TherapeuticsMD, Inc.
Form 424B2
August 02, 2018
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**Filed pursuant to Rule 424(b)(2)**
**Registration No. 333-207837**

**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 $5.10.

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 August 1, 2018 was $5.18 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 12,745,098 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 1,911,764 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 6, 2018.

Prospectus Supplement dated August 1, 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

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**

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| **Common stock offered by us** | 3,921,568 shares. |
| **Concurrent underwritten offering** | Concurrently with this offering, we are offering to sell 12,745,098 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)]** | 233,500,725 shares, or 235,412,489 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. |

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| **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 public offering price of $5.10 per share, you will incur an immediate substantial dilution of $4.44 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

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

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

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

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

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

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

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

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

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

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

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

or to more stringent interpretations of current laws or

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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 menopause, such as IMVEXXY™, were excluded under Medicare Part D, which resulted in limited Medicare coverage for such products. Recent clarification issued by CMS in May 2018 indicated that drugs, such as IMVEXXY™, that are approved for the treatment of moderate to severe dyspareunia (as well as drugs approved for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause) are not excluded from Medicare Part D coverage. CMS s clarification, however, is no guarantee that such coverage will be obtained for IMVEXXY™, and obtaining Medicare or other government health care program reimbursement for any new drug products may take up to several years following FDA approval. While the MMA applies only to drug benefits for Medicare beneficiaries, third-party payors often follow Medicare coverage policies

and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under Medicare may result in a similar reduction in payments from third-party payors.

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Our ability to commercialize successfully the one-year vaginal contraceptive system, if approved, depends on coverage and reimbursement levels set by government health care programs and third-party private payors. The ACA mandates that private health plans provide coverage for women s preventative services, without imposing patient cost-sharing requirements, as recommended by HRSA. HRSA Guidelines require private health plans to cover, with no patient out-of-pocket costs, at least one form of treatment (e.g., one product) in each of the methods (e.g., classes of contraception) identified by the FDA for women in its Birth Control Guide. If the one-year vaginal contraceptive system is deemed a new class of contraception by the FDA, this designation could allow for coverage by private health plans with no patient out-of-pocket costs. However, there is no guarantee that the FDA will designate the one-year vaginal contraceptive system as a new class of contraception, or that such coverage will be obtained. Even if the FDA does designate it as a new class of contraception, it is possible that other FDA-approved products could also be included in this new class. Pursuant to HRSA Guidelines, private payors need only provide no-cost coverage for one product in each class, and may use reasonable medical management to determine whether and to what extent to cover other products in the class. To the extent 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.

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

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

The availability of generic products at lower prices than branded products may substantially reduce the likelihood of reimbursement for branded products, such as IMVEXXY™, our one-year vaginal contraceptive system candidate, or our other hormone therapy drug candidates, if approved.

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

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

Legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in

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

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

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

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

We do not currently have, nor do we currently plan to build or accure, the infrastructure or capability to internally manufacture our existing women s health care products, our one-year vaginal contraceptive system candidate, or our hormone therapy drug candidates. We have relied, and will continue to rely, on third parties to manufacture these products in accordance with our specifications and in compliance with applicable regulatory requirements. We have entered into long-term supply agreements with Catalent for the commercial supply of IMVEXXY™ and our TX-001HR hormone therapy drug candidate, if approved. Under the terms of the agreements, we will be obligated to purchase certain minimum annual amounts of each product once we commence commercial sales of such product following regulatory approval of Catalent as a manufacturer of such product. We depend on Lang, a full-service, private label and corporate brand manufacturer, to supply approximately 100% of our vitaMedMD and BocaGreen products. We do not have long-term contracts for the commercial supply of our existing women s health care products,

however, in certain circumstances, including our failure to satisfy our production forecasts to Lang, we may be obligated to reimburse Lang for the costs of excess raw materials purchased by Lang that it cannot use in another product category that it then sells. We intend to enter into agreements with

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Crystal Pharma SAU and QPharma AB for the commercial supply of one of the active pharmaceutical ingredients for, and the manufacturing of, our one-year vaginal contraceptive system, respectively. However, if we experience delays in finalizing these agreements or are unable to execute these agreements on commercially reasonable terms, we may need to find alternative manufacturing facilities, which would result in disruption in our commercialization of the one-year vaginal contraceptive system, if approved.

Regulatory requirements could pose barriers to the manufacture of our existing women s health care products and our hormone therapy drug product and drug candidates. Our third-party manufacturers are required to comply with cGMP regulations. As a result, the facilities used by any of our current or future manufacturers may be subject to an NDA pre-approval inspection, or PAI, by the FDA, and any noncompliance could cause the NDA to be disapproved or delayed in approval. Holders of NDAs, or other forms of FDA approvals or clearances, or those distributing a regulated product under their own name, are ultimately responsible for compliance with manufacturing obligations even if the manufacturing is conducted by a third-party contract manufacturing organization, or CMO. All of our existing products are, and our hormone therapy drug candidates, if approved, will be manufactured by CMOs. These CMOs are required by the terms of our contracts to manufacture our products in compliance with the applicable regulatory requirements. The CMO that will manufacture IMVEXXY™ and our TX-001HR hormone therapy drug candidate, if approved, has previously been inspected by the FDA and received Form 483 observations with respect to its softgel manufacturing plant that will be used for the manufacture of the commercial supply of IMVEXXY™ and TX-001HR, if approved. We anticipate that as part of a PAI of our NDA for TX-001HR, the FDA may inspect Catalent s manufacturing facilities that would be used to manufacture that product. If this inspection results in Form 483 observations, the approval of our NDA could be delayed significantly. The CMO that manufactured the hormone therapy drug candidate used in our phase 3 clinical trial for TX-001HR was previously inspected by the FDA, which issued it a Form FDA 483 listing various observations, some of which pertained to the clinical supply of TX-001HR. The CMO has submitted its written response to the Form 483 observations to the FDA. We believe the responses satisfactorily address the FDA s observations with respect to the clinical supply of TX-001HR and in a subsequent inspection the FDA did not find the CMO out of compliance with the commitments and associated deliverables contained in its response to the Form 483 observations. However, if the FDA were to determine that this CMO did not comply with cGMP regulations, it could cause the NDA for TX-001HR to be disapproved or delayed in approval. As noted above, we have contracted with a different CMO, Catalent, to provide the commercial supply of IMVEXXY™ and our TX-001HR drug candidate, if approved.

QPharma, the CMO that will manufacture our one-year vaginal contraceptive system, if approved, has previously been inspected by the FDA and received Form 483 observations on December 15, 2017, with respect to its facility that will be used for the commercial supply of the one-year contraceptive system. The FDA classified the inspection as Voluntary Action Indicated, meaning that the FDA found instances of noncompliance but the problems likely would not result in further regulatory action. QPharma submitted its written response to the Form 483 observations to the FDA on December 22, 2017, however neither we nor QPharma has been informed by the FDA as to whether QPharma s response addresses and remediates these observations in a manner satisfactory to the FDA. If QPharma is unable to address and remediate the FDA s observations, it could have a material adverse effect on the manufacture of the commercial supply of our one-year vaginal contraceptive system, if approved.

If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, our regulatory submissions may be delayed or disapproved, and our marketed products may be affected. If these facilities are not in compliance for the manufacture of our vitamin products, our hormone therapy drug product and our drug candidates, we may need to find alternative manufacturing facilities, which would result in disruptions of our sales and significant delays of up to several years in obtaining approval for our hormone therapy drug candidates. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for

compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to

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comply with applicable cGMP regulations or other applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, violation letters, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts, and criminal prosecutions, any of which could have a material adverse impact on our business, financial condition, results of operations, and prospects. We do not currently have alternative manufacturers, and we may not be able to enter into a long-term agreement with alternative manufacturers, or do so on commercially reasonable terms, which could have a material adverse impact on our business. Finally, we also could experience manufacturing delays if our CMOs give greater priority to the supply of other products over our products and proposed products to the delay or other detriment of our products and proposed products, or otherwise do not satisfactorily perform according to the terms of their agreements with us.

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

***Even after the approval of IMVEXXY™, and even if we obtain regulatory approval for our one-year vaginal contraceptive system candidate and for our other hormone therapy drug candidates, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.***

Even if we obtain regulatory approval for our one-year vaginal contraceptive system or for one or more of our hormone therapy drug candidates in the United States, and with respect to IMVEXXY™, the FDA may still impose significant restrictions on a product s indicated uses or marketing or to the conditions for approval, or impose ongoing requirements for potentially costly post-approval studies, including phase 4 clinical trials or post-market surveillance. As a condition to granting marketing approval of a product, the FDA may require a company to conduct additional clinical trials. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. For example, the labeling for IMVEXXY™ contains restrictions on use and warnings, and the labeling for our hormone therapy drug candidates and our one-year vaginal contraceptive system candidate, if approved, may also include restrictions on use or warnings. The Food and Drug Administration Amendments Act of 2007, or FDAAA, gives the FDA enhanced post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved REMS programs. IMVEXXY™ and our hormone therapy drug candidates and our one-year vaginal contraceptive system candidate, if approved, will also be subject to ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record keeping, and reporting of safety and other post-market information. The FDA s exercise of its authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements, and potential restrictions on sales of approved products. As part of the FDA s approval of IMVEXXY™, we have committed to conduct a post-approval observational study to evaluate the risk of endometrial cancer in post-menopausal women with a uterus who use a low-dose vaginal estrogen unopposed by a progestogen such as IMVEXXY . Foreign regulatory agencies often have similar authority and may impose comparable costs. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our hormone therapy drug candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems

with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty

regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

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

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

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

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

issue warning letters or untitled letters asserting that we are in violation of the law;

seek an injunction or impose civil or criminal penalties or monetary fines;

suspend or withdraw regulatory approval;

require that we suspend or terminate any ongoing clinical trials;

refuse to approve pending applications or supplements to applications filed by us;

suspend or impose restrictions on operations, including costly new manufacturing requirements;

seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or

exclude us from providing our products to those participating in government health care programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

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

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

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

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

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

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

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

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

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

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

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product and product candidates, and what activities satisfy those diligence obligations;
- the scope of rights granted under the agreement and other interpretation-related issues;
- our obligations to make milestone, royalty or other payments under those agreements;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;

the ownership of inventions and know-how arising under the agreement or resulting from the joint creation or use of intellectual property by our licensors and us and our partners;

our right to transfer or assign the license; and

the effects of termination.

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

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

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

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

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

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

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

We must satisfy certain conditions to be eligible to draw down the second tranche of $75.0 million and the third tranche of $50.0 million. The second tranche may be drawn by us on or before May 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including (i) the approval by the FDA of the NDA for our TX-001HR drug candidate and (ii) that we have consummated our first commercial sale in the United States of

TX-001HR. The third tranche of $50.0 million may be drawn by us on or before December 31, 2019, provided that we satisfy certain conditions described in the Credit Agreement, including that (i) tranche 2 has been drawn and (ii) we and our subsidiaries party to the Credit Agreement have generated at least $75.0 million of consolidated net revenue attributable to commercial sales of TX-001HR and IMVEXXY during the twelve-month period ending immediately prior to the funding of tranche 3. If we are unable to satisfy those conditions, we would not be able to draw down the respective tranche of financing and may not be able to obtain alternative financing on commercially reasonable terms or at all.

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

As part of an amendment to the Credit Agreement entered in connection with entering into the Council License Agreement, 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.

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

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## CAUTIONARY STATEMENT ABOUT FORWARD-LOOKING INFORMATION

This prospectus supplement, the accompanying prospectus and the documents and information incorporated by reference herein and therein may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies as well as statements, other than historical facts, that address activities, events, or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as may, will, should, expects, plans, anticipates, could, intends, target, projects, contemplates, b predicts, potential, or continue or the negative of these terms or other similar expressions.

Forward-looking statements are based on assumptions and assessments made in light of our experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. You should not place undue reliance on these forward-looking statements, which reflect our view only as of the date of this prospectus supplement, and we undertake no obligation to update these forward-looking statements in the future, except as required by applicable law.

A number of important factors could cause actual results to differ materially from those indicated by the forward-looking statements, including, without limitation, those factors described under the caption Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which is incorporated by reference in this prospectus supplement and the accompanying prospectus, and under similar headings in our subsequently filed quarterly reports on Form 10-Q, as well as the other risks and uncertainties described herein and in the other documents incorporated by reference in this prospectus supplement. Some of the key factors that could cause actual results to differ from our expectations include the following:

- our operating losses incurred since inception and anticipated for the foreseeable future;
- our ability to maintain or increase sales of our products;
- the ability of our products to produce the intended effects;
- our ability to develop and commercialize our hormone therapy drug product and drug candidates;
- our ability to obtain additional financing necessary to complete the development and commercialization of our hormone therapy drug product and drug candidates;
- whether the FDA will approve our NDAs for our TX-001HR drug candidate and our one-year vaginal contraceptive system candidate and whether such approvals will occur by their respective PDUFA target action dates;

our lack of experience in bringing a drug to regulatory approval or marketing and selling a drug after regulatory approval;

the length, cost and uncertain results of our clinical trials;

delays, suspensions, or discontinuation of our clinical trials;

the potential of adverse side effects or other safety risks that could preclude the approval of our drug candidates;

our reliance on third parties to conduct our clinical trials, research and development and manufacturing;

the effects of laws, regulations and enforcement;

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our ability to gain and retain market acceptance for our hormone therapy drug product or drug candidates;

the competitive nature of the industries in which we conduct our business;

the availability of reimbursement from government authorities and health insurance companies for our products;

the impact of product liability lawsuits;

the influence of extensive and costly government regulation;

the effect of governmental regulations on our business;

whether we will be able to comply with the covenants and conditions under our credit agreement;

the ability of our partners and third-party manufacturers to manufacture and distribute sufficient amounts of our hormone therapy drug product;

the ability of our licensees to commercialize and distribute our hormone therapy drug product and drug candidates;

the volatility of the trading price of our common stock; and

the concentration of power in our stock ownership.

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## USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of common stock in this offering and the concurrent underwritten offering will be approximately $80.8 million, or approximately $90.0 million if the underwriters in the concurrent underwritten offering exercise in full their option to purchase additional shares, based on the public offering price of $5.10 per share, after deducting underwriting discounts and commissions (payable only in the concurrent underwritten offering) and estimated offering and concurrent underwritten offering expenses payable by us.

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 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.

As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses of the proceeds from this offering and the concurrent underwritten offering. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of regulatory approvals, commercialization activities, the timing of our revenue and the amount of cash used by our operations. Accordingly, we will retain broad discretion over the use of such proceeds.

The closing of this offering is contingent upon the closing of the concurrent underwritten offering, and we can offer no assurance that the concurrent underwritten offering will close. If the concurrent underwritten offering does not close, then this offering will not be completed. See Risk Factors 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.

Pending use of the proceeds as described above or otherwise, we intend to invest the net proceeds in short-term interest-bearing, investment-grade securities.

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## DILUTION

Our net tangible book value as of June 30, 2018 was approximately $74.1 million, or $0.34 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of June 30, 2018. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering and the concurrent underwritten offering.

After giving effect to the sale of $85 million of shares of our common stock in this offering and the concurrent underwritten offering at the public offering price of $5.10 per share, and after deducting the underwriting discounts and commissions (payable only in the concurrent underwritten offering) and estimated offering and concurrent underwritten offering expenses we must pay, our as adjusted net tangible book value as of June 30, 2018 would have been approximately $154.9 million, or $0.66 per share. This would represent an immediate increase in net tangible book value of $0.32 per share to existing stockholders and immediate dilution in net tangible book value of $4.44 per share to new investors purchasing our common stock in this offering and the concurrent underwritten offering. The following table illustrates this dilution on a per share basis.

| | | |
|---|---|---|
| Public offering price per share | | $ 5.10 |
| Net tangible book value per share as of June 30, 2018 | $ 0.34 | |
| Increase per share attributable to new investors | $ 0.32 | |
| As adjusted net tangible book value per share after this offering and the concurrent underwritten offering | | $ 0.66 |
| Dilution per share to new investors in this offering | | $ 4.44 |

If the underwriters in the concurrent underwritten offering exercise in full their option to purchase 1,911,764 additional shares of common stock in the concurrent underwritten offering at the public offering price of $5.10 per share, the as adjusted net tangible book value after this offering and the concurrent underwritten offering would be $0.70 per share, representing an increase in net tangible book value of $0.36 per share to existing stockholders and immediate dilution in net tangible book value of $4.40 per share to new investors purchasing our common stock in this offering.

The above discussion and table are based on 216,834,059 shares outstanding on June 30, 2018 and exclude 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.

To the extent that outstanding options or warrants are exercised or we issue shares of common stock under our stock incentive plans, investors purchasing our common stock in this offering will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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## PLAN OF DISTRIBUTION

We are offering 3,921,568 shares of common stock under this prospectus supplement directly to Knight in a privately negotiated transaction in which no party is acting as an underwriter or placement agent. Similarly, no broker or dealer has been retained by us in connection with this offering. Subject to the terms of the Subscription Agreement, Knight has agreed to purchase from us and we have agreed to sell to Knight, an aggregate of 3,921,568 shares of common stock at the public offering price per share for our common stock in the concurrent underwritten offering.

We expect to deliver the shares of common stock against payment of the aggregate purchase price therefor on or about August 6, 2018. The closing of this offering is contingent upon the closing of the concurrent underwritten offering, but the closing of the underwritten offering is not contingent upon the closing 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 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.

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## LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Greenberg Traurig, LLP, Las Vegas, Nevada.

## EXPERTS

The audited financial statements and management s assessment of the effectiveness of internal control over financial reporting incorporated by reference in this prospectus supplement and elsewhere in the registration statement have been incorporated by reference in reliance upon the reports of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Through our website at *www.therapeuticsmd.com*, you may access, free of charge, our filings, as soon as reasonably practical after we electronically file them with or furnish them to the SEC. The information contained in, or available through, our website is not incorporated by reference in, and should not be considered a part of, this prospectus supplement or the accompanying prospectus. You also may read and copy any document we file with the SEC at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. Our SEC filings are also available to the public at the SEC s website at *www.sec.gov*.

The accompanying prospectus is part of a registration statement on Form S-3 that we filed with the SEC to register the securities offered hereby under the Securities Act. The accompanying prospectus does not contain all of the information included in the registration statement, including certain exhibits and schedules. You may obtain the registration statement and exhibits to the registration statement from the SEC at the address listed above or from the SEC s website listed above.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference the information we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information that we incorporate by reference is considered to be part of this prospectus supplement and the accompanying prospectus. Information that we file with the SEC in the future and incorporate by reference in this prospectus supplement and the accompanying prospectus automatically updates and supersedes previously filed information as applicable.

We incorporate by reference into this prospectus supplement and the accompanying prospectus the following documents filed by us with the SEC, other than any portion of any such documents that is not deemed filed under the Exchange Act in accordance with the Exchange Act and applicable SEC rules:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on February 23, 2018;

our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2018 and June 30, 2018, filed with the SEC on May 7, 2018 and July 30, 2018;

our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 27, 2018;

our Current Reports on Form 8-K filed with the SEC on April 2, 2018, May 3, 2018, June 7, 2018 and June 26, 2018; and

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the description of our common stock included under the heading Description of Common Stock in the prospectus forming a part of the Registration Statement on Form S-3 (File No. 333-207837), as filed with the SEC on November 5, 2015, which description has been incorporated by reference in Item 1 of our Form 8-A (File No. 001-00100), as filed with the SEC on October 6, 2017, including any amendment or report filed with the SEC for the purpose of updating such description.

In addition, all documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (not including any information furnished under Item 2.02, 7.01 or 9.01 of Form 8-K and any other information that is identified as furnished rather than filed, which information is not incorporated by reference herein) prior to the termination of this offering, will be deemed to be incorporated herein by reference and to be a part of this prospectus supplement and the accompanying prospectus from the date of filing of such documents. Any statement contained in a document incorporated herein by reference will be deemed to be modified or superseded for purposes of this prospectus supplement and the accompanying prospectus to the extent that a statement contained herein, or in a subsequently filed document incorporated herein by reference, modifies or supersedes the statement. Any statement modified or superseded will not be deemed, except as modified or superseded, to constitute a part of this prospectus supplement and the accompanying prospectus.

We will provide without charge to each person, including any beneficial owner, to whom a prospectus supplement is delivered, upon written or oral request of that person, a copy of any and all of the information that has been incorporated by reference in this prospectus supplement and the accompanying prospectus but not delivered with this prospectus supplement (excluding exhibits unless specifically incorporated by reference into those documents). Please direct requests to us at the following address:

**TherapeuticsMD, Inc.**

**Attention: Corporate Secretary**

**6800 Broken Sound Parkway NW, Third Floor**

**Boca Raton, Florida 33487**

**(561) 961-1900**

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**PROSPECTUS**

# $250,000,000

## Common Stock

## Preferred Stock

## Debt Securities

## Depositary Shares

## Warrants

## Purchase Contracts

## Units

We may offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any combination of the securities described in this prospectus, up to an aggregate amount of $250,000,000.

This prospectus provides you with a general description of the securities we may offer and sell. We will provide specific terms of any offering in a supplement to this prospectus. Any prospectus supplement may also add, update, or change information contained in this prospectus. You should carefully read this prospectus and the applicable prospectus supplement as well as the documents incorporated or deemed to be incorporated by reference in this prospectus before you invest in any of our securities.

These securities may be offered and sold in the same offering or in separate offerings; to or through underwriters, dealers and agents; or directly to purchasers. The names of any underwriters, dealers, or agents involved in the sale of our securities and any applicable fees, commissions, or discounts will be described in the applicable prospectus supplement. Our net proceeds from the sale of securities will also be set forth in the applicable prospectus supplement.

This prospectus may not be used to consummate a sale of our securities unless accompanied by the applicable prospectus supplement.

**Investing in our securities involves a high degree of risk. See Risk Factors beginning on page 1 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.**

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

**The date of this prospectus is November 17, 2015.**

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a shelf registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings, up to a total dollar amount of $250,000,000. This prospectus provides you with general information regarding the securities we may offer. We will provide a prospectus supplement that contains specific information about any offering by us.

The prospectus supplement also may add, update, or change information contained in the prospectus. You should read both this prospectus and the prospectus supplement related to any offering as well as additional information described under the headings Where You Can Find More Information and Incorporation of Certain Information by Reference.

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus or any accompanying prospectus supplement or any free writing prospectus. We are offering to sell, and seeking offers to buy, securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus and in any accompanying prospectus supplement is accurate only as of the dates of their covers, regardless of the time of delivery of this prospectus or any prospectus supplement or of any sale of our securities. Our business, financial condition, results of operations, and prospects may have changed since those dates. You should rely only on the information contained or incorporated by reference in this prospectus or any accompanying prospectus supplement. To the extent there is a conflict between the information contained in this prospectus and the prospectus supplement, you should rely on the information in the prospectus supplement, provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference into this prospectus or any prospectus supplement the statement in the document having the later date modifies or supersedes the earlier statement.

Unless the context otherwise requires, the terms Therapeutics, TXMD, Company, we, us, or our refer to TherapeuticsMD, Inc., a Nevada corporation, and its subsidiaries, vitaMedMD, LLC, a Delaware limited liability company, or VitaMed, BocagreenMD, Inc., a Nevada corporation, or BocaGreen, and VitaCare Prescription Services, Inc., a Florida corporation, or VitaCare.

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## RISK FACTORS

Investing in our securities involves a high degree of risk. Before making an investment decision, you should carefully consider the discussion of risks and uncertainties under the heading Risk Factors contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which is incorporated by reference in this prospectus, and under similar headings in our subsequently filed quarterly reports on Form 10-Q and annual reports on Form 10-K, as well as the other risks and uncertainties described in any applicable prospectus supplement or free writing prospectus and in the other documents incorporated by reference in this prospectus. See the sections entitled Where You Can Find More Information and Incorporation of Certain Information by Reference in this prospectus. The risks and uncertainties we discuss in this prospectus, in any applicable prospectus supplement or free writing prospectus and in the other documents incorporated by reference in this prospectus are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial also may materially and adversely affect our business, financial condition and results of operations.

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## FORWARD-LOOKING STATEMENTS

This prospectus, any applicable prospectus supplement and the documents and information incorporated by reference herein and therein may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies as well as statements, other than historical facts, that address activities, events, or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as may, will, should, expects, plans, anticipates, could, intends, target, projects, contemplates, believes, estimates, predicts, potential, or continue or th or other similar expressions.

Forward-looking statements are based on assumptions and assessments made in light of our experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. You should not place undue reliance on these forward-looking statements, which reflect our view only as of the date of this prospectus, and we undertake no obligation to update these forward-looking statements in the future, except as required by applicable law.

A number of important factors could cause actual results to differ materially from those indicated by the forward-looking statements, including, without limitation, those factors described under the caption Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which is incorporated by reference in this prospectus, and under similar headings in our subsequently filed quarterly reports on Form 10-Q and annual reports on Form 10-K, as well as the other risks and uncertainties described in any applicable prospectus supplement or free writing prospectus and in the other documents incorporated by reference in this prospectus. Some of the key factors that could cause actual results to differ from our expectations include the following:

- our operating losses incurred since inception and anticipated for the foreseeable future;
- our ability to maintain or increase sales of our products;
- the ability of our products to produce the intended effects;
- our ability to develop and commercialize our hormone therapy drug candidates;
- our ability to obtain additional financing necessary to complete the development and commercialization of our hormone therapy drug candidates;
- our lack of experience in bringing a drug to regulatory approval;
- the length, cost and uncertain results of our clinical trials;
- delays, suspensions, or discontinuation of our clinical trials;
- the potential of adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates;
- our reliance on third parties to conduct our clinical trials and research and development;
- the effects of laws, regulations and enforcement;
- our dependence on third-party manufacturers;
- our ability to gain and retain market acceptance for our hormone therapy drug candidates;
- the competitive nature of the industries in which we conduct our business;
- the availability of reimbursement from government authorities and health insurance companies for our products;
- the impact of product liability lawsuits;
- the influence of extensive and costly government regulation;
- the effect of governmental regulations on our business;
- the volatility of the trading price of our common stock; and
- the concentration of power in our stock ownership.

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## OUR COMPANY

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

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.vitamedmd.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 or any prospectus supplement.

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## RATIO OF EARNINGS TO FIXED CHARGES

Our ratio of earnings to fixed charges for each of the five most recently completed fiscal years and any required interim periods will each be specified in a prospectus supplement or in a document that we file with the SEC and incorporate by reference pertaining to the issuance, if any, by us of debt securities in the future.

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## DILUTION

We will set forth in a prospectus supplement the following information regarding any material dilution of the equity interests of investors purchasing securities in an offering under this prospectus:

- the net tangible book value per share of our equity securities before and after the offering;
- the amount of the increase in such net tangible book value per share attributable to the cash payments made by purchasers in the offering; and
- the amount of the immediate dilution from the public offering price which will be absorbed by such purchasers.

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## USE OF PROCEEDS

Except as may be otherwise set forth in any prospectus supplement accompanying this prospectus, we will use the net proceeds we receive from sales of securities offered hereby for general corporate purposes, which may include the repayment of indebtedness outstanding from time to time and for working capital, capital expenditures, acquisitions and repurchases of our common stock or other securities. Pending these uses, the net proceeds may also be temporarily invested in cash equivalents or short-term securities. When specific securities are offered, the prospectus supplement relating thereto will set forth our intended use of the net proceeds that we receive from the sale of such securities.

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## DESCRIPTION OF COMMON STOCK

This section describes the general terms of our common stock. A prospectus supplement may provide information that is different from this prospectus. If the information in the prospectus supplement with respect to our common stock being offered differs from this prospectus, you should rely on the information in the prospectus supplement. A copy of our amended and restated articles of incorporation, as amended, has been incorporated by reference from our filings with the SEC as an exhibit to the registration statement of which this prospectus forms a part. Our common stock and the rights of the holders of our common stock are subject to the applicable provisions of the Nevada Private Corporation Code, which we refer to as Nevada law, our amended and restated articles of incorporation, our bylaws, the rights of the holders of our preferred stock, if any, as well as some of the terms of our outstanding indebtedness.

Under our amended and restated articles of incorporation, as amended, we have the authority to issue 350,000,000 shares of common stock, par value $0.001 per share. As of November 2, 2015, there were 177,848,041 shares of our common stock outstanding.

The following description of our common stock, and any description of our common stock in a prospectus supplement, may not be complete and is subject to, and qualified in its entirety by reference to, Nevada law and the actual terms and provisions contained in our amended and restated articles of incorporation and our bylaws, each as amended from time to time.

### Voting Rights

Each outstanding share of our common stock is entitled to one vote per share of record on all matters submitted to a vote of stockholders and to vote together as a single class for the election of directors and in respect of other corporate matters. At a meeting of stockholders at which a quorum is present, for all matters other than the election of directors, an affirmative vote of the majority of shares entitled to vote on a matter and that are represented either in person or by proxy at a meeting of stockholders decides all questions, unless the matter is one upon which a different vote is required by express provision of law or our amended and restated articles incorporation or our bylaws. Directors will be elected by a plurality of the votes of the shares present at a meeting. Holders of shares of common stock do not have cumulative voting rights with respect to the election of directors or any other matter.

### Dividends

Holders of our common stock are entitled to receive dividends or other distributions when, as and if declared by our board of directors. The right of our board of directors to declare dividends, however, is subject to any rights of the holders of other classes of our capital stock, any indebtedness outstanding from time to time and the availability of sufficient funds, as determined under Nevada law, to pay dividends.

### Preemptive Rights

The holders of our common stock do not have preemptive rights to purchase or subscribe for any of our capital stock or other securities.

### Redemption

Shares of our common stock are not subject to redemption by operation of a sinking fund or otherwise.

### Liquidation Rights

In the event of any liquidation, dissolution, or winding up of our company, subject to the rights, if any, of the holders of other classes of our capital stock, the holders of shares of our common stock are entitled to receive any of our assets available for distribution to our stockholders ratably in proportion to the number of shares held by them.

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**Options and Other Stock-Based Rights**

From time to time, we have issued and expect to continue to issue options and other stock-based rights to various lenders, investors, consultants, employees, officers and directors of our company. As of November 2, 2015, we had outstanding (i) stock options to purchase 17,479,325 shares of our common stock, of which 13,898,297 shares of common stock were issuable upon exercise of vested stock options as of that date, and (ii) warrants for the purchase of 12,722,431 shares of our common stock.

**Listing**

Our common stock is listed on the NYSE MKT under the symbol TXMD.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A., 350 Indiana Street, Suite 800, Golden, Colorado 80401.

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## DESCRIPTION OF PREFERRED STOCK

This section describes the general terms of our preferred stock to which any prospectus supplement may relate. A prospectus supplement will describe the terms relating to any preferred stock to be offered by us in greater detail and may provide information that is different from terms described in this prospectus. If the information in the prospectus supplement with respect to the particular preferred stock being offered differs from this prospectus, you should rely on the information in the prospectus supplement. A copy of our amended and restated articles of incorporation, as amended, has been incorporated by reference from our filings with the SEC as an exhibit to the registration statement of which this prospectus forms a part. A certificate of designation or amendment to the amended and restated articles of incorporation, as amended, will specify the terms of the preferred stock being offered, and will be filed or incorporated by reference as an exhibit to the registration statement before the preferred stock is issued. The following description of our preferred stock, and any description of the preferred stock in a prospectus supplement may not be complete and is subject to, and qualified in its entirety by reference to, Nevada law and the actual terms and provisions contained in our amended and restated articles of incorporation, as amended, and bylaws, each as amended from time to time.

Under our amended and restated articles of incorporation, as amended, we have the authority to issue 10,000,000 shares of preferred stock, par value $0.001 per share, which are issuable in series on terms to be determined by our board of directors. Accordingly, our board of directors is authorized, without action by the stockholders, to issue preferred stock from time to time with such dividend, liquidation, conversion, voting, redemption, sinking fund and other rights and restrictions as it may determine. All shares of any one series of our preferred stock will be identical, except that shares of any one series issued at different times may differ as to the dates from which dividends may be cumulative. All series will rank equally and will provide for other terms as described in the applicable prospectus supplement. As of the date of this prospectus, there were no outstanding shares of our preferred stock.

**Terms of Preferred Stock**

Unless provided in a prospectus supplement, the shares of our preferred stock to be issued will have no preemptive rights. Any prospectus supplement offering our preferred stock will furnish the following information with respect to the preferred stock offered by that prospectus supplement:

- the title and stated value of the preferred stock;
- the number of shares of preferred stock to be issued and the offering price of the preferred stock;
- any dividend rights;
- any dividend rates, periods, or payment dates, or methods of calculating dividends applicable to the preferred stock;
- the date from which distributions on the preferred stock will accumulate, if applicable;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into our common stock, including the conversion price (or manner of calculation thereof);
- any right to convert the preferred stock into a different type of security;
- any voting rights attributable to the preferred stock;

any rights and preferences upon our liquidation, dissolution, or winding up of our affairs;

any terms of redemption;

any procedures for any auction and remarketing for the preferred stock;

any provisions for a sinking fund for the preferred stock;

any listing of the preferred stock on any securities exchange;

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a discussion of material U.S. federal income tax considerations applicable to the preferred stock;

the relative ranking and preferences of the preferred stock as to distribution rights (including whether any liquidation preference as to the preferred stock will be treated as a liability for purposes of determining the availability of assets for distributions to holders of stock ranking junior to the shares of preferred stock as to distribution rights);

any limitations on issuance of any series of preferred stock ranking senior to or on a parity with the series of preferred stock being offered as to distribution rights and rights upon the liquidation, dissolution, or winding up or our affairs; and

any other specific terms, preferences, rights, limitations, or restrictions of the preferred stock.

**Rank**

Unless otherwise indicated in the applicable prospectus supplement, shares of our preferred stock will rank, with respect to payment of distributions and rights upon our liquidation, dissolution, or winding up, and allocation of our earnings and losses as follows:

senior to all classes or series of our common stock and to all of our equity securities ranking junior to the preferred stock;

on a parity with all equity securities issued by us, the terms of which specifically provide that such equity securities rank on a parity with the preferred stock; and

junior to all equity securities issued by us, the terms of which specifically provide that such equity securities rank senior to the preferred stock.

**Distributions**

Subject to any preferential rights of any outstanding stock or series of stock, our preferred stockholders will be entitled to receive distributions, in accordance with the applicable terms of each series of preferred stock, when, as, and if declared by our board of directors, out of legally available funds, and to share pro rata based on the number of preferred shares, common stock, and other parity equity securities outstanding. The rates and dates of payment of dividends, if any, will be set forth in the prospectus supplement relating to the applicable series of preferred stock. Dividends, if any, will be payable to holders of record of preferred stock as they appear on our books or, if applicable, the records of the depositary, if any, referred to below on the record dates fixed by our board of directors. Dividends on a series of preferred stock may be cumulative or noncumulative.

We may not declare, pay, or set apart for payment dividends on the preferred stock unless full dividends on other series of preferred stock that rank on an equal or senior basis have been paid or sufficient funds have been set apart for payment for:

all prior dividend periods of other series of preferred stock that pay dividends on a cumulative basis; or

the immediately preceding dividend period of other series of preferred stock that pay dividends on a noncumulative basis.

Partial dividends declared on shares of preferred stock and each other series of preferred stock ranking on an equal basis as to dividends will be declared pro rata. A pro rata declaration means that the ratio of dividends declared per share to accrued dividends per share will be the same for each series of preferred stock. Similarly, we may not declare, pay, or set apart for payment non-stock dividends or make other payments on the common stock or any other of our stock ranking junior to the preferred stock until full dividends on the preferred stock have been paid or set apart for payment for:

all prior dividend periods if the preferred stock pays dividends on a cumulative basis; or

the immediately preceding dividend period if the preferred stock pays dividends on a noncumulative basis.

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**Voting Rights**

Unless otherwise indicated in the applicable prospectus supplement, or as required by Nevada law, holders of our preferred stock will not have any voting rights.

**Liquidation Preference**

Upon the voluntary or involuntary liquidation, dissolution, or winding up of our affairs, then, before any distribution or payment will be made to the holders of any common stock or any other class or series of stock ranking junior to the preferred stock in our distribution of assets upon any liquidation, dissolution, or winding up, the holders of each series of our preferred stock will be entitled to receive, after payment or provision for payment of our debts and other liabilities, out of our assets legally available for distribution to stockholders, liquidating distributions in the amount of the liquidation preference per share (set forth in the applicable prospectus supplement), plus an amount, if applicable, equal to all distributions accrued and unpaid thereon (which will not include any accumulation in respect of unpaid distributions for prior distribution periods if the preferred stock is not entitled to a cumulative distribution). Unless otherwise specified in the applicable prospectus supplement, after payment of the full amount of the liquidating distributions to which they are entitled, the holders of preferred stock will have no right or claim to any of our remaining assets. In the event that, upon our voluntary or involuntary liquidation, dissolution, or winding up, the legally available assets are insufficient to pay the amount of the liquidating distributions on all of our outstanding preferred stock and the corresponding amounts payable on all of our other classes or series of equity securities ranking on a parity with the preferred stock in the distribution of assets upon liquidation, dissolution, or winding up, then the holders of our preferred stock and all other such classes or series of equity securities will share ratably in the distribution of assets in proportion to the full liquidating distributions to which they would otherwise be respectively entitled.

If the liquidating distributions are made in full to all holders of preferred stock, our remaining assets will be distributed among the holders of any other classes or series of equity securities ranking junior to the preferred stock upon our liquidation, dissolution, or winding up, according to their respective rights and preferences and in each case according to their respective number of shares of stock.

**Conversion Rights**

The terms and conditions, if any, upon which shares of any series of preferred stock are to be convertible into other securities will be set forth in the applicable prospectus supplement. These terms will include the amount and type of security into which the shares of preferred stock are convertible, the conversion price (or manner of calculation thereof), the conversion period, provisions as to whether conversion will be at the option of the holders of the preferred stock or us, the events requiring an adjustment of the conversion price, and provisions affecting conversion in the event of the redemption of that preferred stock.

**Redemption**

If so provided in the applicable prospectus supplement, our preferred stock will be subject to mandatory redemption or redemption at our option, in whole or in part, in each case upon the terms, at the times and at the redemption prices set forth in such prospectus supplement. Unless we default in the payment of the redemption price, dividends will cease to accrue after the redemption date on shares of preferred stock called for redemption and all rights of holders of such shares will terminate, except for the right to receive the redemption price. No series of preferred stock will receive the benefit of a sinking fund except as set forth in the applicable prospectus supplement.

**Registrar and Transfer Agent**

The registrar and transfer agent for our preferred stock will be set forth in the applicable prospectus supplement.

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If our board of directors decides to issue any shares of preferred stock, it may discourage or make more difficult a merger, tender offer, business combination or proxy contest, assumption of control by a holder of a large block of our securities, or the removal of incumbent management, even if these events were favorable to the interests of stockholders. Our board of directors, without stockholder approval, may issue preferred stock with voting and conversion rights and dividend and liquidation preferences that may adversely affect the holders of our other equity or debt securities.

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## DESCRIPTION OF DEBT SECURITIES

This prospectus describes certain general terms and provisions of the debt securities that we may offer under this prospectus and one or more prospectus supplements. When we offer to sell a particular series of debt securities, we will describe the specific terms of the series in a prospectus supplement. The following description of debt securities will apply to the debt securities offered by this prospectus unless we provide otherwise in the applicable prospectus supplement. The applicable prospectus supplement for a particular series of debt securities may specify different or additional terms.

We may issue senior, senior subordinated, or subordinated debt securities. Senior securities will be direct obligations of ours and will rank equally and ratably in right of payment with other indebtedness of ours that is not subordinated. Senior subordinated securities will be subordinated in right of payment to the prior payment in full of senior indebtedness, as defined in the applicable prospectus supplement, and may rank equally and ratably with any other senior subordinated indebtedness. Subordinated securities will be subordinated in right of payment to senior subordinated securities.

We need not issue all debt securities of one series at the same time. Unless we provide otherwise, we may reopen a series, without the consent of the holders of such series, for issuances of additional securities of that series.

We will issue the senior debt securities and senior subordinated debt securities under a senior indenture, which we will enter into with a trustee to be named in the senior indenture, and we will issue the subordinated debt securities under a subordinated indenture, which we will enter into with a trustee to be named in the subordinated indenture. We use the term indenture or indentures to refer to both the senior indenture and the subordinated indenture. Each indenture will be subject to and governed by the Trust Indenture Act of 1939, as amended, or the Trust Indenture Act, and we may supplement the indenture from time to time. Any trustee under any indenture may resign or be removed with respect to one or more series of debt securities, and we may appoint a successor trustee to act with respect to that series. We have filed a form of indenture as an exhibit to this registration statement, of which this prospectus forms a part. The terms of the senior indenture and subordinated indenture will be substantially similar, except that the subordinated indenture will include provisions pertaining to the subordination of the subordinated debt securities and senior subordinated debt securities to the senior debt securities and any other of our senior securities. The following statements relating to the debt securities and the indenture are summaries only, are subject to change, and are qualified in their entirety to the detailed provisions of the indenture, any supplemental indenture, and the discussion contained in any prospectus supplements.

### General

The debt securities will be our direct obligations. We may issue debt securities from time to time and in one or more series as our board of directors may establish by resolution or as we may establish in one or more supplemental indentures. The particular terms of each series of debt securities will be described in a prospectus supplement relating to the series. We may issue debt securities with terms different from those of debt securities that we previously issued.

We may issue debt securities from time to time and in one or more series with the same or various maturities, at par, at a premium, or at a discount. We will set forth in a prospectus supplement, relating to any series of debt securities being offered, the initial offering price, and the following terms of the debt securities:

- the title of the debt securities;
- the series designation and whether they are senior securities, senior subordinated securities, or subordinated securities;
- the aggregate principal amount of the debt securities and any limit on the aggregate amount of the series of debt securities;

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the price or prices (expressed as a percentage of the aggregate principal amount) at which we will issue the debt securities and, if other than the principal amount of the debt securities, the portion of the principal amount of the debt securities payable upon the maturity of the debt securities;

the date or dates on which we will pay the principal on the debt securities;

the rate or rates (which may be fixed or variable) per annum or the method used to determine the rate or rates (including any commodity, commodity index, stock exchange index, or financial index) at which the debt securities will bear interest, the date or dates from which interest will accrue, the date or dates on which interest will commence and be payable, and any regular record date for the interest payable on any interest payment date;

the place or places where principal, interest, and any additional amounts will be payable and where the debt securities can be surrendered for transfer, exchange, or conversion;

the terms, if any, by which holders of the debt securities may convert or exchange the debt securities for our common stock, preferred stock, or any other security or property;

if convertible, the initial conversion price, the conversion period, and any other terms governing such conversion;

any subordination provisions or limitations relating to the debt securities;

any sinking fund requirements;

any obligation we have to redeem, purchase or repay the debt securities pursuant to any sinking fund or analogous provisions or at the option of a holder of debt securities and the price or prices at which and the period and periods within which and the terms and conditions upon which debt securities of the series shall be redeemed, purchased, or repaid pursuant to such obligation;

the dates on which and the price or prices at which we will repurchase the debt securities at the option of the holders of debt securities and other detailed terms and provisions of these repurchase obligations;

the denominations in which the debt securities will be issued, if other than denominations of $1,000 and any integral multiple thereof;

the portion of principal amount of the debt securities payable upon declaration of acceleration of the maturity date, if other than the principal amount;

whether we will issue the debt securities in certificated or book-entry form;

the price or prices at which (if any), the period or periods within which (if any), and the terms and conditions upon which (if other than as provided herein) the debt securities may be redeemed, in whole or in part, at the option, or as an obligation, of the Company;

whether the debt securities shall be issued in whole or in part in the form of a global security or securities; the terms and conditions, if any, upon which such global security or securities may be exchanged in whole or in part for other individual debt securities, and the depositary for such global security and securities;

whether the debt securities will be in registered or bearer form and, if in registered form, the denominations if other than in even multiples of $1,000 and, if in bearer form, the denominations and terms and conditions relating thereto;

the currency of denomination of the debt securities;

the designation of the currency, currencies, or currency units in which payment of principal of, premium, and interest on the debt securities will be made;

if payments of principal of, and interest and any additional amounts on the debt securities will be made in one or more currencies or currency units other than that or those in which the debt securities are

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denominated, the manner in which the exchange rate with respect to these payments will be determined;

the manner in which the amounts of payment of principal of, and interest and any additional amounts on the debt securities will be determined, if these amounts may be determined by reference to an index based on a currency or currencies other than that in which the debt securities are denominated or designated to be payable or by reference to a commodity, commodity index, stock exchange index, or financial index;

any applicability of the defeasance provisions described in this prospectus or any prospectus supplement;

the trustee for the debt securities;

whether and under what circumstances, if any, we will pay additional amounts on any debt securities in respect of any tax, assessment, or governmental charge and, if so, whether we will have the option to redeem the debt securities instead of making this payment;

any addition to or change in the events of default described in this prospectus or in the indenture with respect to the debt securities and any change in the acceleration provisions described in this prospectus or in the indenture with respect to the debt securities;

any addition to or change in the covenants described in this prospectus or in the indenture with respect to the debt securities;

if the debt securities are to be issued upon the exercise of debt warrants, the time, manner, and place for them to be authenticated and delivered;

any securities exchange on which we will list the debt securities;

any restrictions on transfer, sale, or other assignment;

any provisions relating to any security provided for the debt securities;

any provisions relating to any guarantee of the debt securities;

any other terms of the debt securities, which may modify or delete any provision of the indenture as it applies to that series; and

any depositaries, interest rate calculation agents, exchange rate calculation agents, or other agents with respect to the debt securities.

We may issue debt securities that are exchangeable for or convertible into shares of our common stock or other securities or property. The terms, if any, on which the debt securities may be exchanged for or converted into shares of our common stock or other securities or property will be set forth in the applicable prospectus supplement. Such terms may include provisions for conversion, either mandatory, at the option of the holder or at our option, in which case the number of shares of common stock or other securities or property to be received by the holders of debt securities would be calculated as of a time and in the manner stated in the prospectus supplement.

We may issue debt securities at less than the principal amount payable upon maturity. We refer to these securities as original issue discount securities. If material or applicable, we will describe in the applicable prospectus supplement special U.S. federal income tax, accounting, and other considerations applicable to original issue discount securities.

If we denominate the purchase price of any of the debt securities in a foreign currency or currencies or a foreign currency unit or units, or if the principal of and interest and any additional amounts on any series of debt securities is payable in a foreign currency or currencies or a foreign currency unit or units, we will describe the restrictions, elections, general tax considerations, specific terms, and provide other information with respect to that issue of debt securities and such foreign currency or currencies or foreign currency unit or units in the applicable prospectus supplement.

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Except as may be set forth in any prospectus supplement relating to the debt securities, no indenture will contain any other provisions that would limit our ability to incur indebtedness or that would afford holders of the debt securities protection in the event of a highly leveraged or similar transaction involving us or in the event of a change in control. You should review carefully the applicable prospectus supplement for information with respect to events of default and any covenants applicable to the debt securities being offered.

**Payments and Paying Agents**

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of, and interest and any additional amounts on, the debt securities of a particular series at the office of the paying agents designated by us, except that, unless we otherwise indicate in the applicable prospectus supplement, we may make interest payments by check, which we will mail to the holder, or by wire transfer to certain holders. Unless we otherwise indicate in a prospectus supplement, we will designate the corporate trust office of the trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series.

**Form, Transfer, and Exchange**

Each debt security will be represented by either one or more global securities registered in the name of The Depository Trust Company, as depositary, or a nominee of the depositary (as a book-entry debt security ), or a certificate issued in definitive registered form (as a certificated debt security ), as described in the applicable prospectus supplement. Except as described under Global Debt Securities and Book-Entry System below, book-entry debt securities will not be issuable in certificated form.

*Certificated Debt Securities*

A holder of our debt securities may transfer or exchange certificated debt securities at the trustee s office or paying agencies in accordance with the terms of the indenture. No service charge will be made for any transfer or exchange of certificated debt securities, but we may require payment of a sum sufficient to cover any tax or other governmental charge payable in connection with a transfer or exchange.

A holder of our debt securities may transfer certificated debt securities and the right to receive the principal of, and interest and any additional amounts on, certificated debt securities only by surrendering the old certificate representing those certificated debt securities and either we or the trustee will reissue the old certificate to the new holder, or we or the trustee will issue a new certificate to the new holder.

*Global Debt Securities and Book-Entry System*

Each global debt security representing book-entry debt securities will be deposited with, or on behalf of, the depositary, and registered in the name of the depositary or a nominee of the depositary. Ownership of beneficial interests in book-entry debt securities will be limited to persons that have accounts with the depositary for the related global debt security, whom we refer to as participants, or persons that may hold interests through participants.

Except as described in this prospectus or any applicable prospectus supplement, beneficial owners of book-entry debt securities will not be entitled to have securities registered in their names, will not receive or be entitled to receive physical delivery of a certificate in definitive form representing securities, and will not be considered the owners or holders of those securities under the indenture. Accordingly, to exercise any rights of a holder under the indenture, each person beneficially owning book-entry debt securities must rely on the procedures of the depositary for the related global debt security and, if that person is not a participant, on the procedures of the participant through which that person owns its interest.

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We understand, however, that under existing industry practice, the depositary will authorize the persons on whose behalf it holds a global debt security to exercise certain rights of holders of debt securities, and the indenture provides that we, the trustee, and our respective agents will treat as the holder of a debt security the persons specified in a written statement of the depositary with respect to that global debt security for purposes of obtaining any consents or directions required to be given by holders of the debt securities pursuant to the indenture.

We will make payments of principal of, and interest and any additional amounts on, book-entry debt securities to the depositary or its nominee, as the case may be, as the registered holder of the related global debt security. We, the trustee, and any other agent of ours or agent of the trustee will not have any responsibility or liability for any aspect of the records relating to or payments made on account of beneficial ownership interests in a global debt security or for maintaining, supervising, or reviewing any records relating to such beneficial ownership interests.

Any certificated debt securities issued in exchange for a global debt security will be registered in such name or names as the depositary shall instruct the trustee. We expect that such instructions will be based upon directions received by the depositary from participants with respect to ownership of book-entry debt securities relating to such global debt security.

For additional discussion of book entry and certificated securities, see the section entitled Legal Ownership of Securities included in this prospectus. We have obtained the foregoing information in this section and the Legal Ownership of Securities section concerning the depositary and the depositary s book-entry system from sources we believe to be reliable. We take no responsibility for the depositary s performance of its obligations under the rules and regulations governing its operations.

**No Protection in the Event of a Change in Control**

Unless we provide otherwise in the applicable prospectus supplement, the debt securities will not contain any provisions that may afford holders of the debt securities protection in the event we have a change in control or in the event of a highly leveraged transaction (whether or not such transaction results in a change in control).

**Covenants**

Unless we provide otherwise in the applicable prospectus supplement, the debt securities will not contain any restrictive covenants, including covenants restricting us or any of our subsidiaries from incurring, issuing, assuming, or guaranteeing any indebtedness secured by a lien on any of our or our subsidiaries property or capital stock or restricting us or any of our subsidiaries from entering into any sale and leaseback transactions.

**Merger, Consolidation, and Sale of Assets**

Unless we provide otherwise in the applicable prospectus supplement, we may not merge with or into or consolidate with, or convey, transfer, or lease all or substantially all of our properties and assets to, any person (a successor person ), unless the following applies:

- either (a) the company is the surviving entity or (b) the successor person is a corporation, partnership, trust, or other entity organized and validly existing under the laws of any U.S. domestic jurisdiction and expressly assumes our obligations on the debt securities and under the indenture;
- immediately after giving effect to the transaction, no event of default, and no event that, after notice or lapse of time, or both, would become an event of default, will have occurred and be continuing under the indenture; and
- certain other conditions that may be set forth in the applicable prospectus supplement are met.

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This covenant would not apply to any recapitalization transaction, a change in control of us, or a transaction in which we incur a large amount of additional debt unless the transactions or change in control included a merger, consolidation, or transfer or lease of substantially all of our assets. Except as may be described in the applicable prospectus supplement, there are no covenants or other provisions in the indenture providing for a put right or increased interest or that would otherwise afford holders of debt securities additional protection in the event of a recapitalization transaction, a change in control of us, or a transaction in which we incur a large amount of additional debt.

**Events of Default Under the Indenture**

Unless we provide otherwise in the applicable prospectus supplement, an event of default will mean, with respect to any series of debt securities, any of the following:

- default in the payment of any interest upon any debt security of that series when it becomes due and payable and continuance of that default for a period of 30 days (unless the entire amount of such payment is deposited by us with the trustee or with a paying agent before the expiration of the 30-day period);

- default in the payment of principal of, and any other amounts due on, any debt security of that series when due and payable either at maturity, redemption, or otherwise;

- default in the deposit of any sinking fund payment, when and as due in respect of any debt security of that series;

- default in the performance or breach of any other covenant or warranty by us in the indenture (other than a covenant or warranty that has been included in the indenture solely for the benefit of a series of debt securities other than that series) or in the debt security, which default continues uncured for a period of 60 days after we receive written notice from the trustee or we and the trustee receive written notice from the holders of not less than a majority in principal amount of the outstanding debt securities of that series as provided in the indenture;

- we, pursuant to or within the meaning of any applicable bankruptcy law, commence a voluntary case, consent to the entry of an order for relief against us in an involuntary case, consent to the appointment of a custodian for all or substantially all of our property, make a general assignment for the benefit of our creditors, or admit in writing our inability generally to pay our debts as they become due; or, similarly, a court enters an order or decree under any applicable bankruptcy law that provides for relief against us in an involuntary case, appoints a custodian for all or substantially all of our properties, or orders our liquidation (and the order remains in effect for 60 days); and

- any other event of default provided with respect to debt securities of that series that is included in any supplemental indenture or is described in the applicable prospectus supplement accompanying this prospectus.

No event of default with respect to a particular series of debt securities (except as to certain events of bankruptcy, insolvency, or reorganization) necessarily will constitute an event of default with respect to any other series of debt securities. An event of default may also be an event of default under our bank credit agreements or other debt securities in existence from time to time and under certain guaranties by us of any subsidiary indebtedness. In addition, certain events of default or an acceleration under the indenture may also be an event of default under some of our other indebtedness outstanding from time to time.

Unless we provide otherwise in the applicable prospectus supplement, if an event of default with respect to debt securities of any series at the time outstanding occurs and is continuing (other than certain events of our bankruptcy, insolvency, or reorganization), then the trustee or the holders of not less than a majority in principal amount of the outstanding debt securities of that series may, by written notice to us (and to the trustee if given by the holders), declare to be due and payable immediately the principal (or, if the debt securities of that series are

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discount securities, that portion of the principal amount as may be specified in the terms of that series) of and accrued and unpaid interest, if any, of all debt securities of that series. In the case of an event of default resulting from certain events of bankruptcy, insolvency, or reorganization, the principal (or such specified amount) of and accrued and unpaid interest, if any, of all outstanding debt securities will become and be immediately due and payable without any declaration or other act by the trustee or any holder of outstanding debt securities.

At any time after an acceleration with respect to debt securities of a series has been made, but before a judgment or decree for payment of the money due has been obtained by the trustee, the holders of not less than a majority in principal amount of the outstanding debt securities of that series may cancel the acceleration and annul its consequences if the rescission would not conflict with any judgment or decree and if all existing events of default with respect to that series have been cured or waived except nonpayment of principal (or such lesser amount) or interest that has become due solely because of the acceleration.

The indenture also provides that the holders of not less than a majority in principal amount of the outstanding debt securities of any series may waive any past default with respect to that series and its consequences, except a default involving the following:

- our failure to pay the principal of, and interest and any additional amounts on, any debt security; or
- a covenant or provision contained in the indenture that cannot be modified or amended without the consent of the holders of each outstanding debt security affected by the default.

The trustee is generally required to give notice to the holders of debt securities of each affected series within 90 days of a default actually known to a responsible officer of the trustee unless the default has been cured or waived. The indenture provides that the trustee may withhold notice to the holders of debt securities of any series of any default or event of default (except in payment on any debt securities of that series) with respect to debt securities of that series if it in good faith determines that withholding notice is in the interest of the holders of those debt securities.

Unless we provide otherwise in the applicable prospectus supplement, the indenture will provide that the trustee will be under no obligation to exercise any of its rights or powers under the indenture at the request or discretion of any holder of any such outstanding debt securities unless the trustee receives indemnity satisfactory to it against any loss, liability, or expense. Subject to certain rights of the trustee, the holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method, and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee with respect to the debt securities of that series. The trustee may, however, refuse to follow any discretion that conflicts with the indenture or any law or which may be unduly prejudicial to the holders of the debt securities of the applicable series not joining in the discretion.

Unless we provide otherwise in the applicable prospectus supplement, no holder of any debt security of any series will have any right to institute any proceeding, judicial or otherwise, with respect to the indenture or for the appointment of a receiver or trustee, or for any remedy under the indenture, unless:

- that holder has previously given to the trustee written notice of a continuing event of default with respect to debt securities of that series; and
- the holders of at least 25% in principal amount of the outstanding debt securities of that series have made written request, and offered reasonable indemnity, to the trustee to institute such proceeding as trustee, and the trustee will not have received from the holders of a majority in principal amount of the outstanding debt securities of that series a direction inconsistent with that request and has failed to institute the proceeding within 60 days.

Notwithstanding the foregoing, except as provided in the subordination provisions, if any, the holder of any debt security will have an absolute and unconditional right to receive payment of the principal of, and any interest or additional amounts on, that debt security on or after the due dates expressed in that debt security and to institute suit for the enforcement of payment.

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The indenture requires us, within 120 days after the end of our fiscal year, to furnish to the trustee a certificate as to compliance with the indenture, or, in the event of noncompliance, specify the noncompliance and the nature and status of the noncompliance.

**Modification of Indenture and Waiver**

Except as specified below, modifications and amendments to the indenture require the approval of not less than a majority in principal amount of our outstanding debt securities.

*Changes Requiring the Unanimous Approval*

We and the trustee may not make any modification or amendment to the indenture without the consent of the holder of each affected debt security then outstanding if that amendment will have any of the following results:

reduce the rate of or extend the time for payment of interest, including default interest, on any debt security;

reduce the principal of or any additional amounts on or change the fixed maturity of any debt security or reduce the amount of, or postpone the date fixed for, the payment of any sinking fund or analogous obligation with respect to any series of debt securities;

reduce the principal amount of discount securities payable upon acceleration of maturity;

waive a default in the payment of the principal, i