AGILE THERAPEUTICS INC
Form 10-K
March 12, 2018

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the year ended December 31, 2017

OR

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

For the transition period from to

Commission File Number 001-36464

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**23-2936302**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

101 Poor Farm Road
Princeton, New Jersey 08540
(Address including zip code of principal executive offices)

(609) 683-1880
(Registrant's telephone number, including area code)

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

Title of each class	**Name of exchange on which registered:**
Common stock, par value $0.0001 per share	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (Do not check if smaller reporting company)	Smaller reporting company o
			Emerging growth company ý

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ý

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No ý

The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2017 was approximately $108.0 million.

As of March 9, 2018 there were 34,248,268 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2018 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the registrant's fiscal year ended December 31, 2017, are incorporated by reference in Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

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Agile Therapeutics, Inc.
Annual Report on Form 10-K
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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "designed," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Annual Report on Form 10-K and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned development, commercialization, and market uptake of Twirla® (AG200-15) and our other potential product candidates, the strength and breadth of our intellectual property, our ongoing and planned clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the legal and regulatory landscape impacting our business, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our development and validation of manufacturing capabilities, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 10-K, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Annual Report on Form 10-K. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Annual Report on Form 10-K, they may not be predictive of results or developments in future periods.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- our ability to adequately and timely respond to the deficiencies in the second Twirla complete response letter, or 2017 CRL, issued by the U.S. Food and Drug Administration, or FDA, on December 21, 2017;
- the potential that the FDA could require us to conduct additional studies to address the concerns raised in the 2017 CRL;
- our ability to resubmit the Twirla new drug application, or NDA, and obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- our available cash;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain additional funding;
- our ability along with our third-party manufacturer, Corium International, Inc., or Corium, to complete successfully the scale-up of the commercial manufacturing process for Twirla, including

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- the qualification and validation of equipment related to the expansion of Corium's manufacturing facility and to pass an FDA pre-approval inspection;
- the performance and financial condition of third-party manufacturers;
- the success and timing of our clinical trials;
- our ability to retain key employees;
- regulatory and legislative developments in the United States and foreign countries;
- our plans to develop and commercialize our product candidates;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any of our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the successful development of our sales and marketing capabilities;
- our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Annual Report on Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report on Form 10-K. You should also read carefully the factors described in the "Risk Factors" section of this Annual Report on Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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Item 1. Business

Overview

We are a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Twirla and our other current potential product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla®, also known as AG200-15, is a once-weekly prescription combination hormonal contraceptive patch that is at the end of Phase 3 clinical development. We completed the third of three Phase 3 clinical trials for Twirla in December 2016 and resubmitted our new drug application, or NDA, which was received by the U.S. Food and Drug Administration, or FDA, on June 26, 2017 and acknowledged as a complete response for FDA review on July 27, 2017. In connection with the NDA resubmission, we were assigned Prescription Drug User Fee Act, or PDUFA, goal date of December 26, 2017 by the FDA. On December 21, 2017, the FDA issued a complete response letter, or CRL, in response to the NDA resubmission for Twirla, which stated that the FDA could not approve our NDA in its present form due to deficiencies related to the manufacturing process and facility for Twirla, and due to questions it had on the in vivo adhesion properties of Twirla and their potential relationship to our phase 3 clinical trial results. Under the FDA's regulations, we are entitled to request a Type A meeting with the FDA within 90 days of receiving a CRL, and the FDA has a goal to grant us a meeting date within 30 days of the meeting request. We have submitted a request for a Type A meeting to the FDA to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla. We plan to provide an update on the outcome of the Type A meeting after we receive the official meeting minutes from the FDA and we will then be better able to determine when we will resubmit our Twirla NDA. Our short-term goal is to establish a market-leading franchise in the U.S. hormonal contraceptive market, which had total market sales of approximately $5.7 billion in 2017. Over half of those sales were generated by branded products. Currently, there is only one other contraceptive patch available in the United States and we believe it has limitations due to its dose and physical characteristics. Twirla is designed to address these limitations. We have developed a proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over the currently available patch and is intended to optimize patch adhesion and patient wearability. We believe there is an unmet market need for a low-dose contraceptive patch that is designed to address the limitations of the existing patch, while increasing patient convenience and compliance in a non-invasive fashion.

Twirla is a combined hormonal contraceptive, or CHC, patch that contains the active ingredients ethinyl estradiol, or EE, which is a synthetic estrogen, and levonorgestrel, or LNG, which is a type of progestin, a synthetic steroid hormone, both of which have an established history of efficacy and safety in currently marketed combination low-dose, oral contraceptives. Twirla is designed using our proprietary Skinfusion technology to deliver both hormones over a seven-day period at levels comparable to currently marketed low-dose oral contraceptives. By delivering these active ingredients over seven days, in a comfortable, convenient and easy-to-use weekly patch, Twirla is designed to promote ease of use and enhanced patient compliance. The patch is applied once weekly for three weeks, followed by a week without a patch. If approved, Twirla will be packaged with three individually-wrapped patches per carton to provide for one 28-day cycle of therapy.

We have conducted a comprehensive clinical program, with completed Phase 1, Phase 2, and Phase 3 trials enrolling over 4,100 women, over 3,500 of whom received Twirla. Most recently, in December 2016, we completed a Phase 3 trial, the SECURE clinical trial, in which we enrolled over 2,000 women for up to one year of treatment. In the Phase 1 and Phase 2 clinical trials, we demonstrated that Twirla delivers levels of both EE and LNG to the blood stream that are consistent with those delivered by current low-dose oral contraceptives. Prior to the SECURE clinical trial, we completed two Phase 3 clinical trials that enrolled over 1,900 women in the aggregate for up to 12 months, and we demonstrated that Twirla generally had comparable efficacy and tolerability to an

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approved low-dose oral contraceptive. In the SECURE clinical trial, we observed positive evidence of efficacy for Twirla based on use for up to one year. In our completed Phase 3 trials to date, over 1,000 women have received Twirla for 12 months. Across all completed clinical trials, Twirla was generally well tolerated and had a favorable safety profile.

In April 2012, we filed a Section 505(b)(2) NDA, for approval of Twirla by the FDA, which is required before marketing a new drug in the United States. Our 505(b)(2) NDA relies in part on clinical trials that we conducted and in part on the FDA's findings of safety and efficacy from investigations for approved products containing the active ingredients and published scientific literature for which we have not obtained a right of reference. In connection with this original submission of our NDA, the FDA indicated in a CRL, issued in February 2013, or the 2013 CRL, that our NDA was not sufficient for approval as originally submitted. After multiple communications with the FDA, we received significant guidance as to what additional clinical development and other activities needed to be completed prior to approval. In accordance with the FDA's advice and comments, we conducted an additional Phase 3 clinical trial, the SECURE clinical trial, which was initiated in 2014 and completed in December 2016. We announced the top-line results for the SECURE trial in January 2017. Based on the guidance that we received from the FDA in connection with our discussions on clinical trial design, we believed that the results from the SECURE clinical trial would address all of the clinical issues raised in the 2013 CRL. In June 2017, we resubmitted our Twirla NDA, which was accepted for review and assigned a PDUFA goal date of December 26, 2017. On December 21, 2017, the FDA issued a second CRL, or the 2017 CRL, indicating that our resubmitted NDA could not be approved in its present form. The 2017 CRL identifies deficiencies relating to quality control adhesion test methods which are part of the manufacturing process for Twirla. The 2017 CRL also noted that observations identified during a pre-approval inspection, or PAI, of a facility of our third-party manufacturer, Corium International Inc., or Corium, for the Twirla NDA must be resolved. Lastly, the 2017 CRL questions the *in vivo* adhesion properties of Twirla and their potential relationship to the SECURE phase 3 clinical trial results. The 2017 CRL contains recommendations for developing manufacturing in-process tests for ensuring the quality and *in vivo* adhesion of the commercial scale product as well as the finished drug specifications and release test method for adhesion. The 2017 CRL also recommends that we assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial. Finally, the 2017 CRL recommends that we address the implications of clinical trial subject patch compliance and the withdrawal and dropout rates. The 2017 CRL does not identify any specific issues relating to the safety of Twirla. Prior to receiving the 2017 CRL, we submitted an amendment to our NDA on December 1, 2017 in response to an information request from the FDA on the issues related to the quality control adhesion test methods cited in the 2017 CRL. In the 2017 CRL, the FDA acknowledged receipt of the amendment and stated that the amendment was not reviewed prior to the FDA's action. In addition, on November 20, 2017 and December 1, 2017, Corium provided the FDA with responses to each of the observations made during the FDA's facility inspection, which included a PAI for Twirla. We believe that the Corium submissions along with our December 1, 2017 NDA amendment and the information we intend to provide to the FDA in advance of our Type A meeting will provide a basis for addressing the 2017 CRL. Under the FDA's regulations, we are entitled to request a Type A meeting with the FDA within 90 days of receiving a CRL, and the FDA has a goal to grant us a meeting date within 30 days of the meeting request. We have submitted a request for a Type A meeting to the FDA to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla. We plan to provide an update on the outcome of the Type A meeting after we receive the official meeting minutes from the FDA and we will then be better able to determine when we will resubmit our Twirla NDA.

Consistent with our previous NDA resubmission in 2017, we currently expect that our resubmission of the NDA responding to the 2017 CRL will be categorized as a Type 2 resubmission and receive a review period of six months from the date of resubmission of the NDA.

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In January 2018, following our receipt of the 2017 CRL, we significantly scaled back our preparations for commercialization of Twirla, including commercial pre-launch and manufacturing validation activities, pending our ability to address the 2017 CRL and receive approval of Twirla. However, if Twirla is approved, we intend to commercialize Twirla in the United States through a direct sales force. Obstetricians and gynecologists, or ObGyns, contribute 51% of the U.S. CHC prescription volume, and Nurse Practitioners and Physician Assistants, or NP/PAs, who are often affiliated with an ObGyn practice, contribute an additional 27% of the U.S. prescriptions. We anticipate that a targeted sales force focused initially on ObGyns, NPs, PAs and primary care providers who comprise the top prescribers of contraceptives will be highly effective. We believe that we can address this market with a specialty sales force of approximately 70 to 100 representatives. We also intend to augment our sales force through digital marketing and other techniques to market directly to patients. We will require additional capital to fully implement our commercialization plan for Twirla, if approved.

Our Skinfusion technology makes Twirla the first patch capable of delivering a contraceptive dose of LNG across the skin, allowing weekly application using a patch that is soft and flexible and is designed to adhere well with low levels of skin irritation. We, along with Corium, our manufacturing partner, have made a significant investment in a proprietary process to manufacture Twirla. We believe we have developed a robust process to reliably manufacture Twirla on a commercial scale. The materials produced for our clinical trials were manufactured using the same process that we expect will be used for our commercial-scale manufacturing, and we have made a significant investment in equipment for commercial-scale manufacturing if Twirla is approved. Along with Corium, we are enhancing our quality-control test methods in a way that we believe will address the issues identified by the FDA in both the 2017 CRL and the Corium facility inspection and that will allow us to continue to use our current commercial manufacturing process for Twirla. We believe that the technical challenges and know-how involved in manufacturing, including proprietary chemistry, production to scale and use of custom equipment and reproducibility, present significant barriers to entry for other pharmaceutical companies who might potentially want to replicate our Skinfusion technology.

Our intellectual property represents an additional barrier to potential competitors. We have thirteen issued U.S. patents, eight of which cover Twirla and that we intend to list in the Orange Book, the first of which expires in 2021 and the last of which expires in 2028, and five that provide additional coverage for other potential product candidates in our pipeline. The Orange Book lists drug products, including related patent and exclusivity information, approved by the FDA under the Federal Food, Drug, and Cosmetic Act. If a patent is listed in the Orange Book, potential competitors seeking approval of drug products under an Abbreviated New Drug Application, which provides for the marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, of a previously approved product, or a 505(b)(2) application, for which the listed drug is a reference product, must provide a patent certification in their application stating either that (1) no patent information on the drug product has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. In addition, we continue to prosecute additional patent applications relating to Twirla, as well as our other potential product candidates, both in the United States and internationally. The intellectual property behind all of our potential product candidates in the pipeline and our Skinfusion technology consists of patent families developed and wholly-owned by us. There are no royalties or payments owed to third parties on our Skinfusion technology or any of our product candidates.

In addition to Twirla, we plan to develop a pipeline of other new transdermal contraceptive products, including AG200-ER, which is a regimen designed to allow a woman to extend the length of her cycle, AG200-SP, which is a regimen designed to provide shorter lighter periods, AG200-ER (SmP), which is a regimen designed to allow a woman to extend the length of her cycle and experience shorter,

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lighter periods, and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We will require additional capital to advance the development of our other potential product candidates.

Background

Hormonal Contraception Overview

A woman is biologically capable of pregnancy from the time of her first menstrual cycle, at the average age of 12.6 years, to natural menopause, at the average age of 51.3 years. This is nearly half of a typical woman's lifespan and, for the typical woman, the majority of this time frame is spent trying to avoid pregnancy or is characterized by no desire to become pregnant. Nearly half of the pregnancies that occur each year in the United States are unplanned. The United States was the first country to approve a hormonal contraceptive, with the approval of the first contraceptive pill in 1960. The latest data from 2011 to 2013 from the Centers for Disease Control, or CDC, indicate that approximately 28% of women aged 15 to 44 use some form of hormonal contraception, which amounts to approximately 17 million U.S. women.

Hormonal contraceptives can be composed of synthetic estrogens and progestins. Contraceptives containing both estrogen and a progestin are referred to as CHCs, and contraceptives containing only progestin are referred to as P-only. There are three synthetic estrogens approved in the United States for use in contraceptive products: EE, mestranol, and estradiol valerate. EE has been available for over 40 years and is the estrogen component in nearly all CHCs today. There are 10 different progestins that have been used in contraceptives sold in the United States. The progestin component provides most of the contraceptive effect, while the estrogen component primarily provides cycle control, for example, minimizing bleeding or spotting between cycles. The progestin exerts its contraceptive effect by inhibiting ovulation, or release of an egg from the ovary, and by thickening cervical mucus. Thickening cervical mucus helps to prevent sperm entry into the upper genital tract. The estrogen component, in addition to providing cycle control, makes a small contribution to contraception by decreasing the maturation of the egg in the ovary.

Hormonal contraceptives are generally well-tolerated and are generally safer than pregnancy. A risk associated with hormonal contraceptives is a rare but serious adverse event called venous thromboembolism, or VTE, which involves the formation of a blood clot in a vein. VTEs can be life-threatening, and typically present as either deep vein thrombosis or pulmonary embolism. Evidence supports that the increased risk of VTE in CHC users is related to the estrogen dose and duration of use, with higher doses of estrogen being associated with a potentially increased risk of VTE. Estrogen increases formation of clotting factors in the liver and decreases production of elements that promote breakdown of blood clots. Most experts believe that progestins on their own have minimal to no impact on the clotting system, but some progestins, when combined with estrogen, can increase estrogen's effect on the clotting system.

The likelihood of a woman spontaneously developing a VTE is extremely low and the use of combination oral contraceptives, or COCs, increases the incidence only slightly, and less than

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pregnancy. Epidemiologic studies evaluated by the FDA have demonstrated the incidence of VTE in women based on pregnancy or use of COCs as follows:

Incidence of VTE Based on Pregnancy Status or use of COCs

Population	VTE incidence (cases per 10,000 woman years*)
Non-pregnant woman who does not use a COC	1 to 5
COC users	3 to 12
Pregnant women	5 to 20
Postpartum women (in the 12 weeks following delivery)	40 to 65

*
One woman year is one woman using a contraceptive for one year, which is either 12 months or 13 cycles

The available progestins are commonly categorized into generations, based on their history of introduction in the United States. The first and second generation progestins, including LNG, have been available in contraceptive formulations in the United States for over 25 years. The third and fourth generation progestins, for example desogestrel and drospirenone, respectively, were introduced to reduce androgenic side effects, such as oily skin and acne. Epidemiologic data suggest that CHCs containing third and fourth generation progestins are associated with an increased risk of VTE as compared to those containing the second generation progestin, LNG.

Effectiveness of Hormonal Contraceptives

For the purpose of FDA approval, contraceptive effectiveness is measured by a calculation called the Pearl Index, or PI, and its associated 95% confidence interval, or CI. The PI is a measure of the rate of pregnancies over a specific period of time in a clinical trial and is expressed as the number of pregnancies per 100 woman years, or WY, of use. Each cycle lasts 28 days, so there are approximately 13 cycles in one year. The PI calculation typically includes all pregnancies for which conception is estimated to have occurred while the subject was using the drug (i.e., on-treatment pregnancies), but only includes cycles where the woman did not use backup contraception, such as a condom. The PI values from clinical trials are affected by several factors, including differences in study design, increased sensitivity of early pregnancy tests, weight and body mass index, or BMI, of the study population, user experience and inconsistent or incorrect use of the contraceptive method. In addition, there has been an observable trend in PIs for approved CHCs demonstrating an increase in the PIs over time, believed to be related to changes in study design and study populations. The FDA has not established any regulatory guidance on specific parameters for an acceptable PI or CI to support approval.

The contraceptive failure rates observed in clinical trials are generally lower than those seen once a CHC is approved and in use by a broad population, referred to as typical use, without the close monitoring of a clinical trial setting. There is a large difference in pregnancy rates under conditions of perfect use, where the method is used following the directions exactly, and typical use. For example, for CHCs, including oral contraceptives, the vaginal ring and the transdermal patch, the percent of women experiencing an unintended pregnancy during the first year of use is 0.3% for perfect use and 9.0% for typical use.

U.S. Hormonal Contraceptive Market Background

Contraceptive methods, other than sterilization, can be divided into non-hormonal and hormonal alternatives. Examples of non-hormonal products available in the United States include the diaphragm,

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male condom, female condom, and non-hormonal intrauterine device, or IUD. There are several categories of hormonal contraception products available in the United States, including:

- oral contraceptive;
- vaginal ring;
- transdermal patch;
- hormonal IUD;
- subcutaneous implant; and
- injectable.

The U.S. hormonal contraceptive market recorded annual sales in 2017 of approximately $5.7 billion, according to IMS Health. The CHC portion of the market, consisting of pills, a transdermal patch and a vaginal ring, generates significantly greater prescription volume and sales compared to the P-only portion of the market, consisting of IUDs, injectables, implants, and P-only pills. In 2017, IMS Health reported total U.S. sales of $3.9 billion for the CHC market and $1.8 billion for the P-only market. Twirla is a CHC and, if approved, we believe it will compete primarily with products in the CHC market.

The U.S. hormonal contraceptive market is a mature market, with many branded and generic products available. In the past 10 years, the market growth was flat to declining as measured by prescription volume, with the exception of a 4.8% increase in 2013 compared to 2012. Compared to 2016, prescriptions for hormonal contraceptives decreased by 3.7% in 2017. The average annual growth rate in dollar sales for the five years ended December 31, 2017 was 1.4% for the total hormonal contraceptive market and 0.6% for the CHC market. Market growth in gross sales is primarily due to price increases amongst branded products.

We believe there are two possible factors primarily affecting prescription volume in the contraceptive market. First, according to U.S. Census Bureau data and projections, the population of women aged 15 to 44 years has been growing at a rate of approximately 0.4% to 0.5% per year since 2011, increasing this population by 250,000 to 300,000 women per year.

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Contraceptive Population
(Total women aged 15-44 yrs)

Source: U.S. Census Bureau, National projections released 2008 based on 2000 census data.

Second, in 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or collectively, the ACA, was signed into law, which, among other things, requires all health plans, with limited exceptions, to cover certain preventive services for women with no cost-sharing, which means no deductible, no co-insurance and no co-payments by the patient, effective August 1, 2012. These services include those set forth in the Guidelines for Women's Preventive Services, or HRSA Guidelines, and adopted by the U.S. Department of Health and Human Services Health Resources and Services Administration. Contraceptive methods and counseling, including all FDA approved contraceptive methods as prescribed, are included in the HRSA Guidelines. Since these new ACA provisions went into effect in August 2012, quarterly prescription volume growth for the CHC market rose from negative growth year-on-year to positive growth between 4.0% and 5.0% for each of the six quarters following implementation. However, this appears to be a one-time phenomenon, as the market volume has declined on average 0.4% annually from 2014 to 2017.

During the period following enactment of the ACA, generic oral contraceptives have shown the greatest growth, primarily at the expense of branded oral contraceptives. This is likely due to the policies that were implemented by many managed care plans, which generally only provided generic oral contraceptives with no cost-sharing to the patient. The effect on non-oral products is less clear, but prescription volume for the vaginal ring showed a 10.0% decline from 2013 to 2017, while the prescription volume for the patch increased by 30.0% over the same time period. In May 2015, several government agencies, such as the U.S. Department of Health and Human Services, or HHS, the Department of Labor, or DOL, and the U.S. Department of Treasury, or Treasury, issued a clarification in the form of an FAQ which clarified the requirements for coverage of contraceptives under the ACA. The FAQ states that plans and issuers must cover without cost-sharing at least one form of contraception in each of the 18 current methods that the FDA has identified for women in its current

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Birth Control Guide. The patch is identified as a specific method in the FDA Birth Control Guide, and therefore insurers must cover at least one patch product with no cost-sharing to the patient. Because this clarifying guidance is applied for plan years (or in the individual market, policy years) beginning on or after 60 days from the date of publication of the FAQs, patients did not have the benefit of this clarification until their new plan year, which generally started in January 2016.

On January 20, 2017, the administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, among others. Congress also could consider subsequent legislation to repeal and replace elements of the ACA that are repealed. Additionally, in October 2017, the Department of Health and Human Services, jointly with the Department of Labor and the Treasury, issued two interim rules outlining exemption processes for employers not wanting to offer contraceptive coverage based on their religious beliefs or sincerely held moral convictions. While there is an injunction against the administration prohibiting it from implementing these rules, the ultimate outcome of that litigation cannot be predicted. Therefore, it is difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business. We will continue to monitor the healthcare reform efforts and agency implementation. We believe the CHC market will maintain a long-term neutral annual growth rate.

In spite of the availability of generic contraceptives for over 25 years, branded products have maintained a significant, though declining, share of the CHC market, with 50% of dollar sales and 15% of prescriptions for 2017. Branded contraceptives in the CHC market have driven significant increases in the value of branded total prescriptions, or TRx. In the five years ended December 2017, the average annual price increase among the top branded products was 11.8%. The average price per cycle, referred to as the wholesale acquisition cost, or WAC, for a single 28-day cycle of the top branded products was $41.53 in 2006 and rose to $141.17 by December 2017. As of October 2014, the branded CHC transdermal patch (Ortho Evra) has been discontinued, and the generic CHC transdermal patch (Xulane) is currently priced at $115.45 per cycle. The other non-oral form of CHC, the vaginal ring, is currently priced at $140.93 per cycle. We cannot predict whether the manufacturers of branded products will continue to increase prices going forward, but we believe we will be able to set a WAC price for Twirla, if approved, that is comparable to other branded CHC products at the time of launch. Based on IMS Health data, we estimate that each percentage point of market share of CHC total prescriptions in the United States currently represents approximately $169 million of annual gross sales potential for Twirla, if approved.

Contraceptive Pills

Based on 2014 data from the CDC, of women who choose to use a hormonal contraceptive, approximately 64% use the contraceptive pill, vaginal ring or patch, the majority of which use the contraceptive pill. The remaining 36% of women using hormonal contraception are split between using injectables, implants, or IUDs. Based on this information, we believe that contraceptive pills are the most popular choice because:

- patients and physicians are familiar with pills;
- pills were the first to market and have been aggressively promoted for a long period of time;
- historically, pills have been a covered benefit with good reimbursement in private and public healthcare plans; and
- pills are a non-invasive option.

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However, compliance remains a significant draw-back with pills. Published studies have shown that the average woman who uses oral contraceptives misses approximately two to four pills per month, which increases the potential for unintended pregnancies. We believe that a patch can offer greater convenience than a pill, as it does not require daily administration and, for certain women, could lead to greater compliance and ease of use.

Contraceptive Patch Market Experience

The Ortho Evra® contraceptive patch, or Evra, was introduced in early 2002 and was the first FDA-approved contraceptive patch. The initial approved labeling for Evra indicated that it delivered a daily EE dose of 20 micrograms. Evra had rapid uptake in the contraceptive market and achieved a 10% share of the CHC market by September 2003. Following FDA approval of Evra, users of Evra began to report thrombotic and thromboembolic events to the FDA. Johnson & Johnson, the manufacturer of Evra, revised the Evra labeling in November 2005 to include information that EE exposure with Evra is 60% higher than that of an oral contraceptive containing EE of 35 micrograms, based on area under the curve, a commonly-used metric for measuring EE exposure in contraceptives. This information was ultimately included in a boxed warning and bolded warnings unique to the Evra label. The Evra market share declined rapidly following the labeling changes, from a peak share of 11% in 2005, to 4% by the end of 2006, to 1.4% by the end of 2013, where it stabilized, with a 1.5% share of the market based on combined prescriptions for Evra and its generic equivalent in 2014. In the past two years, the patch share of the CHC market grew slightly, with a 1.7% TRx share in 2016 and 1.8% TRx share in 2017.

In April 2014, Mylan Inc. announced the launch of Xulane®, a generic version of Evra. Generic pharmaceutical products are the chemical and pharmaceutical equivalents of the brand or a reference listed drug, or RLD. Generic drugs are bioequivalent to their reference brand name counterparts. Bioequivalence studies compare the bioavailability of the proposed drug product with that of the RLD product containing the same active ingredients. Bioavailability is a measure of the rate and extent to which the active ingredient is absorbed from a drug product and becomes available at the site of action. Under pharmacy dispensing rules governed by state law, depending on the state, if an automatic generic substitute is introduced, the pharmacist may dispense either the prescribed product, or they may replace it with an equivalent generic without being required to inform the patient or healthcare professional. In addition, the FDA offers a 180-day exclusivity period for generic products in specific cases. The first generic applicants to submit a substantially complete Abbreviated New Drug Application containing a paragraph IV certification to a listed patent are protected from competition from other generic versions of the same drug for the 180 days. As of December 2017, no other generic equivalents to Evra have been introduced.

The FDA has maintained, in spite of the wording in the labeling for Evra and its approved generic, that none of the epidemiologic studies to date provides a definitive answer regarding the relative risk of VTE with Evra compared to combined oral contraceptive use or whether the increased risk that some studies demonstrated is directly attributable to Evra. An advisory committee for the FDA stated that the benefits of Evra outweigh the risks. In its denial of a Citizen's Petition calling for the withdrawal of Evra, the FDA followed the committee's recommendations stating that the increased VTE risk does not warrant removal from the market, and that the labeling revisions to the Evra label provide a sufficient update and guidance on the interpretation of the epidemiologic data about the risk of VTE with Evra. In spite of the labeling changes, and Johnson & Johnson ceasing promotion of Evra in 2007, Evra and its generic equivalent generated $234 million in gross sales in 2017.

We believe that the rapid uptake and acceptance of Evra upon its introduction and its continued sales over the past several years demonstrate that there is an unmet market need for a transdermal patch as a contraceptive option. Also, the epidemiologic data on VTE risk suggest that there is a need for a contraceptive patch that delivers both a low dose of EE similar to oral contraceptives and a first or second generation progestin.

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Our Product Candidates

Twirla and each of our other potential product candidates utilizes our proprietary Skinfusion technology, which is designed to provide advantages over the currently available patch. Skinfusion is designed to deliver contraceptive levels of hormones to the blood stream through the skin over a seven-day period. It is also designed to optimize patch adhesion and patient wearability. Our lead product candidate is Twirla, a prescription CHC patch which contains both EE and LNG and is designed to deliver a low dose of EE and LNG comparable to the total dose delivered with low-dose oral contraceptives. In addition to Twirla, we plan to develop a pipeline of other new transdermal contraceptive products, including AG200-SP, which is a regimen designed to provide shorter, lighter periods; AG200-ER, which is a regimen designed to allow a woman to extend the length of her cycle; AG200-ER (SmP), which is a regimen designed to allow a woman to extend the length of her cycle and experience shorter, lighter periods; and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen. AG200-SP, AG200-ER, and AG200-ER (SmP) are intended to be Twirla line extensions that would expand the use of Twirla beyond its initial, approved use. In July 2016, we began preparations for an initial Phase 2 clinical trial examining the use of AG200-SP along with a smaller lower-dose combination ethinyl estradiol/levonorgestrel patch (SmP) in the fourth week of the woman's cycle. The Phase 2 clinical trial is aimed at identifying the optimal dose of the SmP, and will evaluate bleeding profiles, pharmacokinetic parameters, ovulation inhibition and safety over three cycles of treatment with AG200-SP (SmP). We have decided to postpone the trial and will continue to evaluate the timing for initiating dosing of subjects for this Phase 2 clinical trial, which is dependent on financial and other capital resources.

The National Institutes of Health, through a clinical trial agreement with us, conducted a Phase 1/2 trial with AG890. The Phase 1/2 study was a multicenter study to evaluate the pharmacokinetics, safety and mechanisms of potential contraceptive efficacy of AG890. The trial is complete and we continue to evaluate the findings. After we complete our evaluation, we may need to perform additional patch development work to determine the optimal formulation and dose to advance to Phase 3. Based upon a number of factors, including, but not limited to, our available capital resources and feedback from the FDA, we continue to review the clinical path and budgetary requirements for each of AG200-SP, AG200-ER and AG890.

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Our current potential product candidate pipeline is summarized in the graphic below:

Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We will require additional capital to advance the development of our other potential product candidates.

Twirla Product Overview

Twirla is a CHC patch which contains both EE and LNG. Twirla is designed to address an unmet medical need for increased compliance and improved ease of use as compared to oral contraceptives. A single Twirla patch delivers the active ingredients LNG and EE over a seven-day dosing interval, and thereby eliminates the need to take a daily pill as is necessary with an oral contraceptive. Twirla uses a traditional 28-day contraceptive regimen, where one patch is applied weekly for three consecutive weeks and then there is a fourth, patch-free week in each 28-day time period. Twirla may be applied to the buttock, abdomen or upper torso, but not the breast. In clinical trials reported to date, women most frequently chose the buttock and abdomen for patch placement. The exact patch location needs to be rotated with each patch change. Twirla has demonstrated a therapeutically equivalent pharmacokinetic profile when worn on the buttock, abdomen or upper torso. A drug's pharmacokinetic profile refers to the specific way in which a given drug is handled by the body over time, reflecting the particular patterns of absorption, distribution and elimination of the drug in the body.

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Twirla is designed to be highly appealing to patients as a method of contraception. The patch is round and made of a soft, flexible fabric, designed to flex with the movement of a woman's body. Twirla is a matrix patch consisting of several layers of material that contain the active ingredients EE and LNG, as well as the inactive ingredients Dimethylsulfoxide, Ethyl Lactate, Capric Acid and Lauryl Lactate, which are ingredients to assist in the transport of EE and LNG across the skin, and adhesives that enable adherence to the skin. The final top layer is the one seen on the skin, and consists of a thin, cloth-like material consisting of only adhesive. There is a barrier formed between the inner portion of the patch, which contains the active ingredients, and the outer portion of the patch, which only contains the adhesive. This barrier is intended to prevent the active and inactive ingredients from migrating to the peripheral portion of the patch, and from breaking down the adhesive in that portion of the patch. Twirla is also designed to help prevent seepage of the adhesives from around the edge of the patch where it could collect dirt and leave a sticky black ring on the skin. The six layers of the patch are integrated to create a patch which has a slim profile and is unobtrusive when applied. The results of multiple clinical trials suggest that Twirla delivers the active ingredients needed for contraception over a seven-day period and that it remains adhered to the skin of most subjects for the full seven-day period, even under conditions of heat, humidity, showering, exposure to water and vigorous exercise.

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Twirla Patch Profile

The following table compares Twirla with the Evra product and its generic equivalent, Xulane, as stated in their labels, based upon publicly-available information regarding the products and the

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characteristics of Twirla and other Twirla attributes observed in our completed Phase 3 clinical trials. We have not performed a head-to-head comparison of Twirla to Evra.

Characteristic	Twirla	Ortho Evra*/Xulane
Form of product	Transdermal patch Round, approximately 28 square centimeters Soft, cloth-like, stretchy fabric	Transdermal patch Square, Evra approximately 20 square centimeters; Xulane approximately 14 square centimeters Smooth, plastic film
Active ingredients	EE, LNG	EE, norelgestromin
Pharmacokinetic profile of EE per day	~30 micrograms	60% higher than that of an oral contraceptive containing 35 micrograms (~56 micrograms)**
Regimen	One patch weekly 21 days active / 7 days patch-free	Same as Twirla;
Package configurations	1 box of 3 patches for each cycle	Evra has 1 box of 3 patches per cycle and 1 box containing a single replacement patch; Xulane is packaged like Twirla
Top four potentially hormone-related adverse events/reactions	Nausea 3.0% Headache 3.6% Cervical dysplasia 3.1% Dysmenorrhoea 2.1%***	Breast symptoms 22.4% Headache 21.0% Application site disorders 17.1% Nausea 16.6%

*
Source of Ortho Evra and Xulane data are U.S. prescribing information or package inserts.

**
The Ortho Evra and Xulane package inserts indicate a strength of 35 micrograms of EE per day.

***
Most common treatment emergent adverse events related to Twirla in three Phase 3 clinical trials.

Twirla employs our Skinfusion patch technology, resulting in a unique appearance and feel of the patch. Evra/Xulane does not utilize our Skinfusion technology; its active ingredients and adhesives are dispersed to its edges. One frequent complaint about patches that do not utilize Skinfusion is that they collect dirt and lint and may leave a sticky black ring of residue on the skin which can be difficult to remove. We do not have any direct comparison of the appearance of the patch on the skin at the end of seven days between Twirla and Evra/Xulane, but we believe, based on anecdotal feedback from our clinical trial investigators, as well as on the differences in the design of the patches, that Twirla may have an advantage in this regard.

We have not performed a head-to-head comparison of Twirla to Evra/Xulane, however, a pharmacokinetic study that we conducted with Twirla was similar in design to the pharmacokinetic study conducted with Evra that provided the information regarding the daily amount of EE delivered that is currently in the Evra/Xulane package insert. The figure below combines the results for average EE concentrations from these two studies and suggests a comparison of the observed blood concentration of EE for Twirla versus Evra versus observed and estimated data for the pill. The lower amount of EE delivered from Twirla as compared to Evra can be observed. If Twirla is approved by the FDA, we will not be able to make direct comparative claims regarding the safety, efficacy or pharmacokinetics of Twirla and Evra/Xulane, since none of our completed clinical trials studied Twirla in a head-to-head comparison with Evra/Xulane.

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EE Concentrations (pg/ml)

The Evra curve presented in the graphic above was estimated based on the graph provided in the Evra label. In the legend to the figure above, "OC" refers to an oral contraceptive containing 35 micrograms of EE. The OC data prior to Day 21 are estimated steady-state data based on Day 21 EE concentrations observed during our pharmacokinetic study.

Twirla contains LNG, which is the progestin used as the reference standard when comparing risk of VTE between progestins. Evra/Xulane contains the progestin norelgestromin, which is a prodrug of norgestimate, a second generation progestin that has not demonstrated an increased risk of VTE independent of EE. We do not expect any meaningful clinical differences between Twirla and Evra/Xulane based on the progestin component, but our market research with ObGyns has demonstrated that they perceive LNG to be one of the safest progestins available.

Twirla Product Profile

Assuming approval of our marketing application by the FDA based on the results of the SECURE trial, we believe a number of factors, including clinical trial data from SECURE, support our future marketing of Twirla:

- Twirla is a once-weekly contraceptive patch, designed to offer convenience and compliance.
- Twirla is designed to meet the contraceptive needs and the busy lifestyles of today's women.
- Twirla contains the active ingredients EE and LNG, both of which have been used in contraceptives for over 25 years.
- Twirla delivers the low daily dose of EE of approximately 30 micrograms, comparable to low-dose oral contraceptives.
- Twirla is designed to demonstrate efficacy comparable to other approved prescription contraceptives.

Twirla has a favorable safety and tolerability profile.

Twirla was designed with Skinfusion technology, which has demonstrated adhesion over the seven-day wear period, even under conditions of heat, humidity, showering, exposure to water and vigorous exercise.

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Because Twirla contains the progestin LNG, we believe that the final approved label for Twirla will be consistent with the class labeling for other contraceptives containing EE and LNG, including the class boxed warning.

Based on the results of the SECURE clinical trial, we believe it is possible the final approved label for Twirla may contain language on the use of Twirla in women based on weight.

Twirla Clinical Development Program

Clinical Trials Completed prior to SECURE

Our clinical program includes three Phase 1 studies, one Phase 2 study, and three Phase 3 studies, as well as other supporting studies. In December 2016, we completed our third Phase 3 clinical trial, SECURE, in response to FDA comments and guidance. In Phase 1 and Phase 2 clinical trials, we demonstrated that Twirla delivers levels of both EE and LNG to the blood stream that are consistent with currently marketed low-dose oral contraceptives. In our Phase 3 clinical trials completed prior to SECURE, we demonstrated that Twirla was comparable to an approved low-dose oral contraceptive in two randomized studies, one that enrolled over 1,500 women over 12 months and the other that enrolled over 400 women over six months. Across all completed clinical trials, Twirla was generally well-tolerated and had a favorable safety profile. Because we relied, in part, on the FDA's findings of safety and efficacy from investigations for approved products containing EE and LNG and published scientific literature for which we have not obtained a right of reference, we were not required to conduct preclinical studies. In the pharmacokinetic study comparing Twirla to an approved low-dose oral contraceptive, results demonstrated that Twirla delivers a daily dose of EE that results in estrogen exposure similar to low-dose oral contraceptives containing approximately 30 micrograms.

style="font-size:10.0pt;">2,197,958

Common stock of KEMET Corporation

(11,034,932

)

2,656,167

$

(20,641,073

)

4,854,125

(8) Subsequent Event

Effective July 1, 2003, the Plan was amended to allow for immediate vesting of the Company matching contributions, to reduce the minimum salary deferral election permitted to 1% of compensation, and to increase the maximum salary deferral to 25% of compensation. In addition, after-tax voluntary employee contributions to the Plan are no longer permitted.

Schedule 1

KEMET EMPLOYEES SAVINGS PLAN

Schedule H, Line 4i Schedule of Assets (Held at End of Year)
March 30, 2003

(a) Party in-interest	(b) Identity of issue, borrower, lessor, or similar party	(c) Description of investment including maturity date, rate of interest, collateral, par, or maturity value	(d) Cost		(e) Current value
*	T. Rowe Price	Stable Value Fund	**	$	25,238,119
*	T. Rowe Price	Equity Income Fund	**		10,306,473
*	KEMET Corp.	Common Stock	**		9,323,362
*	T. Rowe Price	Balanced Fund	**		7,553,290
*	T. Rowe Price	Mid-Cap Growth Fund	**		7,256,124
*	T. Rowe Price	Small-Cap Value Fund	**		3,732,349
*	T. Rowe Price	Blue Chip Growth Fund	**		2,472,006
*	T. Rowe Price	Science & Technology Fund	**		2,187,811
*	T. Rowe Price	International Stock Fund	**		1,175,796
*	T. Rowe Price	Spectrum Income Fund	**		848,038
*	Participants	Loans, interest rates ranging 5.25% to 10.00%	**		2,222,455
				$	72,315,823

* A party-in-interest as defined by ERISA.

** Cost omitted for participant-directed investments.

See accompanying independent auditors report.

Exhibit Index

Exhibit Number	Description
23	Independent Auditor's Consent
99	Certification of Plan Administrator pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002