a straight-line basis over the options' vesting period. Stock-based compensation was $80,408 and $32,284 for the six months ended February 28, 2011 and 2010, respectively, and is included in the condensed consolidated statements of operations as Salaries, Consulting, and Research and Development expense.

Concentrations and Uncertainties

International sales accounted for 34% and 30% of net sales for the six months ended February 28, 2011 and 2010, respectively. For Simulations Plus, Inc. (pharmaceutical segment), three customers accounted for 15%, 8% and 7% of net sales during the six months ended February 28, 2011, compared with two customers accounting for 22% and 15% of net sales during the six months ended February 28, 2010.

For Words+, Inc., third-party billing, which includes various government agencies as well as private insurance companies, accounted for 58% of net sales during the six months ended February 28, 2011, compared with 61% of net sales during the six months ended February 28, 2010. If changes are made in government funding policies for Words+ products, Words+ revenue could be impacted. We continually evaluate and monitor regulatory developments in funding matters. We do not expect that Medicare and Medicaid within all 50 states would discontinue their funding of Words+ products; however, there can be no assurances that the current level of revenue from third parties will continue.

We operate in the computer software industry, which is highly competitive and changes rapidly. Our operating results could be significantly affected by our ability to develop new products and find new distribution channels for new and existing products.

For Simulations Plus (pharmaceutical segment), three customers comprised 14%, 12% (a dealer account representing various customers), and 10% of its accounts receivable at February 28, 2011, and three customers comprised 19%, 15% (a dealer account representing various customers), and 10% of its accounts receivable at February 28, 2010. For

Words+, third-party billing, which includes various government agencies, comprised 77%, and a school district comprised 9%, of its accounts receivable at February 28, 2011, while third-party billing comprised 90% of its accounts receivable at February 28, 2010. The collection of accounts receivable in a timely manner is critical to Words+' cash flow and its operations. We have three dedicated funding personnel who continually track such collections.

Our subsidiary, Words+, Inc., purchases components for its main computer products from four manufacturers. Words+, Inc. also uses a number of pictographic symbols that are used in its software products which are licensed from a third party. The inability of Words+ to obtain computers used in its products or to renew its licensing agreement to use pictographic symbols could negatively impact our financial position, results of operations, and cash flows.

Recently Issued Accounting Pronouncements
In September 2009, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2009-14 which amends FASB ASC Topis 985 to exclude tangible products containing software components and non-software components that function together to deliver the product’s essential functionality. ASU 2009-14 applies to revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with early application permitted. We adopted this standard in this first quarter of fiscal 2011 and believe adoption did not have a material impact on the Company’s consolidated financial statements.

In September 2009, the FASB issued ASU 2009-13, “Revenue Arrangements with Multiple Deliverables”. ASU 2009-13 amends FASB ASC Topic 605 to require an entity to use an estimated selling price when vendor-specific objective evidence or acceptable third-party evidence does not exist for any products or services included in a multiple element arrangement. The arrangement consideration should be allocated among the products and services based upon their relative selling prices, thus eliminating the use of the residual method of allocation. ASU 2009-13 also requires expanded qualitative and quantitative disclosures regarding significant judgments made and changes in applying the guidance. ASU 2009-13 applies to fiscal years beginning after June 15, 2010, with early application permitted. We adopted this standard in this first quarter of fiscal 2011 and believe adoption did not have a material impact on the Company’s consolidated financial statements.

Note 3: PROPERTY AND EQUIPMENT

Property and equipment as of February 28, 2011 consisted of the following:

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- 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 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.

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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

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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, advertising 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:

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- 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 98% of our product shipments since inception were to only three customers: AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation. 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 June 30, 2014, we had 90 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

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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;

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- 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.

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 in commencement of 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;
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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;

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- 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 April 3rd , April 18th, and April 29th 2014, we issued 10,000 shares, 61,372 shares and 40,000 shares, respectively, of our common stock upon the exercise of warrants previously issued to outside service providers. We received proceeds of $24,000, $25,000 and $15,200, respectively, in connection with each exercise. On each of June 9th and June 19th 2014 we issued 30,000 shares of our common stock upon the exercise of warrants previously issued to outside service providers. We received proceeds of $11,400 in connection with each of these two exercises. 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
31.1*	August 7, 2014	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
31.2*	August 7, 2014	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)
32.1*	August 7, 2014	Section 1350 Certification of Chief Executive Officer
32.2*	August 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: August 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)

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