TherapeuticsMD, Inc.
Form 424B5
July 31, 2018
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Registration No. 333-207837

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated July 31, 2018.

Prospectus Supplement

to Prospectus dated November 17, 2015

$20,000,000

TherapeuticsMD, Inc.

Common Stock

We are offering $20.0 million of shares of our common stock, par value $0.001 per share, at an offering price per share of $.

Our common stock is listed on the Nasdaq Global Select Market of The Nasdaq Stock Market LLC under the symbol TXMD. The last reported sale price of our common stock on the Nasdaq Global Select Market on July 30, 2018 was $5.52 per share.

Investing in our common stock involves a high degree of risk. See Risk Factors on page S-12 of this prospectus supplement, page 1 of the accompanying prospectus and in the documents we incorporate by reference in this prospectus supplement to read about factors you should consider before buying shares of our common stock.

This offering is being made without an underwriter or a placement agent, and we will not be paying any underwriting discounts or commissions in connection with this offering. We will receive proceeds from the sale of these shares of $20.0 million before deducting customary offering expenses.

Concurrently with this offering and pursuant to a separate prospectus supplement, we agreed to sell shares of common stock in an underwritten public offering, for aggregate gross proceeds of $65.0 million, which we refer to herein as the concurrent underwritten offering. The offering price per share in this offering will be the same as the offering price per share in the concurrent underwritten offering. We have granted the underwriters in the concurrent underwritten offering a 30-day option to purchase up to an additional shares of common stock at the public

offering price, less underwriting discounts and commissions. The closing of this offering is contingent upon the closing of the concurrent underwritten offering, but the closing of the concurrent underwritten offering is not contingent upon the closing of this offering. See Plan of Distribution on page S-31 of this prospectus supplement for more information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

Delivery of the shares of common stock issued at the closing of this offering is expected to be made on or about August , 2018.

Prospectus Supplement dated , 2018.

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We have not authorized anyone to provide any information or to make any representations other than those contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus supplement and the accompanying prospectus is an

offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus supplement and the accompanying prospectus is current only as of the respective dates of such documents.

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ABOUT THIS PROSPECTUS SUPPLEMENT

Unless the context otherwise requires, all references in this prospectus supplement to TherapeuticsMD, TXMD, Company, our company, we, us, or our refer to TherapeuticsMD, Inc., a Nevada corporation, and its subsidiaries VitaMedMD, LLC, a Delaware limited liability company, BocagreenMD, Inc., a Nevada corporation, and VitaCare Prescription Services, Inc., a Florida corporation.

This prospectus supplement and the accompanying prospectus form part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, using a shelf registration process. This document contains two parts. The first part consists of this prospectus supplement, which provides you with specific information about this offering. The second part consists of the accompanying prospectus, which provides more general information, some of which may not apply to this offering. Generally, when we refer only to the prospectus, we are referring to both parts combined. This prospectus supplement may add, update, or change information contained in the accompanying prospectus. To the extent that any statement we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference herein or therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference herein and therein.

This prospectus supplement and the accompanying prospectus relate to the offering of shares of our common stock. Before buying any shares of our common stock offered hereby, we urge you to carefully read this prospectus supplement and the accompanying prospectus, together with the information incorporated herein and therein by reference as described under the headings Where You Can Find More Information and Incorporation of Certain Information by Reference. These documents contain important information that you should consider when making your investment decision.

You should rely only on the information contained in or incorporated by reference into this prospectus supplement, the accompanying prospectus and any free writing prospectus authorized by us. To the extent the information contained in this prospectus supplement differs or varies from the information contained in the accompanying prospectus or any document filed prior to the date of this prospectus supplement and incorporated by reference, the information in this prospectus supplement will control. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision.

The industry and market data and other statistical information contained in the documents we incorporate by reference are based on management s own estimates, independent publications, government publications, reports by market research firms or other published independent sources and, in each case, are believed by management to be reasonable estimates. Although we believe these sources are reliable, we have not independently verified the information.

TherapeuticsMD®, vitaMedMD®, and BocaGreenMD® are registered trademarks of our company. This prospectus supplement also contains trademarks and trade names of other companies.

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PROSPECTUS SUPPLEMENT SUMMARY

The following summary of our business highlights some of the information contained elsewhere in or incorporated by reference into this prospectus supplement or the accompanying prospectus. Because this is only a summary, however, it does not contain all of the information that may be important to you. You should carefully read this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, which are described under Incorporation of Certain Information by Reference in this prospectus supplement and under Incorporation of Certain Information by Reference in the accompanying prospectus. You should also carefully consider the matters discussed in the section in this prospectus supplement entitled Risk Factors and in the accompanying prospectus, in our Annual Report on Form 10-K for the year ended December 31, 2017 and in other documents incorporated herein by reference.

Our Company

We are a women s health care company focused on creating and commercializing products targeted exclusively for women. Currently, we are focused on commercializing our recently U.S. Food and Drug Administration, or FDA, approved product, IMVEXXY (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy, or VVA, due to menopause, and pursuing the regulatory approvals and pre-commercialization activities necessary for commercialization of TX-001HR, our bio-identical hormone therapy combination of 17ß- estradiol and progesterone in a single, oral softgel drug candidate, for the treatment of moderate to severe vasomotor symptoms, or VMS, due to menopause in menopausal women with an intact uterus, and our one-year vaginal contraceptive system candidate in-licensed from the Population Council. The new drug applications, or NDAs, for TX-001HR and our one-year vaginal contraceptive system candidate have Prescription Drug User Fee Act, or PDUFA, target action dates for the completion of the FDA s review of October 28, 2018 and August 17, 2018, respectively. IMVEXXY and TX-001HR are designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies, including hot flashes, osteoporosis and vaginal discomfort. More than 32 million women in the U.S. have symptoms of VVA due to menopause and more than 36 million women in the U.S. may experience VMS due to menopause, representing potential total addressable markets for IMVEXXY™ and TX-001HR, if approved, of approximately $20 billion and $25 billion, respectively. With our SYMBODA technology, we are developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. In addition, we manufacture and distribute branded and generic prescription prenatal vitamins.

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We are a Nevada corporation. We maintain our principal executive offices at 6800 Broken Sound Parkway NW, Third Floor, Boca Raton, Florida 33487. Our telephone number is (561) 961-1900. We maintain websites at *www.therapeuticsmd.com*, *www.vitamedmdrx.com* and *www.bocagreenmd.com*. The information contained on our websites or that can be accessed through our websites does not constitute part of this prospectus supplement or the accompanying prospectus.

Recent Developments

FDA Approval of IMVEXXY

On May 30, 2018, we announced that the FDA had approved the 4 mcg and 10 mcg doses of IMVEXXY (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of VVA, due to menopause. VVA is diagnosed in approximately 50% of post-menopausal women. The 4 mcg dose of IMVEXXY represents the lowest approved dose of vaginal estradiol available.

On July 9, 2018, we initiated our early experience program for IMVEXXY with a limited launch of the 10 mcg dose to a targeted sample of healthcare providers throughout the country. In the first three weeks of our early experience program (July 9 27, 2018), approximately 1,363 healthcare providers have initiated at least one patient on treatment of the starter pack of IMVEXXY and sent in the follow-on prescription for continuation of treatment on the maintenance pack. We anticipate that the national launch of the 10 mcg dose of IMVEXXY will begin on August 6, 2018 and that our Bio-Ignite compounding pharmacy customers will begin to receive IMVEXXY in late August 2018. We plan to launch the 4 mcg dose of IMVEXXY in September 2018.

We believe the patient engagement programs that we created and piloted around our prescription prenatal vitamin business have the potential to improve patient compliance for IMVEXXY™, compared to other products in the VVA category. For example, in our prescription prenatal vitamin business, our patient engagement programs have achieved over 75% utilization of our co-pay assistance program, compared to an industry standard of 30%. We plan to use our patient engagement programs to help patients manage out pocket costs IMVEXXY™ and improve education regarding VVA, with the goal of increasing patient compliance.

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

License Agreement with Knight Therapeutics Inc.

On July 30, 2018, we entered into a license and supply agreement, or the Knight License Agreement, with Knight Therapeutics Inc., or Knight, pursuant to which we granted Knight an exclusive license to commercialize IMVEXXY and TX-001HR in Canada and Israel.

Pursuant to the terms of the Knight License Agreement, Knight will pay us a milestone fee upon first regulatory approval in Canada of each of IMVEXXY and TX-001HR, sales milestone fees based upon certain aggregate annual sales in Canada and Israel of each of IMVEXXY and TX-001HR and royalties based on aggregate annual sales of each of IMVEXXY and TX-001HR in Canada and Israel. Knight will be responsible for all regulatory and commercial activities in Canada and Israel related to IMVEXXY and TX-001HR.

We may terminate the Knight License Agreement if Knight does not submit all regulatory applications, submissions and/or registrations required for regulatory approval to use and commercialize IMVEXXY and TX-001HR in Canada and Israel within certain specified time periods. We also may terminate the Knight License Agreement if Knight challenges our patents. Either party may terminate the Knight License Agreement for any material breach by the other party that is not cured within certain specified time periods or if the other party files for bankruptcy or other related matters.

In connection with the Knight License Agreement, Knight entered into a subscription agreement, or the Subscription Agreement, with us pursuant to which Knight agreed to purchase from us $20 million of shares of our common stock concurrently with the closing of the first underwritten public offering of our

common stock to occur within 60 days following the date of the Knight License Agreement with gross proceeds to us of not less than $50 million, at a price per share equal to the price per share to the public in such public offering. In the event that such an offering does not close, Knight will, in lieu of such $20 million investment, pay us a previously negotiated upfront license fee. An uncured breach of the Subscription Agreement by Knight will give us the right to terminate the Knight License Agreement. Knight will be effectuating such purchase pursuant to the terms of this offering.

Goldman Sachs & Co. LLC is acting as underwriter in the concurrent underwritten offering. In connection with this offering, Knight has agreed that, without our prior written consent, which cannot be given without Goldman Sachs & Co. LLC s prior written consent, Knight will not offer or contract to sell any shares of our common stock until the date that is 90 days after the date of this prospectus supplement, after which date, the agreement will terminate and Knight will be released from its related obligations. Knight s agreement is subject to certain customary exceptions, including in respect of bona fide gifts of shares. Additionally, provided that no public disclosure is required pursuant to the Securities Exchange Act of 1934, as amended, or the Exchange Act, Knight may, immediately and without restriction, sell or contract to sell up to 50% of the shares of common stock acquired by Knight in this offering, as well as up to an additional 16.67% of such shares on or after each of the 30th day and the 60th day following the date of this prospectus supplement. See Plan of Distribution on page S-31 of this prospectus supplement.

License Agreement with the Population Council

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

The NDA for the one-year vaginal contraceptive system is currently under review by the FDA and has a PDUFA target action date for the completion of the FDA s review of the NDA of August 17, 2018. If approved, the one-year vaginal contraceptive system would be the first and only procedure-free, reversible prescription contraceptive to provide a full year of protection against unintended pregnancy while fully under a woman s control. If approved by its PDUFA target action date, we currently estimate that the one-year vaginal contraceptive system would be commercially available as early as the third quarter of 2019 with commercial launch as early as the fourth quarter of 2019 or first quarter of 2020.

Under the terms of the Council License Agreement, we are required to pay the Population Council milestone payments of $20 million within 30 days following approval by the FDA of the NDA for the one-year vaginal contraceptive system and $20 million within 30 days following the release of the first commercial batch of the one-year vaginal contraceptive system. The Population Council is also eligible to receive milestone payments and royalties from commercial sales of the one-year vaginal contraceptive system, as detailed below.

We will assume responsibility for marketing expenses related to the commercialization of the one-year vaginal contraceptive system.

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

The Population Council has previously developed long-acting, reversible contraception products including intrauterine devices, or IUDs, like ParaGard® and Mirena®; implants like Norplant® and Jadelle®; and the contraceptive vaginal

ring for breastfeeding women Progering®.

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Contraceptive Market

An estimated 18 million women in the U.S. want to avoid pregnancy and nearly half of all pregnancies that occur each year in the U.S. are unintended. The U.S. market for prescription contraceptives generated more than $5 billion in net sales in 2017 based on approximately 90 million prescriptions. The U.S. market for prescription contraceptives includes oral contraceptives, patches, rings, IUDs and implants. U.S. net sales of prescription oral contraceptives have fallen from approximately $3.5 billion in 2012 to approximately $2.8 billion in 2017, while during such time net sales of long acting reversible contraceptives have grown from approximately $800 million to approximately $1.5 billion. According to the National Center for Health and Statistics, the use of long acting reversible contraceptives in the U.S. has increased nearly five-fold in the last decade among women aged 15 to 44.

NuvaRing, (etonogestrel/ethinyl estradiol vaginal ring), a monthly contraceptive ring marketed by Merck, generated approximately $564 million, $576 million and $515 million in net sales in 2017, 2016 and 2015, respectively, based on approximately 4.3 million, 4.5 million and 4.4 million prescriptions, respectively. We believe that the one-year vaginal contraceptive system, if approved, will have significant competitive advantages to NuvaRing, and anticipated generic versions of NuvaRing, including an anticipated price 40% lower than its current annual pricing, the ability to fill a one-year prescription in one pharmacy visit and the lack of a requirement to refrigerate the ring.

Product

The one-year vaginal contraceptive system is a combination of Nestorone with a widely used estrogen (ethinyl estradiol). Nestorone is a progesterone-derived unique natural progestin with high progestational potency and antiovulatory activity and no androgenic, estrogenic or glucocorticoid effects at contraceptive doses. The active pharmaceutical ingredients are contained within a single ring that can prevent ovulation for an entire year with cyclical use (13 cycles). During each cycle, the one-year vaginal contraceptive system is intended to be used following a 21/7 regimen, remaining in the vagina for three weeks (21 days) followed by one week (7 days) in which the one-year vaginal contraceptive system is removed from the vagina and placed in the accompanying case. The one-year vaginal contraceptive system is composed of a soft, flexible silicone elastomer. It is roughly 2 ¼ inches in diameter, and can be inserted and removed by the woman without the help of a healthcare professional.

In a phase 3 acceptability study of 905 subjects, the one-year vaginal contraceptive system had overall satisfaction of 89% related to ease of use, side effects, expulsions/feeling the product and physical effect during sexual activity. The study also demonstrated high rates of adherence (94.3%) and continuation (78%).

We believe that the one-year vaginal contraceptive system will serve significant unmet needs in the U.S. contraceptive market for both patients and healthcare providers, if approved.

For patients, if approved, the one-year vaginal contraceptive system would provide a single long-acting reversible birth control product that would not require a procedure for insertion at a doctor s office, empowering women to be in complete control of their fertility and menstruation with a 21/7 regime. The one-year vaginal contraceptive system would allow women to receive an entire year s worth of contraception with a single annual pharmacy visit. In addition, if approved, we anticipate that the one-year vaginal contraceptive system would be acceptable for nulliparous women, or women who have never given birth. Further, the one-year

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vaginal contraceptive system is softer and more pliable than NuvaRing and, unlike NuvaRing, does not require refrigeration before being prescribed.

We believe that the one-year vaginal contraceptive system, if approved, may allow healthcare providers to more easily follow medical standards of care and society guidelines to promote long-acting reversible birth control as first-line option. Existing long-acting reversible contraceptives, including IUDs and implants, require a procedure by a healthcare provider for both insertion and removal and often require healthcare providers to buy, hold and manage inventory of the product. The one-year vaginal contraceptive system, if approved, could be prescribed by healthcare providers to a broader range of patients than many existing long-acting reversible contraceptive methods, including nulliparous women, without the need for providers to maintain inventory, since the prescription for the one-year vaginal contraceptive system would be filled at a pharmacy.

The below chart sets certain comparative information between the one-year vaginal contraceptive system and currently-approved contraceptive products.

Regulatory Status

The NDA for the one-year vaginal contraceptive system was submitted to the FDA by the Population Council on August 17, 2017 and has a PDUFA target action date for the completion of the FDA s review of the NDA of August 17, 2018. The NDA for the one-year vaginal contraceptive system is supported by data from two pivotal phase 3 open-label safety and efficacy trials that were completed involving 2,308 healthy women at 27 sites in the U.S., Latin America, Europe, and Australia.

The phase 3 trials of the one-year vaginal contraceptive system demonstrated efficacy consistent with existing combination hormonal contraceptives, or CHCs, such as birth control pills, patches and hormonal rings. Approximately 1 to 3 women out of 100 women may get pregnant during the first year of use of the one-year vaginal contraceptive system, consistent with other CHCs.

The phase 3 trials of the one-year vaginal contraceptive system also demonstrated safety consistent with existing CHCs. Consistent with other CHCs, women are at increased risk of a venous

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thrombotic event, or VTE, when using the one-year vaginal contraceptive system. Limited data are available on use of the one-year vaginal contraceptive system in women with a Body Mass Index, or BMI, greater than 29 because this population was excluded from the clinical trials after VTEs were reported. Consistent with other CHCs, the most common adverse reactions are headache and nausea/vomiting and the most common adverse reactions leading to discontinuation are mild, and include: irregular bleeding, headache, vaginal discharge, and nausea/vomiting. We anticipate that the one-year vaginal contraceptive system will receive class labeling for CHCs, if approved. All CHCs carry a boxed warning that the product should not be used by patients who smoke cigarettes and are over age 35.

We anticipate that the one-year vaginal contraceptive system will be classified as a new chemical entity, or NCE, by the FDA and thus have five years of regulatory exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act, if approved. However, such classification is not guaranteed.

Council License Agreement

Under the terms of the Council License Agreement, we are required to pay the Population Council milestone payments of $20 million within 30 days following approval by the FDA of the NDA for the one year vaginal contraceptive system and $20 million within 30 days following the release of the first commercial batch of the one-year vaginal contraceptive system.

However, if a complete response letter or continuance of greater than 90 days is received by the Population Council with respect to the one-year vaginal contraceptive system or the one-year vaginal contraceptive system is approved with additional post-marketing requirements or commitments in excess of $1.0 million, beyond the post-approval studies that may be required by the FDA noted below, then we or the Population Council may terminate the Council License Agreement, provided that we cannot agree with the Population Council on a strategy to address such issues. If the one-year vaginal contraceptive system is approved with shelf life of less than 18 months of stability or is not approved as an NCE that is entitled to five years regulatory exclusivity in the U.S., then we may terminate the Council License Agreement.

We are required to pay the Population Council milestone payments of $40 million upon cumulative net sales of the one-year vaginal contraceptive system in the U.S. by us and our affiliates and permitted sublicensees of $200.0 million, $400.0 million and $1.0 billion.

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

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

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

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The Population Council has agreed to perform and pay the costs and expenses associated with four post-approval studies that may be required by the FDA for the one-year vaginal contraceptive system. We have agreed to perform and pay the costs and expenses associated with a post-approval study that may be required by the FDA to measure risk for venous thromboembolism, provided that if the costs and expenses associated with such post-approval study exceed $20 million, half of such excess will offset against royalties or other payments owed by us to the Population Council under the Council License.

We and the Population Council have agreed to form a joint product committee responsible for overseeing activities under the Council License Agreement. We will be responsible for all aspects of promotion, product positioning, pricing, education programs, publications, sales messages and any additional desired clinical studies for the one-year vaginal contraceptive system, subject to oversight and decisions made by the joint product committee.

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

Population Council Contraceptive Ring Pipeline

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

Commercialization Strategy

If the one-year vaginal contraceptive system is approved by its PDUFA date, we currently estimate that it would be commercially available as early as the third quarter of 2019, with commercial launch as early as the fourth quarter of 2019 or first quarter of 2020.

We intend to leverage our existing infrastructure, including our sales force, to commercialize the one-year vaginal contraceptive system, if approved, together with our recently-approved IMVEXXY™ (estradiol vaginal inserts) and TX-001HR product candidate, if approved.

We believe that our existing sales force overlaps with over 80% of existing prescribers of the leading monthly contraceptive ring and that no additional sales representatives would be needed for us to

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commercialize the one-year vaginal contraceptive system, if approved. We intend to add a dedicated marketing team exclusively focused on the one-year vaginal contraceptive system. We also believe that we are uniquely positioned to market the one-year vaginal contraceptive system, if approved, to the more than 60,000 annual vitaMedMD prenatal customers, who may proceed to contraception following pregnancy.

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

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

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

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

Amendment to MidCap Credit Agreement

On July 30, 2018, we entered into Amendment No. 1 to that certain Credit and Security Agreement, or the Credit Agreement, by and among our company, as borrower, our company s subsidiaries party thereto from time to time, each as a borrower, MidCap Financial Trust, as agent and as lender, and the additional lenders party thereto from time to

time, in order to permit our entry into the

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Council License Agreement. As part of the amendment, we are required to receive aggregate net cash proceeds of at least $75 million from the issuance of our equity securities within thirty days of entering into the Council License Agreement. Failure to complete this obligation will constitute an automatic event of default under the Credit Agreement.

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The Offering

Common stock offered by us	shares.
Concurrent underwritten offering	Concurrently with this offering, we are offering to sell shares of our common stock in the concurrent underwritten offering. The closing of this offering is contingent upon the closing of the concurrent underwritten offering, but the closing of the concurrent underwritten offering is not contingent upon the completion of this offering. See Plan of Distribution on page S-31 of this prospectus supplement.
Shares of common stock to be outstanding immediately after this offering and the concurrent underwritten offering[(1)]	shares, or shares if the underwriters option to purchase additional shares in the concurrent underwritten offering is exercised in full. The offering price per share in this offering will be the same as the offering price per share in the concurrent underwritten offering.
Use of proceeds	We intend to use the net proceeds from this offering and the concurrent underwritten offering to fund a portion of the costs for the commercial launch of our recently FDA approved product, IMVEXXY (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of VVA, due to menopause, and to fund a portion of the costs for pre-commercialization and commercialization activities for TX-001HR, our bio-identical hormone therapy combination of 17ß-estradiol and progesterone in a single, oral softgel drug candidate, for the treatment of moderate to severe VMS due to menopause in menopausal women with an intact uterus, and our one-year vaginal contraceptive system candidate in-licensed from the Population Council. We additionally intend to use a portion of the net proceeds from this offering and the concurrent underwritten offering for working capital and general corporate purposes. We may also use a portion of the net proceeds from this offering and the concurrent underwritten offering to acquire or invest in businesses and products that we believe would complement our women s health products and drug candidates. We can offer no assurance that the concurrent underwritten offering will close, and if it does not close, this offering will not be completed. Please see the section entitled Use of Proceeds on page S-29 of this prospectus supplement.

Risk factors	Investing in our common stock involves a high degree of risk. You should carefully read and consider the information set forth under Risk Factors on page S-12 of this prospectus supplement and page 1 of the accompanying prospectus and in the documents incorporated by reference herein and therein to read about factors you should consider before buying shares of our common stock.

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Common stock symbol	Our common stock is listed on the Nasdaq Global Select Market under the symbol TXMD.

(1) The number of shares of common stock to be outstanding immediately after this offering and the concurrent underwritten offering is based on 216,834,059 shares outstanding on June 30, 2018 and excludes the following as of that date:

- outstanding options representing the right to purchase a total of 25,210,899 shares of common stock at a weighted average exercise price of $3.92 per share;
- outstanding warrants representing the right to purchase a total of 3,007,571 shares of common stock at a weighted-average exercise price of $2.78 per share; and
- 5,052,120 shares of common stock reserved for future issuance under our non-qualified stock option plans.

Except as otherwise noted, all information in this prospectus supplement assumes no exercise of the underwriters option to purchase additional shares.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should carefully consider the risks described below and the risks described under Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2017, as well as the other risks and uncertainties described in the other documents incorporated by reference in this prospectus supplement and the accompanying prospectus and the information contained in our other filings with the SEC, which are incorporated by reference in this prospectus supplement and the accompanying prospectus in their entirety, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

Additional Risks Related to this Offering and our Common Stock

You will experience immediate and substantial dilution in the book value per share of the common stock you purchase and may experience further dilution in the future as a result of equity offerings and other issuances of our common stock or other securities.

The offering price of our common stock being offered in this offering and the concurrent underwritten offering is substantially higher than the net tangible book value per share of our common stock outstanding prior to this offering. Therefore, if you purchase our common stock in this offering at the assumed public offering price of $5.52 per share, which was the last reported sale price of our common stock on the Nasdaq Global Select Market on July 30, 2018, you will incur an immediate substantial dilution of $4.85 in net tangible book value per share from the price you paid based on our net tangible book value and outstanding shares as of June 30, 2018. For a further description of the dilution that you will experience immediately after this offering, see the section titled Dilution.

To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

As of June 30, 2018, there were outstanding options representing the right to purchase a total of 25,210,899 shares of our common stock at a weighted average exercise price of $3.92 per share, outstanding warrants representing the right to purchase a total of 3,007,571 shares of our common stock at a weighted-average exercise price of $2.78 per share and 5,052,120 shares of our common stock reserved for future issuance under our non-qualified stock option plans. You will incur dilution upon exercise of any outstanding stock options or warrants or upon the issuance of shares of common stock under our stock incentive programs.

In addition, the sale of shares in this offering and the concurrent underwritten offering and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock.

We have broad discretion to determine how to use the proceeds raised in this offering and the concurrent underwritten offering, and we may not use the proceeds effectively.

Our management will have broad discretion over the use of proceeds from this offering and the concurrent underwritten offering, and we could spend the proceeds from this offering in ways with which you may not agree or that do not yield a favorable return. We intend to use the net proceeds from this

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offering and the concurrent underwritten offering to fund a portion of the costs for the commercial launch of our recently approved product, IMVEXXY (estradiol vaginal inserts) for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of VVA, due to menopause, and to fund a portion of the costs for pre-commercialization and commercialization activities for TX-001HR, our bio-identical hormone therapy combination of 17ß-estradiol and progesterone in a single, oral softgel drug candidate, for the treatment of moderate to severe VMS due to menopause in menopausal women with an intact uterus, and our one-year vaginal contraceptive system candidate. We additionally intend to use a portion of the net proceeds from this offering and the concurrent underwritten offering for working capital and general corporate purposes. We may also use a portion of the net proceeds from this offering and the concurrent underwritten offering to acquire or invest in businesses and products that we believe would complement our women s health products and drug candidates. If we do not invest or apply the proceeds of this offering and the concurrent underwritten offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

Sales of a substantial number of shares of our common stock, or the perception that such sales might occur, could adversely affect the trading price of our common stock.

As of June 30, 2018, we had 216,834,059 shares of our common stock outstanding. Also, we had, as of June 30, 2018, 28,218,470 shares of our common stock issuable upon the exercise of outstanding options and warrants. If this offering and the concurrent underwritten offering are completed, the number of shares of common stock that we have outstanding will increase. Sales of a substantial number of shares of our common stock, or the perception that such sales might occur, could adversely affect the trading price of our common stock. Further, sales of shares underlying stock options and warrants, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Because the closing of this offering is contingent upon the closing of the concurrent underwritten offering, there can be no assurance that this offering will ultimately be completed.

Pursuant to the terms of the Subscription Agreement, closing of this offering is contingent upon the closing of the concurrent underwritten offering. In the event we do not close the concurrent underwritten offering, we cannot close this offering. There can be no assurance that we will close the concurrent underwritten offering, and, if we do not consummate the concurrent underwritten offering, then this offering will not be completed.

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

We need substantial amounts of cash to complete the commercialization of IMVEXXY and the clinical development and commercialization of our hormone therapy drug candidates and our one-year vaginal contraceptive system candidate. Our existing cash may not be sufficient to fund these requirements. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected on these programs. We may attempt to raise additional capital from the issuance of equity securities, collaborations with third parties, licensing of rights to our products, the issuance of debt securities and the incurrence of debt, to the extent permitted under our $200 million term loan facility with MidCap Financial Trust, as agent and as lender, and the additional lenders party thereto from time to time, or the Credit Agreement, or other means, or a combination of any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of management s attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations.

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

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

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

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

We are subject to extensive and costly government regulation.

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

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

The federal health care Anti-Kickback Statute, or AKS, prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be

made under federal health care programs, such as Medicare, Medicaid, TriCare, and Children s Health Insurance Program. Liability may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, federal law provides that the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA, described below. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in government health care programs.

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

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

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

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

The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, imposes annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which

payment is available under certain government health care programs for certain payments and transfers of value provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Numerous state laws may also require disclosure of transfers of value to health care providers, pharmaceutical pricing information and marketing expenditures.

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

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

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

In addition, from time to time in the future, we may become subject to additional laws or regulations administered by the FDA, the FTC, or by other federal, state, local, or foreign regulatory authorities, to the repeal of laws or regulations that we generally consider favorable, such as the Dietary Supplement Health and Education Act of 1994,

or to more stringent interpretations of current laws or

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regulations. We are not able to predict the nature of such future laws, regulations, repeals, or interpretations, and we cannot predict what effect additional governmental regulation, if it occurs, would have on our business in the future. Such developments could, however, require reformulation of certain products to meet new standards, recalls or discontinuance of certain products not able to be reformulated, additional record-keeping requirements, increased documentation of the properties of certain products, additional or different labeling, additional scientific substantiation, additional personnel, or other new requirements. Any such developments could have a material adverse effect on our business.

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

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

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain others by establishing a new Part D to the Medicare program. However, unlike Medicare Part A and Part B through which Medicare provides coverage for certain drugs in certain circumstances coverage under Part D is provided by private insurers operating under contract with CMS. In addition, this legislation provided authority for limiting the number of certain outpatient drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These and future cost-reduction initiatives could decrease the coverage and price that we receive for our products from Medicare, if any, including IMVEXXY™ and our other hormone therapy drug candidates, if approved, and could significantly harm our business. It was historically unclear whether products approved to treat moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to