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### UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

| Case No.   |
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| CLASS ACTION   |
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| CLASS ACTION COMPLAINT FOR<br>VIOLATION OF THE FEDERAL |
| SECURITIES LAWS  |
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| JURY TRIAL DEMANDED                                    |
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### **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES**

### LAWS

This action is brought against Defendants Ocular Therapeutix, Inc. ("Ocular"

or the "Company"), Amarpreet Sawhney, George Migausky, Andrew Hurley, and

Eric Ankerud ("collectively, the "Defendants") whose address is 34 Crosby Drive,

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Suite 105, Bedford, Massachusetts. Plaintiff Shawna Kim ("Plaintiff"), whose address is 15509 N Scottsdale Road, Unit 2038, Scottsdale, AZ 85254, by her, except for her own acts, which are based on knowledge, alleges the following based upon the investigation of counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings by Ocular, as well as regulatory filings and reports, securities analyst reports and advisories by the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery:

### **NATURE OF THE ACTION**

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Ocular securities between March 10, 2016 and July 11, 2017, inclusive (the "Class Period"), seeking remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Ocular focuses on the development and commercialization of therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology in the United States. Ocular is incorporated in the state of Delaware and its principal executive offices are located at 34 Crosby Drive, Suite 105, Bedford, Massachusetts. Ocular is registered to do business in the state of New Jersey.

Ocular's securities are traded on the NASDAQ Global Select Market ("NASDAQ") under the ticker symbol "OCUL."

3. As a result of the fraudulent conduct alleged herein, Plaintiff and other members of the Class purchased Ocular securities at artificially inflated prices and suffered significant losses and damages once the truth emerged.

### JURISDICTION AND VENUE

4. The federal law claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 27 of the Securities Act (15 U.S.C. §78aa). This Court has jurisdiction over each Defendant named herein because each Defendant is an individual who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

6. Venue is properly laid in this Judicial District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). The acts and conduct complained of herein occurred in substantial part in this Judicial District.

7. In connection with the acts, conduct and other wrongs alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities

of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

### **PARTIES**

8. Plaintiff purchased Ocular securities within the Class Period and, as a result, was damaged thereby. Plaintiff's certification evidencing his transactions is attached hereto as Exhibit A.

9. Defendant Ocular focuses on the development and commercialization of therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology in the United States.

10. Defendant Amarpreet "Amar" Sawhney ("Sawhney") is the Company's Chief Executive Officer ("CEO").

11. Defendant George Migausky ("Migausky") is the Company's Chief Financial Officer ("CFO").

12. Defendant Andrew "Andy" Hurley ("Hurley") is the Company's Chief Commercial Officer ("CCO").

13. Defendant Eric Ankerud ("Ankerud") is the Company's Executive Vice President of Regulatory, Quality, and Compliance.

14. Defendants in paragraphs 10-13 are collectively referred to herein as the "Individual Defendants."

15. Each of the Individual Defendants:

- (a) directly participated in the management of the Company;
- (b) was directly involved in the day-to-day operations of the Company at the highest levels;
- (c) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;
- (d) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;
- (e) was aware of or deliberately recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or
- (f) approved or ratified these statements in violation of the federal securities laws.

16. Because of the Individual Defendants' positions within the Company, they had access to undisclosed information about Ocular's business, operations, operational trends, financial statements, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations and performance), conversations and connections with other corporate officers and employees, attendance at management and Board meetings and committees thereof

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and via reports and other information provided to them in connection therewith.

As officers of a publicly-held company whose securities were, and are, 17. registered with the SEC pursuant to the federal securities laws of the United States, the Individual Defendants each had a duty to disseminate prompt, accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based truthful information. The Individual Defendants' upon and accurate misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

18. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Ocular's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available

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to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

19. Each of the Individual Defendants are liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Ocular securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Ocular's business, operations, management and the intrinsic value of its securities and (ii) caused Plaintiff and other shareholders to purchase Ocular securities at artificially inflated prices.

### **SUBSTANTIVE ALLEGATIONS**

### A. <u>Company Background</u>

20. Ocular is a biopharmaceutical company dedicated to the discovery, development, manufacturing and commercialization of innovative drug products focused on the treatment of ocular diseases and conditions.

21. Ocular's proprietary hydrogel drug delivery technology enables the use of drugs that are known to be efficacious of ocular diseases and conditions when

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formulated as drops or injections, into one-time or several month dosage forms. Ocular is able to encapsulate a wide range of ophthalmic pharmaceuticals within its hydrogel to deliver sustained and therapeutic levels of drugs to targeted ocular tissues.

22. The hydrogel provides containment, localization and protection from inflammatory response, providing an ideal material for sustained delivery of drugs to the eye.

23. Ocular's lead product is DEXTENZA, which is in Phase III clinical trial for the treatment of post-surgical pain and inflammation, allergic conjunctivitis; and in Phase II clinical trial for the treatment of inflammatory dry eye disease

24. Form 483 is a form used by the U.S. Food and Drug Administration ("FDA") to document and communicate concerns discovered during inspection.

### B. <u>Material Misstatements and Omissions during the Class Period</u>

25. The Class Period begins on March 10, 2016, when the Company filed a Form 10-K with the SEC announcing the Company's financial and operating results for the fiscal fourth quarter and fiscal year ended December 31, 2015 ("2015 10-K"), which was signed and certified under the Sarbanes Oxley Act of 2002 by the Individual Defendants. Ocular disclosed receiving a Form 483 from the FDA in February 2016 ("First Form 483"). The 2015 10-K stated in relevant part:

In addition, in February 2016, as part of the ongoing review of our NDA for DEXTENZA, the FDA conducted a pre-NDA approval inspection

of our manufacturing operations. As a result of this inspection, we received an FDA Form 483 containing inspectional observations focused on process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes. We addressed some observations before the inspection was closed and have responded to the FDA with a corrective action plan to complete the inspection process. The FDA or similar foreign regulatory authorities at any time also may implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of our products. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of ReSure Sealant and our product candidates that we manufacture. The failure to resolve the Form 483 inspectional observations from the February 2016 inspection could result in a delay in the PDUFA date and potential approval for the NDA we have filed for DEXTENZA for the treatment of post-surgical ocular pain.

Emphasis added.

26. On July 25, 2016, Ocular issued a press release, also attached as exhibit

99.1 to the Form 8-K filed with the SEC announcing that the receipt of a FDA

Complete Response Letter ("CRL") regarding its product DEXTENZA ("July 2016

Press Release"). The July 2016 Press Release stated in pertinent part:

BEDFORD, Mass.--(BUSINESS WIRE)--Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for DEXTENZA<sup>TM</sup> (dexamethasone insert) 0.4 mg, for intracanalicular use in the treatment of ocular pain occurring after ophthalmic surgery.

The concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility. The FDA's letter did not provide any details as to which manufacturing deficiencies identified during the facility inspection remain open since the last response submitted by the Company.

Satisfactory resolution of the manufacturing deficiencies identified during the FDA facility inspection is required before the NDA may be approved. The FDA's letter did not identify any efficacy or safety concerns with respect to the clinical data provided in the NDA nor any need for additional clinical trials for the approval of the NDA.

"We have previously responded to all requests in an effort to address the manufacturing items raised by the FDA during the application process, and we await completion of the review," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "Importantly, there were no clinical issues identified in the CRL pertaining to efficacy or safety related to the post-surgical pain indication. Labeling discussions with the FDA are ongoing. We remain optimistic that DEXTENZA will be approved once these open manufacturing items are closed. We will continue to work collaboratively with the FDA so they can finalize their review of our NDA, and are committed to bringing DEXTENZA to market as rapidly as possible."

Emphasis added.

27. On August 3, 2016, Ocular issued a press announcing and update on

the Company's NDA for DEXTENZA ("August 3, 2016 Press Release"). The

August 3, 2016 Press Release stated in relevant part:

### Ocular Therapeutix<sup>™</sup> Provides Update on NDA for DEXTENZA<sup>™</sup> for the Treatment of Post-Surgical Ocular Pain One outstanding item remains pertaining to manufacturing process and controls

BEDFORD, Mass.--(BUSINESS WIRE)--Aug. 3, 2016-- Ocular Therapeutix, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today provided an update on the status of its New Drug Application (NDA) for DEXTENZA<sup>TM</sup> (dexamethasone insert) 0.4 mg, for intracanalicular use in the treatment of ocular pain occurring after ophthalmic surgery.

On July 25, 2016, Ocular Therapeutix announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its NDA for DEXTENZA that identified issues pertaining to deficiencies in the manufacturing process and controls identified during a pre-NDA approval inspection of the Company's manufacturing facility. The CRL for DEXTENZA did not identify any efficacy or safety concerns with respect to the clinical data provided in the NDA nor any need for additional clinical trials for the approval of the NDA.

Recently, the FDA issued a letter to Ocular Therapeutix noting that corrective actions detailed in its responses as a whole appear to address the ten inspectional observations raised in the Form FDA 483 with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in the manufacturing process. In this letter, the FDA also requested that the Company provide evidence (e.g., a final report) when migration to automatic integration of analytical testing is complete, which is anticipated during the third quarter of 2016.

"We are working closely with the FDA to address the one remaining item and are planning for a resubmission to our NDA as soon as possible," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "We remain committed to bringing DEXTENZA to market as rapidly as possible."

Emphasis added.

28. On August 9, 2016, Ocular issued a press release, also attached as exhibit 99.1 to the Form 8-K filed with the SEC announcing the Company's financial and operating results for the second fiscal quarter and six month ended June 30, 2016

("Q2 2016 Press Release"). The Q2 2016 Press Release stated in relevant part:

**BEDFORD, Mass, August 9, 2016 (BUSINESS WIRE):** Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced financial results for the second quarter ended June 30, 2016.

"The second half of 2016 will be a busy time for Ocular Therapeutix as we prepare to initiate the first of two planned Phase 3 clinical trials with OTX-TP for the treatment of glaucoma and ocular hypertension during the third quarter," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "*Regarding our NDA for DEXTENZA for the treatment of post-surgical ocular pain, labeling discussions with the FDA are ongoing, and as we just announced, we are working to resolve the one remaining open manufacturing observation identified by the FDA in connection with their facility inspection. We will continue to work collaboratively with the FDA so they can finalize their review of our NDA, and we remain committed to bringing DEXTENZA to market.*"

\* \* \*

### **Recent Highlights and Anticipated Near-Term Milestones for Key Development Programs**

**DEXTENZA** for the treatment of post-surgical ocular inflammation and pain

• A New Drug Application (NDA) for DEXTENZA (dexamethasone insert) 0.4 mg, for intracanalicular use in the

treatment of ocular pain occurring after ophthalmic surgery is pending with the U.S. Food and Drug Administration (FDA).

- In July 2016, Ocular Therapeutix received a complete response letter (CRL) from the FDA that identified issues pertaining to deficiencies in the manufacturing process and controls, originally identified during a pre-NDA approval inspection of the Company's manufacturing facility. The CRL for DEXTENZA did not identify efficacy or safety concerns with respect to the clinical data provided in the NDA nor any need for additional clinical trials for the approval of the NDA.
- The FDA recently issued a letter noting that the corrective actions detailed in the Company's responses as a whole appear to address the ten inspectional observations raised in the Form 483 with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in the DEXTENZA manufacturing process. The FDA also requested that the Company provide evidence (e.g., a final report) when migration to automatic integration of analytical testing is complete, which is anticipated during the third quarter of 2016.

Emphasis added.

29. On November 9, 2016, Ocular filed a Form 10-Q with the SEC announcing the Company's financial and operating results for the third fiscal quarter and nine-months ended September 30, 2016 ("Q3 2016 10-Q"), which was signed and certified under the Sarbanes Oxley Act of 2002 by the Individual Defendants. Throughout the Q3 2016 10-Q the company stated in relevant part:

On July 25, 2016, the Company announced that it had received a Complete Response Letter, or CRL, from the FDA regarding the NDA for DEXTENZA. In the CRL, the concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of the Company's manufacturing

facility in February 2016 that were documented on FDA Form 483. The CRL did not provide any details as to which manufacturing deficiencies identified during the facility inspection remained open since the last response submitted by the Company. The CRL did not identify any efficacy or safety concerns with respect to the clinical data provided in the NDA nor any need for additional clinical trials for the approval of the NDA. On August 3, 2016, the Company announced that it had received a letter ("FDA District Office Letter") from the FDA New England District Office ("District Office") providing additional details pertaining to the manufacturing facility inspection observations. The FDA District Office Letter stated that the corrective actions included in the Company's prior responses appear as a whole to adequately address the ten inspectional observations raised in the Form 483 letter the Company received in February 2016 from the FDA, with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in the Company's manufacturing process. The FDA District Office Letter also requested evidence (e.g., a final report) when the planned migration of analytical testing from manual to an automatic integration is complete. There were no other issues identified in the FDA District Office Letter. The Company has had ongoing communications with the FDA including the New England District Office and offices within the Center for Drug Evaluation and Research ("CDER"), including the Office of Process and Facilities, with regard to manufacturing issues and the Company's plans for a resubmission of its NDA. In October 2016, the Company met with the FDA to discuss plans for resubmission to the NDA and to attempt to gain clarity on the possibility of a re-inspection of the Company's manufacturing facility. The FDA indicated that a decision as to whether a re-inspection is needed will be made during their review of the Company's resubmission. The Company anticipates the close-out of corrective actions to address the FDA District Office Letter and the resubmission of the NDA in the fourth quarter of 2016. Adequate resolution of the outstanding Form 483 manufacturing deficiencies is a prerequisite to the approval of the NDA for DEXTENZA, although the final decision as to the adequacy of the Company's manufacturing processes is made by CDER as part of the NDA review process. The Company anticipates that the FDA will classify the resubmission of the NDA and determine whether a re-inspection is needed within 30 days of the NDA resubmission date. The Company expects that a decision by the FDA to conduct a re-inspection of the Company's manufacturing

facility would result in a classification of the resubmission of the NDA as a class 2, or major review, and would take up to 6 months to complete. If no re-inspection is needed, the Company expects the FDA to classify the NDA resubmission as a class 1, or minor review, and take approximately 2 months to complete.

30. On January 23, 2017, Ocular issued a press release, also attached as

exhibit 99.1 to the Form 8-K filed with the SEC announcing the resubmission of the

Company's NDA for DEXTENZA ("January 2017 Press Release"). The January

2017 Press Release stated in pertinent part:

Ocular Therapeutix<sup>™</sup> Resubmits NDA for DEXTENZA<sup>™</sup> for the Treatment of Ocular Pain Occurring After Ophthalmic Surgery

BEDFORD, Mass.--(BUSINESS WIRE)--Jan. 23, 2017-- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced that it has resubmitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for DEXTENZA<sup>TM</sup> (dexamethasone insert) 0.4 mg, for the treatment of ocular pain occurring after ophthalmic surgery. DEXTENZA is a product candidate administered by a physician as a bioresorbable intracanalicular insert and designed for drug release to the ocular surface for up to 30 days.

"Following productive discussions with the FDA, we are pleased to announce the resubmission of our NDA for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "If DEXTENZA is approved, we believe that its ability to provide a complete course of steroid therapy with one-time administration in the post-surgical setting will be extremely attractive for both ophthalmologists and patients. We continue to build our commercial organization and infrastructure in preparation for the earliest possible launch of DEXTENZA, subject to marketing approval." Ocular Therapeutix resubmitted the NDA in response to a complete response letter (CRL) the Company received from the FDA in July 2016, which identified items pertaining to deficiencies in manufacturing process and controls. The Company expects to receive an indication of the scope and timing of the FDA's review of the Company's NDA resubmission within approximately 30 days. The Company believes that the FDA review period of the NDA resubmission will be up to two months if a Class 1 (minor review) designation is received and up to six months if a Class 2 (major review) designation is received. Class 1 or 2 designation is dependent on whether an FDA re-inspection of the Ocular Therapeutix manufacturing facility will be a condition of NDA approval.

Emphasis added.

31. On August 3, 2016, Ocular issued a press announcing and update on

the Company's NDA for DEXTENZA ("August 3, 2016 Press Release"). The

August 3, 2016 Press Release stated in relevant part:

### Ocular Therapeutix<sup>TM</sup> Announces FDA Acceptance of NDA Resubmission for DEXTENZA<sup>TM</sup> for the Treatment of Ocular Pain Occurring After Ophthalmic Surgery

### PDUFA target action date set for July 19, 2017

DEXTENZA initial target market comprises nearly 4 million cataract surgeries in the U.S.

February 22, 2017 08:00 AM Eastern Standard Time

BEDFORD, Mass.--(BUSINESS WIRE)--Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced that the Company's New Drug Application (NDA) resubmission for DEXTENZA<sup>TM</sup> (dexamethasone insert) 0.4 mg for intracanalicular use, for the treatment of ocular pain occurring after ophthalmic surgery has been accepted as a filing for review by the U.S. Food and Drug

Administration (FDA). DEXTENZA is a product candidate administered by a physician as a bioresorbable intracanalicular insert and designed for drug release to the ocular surface for up to 30 days.

The FDA determined that the NDA resubmission is a complete response and designated the resubmission as a Class 2 review, with a target action date under the Prescription Drug User Fee Act (PDUFA) of July 19, 2017 for the potential approval of DEXTENZA<sup>TM</sup>.

"We are pleased the FDA has accepted our resubmission of the DEXTENZA NDA and that we now have clarity on the PDUFA target action date. We look forward to advancing this process toward our goal of the potential approval and commercial launch of DEXTENZA," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "With nearly four million cataract surgeries performed in the U.S. in 2016 as our initial target, the market opportunity for DEXTENZA is significant. If approved, we believe DEXTENZA will be the first non-invasive therapy available to patients and ophthalmologists that can provide a full post-operative course of therapy with a single placement."

Emphasis added.

32. On May 5, 2017, Ocular issued a press release, also attached as exhibit

99.1 to the Form 8-K filed with the SEC announcing that that it had received a Form

483 ("Second Form 483") related to DEXTENZA ("May 2017 Press Release"). The

May 2017 Press Release stated in pertinent part:

BEDFORD, Mass.--(BUSINESS WIRE)--May 5, 2017-- Ocular Therapeutix, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative therapies for diseases and conditions of the eye, today announced financial results for the first quarter ended March 31, 2017.

"This is an important time for Ocular Therapeutix as we approach the PDUFA target action date for our lead product candidate, DEXTENZA, for the treatment of ocular pain following ophthalmic surgery," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "Should DEXTENZA be approved, its commercial launch will enable our transition into a fully-integrated, commercial-stage, revenue-generating company. DEXTENZA has now been extensively studied for the treatment of post-surgical ocular pain and inflammation in over 550 clinical trial participants. If approved, we believe DEXTENZA will address the compliance issues associated with steroid eyedrops and serve as an attractive alternative for both patients and ophthalmologists."

# Recent Highlights and Anticipated Near-Term Milestones for Key Development Programs

### DEXTENZATM

• A New Drug Application (NDA) for DEXTENZA (dexamethasone insert) 0.4mg for intracanalicular use is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of ocular pain following ophthalmic surgery. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of July 19, 2017 for a decision regarding the potential approval of DEXTENZA. Following a reinspection of manufacturing operations by the FDA which was completed earlier this week, Ocular Therapeutix received an FDA Form 483 containing inspectional observations focused on procedures for manufacturing processes and analytical testing, related to manufacture of drug product for commercial production. The Company plans to evaluate and respond to the FDA within 15 days with corrective action plans to complete the inspection process. Adequate resolution of the outstanding Form 483 inspectional observations is a prerequisite to the approval of the NDA for DEXTENZA.

Emphasis added.

33. Also on May 5, 2017, the Company held an earnings conference call,

during which Defendant Ankerud stated the following regarding the Form 483:

### Eric Ankerud

Good morning, Ken. Thanks for the question. FDA completed the reinspection of our facility as part of the NDA review late yesterday afternoon. As Amar mentioned, 4[8]3 was issued. We were pleased during the re-inspection that the FDA investigator was able to confirm our corrective action plan from prior observations, and indicated that there was no further follow-up necessary to close out those issues. This was a new investigator not the same investigator from prior inspections, and their primary focus in the 43 relates to a particular matter issue as part of our manufacturing process. The issue relates primarily to completion of an investigation that we have underway in regard to the particular matter solidifying specifications for in process, 100% visual inspection of our inserts, as well as enhancing our operator training. We feel quite comfortable that we have the situation under control and we are preparing responses to the 43 as of this morning in anticipation of responding within 15 *calendar days to the agency.* In addition to the particular matter issue, FDA raised a couple of observations in regard to analytical method, testing to be completed, as well as some other issue related to quality oversight of batch records. So in summary, we believe that each of the observations raised by FDA during this continuous improvement review of our fully developed manufacturing process are handled well and will be resolved in our response to FDA. We're also pleased that the collaborative nature of our NDA review has continued between the various offices of FDA, and we're marching toward that PDUFA date and expect that we can resolve the 43 issues in a timely manner.

Emphasis added.

34. During the earnings conference call, Defendant Sawheny had the

following exchange with an analyst regarding the Form 483:

Andrew Berens

Okay. Is there anything in their observations that you think could delay the action date specifically?

Amar Sawhney

Nothing that we can currently see. I think these – as you know, probably 90% plus inspections have 483. *The question is one of the nature of the issues in the 483, we think these are resolvable issues, and we have responses.* Some already prepared and some being prepared to address them in a timely fashion.

Emphasis added.

35. The statements in paragraphs 25-34 above were materially false and misleading as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Ocular failed to adequately address the issues identified in the First Form 483; (ii) Ocular's re-submitted NDA would not be approved by the July 19, 2017 PDUFA date because the Company could not timely and adequately address the FDA-identified manufacturing and control issues; (iii) Ocular's continued manufacturing issues imperil the approval of DEXTENZA; and (v) as a result, Defendants' public statements were materially false and misleading at all relevant times., Ocular's public statements were materially false and misleading at all relevant times.

### C. <u>The Truth Begins to Emerge</u>

36. Shortly before the close of trading on July 6, 2017, a *Seeking Alpha* contributor published an article entitled *Ocular: A Poke in the Eye*. This article discussed the Company's manufacturing issues with DEXTENZA and provided links to the First Form 483 and Second Form 483.

37. More specifically, the *Seeking Alpha* Article, in relevant part, stated:

Dextenza Manufacturing Issues

OCUL has disclosed that they received a second 483 from the FDA after their facility re-inspection. Even a layperson reading this can tell that the company is having serious manufacturing issues, and their whole approach to manufacturing and patient safety is highly questionable. What's more troubling is that either management doesn't fully understand the letter, or they have been misleading investors. Both are bad.

On their last earnings call. management made a number of statements regarding the 483 and the company's manufacturing process:

"We were pleased during the re-inspection that the FDA investigator was able to confirm our corrective action plan from prior observations, and indicated that there was no further follow-up necessary to close out those issues." Ocular Therapeutix's CEO Amar Sawhney on Q1 2017 Results - Earnings Call Transcript.

"So I think that's a strong sign that the manufacturing process has move forward significantly, and is in a fully developed mode."

The CEO concluded:

"Also remembering that this is a new investigator, different one that came last time. So when you have a different one coming, they confirm what the prior one did, and then they probably have some additional helpful suggestions." Now, let's look at reality:

First, OCUL has REPEAT observations. Not only did they not resolve prior issues, but have committed worse transgressions. Here is a copy of the first 483

Observation 6 reads: "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity."

Observation 5 of the second 483 reads: "Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity." Sounds familiar?

Observation 3 of the second 483 reads: "There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically, your firm lacks documentation to show that your product can consistently meet specifications as you have not systemically evaluated the [redacted] lots manufactured from FEB2016 to present, of which [redacted] failed specification and were disposed of in-process"

In plain English, this means, OCUL still doesn't know to make their product consistently. How does OCUL deal with instances when product doesn't meet specifications? They have been discarding bad manufacturing lots without investigation.

Second, OCUL has characterized their manufacturing as "in a fully developed mode." Well, Observation 1 of the second 483 reads: "Particulate matter has been noted in 10/23 lots (intended use clinical, R&D, stability, etc.) manufactured from FEB2016 to date. The remaining [redacted] lots were scrapped prior to the visual inspection therefore their particulate status remains unknown."

In plain English, this means that more than 50% of lots manufactured by OCUL contain bad product. That leaves plenty of room for additional development. Sometimes, OCUL has had to discard entire lots because they were out of spec!!

Third, if OCUL only discarded bad product without investigation, that would be a bad thing. But in fact, they have been using bad product in clinical trials and have released some into their commercial supply!

Observation 1 continues: "Particulates were not logged as product defects prior to FEB2016, therefore lots released prior to that date, such as clinical trial lots [redacted], released [redacted]respectively and used in human clinical trials are unknown with respect to particulate status."

Observation 2 reads: "The following batches were released without an understanding of the defects present, more specifically, particulate matter of unknown origin and composition at the time of release: ....all three lots were released for intended commercial use on 12JAN2017 without critical defect limits"

OCUL believes that their manufacturing is "fully developed" and remaining issues can be resolved quickly. The reality is, IF Dextenza is possible to manufacture on a mass scale, something which hasn't been done before, OCUL needs to revamp their entire process from the ground up, which can take years to do. They need to use the proper scientific tools and procedures. (Observation 5 of the second 483 says that the scales OCUL has been using aren't sensitive enough to weigh the "full range of materials")

Fourth, calling 483 observations "helpful suggestions," reflects a lack of understanding of the FDA compliance function. I have a lot of respect for OCUL's now-former CEO. He is a brilliant person and a highly successful entrepreneur. However, the pharmaceutical world is not his, and he finally recognized that he is not the right person to develop the company further.

38. On that same day, *STAT* published an article on the Company asserting

that DEXTENZA could be rejected by the FDA because of product contamination,

including aluminum, found by an FDA inspector during a visit to the company's

manufacturing facility.

Ocular Therapeutix is still working to resolve manufacturing problems with its eye drug Dextenza, less than two weeks before an FDA approval decision deadline.

In an interview Friday, Ocular CEO Amar Sawhney said a submission to the FDA, responding to an inspection of its Dextenza manufacturing facility in May, is not yet completed.

"We have not completely responded to the FDA but we are in the process of doing that in relatively short order," said Sawhney. Some of the issues raised by FDA about the Dextenza manufacturing and quality control process are taking more time to resolve, he added.

Ocular is running out of time. The FDA is expected to announce an approval decision for Dextenza on July 19. However, the company acknowledges FDA will not approve the drug unless the outstanding manufacturing issues are fixed. And for that to happen, FDA has to review the proposed changes to Dextenza's manufacturing process that Ocular is still working on.

"Dextenza is a unique product that has never been made by anybody else," Sawhney said. "There are quirks in the manufacturing process but we believe FDA is working with us."

As reported Thursday, an FDA inspection raised concerns about batches of Dextenza contaminated with particulates, including aluminum. The FDA also cited Ocular for failing to identify the source of the contamination and not having proper inspection procedures in place to catch and reject contaminated Dextenza before the product reaches patients.

Sawhney says blades in a machine used to cut the solidified steroid into tiny implantable plugs was the source of the aluminum contamination. While some level of particulate contamination is normal and expected, Ocular fixed its machine to reduce it. The company also established new inspection procedures and reporting standards for its employees in charge of Dextenza manufacturing.

"I think we have resolved [the FDA's concerns] but we still need to write them up and submit," said Sawhney.

Ultimately, the FDA will decide if the manufacturing fixes put in place by Ocular are sufficient to allow Dextenza's approval. The FDA may also find it necessary to re-inspect Ocular's facility, which could take additional time. The FDA rejected Dextenza once previously, in July 2016, also for manufacturing problems.

"I wish there was a straight line to approval but there isn't. We're working hard to do something meaningful for patients," said Sawhney.

39. On this news, Ocular's share price fell \$3.69, *or over 36%*, from a closing price of \$10.18 on July 5, 2017 to close at \$6.49 per share on July 10, 2017, severely damaging investors.

### D. <u>The Truth Emerges</u>

40. After market close on July 11, 2017, Ocular issued a press release, announcing the receipt of a FDA Complete Response Letter ("CRL") denying approval of DEXTENZA("July 2017 Press Release"). The July 2017 Press Release stated in pertinent part:

BEDFORD, Mass.--(BUSINESS WIRE)--

Ocular TherapeutixTM, Inc. (OCUL), a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative therapies for diseases and conditions of the eye, announced today that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA), regarding its resubmission of a New Drug Application (NDA) for DEXTENZA<sup>TM</sup> (dexamethasone insert) 0.4mg for the treatment of ocular pain following ophthalmic

surgery. The CRL states that the FDA has determined that it cannot approve the NDA in its present form.

The CRL from the FDA refers to deficiencies in manufacturing processes and analytical testing related to manufacture of drug product for commercial production identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility that was completed in May 2017. As previously announced on July 10, 2017, the Company submitted a response intended to close out all inspectional observations included in the Form FDA-483 issued in May 2017. The Company also submitted details of a manufacturing equipment change on July 10, 2017 as an amendment to the NDA resubmission and requested that this be considered a major amendment that would extend the target action date under the Prescription Drug User Fee Act (PDUFA).

The CRL acknowledges receipt of the Company's NDA amendment dated July 10, 2017 and states that the amendment was not reviewed prior to the FDA's action of the CRL. As a result, the FDA did not have the opportunity to review the Company's close-out response prior to issuing the CRL. In addition, as noted in the CRL, the FDA indicated that applicable sections of the amendment submitted by Ocular Therapeutix could be incorporated when responding to deficiencies noted in the CRL.

Satisfactory resolution of the manufacturing deficiencies detailed in the Form FDA-483 is required before the NDA may be approved. The FDA's letter did not identify any efficacy or safety concerns with respect to the clinical data for DEXTENZA provided in the NDA nor any need for additional clinical trials for the NDA approval.

"We are evaluating the FDA's response and plan to work closely with the agency in an effort to satisfy the requirements related to the NDA," said Ocular Therapeutix President, Chief Executive Officer and Chairman, Amar Sawhney, Ph.D. "Importantly, there were no clinical issues identified in the CRL pertaining to efficacy or safety related to the post-surgical pain indication. We believe that DEXTENZA can be approved once these open manufacturing items are resolved."

Emphasis added.

41. On this news, Ocular's share price fell \$0.93, *or over 12%*, from the closing price of \$7.60 on July 11, 2017 to close at \$6.67 per share on July 12, 2017.

### ADDITIONAL SCIENTER ALLEGATIONS

42. As alleged herein, Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Ocular, their control over, and/or receipt and/or modification of Ocular's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Ocular, participated in the fraudulent scheme alleged herein.

### LOSS CAUSATION AND ECONOMIC LOSS

43. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the Company's stock price, and operated as a fraud or deceit on acquirers of the Company's securities. As detailed above, when the truth about Ocular's misconduct and its lack of operational and financial controls was revealed, the value of the

Company's securities declined precipitously as the prior artificial inflation no longer propped up its stock price. The decline in Ocular's share price was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the common stock price decline negates any inference that the loss suffered by Plaintiff and other members of the Class was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the Defendants' fraudulent conduct. The economic loss, i.e., damages, suffered by Plaintiff and other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the Company's stock price and the subsequent significant decline in the value of the Company's share, price when Defendants' prior misrepresentations and other fraudulent conduct was revealed.

44. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and other Class members. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of Ocular's business, operations and financial condition, as alleged herein. Throughout the Class Period, Defendants publicly issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing Ocular's securities to be artificially inflated. Plaintiff and other Class members purchased Ocular's securities at those artificially inflated prices, causing them to suffer the damages complained of herein.

### **PRESUMPTION OF RELIANCE; FRAUD-ON-THE-MARKET**

45. At all relevant times, the market for Ocular securities was an efficient market for the following reasons, among others:

- (a) Ocular securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient market;
- (b)During the Class Period, Ocular securities were actively traded, demonstrating a strong presumption of an efficient market;
- (c) As a regulated issuer, Ocular filed with the SEC periodic public reports during the Class Period;
- (d)Ocular regularly communicated with public investors via established market communication mechanisms;
- (e) Ocular was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and
- (f) Unexpected material news about Ocular was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

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46. As a result of the foregoing, the market for Ocular securities promptly digested current information regarding Ocular from all publicly available sources and reflected such information in Ocular' stock price. Under these circumstances, all purchasers of Ocular securities during the Class Period suffered similar injury through their purchase of Ocular' securities at artificially inflated prices, and a presumption of reliance applies.

47. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security. Here, the facts withheld are material because an investor would have considered the Company's true net losses and adequacy of internal controls over financial reporting when deciding whether to purchase and/or sell stock in Ocular.

### NO SAFE HARBOR; INAPPLICABILITY OF BESPEAKS CAUTION DOCTRINE

48. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations

and omissions alleged in this Complaint.

49. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

50. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Ocular who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by the defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

### **CLASS ACTION ALLEGATIONS**

51. Plaintiff brings this action on behalf of all individuals and entities who

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purchased or otherwise acquired Ocular securities on the public market during the Class Period, and were damaged, excluding the Company, the defendants and each of their immediate family members, legal representatives, heirs, successors or assigns, and any entity in which any of the defendants have or had a controlling interest (the "Class").

52. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Ocular securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Ocular or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. Upon information and belief, these shares are held by thousands if not millions of individuals located geographically throughout the country and possibly the world. Joinder would be highly impracticable.

53. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by the defendants' respective wrongful conduct in violation of the federal laws complained of herein.

54. Plaintiff has and will continue to fairly and adequately protect the

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interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

55. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by the defendants' respective acts as alleged herein;

(b) whether the defendants acted knowingly or with deliberate recklessness in issuing false and misleading financial statements;

(c) whether the price of Ocular securities during the Class Period was artificially inflated because of the defendants' conduct complained of herein; and

(d) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

56. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them.

There will be no difficulty in the management of this action as a class action.

### COUNT I

### Violation of Section 10(b) and Rule 10b-5 Against All Defendants

57. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

58. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (2) cause Plaintiff and other members of the Class to purchase Ocular securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, each of the Defendants took the actions set forth herein.

59. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Ocular securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

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60. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Ocular as specified herein.

61. These Defendants employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Ocular' value and performance and continued substantial growth, which included the making of, or participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Ocular and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of Ocular securities during the Class Period.

62. Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (1) Individual Defendants were high-level executives, directors, and/or agents at the Company during the Class Period and members of the Company's management team or had control thereof; (2) each

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Individual Defendant, by virtue of his responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's financial condition; (3) each Individual Defendant enjoyed significant personal contact and familiarity with the other Individual Defendant and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (4) each Individual Defendant was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

63. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Ocular' operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's financial condition throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in

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failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

64. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Ocular' securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Ocular' publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Ocular' securities during the Class Period at artificially high prices and were or will be damaged thereby.

65. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding Ocular's financial results, which was not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Ocular securities, or, if they had acquired such securities

during the Class Period, they would not have done so at the artificially inflated prices that they paid.

66. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

67. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

68. This action was filed within two years of discovery of the fraud and within five years of each plaintiff's purchases of securities giving rise to the cause of action.

### COUNT II

### The Individual Defendants Violated Section 20(a) of the Exchange Act

69. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

70. The Individual Defendants acted as controlling persons of Ocular within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, agency, ownership and contractual rights, and participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and

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disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that Plaintiff contends are false and misleading. The Individual Defendants provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to have been misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

71. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

72. As set forth above, Ocular, the Individual Defendants each violated Section 10(b), and Rule 10b-5 promulgated thereunder, by their acts and omissions as alleged in this Complaint.

73. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of

the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

74. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff's purchases of securities giving rise to the cause of action.

### PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment as follows:

- (a) Determining that this action is a proper class action, certifying
   Plaintiff as class representative under Federal Rule of Civil
   Procedure 23 and Plaintiff's counsel as class counsel;
- (b) Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of the defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;
- (d) Granting extraordinary equitable and/or injunctive relief as permitted by law; and

(e) Such other and further relief as the Court may deem just and proper.

### JURY TRIAL DEMANDED

Plaintiff hereby demands a jury trial.

Dated: August 3, 2017

### LEVI & KORSINSKY LLP

/s/ Eduard Korsinsky

Eduard Korsinsky (EK-8989) 30 Broad Street, 24th Floor New York, NY 10004 Tel : 212-363-7500 Fax : 212-363-7171 Email: ek@zlk.com

- and -

Nicholas I. Porritt\* Adam M. Apton\* 1101 30th Street NW, Suite 115 Washington, DC 20007 Tel: (202) 524-4290 Fax: (202) 333-2121 Email: nporritt@zlk.com Email: aapton@zlk.com \*Pro hac vice forthcoming

Counsel for Plaintiff and for the proposed class.

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# **EXHIBIT** A

# CERTIFICATION OF NAMED PLAINTIFF PURSUANT TO FEDERAL SECURITIES LAWS

I, Shawna Kim , duly certify and say, as to the claims asserted under the federal securities laws, that:

1. I have reviewed the complaint and authorized its filing.

2. I did not purchase the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this private action.

3. I am willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

4. My transaction(s) in Ocular Therapeutix Inc which are the subject of this litigation during the class period set forth in the complaint are set forth in the chart attached hereto.

5. Within the last 3 years, I have not sought to serve nor have I served as a class representative in any federal securities fraud case.

6. I will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, except as ordered or approved by the court, including any award for reasonable costs and expenses (including lost wages) directly relating to the representation of the class.

I hereby certify, under penalty of perjury, that the foregoing is true and correct. Executed this July 31, 2017.

Name: Shawna Kim

Signed:

### Shawna Kim Transactions in Ocular Therapeutix, Inc. (OCUL) Securities Class Period: March 10, 2016 and July 11, 2017, inclusive

| Date of Transaction | Buy (B) | or Sell (S) | Quantity | Price (\$) |
|---------------------|---------|-------------|----------|------------|
| 5/8/20              | 7       | В           | 116      | 8.6100     |

#### JS 44 (Rev. 06/17)

### Case 1:17-cv-12286 Deckment 12 Filed 08/03/17 Page 1 of 2

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)* 

| I. (a) PLAINTIFFS  |   |   |                  | DEFENDANTS  |   |  |  |
|--|---|---|------------------|---|---|--|--|
| SHAWNA KIM, INDIVIDUALLY AND ON BEHALF OF THOSE<br>SIMILARILY SITATUATED   |   |   |                  | OCULAR THERAPEUTIX, INC., AMARPREET SAWHNEY, GEORGE MIGAUSKY, ANDREW HURLEY, and ERIC ANKERUD   |   |  |  |
| ( <b>b</b> ) County of Residence of  |   | Aricopa Cty, AZ   |                  | County of Residence   | -   | Middlesex, MA  |  |
| ( <i>E.</i>  | XCEPT IN U.S. PLAINTIFF CA  | ISES)   |                  | NOTE: IN LAND CC<br>THE TRACT   | (IN U.S. PLAINTIFF CASES (<br>ONDEMNATION CASES, USE T<br>OF LAND INVOLVED.   | ·  |  |
| (c) Attorneys (Firm Name,<br>Eduard Korsinsky, LEVI  | & KORSINSKY, LLP (  | <sup>r)</sup><br>212)-363-7500  |                  | Attorneys (If Known)  |   |  |  |
| 30 Broad Street, 24th Flo<br>New York, NY 10004  | oor   |   |                  |   |   |  |  |
| II. BASIS OF JURISDI   | <b>CTION</b> (Place an "X" in C   | ne Box Only)  |                  |   | RINCIPAL PARTIES  | (Place an "X" in One Box for Plaintiff   |  |
| □ 1 U.S. Government<br>Plaintiff   |   |   |                  | (For Diversity Cases Only)<br>P1<br>en of This State  | <b>TF DEF</b><br>1 □ 1 Incorporated or Pr<br>of Business In □   |  |  |
| 2 U.S. Government<br>Defendant   | ☐ 4 Diversity<br>(Indicate Citizensh  | ip of Parties in Item III)  | Citiz            | en of Another State   | 2 🗖 2 Incorporated and I<br>of Business In .  |  |  |
|  |   |   |                  | en or Subject of a<br>reign Country   | 3 🗖 3 Foreign Nation  |  |  |
| IV. NATURE OF SUIT   |   | uly)<br>DRTS  | F                | ORFEITURE/PENALTY   | Click here for: Nature OBANKRUPTCY  | of Suit Code Descriptions.<br>OTHER STATUTES   |  |
| <ul> <li>110 Insurance</li> <li>120 Marine</li> <li>130 Miller Act</li> <li>140 Negotiable Instrument</li> <li>150 Recovery of Overpayment<br/>&amp; Enforcement of Judgment</li> <li>151 Medicare Act</li> </ul>  | 330 Federal Employers'  | <ul> <li>PERSONAL INJUR</li> <li>365 Personal Injury -<br/>Product Liability</li> <li>367 Health Care/<br/>Pharmaceutical<br/>Personal Injury<br/>Product Liability</li> </ul>  |                  | 25 Drug Related Seizure<br>of Property 21 USC 881<br>00 Other   | <ul> <li>422 Appeal 28 USC 158</li> <li>423 Withdrawal<br/>28 USC 157</li> <li>PROPERTY RIGHTS</li> <li>820 Copyrights</li> <li>830 Patent</li> </ul>   | <ul> <li>375 False Claims Act</li> <li>376 Qui Tam (31 USC<br/>3729(a))</li> <li>400 State Reapportionment</li> <li>410 Antitrust</li> <li>430 Banks and Banking</li> <li>450 Commerce</li> <li>460 Deportation</li> <li>470 Racketeer Influenced and<br/>Corrupt Organizations</li> <li>480 Consumer Credit</li> <li>490 Cable/Sat TV</li> <li>\$850 Securities/Commodities/<br/>Exchange</li> <li>890 Other Statutory Actions</li> <li>891 Agricultural Acts</li> <li>893 Environmental Matters</li> <li>895 Freedom of Information</li> </ul> |  |
| <ul> <li>152 Recovery of Defaulted<br/>Student Loans<br/>(Excludes Veterans)</li> <li>153 Recovery of Overpayment<br/>of Veteran's Benefits</li> <li>160 Stockholders' Suits</li> <li>190 Other Contract</li> <li>195 Contract Product Liability</li> <li>196 Franchise</li> </ul> | Liability<br>340 Marine<br>345 Marine Product<br>Liability<br>350 Motor Vehicle<br>9355 Motor Vehicle<br>Product Liability<br>360 Other Personal<br>Injury<br>362 Personal Injury -<br>Medical Malpractice  | <ul> <li>368 Asbestos Personal<br/>Injury Product<br/>Liability</li> <li>PERSONAL PROPER</li> <li>370 Other Fraud</li> <li>371 Truth in Lending</li> <li>380 Other Personal<br/>Property Damage</li> <li>385 Property Damage<br/>Product Liability</li> </ul> | 0 71<br>72<br>74 | LABOR<br>10 Fair Labor Standards<br>Act<br>20 Labor/Management<br>Relations<br>40 Railway Labor Act<br>51 Family and Medical<br>Leave Act | <ul> <li>\$35 Patent - Abbreviated<br/>New Drug Application</li> <li>\$40 Trademark</li> <li><b>SOCIAL SECURITY</b></li> <li>\$61 HIA (1395ff)</li> <li>\$62 Black Lung (923)</li> <li>\$63 DIWC/DIWW (405(g))</li> <li>\$64 SSID Title XVI</li> <li>\$65 RSI (405(g))</li> </ul> |  |  |
| REAL PROPERTY  | CIVIL RIGHTS  | PRISONER PETITION   |                  | 00 Other Labor Litigation   | FEDERAL TAX SUITS   | Act  |  |
| <ul> <li>210 Land Condemnation</li> <li>220 Foreclosure</li> <li>230 Rent Lease &amp; Ejectment</li> <li>240 Torts to Land</li> <li>245 Tort Product Liability</li> <li>290 All Other Real Property</li> </ul>   | <ul> <li>440 Other Civil Rights</li> <li>441 Voting</li> <li>442 Employment</li> <li>443 Housing/<br/>Accommodations</li> <li>445 Amer. w/Disabilities -<br/>Employment</li> <li>446 Amer. w/Disabilities -<br/>Other</li> <li>448 Education</li> </ul> | Habeas Corpus:<br>463 Alien Detainee<br>510 Motions to Vacate<br>Sentence<br>530 General<br>535 Death Penalty<br>Other:<br>540 Mandamus & Oth<br>550 Civil Rights<br>555 Prison Condition<br>560 Civil Detainee -<br>Conditions of<br>Confinement             | □ 46             | Imployee Retirement<br>Income Security Act     IMMIGRATION     Xaturalization Application     Actions                                     | <ul> <li>\$70 Taxes (U.S. Plaintiff<br/>or Defendant)</li> <li>\$71 IRS—Third Party<br/>26 USC 7609</li> </ul>  | <ul> <li>896 Arbitration</li> <li>899 Administrative Procedure<br/>Act/Review or Appeal of<br/>Agency Decision</li> <li>950 Constitutionality of<br/>State Statutes</li> </ul>   |  |
|  |   | Remanded from Appellate Court   | □ 4 Rein<br>Reoj | interiore   | erred from D 6 Multidistr<br>r District Litigation<br>Transfer  |  |  |
| VI. CAUSE OF ACTIO   | DN 15 U.S.C. §§ 78j(<br>Brief description of ca   | (b) and §78t(a)   |                  | Do not cite jurisdictional stat<br>eform Act; Violation   | utes unless diversity):<br>s of the Federal Securiti  | ies Laws   |  |
| VII. REQUESTED IN<br>COMPLAINT:  | CHECK IF THIS<br>UNDER RULE 2   | IS A <b>CLASS ACTION</b><br>3, F.R.Cv.P.  | J D              | EMAND \$  | CHECK YES only<br>JURY DEMAND   | r if demanded in complaint:<br>: X Yes □No   |  |
| VIII. RELATED CASI<br>IF ANY   | E(S) (See instructions):  | JUDGE Susan D.  | Wigento          | on; John M. Vazquez   | DOCKET NUMBER 2:  | 17-cv-5011; 2:17-cv-5095   |  |
| DATE<br>08/03/2017<br>FOR OFFICE USE ONLY  |   | SIGNATURE OF AT   |                  | OF RECORD   |   |  |  |
|  | MOUNT   | APPLYING IFP  |                  | JUDGE   | MAG. JUI  | DGE  |  |
| Print  | Save As   |   |                  |   |   | Reset  |  |

### **INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- **I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below. United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

- **III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- **IV.** Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: <u>Nature of Suit Code Descriptions</u>.
- V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.

Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity. Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P. Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction. Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

# **ClassAction.org**

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: Lawsuit: Ocular Therapeautix Blinded Investors to Issues with New Drug's Approval