Risk Factors Comparison 2024-03-08 to 2023-03-30 Form: 10-K

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An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this Annual Report. Any of the risks and uncertainties set forth herein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. As a result, you could lose all or part of your investment. **Ocuphire Pharma, Inc. Form 10-** ~~Risks~~ **KRisks** Related to **the Commercialization and** Development of Our Product Candidates **We depend heavily on the success of our product pipeline. If we (or our strategic partner) fail to adequately commercialize RYZUMVI or develop and commercialize APX3330 or PS, our business will be materially harmed. Our business depends on the successful clinical development, regulatory approval and commercialization of APX3330 and Phentolamine Ophthalmic Solution 0. 75 % Eye Drops " PS ". Viatris is our strategic partner for the commercialization of FDA- approved RYZUMVI and for the further development and commercialization, if FDA- approved, of PS. APX300 is still in clinical development. We have invested a significant portion of our efforts and financial resources in the development of APX3330, RYZUMVI, and PS, and we (or our strategic partner) expect to invest a significant portion of our efforts and financial resources in the development and commercialization of APX3330, RYZUMVI and PS in the future. There remains a significant risk that we or Viatris will fail to successfully develop and commercialize RYZUMVI or our product candidates. We cannot accurately predict when or if APX3330 will prove effective or safe in humans or whether it will receive marketing approval. Our ability to generate product revenues depends heavily on the continued commercialization of RYZUMVI and obtaining marketing approval for and commercializing APX3330 and PS (together, " our product candidates "). The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of a drug product are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, where regulations may differ. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA or in any foreign countries until we receive the requisite approval from such countries. Before obtaining regulatory approval for the commercial sale of our product candidates for a particular indication, we must demonstrate through nonclinical testing and clinical trials that the applicable product candidate is safe and effective for use in that target indication. This process can take many years and may be followed by post- marketing studies and surveillance together which will require the expenditure of substantial resources beyond the proceeds raised in our equity and debt financings to date. Of the large number of drugs in development in the United States, only a small percentage of drugs successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to complete development and FDA approval of our product candidates, we cannot assure you that our product candidates will be approved or commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, or successfully continue to commercialize RYZUMVI, our commercial opportunity will be limited. The success of APX3330, RYZUMVI and PS could be impacted by several factors, including the following: • delays in the launch or difficulties in the widespread commercialization of RYZUMVI (currently the launch is anticipated in the first half of 2024); • delays in, termination, or numerous unforeseen events during, or as a result of, manufacturing or clinical trials; • obtaining unfavorable results from nonclinical and clinical studies for our product candidates; • the cost of clinical trials being greater than anticipated; • the willingness of patients or medical investigators to follow our clinical trial protocols and the number of patients willing to participate; • delays in applying for and receiving marketing and NDA approvals from applicable regulatory authorities for our product candidates; • other government or regulatory delays and changes in regulatory requirements, policy and guidelines may require us to perform additional clinical trials or use substantial additional resources to obtain regulatory approval; Ocuphire Pharma, Inc. Form 10- K • issues with making arrangements with third- party manufacturers for commercial quantities of RYZUMVI and our product candidates and receiving regulatory approval of our manufacturing processes and our third- party manufacturers' facilities from applicable regulatory authorities; • establishing sales, marketing, and distribution capabilities and launching commercial sales of RYZUMVI and our product candidates, if and when approved, whether alone or in collaboration with others; • acceptance of RYZUMVI and our product candidates by patients, the medical community, and third-party payors; • effectively competing with other therapies, including the existing standard- of- care; • maintaining a continued acceptable safety profile of RYZUMVI and our product candidates following approval; • obtaining and maintaining coverage and adequate reimbursement from third- party payors; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity; • protecting our rights in our intellectual property portfolio related to RYZUMVI and our product candidates; and • our ability to fulfill requests for additional data regarding our product candidates. • In addition, under the Apexian License Agreement, Ocuphire has rights to certain compounds for use in ophthalmic and diabetic diseases. Ocuphire does not control the development of these compounds in other non-ophthalmic indications.** Viatris has exclusive global rights to commercialize ~~our Nyxol products~~ **RYZUMVI and PS** in key global markets. Viatris' failure to timely develop or commercialize these products would have a material adverse effect on our business and operating results. We granted Viatris an exclusive right to commercialize ~~our Nyxol products~~ **RYZUMVI and PS**

in key global markets. Additionally, we granted Viatris the exclusive right and license to develop ~~Nyxol~~ **RYZUMVI and PS** outside of the United States. The collaboration with Viatris may not be successful due to several factors, including the following: • Viatris may not be able to ~~obtain from us or~~ manufacture our products in a timely or cost- effective manner; • Viatris may not timely perform its obligations under the ~~Nyxol~~ **Viatris** License Agreement; • Viatris may fail to effectively commercialize our products; • Viatris may not be able to sublicense ~~Nyxol~~ **RYZUMVI or PS** to one or more suitable parties outside the United States; or • Contractual disputes or other disagreements between us and Viatris, including those regarding the development, manufacture, sub licensure and commercialization of our products, interpretation of the ~~Nyxol~~ License Agreement, and ownership of proprietary rights. Viatris may select a new development partner for ~~Nyxol~~ **RYZUMVI and PS** in the U. S. upon 90 days' notice to Ocuphire. **Ocuphire Pharma, Inc. Form 10-** ~~Any~~ **KAny** of the foregoing could adversely impact the likelihood and timing of any payments we are eligible to receive under the ~~Nyxol~~ **Viatris** License Agreement. The Company will be reliant on Viatris to drive the commercialization and sales of our products. If Viatris does not perform its obligations under the ~~Nyxol~~ **Viatris** License Agreement, this could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline ~~. We currently depend entirely on the success of Nyxol and APX3330, our only product candidates. We currently have only two product candidates, Nyxol and APX3330, in clinical development, and our business depends on their successful clinical development, regulatory approval and commercialization (by us our by our strategic partner). The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of a drug product are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, where regulations may differ. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA or in any foreign countries until we receive the requisite approval from such countries. We have submitted an NDA to the FDA for Nyxol for the treatment of RM. The application was accepted for filing by the FDA with a PDUFA date of September 28, 2023. For other indications, and for APX3330, before obtaining regulatory approval for the commercial sale of our product candidates for a particular indication, we must demonstrate through preclinical testing and clinical trials that the applicable product candidate is safe and effective for use in that target indication. This process can take many years and may be followed by post- marketing studies and surveillance together which will require the expenditure of substantial resources beyond the proceeds raised in our equity and debt financings to date. Of the large number of drugs in development in the United States, only a small percentage of drugs successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to complete development of our product candidates, we cannot assure you that our product candidates will be approved or commercialized. Ocuphire Pharma, Inc. Form 10- KObtaining approval of an NDA is an extensive, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of our product candidates for many reasons, including: • the data collected from preclinical studies and clinical trials of our product candidates may not be sufficient to support the submission or acceptance of an NDA for one or more indications; • we may not be able to demonstrate to the satisfaction of the FDA that our product candidates are safe and effective for any indication; • the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA for approval; • the FDA may disagree with the number, design, size, conduct, or implementation of our clinical trials; • the FDA may not find the data from preclinical studies and clinical trials sufficient to demonstrate that our product candidates' clinical and other benefits outweigh the safety risks; • the FDA may disagree with our interpretation of data from preclinical studies or clinical trials; • the FDA may not accept data generated at our clinical trial sites; • the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions; • the FDA may require development of a Risk Evaluation and Mitigation Strategy (REMS) as a condition of approval; • the FDA may identify deficiencies in the manufacturing processes or facilities of third- party manufacturers with which we entered or enter into agreements for clinical and commercial supplies; or • the FDA may change its approval policies or adopt new regulations.~~ The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non- U. S. regulatory authorities. The results from the prior ~~preclinical~~ **nonclinical** studies and clinical trials for ~~Nyxol and~~ APX3330 **and PS** discussed elsewhere in this Annual Report may not necessarily be predictive of the results of future ~~preclinical~~ **nonclinical** studies or clinical trials. Even if we are able to complete our planned clinical trials of our product candidates according to our current development timeline, the results from our prior clinical trials of our product candidates may not be replicated in these future trials. Many companies in the pharmaceutical and biotechnology industries (including those with greater resources and experience than us) have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, ~~preclinical~~ **nonclinical** findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events (" AEs "). Moreover, ~~preclinical~~ **nonclinical** and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in ~~preclinical~~ **nonclinical** studies and clinical trials nonetheless have failed to obtain FDA approval. If we fail to produce ~~positive~~ **adequate** results **reflecting adequate efficacy and safety** in our clinical trials of any of our product candidates, the development timelines, regulatory approvals, and commercialization prospects for our product candidates, as well as Ocuphire' s business and financial prospects, would be adversely affected. Further, Ocuphire' s product candidates may not be approved even if they achieve their respective primary endpoints in additional Phase 3 registration trials. The FDA or non- U. S. regulatory authorities may disagree with our trial designs or our interpretation of data from ~~preclinical~~ **nonclinical** studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical registration trial that has the potential to result in approval by the FDA or another regulatory

authority. **For instance, although we have reached an SPA agreement with FDA for a Phase 3 study for PS for decreased vision under dim (mesopic or low) light conditions after keratorefractive surgery and plan to seek a SPA agreement for studies to support approval of APX3330, the FDA may ultimately require additional studies for approval. The FDA' s SPA process is designed to facilitate the FDA' s review and approval of drugs and biologics by allowing the FDA to evaluate the proposed design and size of certain clinical or animal studies, including clinical trials that are intended to form the primary basis for determining a product candidate' s efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor' s questions regarding protocol design and scientific and regulatory requirements. The FDA aims to complete SPA reviews within 45 days of receipt of the request. The FDA ultimately assesses whether specific elements of the protocol design of the trial, such as entry criteria, dose selection, endpoints and / or planned analyses, are acceptable to support regulatory approval of the product with respect to the effectiveness of the indication studied. All exchanges between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA. Although the FDA may agree to an SPA, an SPA agreement does not guarantee approval of a product. Even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. Ocuphire Pharma, Inc. Form 10- KIn addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol. Generally, such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. Moreover, if the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval.** Furthermore, any of these regulatory authorities may also approve our product candidates for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post- marketing clinical trials. ~~Ocuphire Pharma, Inc. Form 10- K~~ Before obtaining regulatory approvals for the commercial sale of any product candidate for any target indication, we must demonstrate with substantial evidence gathered in ~~preclinical~~ **nonclinical** studies and adequate and well- controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication. We cannot assure you that the FDA or non- U. S. regulatory authorities would consider our planned clinical trials to be sufficient to serve as the basis for approval of our product candidates for any indication. The FDA and non- U. S. regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that our product candidates are safe and effective. If we are required to conduct clinical trials of our product candidates in addition to those we have planned prior to approval, we may need substantial additional funds, and cannot assure you that the results of any such outcomes trial or other clinical trials will be sufficient for approval. **Furthermore, if** ~~Additional data and / or~~ **our current** ~~time may be required to obtain U. S. regulatory approval for any of our product candidates that are deemed to be a drug / device combination product candidate. Our eye drop product candidates are now considered combination products with both drug and device components. The FDA requires both the drug and device components of combination product candidates to be reviewed as part of an~~ **and planned nonclinical** ~~NDA submission. The FDA' s application of the regulations is evolving for drug / device combination products including single- use~~ and ~~multi- dose eye droppers. We may experience requests for additional data and / or delays in the development and commercialization of our drug- led combination product candidates, due to regulatory uncertainties in the product development and approval process. If~~ clinical trials **do not satisfy** ~~of APX3330 fail to demonstrate safety and efficacy to~~ the ~~satisfaction~~ **requirements** of **the FDA or non- U. S.** regulatory authorities **,** ~~or~~ **our business** ~~do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates. Before obtaining marketing approval from regulatory authorities for the sale of APX3330, we need to conduct further animal toxicology studies and additional clinical trials before obtaining marketing approval from regulatory authorities. Clinical testing is expensive, difficult to design and implement, can take many~~ - **may** ~~years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of development. We may experience delays in manufacturing and our clinical trials, and we, or our future collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could result in increased development costs and delay, and could limit or prevent our, or our future collaborators', ability to receive marketing approval or commercialize our product candidates, including: • regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site including due to the ongoing COVID- 19 pandemic or other public health emergency; Ocuphire Pharma, Inc. Form 10- K • government or regulatory delays and changes in regulatory requirements, policy and guidelines may require us to perform additional clinical trials or use substantial additional resources to obtain regulatory approval; • we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs; • the number of patients required for clinical trials may~~ be ~~larger, enrollment in these clinical trials may be slower or participants may drop out of these clinical trials at a higher rate than we anticipate; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • our patients or medical investigators may be unwilling to follow our clinical trial~~

~~protocols; • we might have to suspend or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks; • the cost of clinical trials may be greater than we anticipate; • the supply or quality of any product candidate or other materials~~ **materially harmed** ~~necessary to conduct clinical trials may be insufficient or inadequate; • the product candidate may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials; • clinical trials may be delayed or terminated; and • federal agencies may, due to reduced manpower or diverted resources, require more time to review clinical trial protocols and INDs~ . If we experience delays or difficulties in the enrollment of patients in clinical trials, our ability to conduct and complete those clinical trials, and our ability to seek and receive necessary regulatory approvals, could be delayed or prevented. We or our future collaborators may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or analogous regulatory authorities outside the United States. Patient enrollment can be affected by many factors, including: • severity of the disease under investigation; • availability and efficacy of medications already approved for the disease under investigation; • eligibility criteria and visit schedule for the trial in question; • competition for eligible patients with other companies conducting clinical trials for product candidates seeking to treat the same indication or patient population; ~~Ocuphire Pharma, Inc. Form 10- K~~ • our payments for conducting clinical trials; • perceived risks and benefits of the product candidate under study; • efforts to facilitate timely enrollment in clinical trials; • patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; **Ocuphire Pharma, Inc. Form 10- K** • proximity and availability of clinical trial sites for prospective patients; ~~andthe~~ **and • the** ability of patients to ~~safely~~ participate in clinical trials during any public health emergencies ~~such as the COVID- 19 pandemic~~ . Our inability to enroll a sufficient number of patients for our clinical trials or retain sufficient enrollment through the completion of our trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and cause our stock price to decline. We or others could discover that our product candidates lack sufficient efficacy, or sufficient efficacy compared to competitor products or that they cause undesirable side effects that were not previously identified, which could delay or prevent regulatory approval or commercialization. Because both ~~Nyxol and~~ APX3330 **and PS** have been tested in relatively small patient populations, at a limited range of daily doses **up to 720 mg and** up to 0. 75 % Phentolamine Ophthalmic Solution (which is the same as 1. 0 % Phentolamine Mesylate Ophthalmic Solution) ~~and up to 720 mg~~ respectively, and for limited durations to date, it is possible that our clinical trials have or will indicate an apparent positive effect of ~~Nyxol or~~ APX3330 **or PS** that is greater than the actual positive effect, if any, or that additional and unforeseen side effects may be observed as its development progresses. The discovery that either ~~Nyxol (alone or with adjunctive LDP) or~~ APX3330 **or PS** lacks sufficient efficacy, or that they cause undesirable side effects (including side effects not previously identified in our completed clinical trials), could cause us or regulatory authorities to interrupt, delay, or discontinue clinical trials, and could result in the denial of regulatory approval by the FDA or other non- U. S. regulatory authorities for any or all targeted indications. The discovery that our product candidates lack sufficient efficacy or that they cause undesirable side effects that were not previously identified could prevent us from commercializing such product candidates and generating revenues from sales. In addition, if we receive marketing approval for our product candidates and we or others later **: •** discover that they are less effective, or identify undesirable side effects caused by our product candidates: • regulatory authorities may withdraw their approval of the product; • we may be required to recall the product, change the way this product is administered, conduct additional clinical trials, or change the labeling or distribution of the product (including REMS); • additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the product; • we may be subject to fines, injunctions, or the imposition of civil or criminal penalties; • we could be sued and held liable for harm caused to patients; • the product may be rendered less competitive and sales may decrease; or • our reputation may suffer generally among both clinicians and patients. ~~Ocuphire Pharma, Inc. Form 10- KAny~~ - **Any** one or a combination of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant, or any, revenues from the sale of the product candidate. **Ocuphire Pharma, Inc. Form 10-** ~~Changes~~ **KChanges** in regulatory requirements or FDA guidance, or unanticipated events during our clinical trials, may result in changes to clinical trial protocols or additional clinical trial requirements, which could result in increased costs to us or delays in development timelines. Changes in regulatory requirements or FDA guidance, or unanticipated events during our clinical trials, may require us to amend clinical trial protocols or the FDA may impose additional clinical trial requirements. Amendments to our clinical trial protocols would require resubmission to the FDA and IRBs for review and approval, and may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any ~~Phase 2 or Phase 3~~ trials, or if we are required to conduct additional clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues ~~will~~ **may** be delayed. If we fail to receive regulatory approval for any of our planned indications for our product candidates or fail to develop additional product candidates, our commercial opportunity will be limited. We are initially focused on the development of our product candidates for our target indications, **DR,** the reversal of pharmacologically-induced mydriasis, treatment of presbyopia, ~~DLD, DR~~ and ~~DME~~ **decreased vision under dim (mesopic or low) lighting conditions after keratorefractive surgery. RYZUMVI has been approved for the treatment of pharmacologically-induced mydriasis** . However, we cannot assure you that we will be able to obtain regulatory approval of our product candidates for any **other** indication, or successfully commercialize our product candidates, ~~if~~ **following** ~~approved~~ **approval** . If we do not receive regulatory approval for, or successfully commercialize, our product candidates for one or more of our targeted or other indications, our commercial opportunity will be limited **. Even if we do receive regulatory approval for, or successfully commercialize, our product candidates, they will be subject to ongoing regulatory review and critique. This ongoing review and critique may cause the loss of regulatory approval** . We may pursue clinical development of additional

acquired or in- licensing product candidates. Developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding beyond the net proceeds of our completed equity and debt financings, and are prone to the risks of failure inherent in drug product development. We cannot assure you that we will be able to successfully advance any additional product candidates through the development process. ~~Even if we obtain FDA approval to market additional product candidates, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited.~~ We have limited drug research and discovery capabilities and may need to acquire or license product candidates from third parties **, raise additional capital, or shift capital resources** to expand our product candidate pipeline. We currently have limited drug research and discovery capabilities. Accordingly, if we are to expand our ~~product candidate~~ pipeline beyond ~~Nyxol and APX3330 and~~ our **product** pipeline candidates, we may need to acquire or license product candidates from third parties **, or either raise additional capital or shift capital resources to fund such expansion** . We would face significant competition in seeking to acquire or license promising product candidates **, may not be able to raise additional capital, or may divert capital resources from other areas of the Company that may then face material consequences from less funding** . Many of our competitors for such promising product candidates may have significantly greater financial resources and more extensive experience in ~~preclinical~~ **nonclinical** testing and clinical trials, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products, and thus, may be a more attractive option to a potential licensor than us. If we are unable to acquire or license additional promising product candidates **, raise additional capital, or shift capital resources** , we may not be able to expand our product candidate pipeline. If we are able to acquire or license other product candidates, such license agreements will likely impose various obligations upon us, and our licensors may have the right to terminate the license thereunder in the event of a material breach or, in some cases, at will. A termination of a future license could result in our loss of the right to use the licensed intellectual property, which could adversely affect our ability to develop and commercialize a future product candidate, if approved, as well as harm our competitive business position and our business prospects. Ocuphire Pharma, Inc. Form 10- **K** ~~KWe~~ **We** may expend our limited resources to pursue a particular indication and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we are currently focusing only on development programs that we identify for specific indications for our product candidates. As a result, we may forego or delay pursuit of opportunities for other indications, or with other potential product candidates that later prove to have greater commercial potential. ~~Our~~ **Due to changes or failure to accurately predict the size of the addressable market, among other reasons, our** resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications or future product candidates may not yield any commercially viable product. If we do not accurately evaluate the commercial potential or target market for our product candidates, we may not gain approval or achieve market acceptance of that candidate, and our business and financial results will be harmed. Risks Related to Our Financial Position and Need for Additional Capital ~~We expect to incur losses for the foreseeable future and may never achieve or maintain profitability. As of December 31, 2022, we had an accumulated deficit of $ 71. 5 million. We have funded our operations primarily through issuance of promissory notes and convertible notes in private placements, and then common stock and warrants after becoming a publicly- traded company, and more recently, through fees received under the Nyxol License Agreement. We have devoted substantially all of our financial resources and efforts to the clinical development of our product candidates. Even assuming we obtain regulatory approval for one or more of our product candidates, we expect it to be at least a year before we potentially receive any royalty payments under the Nyxol License Agreement, and several years before APX3330 is potentially ready for commercialization. To become and remain profitable from our product candidates, we must develop and eventually commercialize a product with market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials, obtaining regulatory approval for a product candidate, manufacturing, marketing, and selling any drug for which it may obtain regulatory approval and satisfying any post- marketing requirements. We are in the early stages of most of these activities. We may never succeed in these activities and, even if we does, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability from our product candidates, we may not be able to sustain or increase profitability on an annual basis. Our failure to become or remain profitable from our product candidates may decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations.~~ We have not generated any revenue from sales of any products **, expect to incur losses for the foreseeable future** and may never ~~be~~ **achieve or maintain** ~~profitable~~ **profitability** . **Our only** ~~We have no products~~ **product** approved for commercial sale **is RYZUMVI** , ~~and~~ **which we expect will be launched in the first half of 2024 by Viatris, our commercialization partner. We** do not anticipate generating any **additional** product revenue, unless and until ~~APX3330 or~~ **our** ~~another~~ product ~~candidate~~ **candidates** ~~receives~~ **receive** the regulatory approvals necessary for commercialization in one or more jurisdictions. Our ability to generate revenue ~~from APX3330~~ depends on a number of factors, including our ability to: **• the successful launch and widespread commercialization of RYZUMVI;** • obtain favorable results from and complete the **nonclinical and** clinical development of ~~APX3330~~ **our product candidates** for their planned indications, including successful completion of additional clinical trials for these indications; • submit applications to regulatory authorities for both product candidates and receive timely marketing approvals in the United States and foreign countries; • establish and maintain commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for **RYZUMVI and our** product candidates that we develop, if approved; ~~Ocuphire Pharma, Inc. Form 10- K~~ • establish sales and marketing capabilities to effectively market and sell our product candidates in the United States or other markets, either alone or with a pharmaceutical partner; • address any competing products and

technological and market developments; • obtain coverage and adequate reimbursement for customers and patients from government and third- party payors for **RYZUMVI and our** product candidates that we develop; and • achieve market acceptance of **RYZUMVI and** our product candidates. **Furthermore, as of December 31, 2023, we had an accumulated deficit of $ 81. 5 million. We have funded our operations primarily through issuance of promissory notes and convertible notes in private placements, and then common stock and warrants after becoming a publicly- traded company, and more recently, through fees and a milestone payment received under the Viatris License Agreement. We have devoted substantially all of our financial resources and efforts to the clinical development of our product candidates.** Even ~~if~~ **assuming we obtain additional regulatory approval for one or more of our product candidates, we expect it to be several years before** APX3330 **[and PS]** is ~~approved~~ **potentially ready** for **commercialization, and** ~~commercial sale in one or~~ **our product candidates** ~~all of the initial indications that we are pursuing, it~~ may not gain market acceptance or achieve commercial success. **We may not achieve profitability soon after generating product revenue, if ever, and may be unable to continue operations without continued funding. Ocuphire Pharma,** ~~In~~ **Inc** ~~addition~~ **. Form 10- KTo become and remain profitable from our product candidates** , we **must develop and eventually commercialize a product with market potential. This will require us to be successful in a range of challenging activities, including completing nonclinical testing and clinical trials, obtaining regulatory approval for a product candidate, manufacturing, marketing, and selling any drug for which it may obtain regulatory approval and satisfying any post- marketing requirements. We** anticipate incurring significant costs associated with **these activities** ~~commercializing our product candidates~~ . We **are in the early stages of most of these activities. We** may ~~not~~ **never succeed in these activities and, even if we do, we may never generate revenues that are significant or large enough to** achieve profitability ~~soon after generating~~ **. If we do achieve profitability from our** product ~~revenue~~ **candidates** , **we** ~~if ever, and~~ may **not** be ~~unable~~ -- **able** to **sustain or increase profitability on an annual basis. Our failure to become or remain profitable from our product candidates may decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or** continue **our** operations ~~without continued funding~~ . Our relatively short operating history may make it difficult for investors to evaluate the success of our business to date and to assess our future viability. We are a clinical- stage company, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, and developing our product candidates. We have not yet demonstrated our ability to ~~successfully obtain regulatory approval,~~ manufacture a product at commercial scale ~~,~~ or conduct sales and marketing activities necessary for successful product commercialization. Additionally, there is no operating history on which investors may evaluate our business and our prospects. Investment in a **clinical stage** ~~start- up~~ company such as ours is inherently subject to many risks. These risks and difficulties include challenges in accurate financial planning as a result of: (a) accumulated losses; (b) uncertainties resulting from a relatively limited time period in which to develop and evaluate business strategies as compared to companies with longer operating histories; (c) compliance with regulations required to commence sales on future products; (d) reliance on third parties for clinical, manufacturing, analytical laboratory work, ~~preclinical~~ **nonclinical** , regulatory, commercialization or other activities; (e) financing the business; and (f) meeting the challenges of the other risk factors described herein. We have no operating history upon which investors may base an evaluation of our performance; therefore, we are subject to all risks incident to the creation and development of a new business. There can be no assurance that we can realize our plans on our projected timetable in order to reach sustainable or profitable operations. Adverse developments affecting the financial services industry could negatively affect our current and projected business operations and our financial condition and results of operations. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. ~~Ocuphire Pharma, Inc. Form 10- KThe~~ - **The** results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: **Ocuphire Pharma, Inc. Form 10- K** • Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; • Loss of access to revolving existing credit facilities or other working capital sources and / or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; • Potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements; or • Termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above ~~,~~ could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by parties with whom

we conduct business, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could result in material losses to us and may material adverse impacts on our business. We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations. We will need to raise additional capital to continue to fund the further development of our product candidates and operations. Our future capital requirements may be substantial and will depend on many factors including: • the scope, size, rate of progress, results, and costs of researching and developing our product candidates, and initiating and completing our ~~preclinical~~ **nonclinical** studies and clinical trials; • the cost, timing and outcome of our efforts to obtain **further** marketing approval for our product candidates in the United States and other countries, including to fund the preparation and filing of NDAs with the FDA for our product candidates and to satisfy related FDA requirements and regulatory requirements in other countries; • the number and characteristics of any additional product candidates we develop or acquire, if any; • our ability to establish and maintain collaborations on favorable terms, if at all; ~~Ocuphire Pharma, Inc. Form 10- K~~ • the amount of revenue, if any, from commercial sales, should our product candidates receive marketing approval; **Ocuphire Pharma, Inc. Form 10- K** • the costs associated with commercializing our product candidates, if we receive marketing approval, including the cost and timing of developing sales and marketing capabilities or entering into strategic collaborations to market and sell our product candidates; • the cost of manufacturing our product candidates or products we successfully commercialize; and • the costs associated with general corporate activities, such as the cost of filing, prosecuting and enforcing patent claims and making regulatory filings. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval and commercialization of our product candidates. Additional financing may not be available when we need it, or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are unavailable to us on a timely basis, or at all, we may not be able to continue the development of our product candidates, or commercialize our product candidates, if approved, unless we find a strategic partner. **Ocuphire Pharma, Inc. Form 10-** ~~Worldwide~~ **KWorldwide** economic and social instability **or adverse global economic conditions** could adversely affect our revenue, financial condition, or results of operations. The health of the global economy, and the equity and credit markets in particular, as well as the stability of the social fabric of our society, affects our business and operating results. For example, the equity and credit markets may be adversely affected by ~~the~~ current ~~conflict~~ **conflicts** ~~between Russia~~ **in Europe** and ~~Ukraine~~ **the Middle East, negative trends in the real estate and other sectors in China,** and measures taken in response thereto. If the equity and credit markets are not favorable, we may be unable to raise additional financing when needed or on favorable terms. Our vendors and development partners may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all **. Any weak or declining economy or political disruption, including international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products** . In addition, adverse economic conditions, such as recent supply chain disruptions and labor shortages and persistent inflation, have affected, and may continue to adversely affect our suppliers' ability to provide our manufacturers with materials and components, which may negatively impact our business. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities. **Furthermore,** ~~Adverse global economic conditions could have~~ a ~~negative effect on our business, results of operations and financial condition and Adverse global economic conditions could have a negative effect on our business, results of operations and financial condition and liquidity. A~~ general slowdown in the global economy, including a recession, or in a particular region or industry, an increase in trade tensions with U. S. trading partners, inflation or a tightening of the credit markets could negatively impact our business, financial condition and liquidity. Adverse global economic conditions have from time to time caused or exacerbated significant slowdowns in the industries and markets in which we operate, which have adversely affected our business and results of operations. Macroeconomic weakness and uncertainty also make it more difficult for us to accurately forecast revenue, gross margin and expenses, and may make it more difficult to raise or refinance debt. **Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.** Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt financings as well as potential strategic collaborations and licensing arrangements. We do not have any committed external source of funds. Debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. **Thus** ~~Ocuphire Pharma~~ , ~~Inc~~ **raising additional capital may not be able to be achieved, even if desired, and if possible to raise additional capital, it may not be done so on terms that are desirable** . ~~Form 10- KIf~~ - **If** we raise funds through strategic collaborations or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. This may reduce the value of our common stock. **Ocuphire Pharma, Inc. Form 10-** ~~Risks~~ **KRisks** Related to Government Regulation ~~The FDA~~

~~requires the completion of a toxicology study of similar duration before trials longer than six months can be conducted such as Phase 3 safety exposure trials for chronic indications or efficacy trials with such six- month endpoints. This may lead to a significant delay in the commencement of long- term clinical trials by us or the failure of our product candidates to obtain marketing approval. At this time, we can run long- term trials for chronic indications using Nyxol based on our completed 6- month toxicology study using phentolamine mesylate in a ocular- relevant rodent species (rabbit). This 6- month study validates the duration of the registration studies and their safety extensions: a planned 1- year Phase 3 safety exposure trial to support chronic indications of presbyopia and DLD. For APX3330, the drug has already been dosed for more than a year in humans and completed over 15 single- and repeat- dose toxicology studies in rats and dogs (including 2 studies up to 3 months in duration); with this data we initiated our 24- week clinical trial for APX3330 without further toxicology studies being requested by the FDA. We expect to complete further toxicology studies in support of future clinical trials, per FDA' s guidelines, prior to any marketing approval from regulatory authorities for the sale of APX3330. Clinical trials may be delayed due to these regulatory restrictions and additional oversight by the FDA. In addition, the findings in the toxicology studies could affect the outcome of NDA reviews, and, if approved, labels and uses of our product candidates.~~ Even if we receive marketing approval for our product candidates in the United States, we may never receive regulatory approval to market such product candidates outside of the United States. In addition to the United States, we intend to seek regulatory approval to market our product candidates in Europe, Japan, Canada, and Australia, and potentially other markets. If we pursue additional product candidates in the future, we may seek regulatory approval of such product candidates outside the United States. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of these other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market our product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could have an adverse impact on our business, results of operations and prospects. ~~Ocuphire Pharma, Inc. Form 10- KEven~~ **Even** if we obtain **further** marketing approval for our product candidates, such product candidates could be subject to post- marketing, obligations, restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or experience unanticipated problems with a product following approval. Any product candidate for which we, or our future collaborators, obtain marketing approval in the future, as well as the manufacturing processes, post- approval studies and measures, labeling, advertising, and promotional activities for such drug, among other things, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could include requirements for a restricted distribution system. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product candidate. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post- approval marketing and promotion of drugs to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use and if we, or any future collaborator, does not market a product candidate for which it receives marketing approval for only its approved indications, we, or the collaborator, may be subject to warnings or enforcement action for off- label promotion. Violation of the Federal Food, Drug, and Cosmetic Act (" FDC Act ") and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs, may lead to investigations or allegations of violations of federal or state healthcare fraud and abuse laws and state consumer protection laws ~~.~~ In addition, later discovery of previously unknown AEs or other problems with our product candidates or our manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: • litigation involving patients taking our drugs; • restrictions on such drugs, manufacturers, or manufacturing processes; • restrictions on the labeling or marketing of a drug; • restrictions on drug distribution or use; • requirements to conduct post- marketing studies or clinical trials; **Ocuphire Pharma, Inc. Form 10- K** • warning letters or untitled letters; • withdrawal of the drugs from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • product recall or public notification or medical product safety alerts to healthcare professionals; • fines, restitution, or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • damage to relationships with any potential collaborators; • unfavorable press coverage and damage to our reputation; ~~Ocuphire Pharma, Inc. Form 10- K~~ • refusal to permit the import or export of drugs; • product seizure; or • injunctions or the imposition of civil or criminal penalties. **Legislative reform** ~~We may seek to avail ourselves of mechanisms to expedite the development or approval for~~ **or changes** ~~product candidates we may pursue~~ in the ~~future, such as fast track or breakthrough designation, but such mechanisms may not actually lead to a faster development or~~ regulatory ~~review~~ **environment affecting** ~~or~~ **our business** ~~approval process. We may seek fast track designation, breakthrough designation, orphan drug designation, priority review, or accelerated approval for product candidates~~

~~we may pursue in the future. For example, if a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. However, the FDA has broad discretion with regard to these mechanisms, and even if we believe a particular product candidate is eligible for any such mechanism, we cannot guarantee that the FDA would decide to grant it. Even if we obtain fast track or priority review designation or pursue an accelerated approval pathway, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw a particular designation if it believes that the designation is no longer supported by data from our clinical development program. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. We cannot be sure that our evaluation of a product candidate as qualifying for breakthrough therapy designation will meet the FDA' s requirements. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review, or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more product candidates qualifies as a breakthrough therapy, the FDA may later decide that the product candidate no longer meets the conditions for qualification or may decide that the time period for FDA review or approval will not be shortened. Recently enacted and future legislation~~ may increase the difficulty and cost for ~~us and our future collaborators to obtain~~ **obtaining** marketing approval of our product candidates ~~and~~ **, or otherwise** affect ~~their~~ -- **the** pricing **and commercial viability of or product candidates** . In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of a product candidate, restrict or regulate post- approval activities and affect our ability, or the ability of our future collaborators, to profitably sell any drug for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and cause downward pressure on the price that we, or our future collaborators, may charge for any approved drug. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act (" ACA "), and the Health Care and Education Reconciliation Act, or the Healthcare Reform Act, which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs. There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices. ~~Ocuphire Pharma, Inc. Form 10- KGeneral~~ **General** legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of 2 % reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2027 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and / or any significant taxes or fees that may be imposed on us could have an adverse impact on results of operations. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our current or future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results. **Ocuphire Pharma, Inc. Form 10-** ~~There~~ **KThere** have been judicial and congressional challenges and amendments to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future, as well as efforts to repeal and replace it. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These new laws have resulted in additional reductions in Medicare and other healthcare funding and otherwise may affect the prices we may obtain for any product candidate for which marketing approval is obtained. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering additional health reform measures, such as capping the costs for prescription drugs covered by Medicare Part D and by setting the annual out- of- pocket limit at $ 2, 000 beginning in 2024, as part of other health reform initiatives. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of a product candidate, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval or subject us or our future collaborators to more stringent drug labeling and post- marketing testing and other requirements. ~~Governments outside of~~ **More recently, President Biden signed** the ~~United States tend to impose strict price controls~~ **Inflation Reduction Act of 2022 into law in August of 2022** , which **, among** ~~may adversely affect our revenue from the~~ **other things** ~~sales of a drug~~ , **requires manufacturers to pay rebates to Medicare** if **prices increase faster than inflation** ~~any. In some countries, particularly in the~~

~~European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval~~ for ~~a drug. To obtain reimbursement or pricing approval in some countries, we, or our future collaborators, may be required to conduct a clinical trial that compares the cost- effectiveness of our~~ products **used by Medicare beneficiaries** ~~to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed~~ . Our relationships with healthcare providers and third- party payors will be subject to applicable fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings, among other penalties and consequences. ~~Ocuphire Pharma, Inc. Form 10- KHealthcare~~ **Healthcare** providers and third- party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain marketing approval. Our current and future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute product candidates for which we obtain marketing approval. Restrictions and obligations under applicable federal and state healthcare laws and regulations include the following **.** ~~: • the federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or~~ **For additional detail on potentially applicable** ~~providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • the federal false claims and civil monetary penalties~~ laws, **see** ~~including the civil False Claims Act, impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government; • HIPAA imposes criminal and civil liability for, among other~~ -- **the** ~~things~~ **section titled " Part I** , **Item 1 – Business –** ~~executing a scheme to defraud any healthcare~~ **Healthcare Fraud** ~~benefit program or making false statements relating to healthcare matters; • HIPAA, as amended by the Health Information Technology for Economic~~ and **Abuse** ~~Clinical Health Act,~~ and ~~its implementing~~ **Compliance Laws and** ~~regulations~~ **Regulations** , ~~also imposes obligations, including mandatory contractual terms, on certain people and entities with respect to safeguarding the privacy, security, and transmission of individually identifiable health information; • the federal Physician Payments Sunshine Act under the Affordable Care Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program, with specific exceptions, to report specially to the Centers for Medicare & Medicaid Services within the U~ . **"** ~~S. Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures.~~ Certain state and foreign laws also govern the privacy and security of health information in ways that differ from each other and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, and administrative sanctions, including exclusions from government funded healthcare programs. Defending against any such actions can be costly, time- consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Ocuphire Pharma, Inc. Form 10- KWe are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations which could harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held

liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Our employees or representatives may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements ~~or engaging in insider trading~~ , which could significantly harm our business. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to: • comply with the regulations of the FDA and applicable non- U. S. regulators; • provide accurate information to the FDA and applicable non- U. S. regulators; • comply with healthcare fraud and abuse laws and regulations in the United States and abroad; • report financial information or data accurately; or • disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing, and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity **, including employee compliance training,** may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Ocuphire Pharma, Inc. Form 10- KThe FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If found to have improperly promoted off- label uses, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. If we receive marketing approval for our product candidates for a certain indication, physicians may nevertheless prescribe such products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would adversely affect our business and financial condition. Changes to U. S. tax laws **and state tax laws, such as those impacting our ability to use our net operating loss carryforwards and certain other tax attributes,** may adversely affect our financial condition or results of operations and create the risk that we may need to adjust our accounting for these changes. **We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused federal net operating losses, or NOLs, for taxable years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current law, federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to the federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period, the corporation' s ability to use its pre- change NOLs and other pre- change tax attributes (such as research tax credits) to offset its post- change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre- change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows or results of operations.** The accounting treatment of ~~these~~ **additional changes in U. S. or state** tax law changes is complex, and ~~some of the~~ changes may affect both current and future periods. Consistent with guidance from the SEC, our consolidated financial statements reflect our estimates of the tax effects of the current tax laws and regulation. **Ocuphire Pharma, Inc. Form 10-** ~~Risks~~ **KRisks** Related to Commercialization of Our Product Candidates We face substantial competition **and rapid technological change** , which may result in others discovering, developing, or commercializing products before or more successfully than we do. The development and commercialization of new drug products is highly competitive. We expect to face competition with respect to our product candidates, if approved, and will face competition with respect to any future product candidates that we may seek to develop or commercialize from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions, and government agencies worldwide. The ophthalmic therapies market is highly competitive and dynamic. Our success will depend, in part, on our ability to obtain a share of the market for our planned

indications. ~~We are developing APX3330 for use in two different indications initially: the treatment of DR and DME, and potentially later the treatment of wAMD. In addition to currently approved therapies, any product that is developed for either of the three indications could directly compete with APX3330. Such a product could reduce the overall market opportunity for APX3330.~~ Other pharmaceutical companies may develop therapies for the same indications that would compete with ~~APX3330~~ **RYZUMVI or our product candidates** , if approved, and that would not infringe the claims of our in- licensed patents, pending patent applications, or other proprietary rights, which could adversely affect our business and results of operations. ~~Ocuphire Pharma, Inc. Form 10- KCompetition in Diabetic Retinopathy / Diabetic Macular Edema / wAMD We may face potential competition from both existing therapies and those in development. Current therapies for these retinal diseases rely on suppressing VEGF activity via intravitreal injection or by mitigating the inflammation via intravitreal corticosteroid- releasing implants including: • Lucentis ® (ranibizumab) and Avastin ® (bevacizumab), which are anti- VEGF monoclonal antibody intravitreal injections, developed by Genentech, Inc and Roche AG. • EYLEA ® (aflibercept), a VEGF inhibitor intravitreal injection, developed by Regeneron Pharmaceuticals. • Vabysmo ® (Faricimab), a bispecific monoclonal antibody targeting VEGF- A and Ang- Tie2 pathway developed by Genentech, Inc and Roche AG. • Beovu ® (Brolucizumab), an anti- VEGF monoclonal antibody intravitreal injection, developed by Novartis AG. • MACUGEN ® (pegaptanib sodium injection), a selective inhibitor of VEGF- 165, developed by Bausch Lomb. • Ozurdex ® (dexamethasone), a corticosteroid IVT implant, developed by Allergan plc. • Iluvien (fluocinolone acetonide), a corticosteroid IVT implant, developed by Alimera Sciences, IncThere are also several pharmacological therapies in development, including: • Abicipar, an anti- VEGF intravitreal injection with a long duration of action, developed by Allergan plc and Molecular Partners. • KSI- 301, an anti- VEGF antibody intravitreal injection coupled with a biopolymer that is intended to increase the time between injections, developed by Kodiak Sciences. • OPT- 302, an intravitreal injection which binds to multiple types of VEGF receptors that could be used with other anti- VEGF agents, developed by Opthea Limited. • ALG- 1001, an integrin peptide therapy intravitreal injection that is being evaluated as a sequential or in- combination therapy with bevacizumab in patients with DME, developed by Allegro Ophthalmics, LLC. • RG- 7774, an orally administered selective CB2 (Cannabinoid 2) receptor agonist that is being evaluated in patients with moderately severe to severe non- proliferative diabetic retinopathy, developed by Hoffmann- LA Roche, AG. • RZ402, a small molecule selective and potent plasma kallikrein inhibitor (PKI) for the chronic treatment of diabetic macular edema (DME), developed by Rezolute, Inc. • Xiflam ™, an oral small molecule drug for the treatment of dry form of Age- Related Macular Degeneration (AMD), Geographic Atrophy (GA), Diabetic Retinopathy (DR) manifesting Diabetic Macular Edema (DME), developed by InflammX. • AKST4290, an oral small molecule CCR3 Eotaxin inhibitor for the treatment of diabetic retinopathy and wet AMD. Ocuphire Pharma, Inc. Form 10- K • BAY1101042, an oral guanylate cyclas activator for the treatment of diabetic retinopathy. Ocuphire is developing Nyxol, with our partner Viatris, for use in three different indications: the reversal of pharmacologically induced mydriasis (" RM "), the treatment of presbyopia and the treatment of NVD. In addition to currently approved therapies, any product that is developed for any of the three indications could compete with Nyxol. Such a product could reduce the overall market opportunity for Nyxol. Other pharmaceutical companies may develop therapies for the same indications that would compete with Nyxol, if approved, and that would not infringe the claims of Ocuphire' s patents, pending patent applications, or other proprietary rights, which could adversely affect its business and results of operations. Currently, there are no available and approved pharmacological therapies for NVD or RM and Ocuphire is not aware of any in development. Rev- Eyes ® (dapiprazole), an alpha- 1 antagonist, was approved by the FDA in 1990 to reverse mydriasis induced by adrenergic or anticholinergic agents. Rev- Eyes was withdrawn in the past from the market for reasons unrelated to safety or efficacy, according to the FDA. Presbyopia The FDA approved VuityTM eye drop for the treatment of presbyopia in October 2021. Vuity was launched in December 2021 and is marketed by Allergan, an AbbVie company. The competition also includes reading glasses, multifocal contact lenses, and monovision contact lenses (e. g., where one eye wears a near vision lens and the other eye wears a distance vision lens). Ocuphire will also compete against several pharmacological therapies in development for the temporary treatment of presbyopia, many of which are cholinergic agonist- based pupil management therapies, including: • CSF- 1, with low dose pilocarpine and a secondary agent (lubricant), developed by Orasis Pharmaceuticals Ltd. • LNZ100 and LNZ101, with aceclidine (another miotic agent), developed by Lenz Therapeutics. • MicroLine ®, which is a micro- dose delivery of pilocarpine using proprietary device developed by Eyenovia, Inc. • KT- 101, which uses pilocarpine in the AcuStream delivery system, developed by Kedalion Therapeutics, Inc. • BrimocholTM, with brimonidine and carbachol (both are miotic agents), developed by Visus Therapeutics, Inc. • UNR844, which uses a mechanism that involves softening the lens to increase near visual acuity, developed by Novartis AG (originally Encore Vision, Inc.). There are approved devices for presbyopia. One of these is the KAMRA Inlay, developed by AcuFocus, Inc. and marketed by SightLife Surgical, Inc. Another is the eyelike NoanPinhole, developed by Koryo Eyetech, the first commercially available pinhole soft contact lens. Nyxol would not directly compete against these devices, but rather would be a non- invasive alternative for presbyopes who are averse to surgical intervention. Ocuphire Pharma, Inc. Form 10- KOur~~ **Our** competitors may develop products that are more effective, safer, more convenient, or less costly than any that we are developing, or that would render our product candidates obsolete or non- competitive. Our competitors may also render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products more rapidly than we obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. **Further information on competition is described in " Item 1, Business " in this Annual Report.** Many of our competitors have significantly greater name recognition, financial resources, and expertise in research and development, manufacturing, ~~preclinical~~ **nonclinical** testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a

smaller number of our competitors. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting, hiring, and retaining qualified scientific and management personnel, engaging contract service providers, manufacturers and consultants, establishing clinical trial sites, recruiting patients for clinical trials, and entering into strategic transactions, as well as in acquiring technologies complementary to, or necessary for, our programs. We **do not currently** ~~lack experience in commercializing products, which may~~ have ~~an~~ **any sales** ~~adverse effect on our~~ **or** ~~business. If APX3330 receives~~ marketing **infrastructure** ~~approval, we will need to transition from a company with a development focus to a company capable of supporting commercial activities, and we may not be successful~~ in **place** ~~making that transition. We have not yet demonstrated the ability to obtain marketing approval for, or to commercialize, any product candidate. As a result, our clinical development~~ and ~~regulatory approval activities, and our ability to successfully commercialize any approved products,~~ may **face difficulties in** ~~involve more inherent risk, take longer, and cost more than would be the case if we were a company with experience obtaining marketing approval for and commercializing a product candidate. If we are unable to establish~~ **establishing** sales and marketing capabilities or **engaging** ~~enter into agreements with~~ third parties to sell, market ~~,~~ and distribute APX3330 ~~, if approved, we may not be successful in commercializing APX3330 if and when it is approved~~ . We do not have any sales or marketing infrastructure and have no capabilities in place at the present time for the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource part or all of these functions to other third parties **. The Viatris License Agreement covers the commercialization of RYZUMVI and PS, if approved, but we do not have a similar agreement for APX3330** . There are risks involved with us both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time- consuming, which could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred ~~these~~ -- **the costs of the** commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. **Ocuphire Pharma, Inc. Form 10-** ~~Factors~~ **KFactors** that may inhibit our efforts to commercialize our product candidates on our own include: • the inability to recruit and retain adequate numbers of effective sales and marketing personnel or enter into distribution agreements with third parties; • the inability of sales personnel to obtain access to physicians or ~~persuade~~ **educate an** adequate ~~numbers~~ - **number** of physicians **as** to ~~prescribe~~ **the benefits of** our ~~product~~ **products** ~~candidate~~ ; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; • unforeseen costs and expenses associated with creating an independent sales and marketing organization; **and** ~~andOcuphire Pharma, Inc. Form 10- K~~ • the inability to obtain sufficient coverage and reimbursement from third- party payors and governmental agencies. • If we enter into arrangements with third parties to perform sales, marketing, and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell a product that we developed ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market any product candidate or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market a drug effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. Our future commercial success depends upon attaining significant market acceptance of **RYZUMVI and** our product candidates, if approved, among physicians, patients, third- party payors, and others in the medical community. **RYZUMVI and our product candidates,** ~~Even~~ **even** if **they do** ~~our product candidates~~ receive marketing approval, ~~they~~ may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, or others in the medical community. If ~~such~~ **RYZUMVI and our** product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and may not become profitable. The degree of market acceptance ~~of a~~ **for RYZUMVI and our** product ~~candidate~~ **candidates** , if approved for commercial sale, will depend on a number of factors, including: • efficacy and potential advantages compared to alternative treatments; • the ability to offer our product for sale at competitive prices; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • any restrictions on the use of our product together with other medications; • interactions of our product with other medicines patients are taking; • inability of certain types of patients to take our product; • demonstrated ability to treat patients and, if required by any applicable regulatory authority in connection with the approval for target indications as compared with other available therapies; • the relative convenience and ease of administration as compared with other treatments available for approved indications; **Ocuphire Pharma, Inc. Form 10- K** • the prevalence and severity of any adverse side effects; • limitations or warnings contained in the labeling approved by the FDA; • availability of alternative treatments already approved or expected to be commercially launched in the near future; • the effectiveness of our sales and marketing strategies; • our ability to increase awareness through marketing efforts; ~~Ocuphire Pharma, Inc. Form 10- K~~ • guidelines and recommendations of organizations involved in research, treatment and prevention of various diseases that may advocate for alternative therapies; • our ability to obtain sufficient third- party coverage and adequate reimbursement; • the willingness of patients to pay out- of- pocket in the absence of third- party coverage; and • physicians or patients may be reluctant to switch from existing therapies even if potentially more effective, safe or convenient. We have not yet sold any of our products. We cannot assure investors that there is a sufficient market demand for our products. Achieving market acceptance for our products will require substantial marketing efforts and expenditure of funds to create awareness and demand by participants in the industry. We have not conducted any independent market research to determine the extent of any demand that exists for the products to be provided by us and there is no guarantee that a sufficient interest in the market will exist for the products and services being produced by, or for, us. Any lack of sufficient demand for the products contemplated to be provided by us will

have a material adverse effect on us. If the FDA or a comparable foreign regulatory authority approves generic versions of **RYZUMVI or** our product candidates that receive marketing approval, or if such authorities do not grant our product candidates appropriate periods of exclusivity before approving generic versions of our products, the sales of our products could be adversely affected. Once an NDA is approved, the product covered thereby becomes a " reference listed drug " in the FDA' s publication, " Approved Drug Products with Therapeutic Equivalence Evaluations. " Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications (" ANDAs ") in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical studies. Rather, the applicant generally must show that its product has the same active ingredient (s), dosage form, strength, route of administration, and conditions of use or labeling as the reference listed drug (" RLD ") and that the generic version is bioequivalent to the RLD, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the RLD, and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or RLD may be lost to the generic product ~~. The FDA may not approve an ANDA for a generic product until any applicable period of non- patent exclusivity for the reference listed drug has expired~~ . The FDC Act provides a period of five years of non- patent exclusivity for a new drug containing a new chemical entity (" NCE "). Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years after approval of the RLD. It is unclear whether the FDA will treat the active ingredients in its product candidates as NCEs and, therefore, afford them five years of NCE exclusivity if they are approved. If any product we develop does not receive five years of NCE exclusivity, we may nonetheless be eligible for three years of exclusivity ~~, which means that the FDA may approve generic versions of such product three years after its date of approval. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product~~ . Competition that our product candidates would face from generic versions could materially and adversely impact our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in any such product candidate. Ocuphire Pharma, Inc. Form 10- KEven if we **(or our partners)** are able to commercialize ~~APX3330~~ **RYZUMVI and our product candidates** , our profitability will likely depend in significant part on third- party reimbursement practices, which, if unfavorable, would harm our business. Our **(or our partners)** ability to commercialize ~~APX3330~~ **RYZUMVI and our product candidates** successfully will depend in part on the extent to which coverage and adequate reimbursement will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for certain medications. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, whether the level of reimbursement will be adequate. Assuming we obtain coverage for our product candidates, if approved, by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third- party payors to reimburse all or some of the costs associated with their prescription drugs. Patients are unlikely to use a product candidate, if approved, unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of its products. Therefore, coverage and adequate reimbursement are critical to new product acceptance. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Furthermore, drug pricing and access policies in the United States and internationally may change and negatively impact our product candidates' commercial viability. Proposed policy changes, including the potential for Medicare to negotiate with drug manufacturers, may limit our ability to competitively price our product candidates, if approved. There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which a product candidate is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for a new product, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, there is no uniform policy requirement for coverage and reimbursement for drug products among third- party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often time- consuming and costly, and it will require us to provide scientific and clinical support for the use of our products to each payor separately. There is no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Any inability to promptly obtain coverage and profitable payment rates from government- funded or private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition. Product liability lawsuits against us, or our

suppliers and manufacturers, could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims might be brought against us by patients, healthcare providers, or others selling or otherwise coming into contact with our product candidates during product testing, manufacturing, marketing, or sale. For example, we may be sued under allegations that a product candidate caused injury or that the product was otherwise unsuitable. Any such product liability claims may include allegations of manufacturing or design defects, failure to warn of dangers inherent in the product, such as interactions with alcohol or other drugs, negligence, or breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our product candidate caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: Ocuphire Pharma, Inc. Form 10- K • decreased demand for any product candidate that we are developing; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • increased FDA warnings on product labels; • significant costs to defend the related litigation; • substantial monetary awards to trial participants or patients; • distraction of management' s attention from our primary business; • loss of revenue; ~~and~~ • the inability to commercialize any product candidate that we may develop **; • the initiation of investigations by regulators; and • the inability to take advantage of limitations on product liability lawsuits that apply to generic drug products, which could increase our exposure to liability for products deemed to be dangerous or defective** . Our product liability and / or clinical trial insurance coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand clinical trials and if we successfully commercialize our product candidates. Insurance coverage is increasingly expensive, and we may not be able to obtain product liability insurance on commercially reasonable terms or for a sufficient amount to satisfy liabilities that may arise. Similarly, we may be a party to, or may be otherwise responsible for, pending or threatened lawsuits or other claims related to products purchased from our manufacturers and suppliers. Although we intend to require our providers to have product liability insurance, the ability to obtain such coverage and the sufficiency thereof is uncertain. Such cases and claims may raise difficult and complex factual and legal issues and may be subject to many uncertainties and complexities, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Such litigation could result in additional expense and exposure in excess of our anticipated reserves, especially if such matters are not covered by insurance. Upon resolution of any pending legal matters or other claims, we may incur charges in excess of established reserves. Product liability lawsuits and claims, safety alerts or product recalls in the future, regardless of their ultimate outcome, could have a material adverse effect on the business and reputation and on our ability to attract and retain customers and strategic partners. The business, profitability and growth prospects could suffer if we face such negative publicity. **Ocuphire Pharma, Inc. Form 10-** ~~If~~ **KIf** we or our third- party manufacturers fail to comply with environmental or health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have an adverse effect on the success of our business. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by ourselves and our third- party manufacturers. Our manufacturers are subject to federal, state, and local laws and regulations in the United States and abroad governing laboratory procedures and the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing, and disposing of these materials comply with legally prescribed standards, we cannot eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability, or federal, state, city, or local authorities may curtail our use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or fined, and such liability or fines could exceed our resources. We do not have insurance for liabilities arising from medical or hazardous materials. Although we maintain workers' compensation insurance for costs and expenses that we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Compliance with applicable environmental and health and safety laws and regulations is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, prospects, financial condition, or results of operations. ~~Ocuphire Pharma, Inc. Form 10- KFederal legislation and actions by state and local governments could permit reimportation of drugs from foreign countries into the United States, which could adversely affect our operating results when the drugs are sold at lower prices in foreign countries than in the United States. We may face competition for our product candidates, if approved, from other therapies sourced from foreign countries that have price controls on pharmaceutical products. The Medicare Modernization Act contains provisions that may change U. S. reimportation laws and expand pharmacists' and wholesalers' ability to import cheaper versions of approved drugs or competing products from Canada, where there are government price controls. These changes to U. S. importation laws would not take effect unless and until the Secretary of Health and Human Services certifies that the changes would pose no additional risk to the public' s health and safety and would result in a significant reduction in the cost of products to consumers. The Secretary of Health and Human Services has so far declined to approve a reimportation plan. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any product we may develop and adversely affect our future revenues and prospects for profitability.~~ Risks Related to Our Reliance on Third Parties We **rely** ~~will be unable to control all aspects of our non-~~ **on** ~~-~~ **third parties to conduct our** ~~clinical~~ **nonclinical** ~~studies~~ and ~~our~~ clinical trials ~~due to our reliance on CROs~~ and **perform** other **tasks for us. If these** third parties ~~that assist us in conducting non- clinical studies~~ **do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates** and ~~clinical trials~~ **our business could be harmed** . We rely on third- party CROs and other third parties to assist in managing, monitoring, and otherwise carrying out our ~~non- clinical~~

nonclinical studies and clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our ~~non- clinical~~ **nonclinical** studies and clinical trials in the future ~~, including our Phase 3 development program for Nyxol~~ . We compete with many other companies for the resources of these third parties. As a result, we will have limited control over the conduct, timing, and completion of these ~~non- clinical~~ **nonclinical** studies and clinical trials and the management of data developed through the ~~non- clinical~~ **nonclinical** studies and clinical trials. We have experienced in the past, and may experience in the future, schedule disruptions due to events affecting the performance of third parties on which we rely. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Additionally, other unexpected natural events and disruptions in the supply chain and operations may affect the ability of third parties to fulfill their obligations to us. Outside parties may ~~: •~~ have staffing difficulties; • fail to comply with contractual obligations; • experience regulatory compliance issues; • undergo changes in ownership or management; • undergo changes in priorities or become financially distressed; or • form relationships with other entities, some of which may be our competitors. ~~Ocuphire Pharma, Inc. Form 10- KThese~~ **These** factors may adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. **Ocuphire Pharma, Inc. Form 10-** ~~While~~ **KWhile** our reliance on these third parties for research and development activities will reduce our control over these activities, it will not relieve us of our responsibilities and requirements. For example, the FDA requires us to comply with standards, commonly referred to as good clinical practices (" GCP "), for conducting ~~,~~ recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Problems with the timeliness or quality of the work of any CRO may lead us to seek to terminate our relationship with any such CRO and use an alternative service provider. Making this change may be costly or delay our clinical trials, and contractual restrictions may make such a change difficult or impossible. If we must replace any CRO that is conducting our clinical trials, our clinical trials may have to be suspended until we find another CRO that offers comparable services. The time that it would take us to find alternative organizations may cause a delay in the commercialization of our product candidates, or it may cause us to incur significant expenses to replicate any lost data. Although we do not believe that any CRO on which we would rely would offer services that are not available elsewhere, we may be difficult to find a replacement organization that can conduct our clinical trials in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical trials could significantly compromise our ability to secure regulatory approval for our product candidates and preclude our ability to commercialize our product candidates, thereby limiting or preventing our ability to generate sales revenue. **Further, requirements related to clinical trials continue to evolve, which may require additional oversight, greater costs, and / or delay. In 2023, FDA published guidance documents related to informed consent and GCPs that may present additional requirements to CROs. In August 2023, FDA published a guidance document, Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. Further, in December 2023, FDA published a final rule, Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations, which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. These guidance documents present evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial, which may increase costs and delay clinical programs. Additionally, in June 2023, FDA published a draft guidance, E6 (R3) Good Clinical Practice (GCP), which seeks to unify standards for clinical trial data for ICH member countries and regions. Changes to data requirements may cause FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies.** We rely completely on third parties to supply and manufacture bulk drug substances and to formulate and package ~~preclinical~~ **nonclinical** and clinical drug supplies of our product candidates as well as to conduct analytical testing of drug substances and products in the manufacturing processes and **we** intend to rely on third parties to produce and test commercial supplies of our current and any future product candidates. We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our clinical drug supply of product candidates for use in the conduct of our ~~preclinical~~ **nonclinical** studies and clinical trials. We lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. The process of manufacturing drug products is complex, highly regulated, and subject to several risks. For example, the facilities used by our contract manufacturers to manufacture and conduct analytical testing of the active pharmaceutical ingredient (or drug substance) and final drug product for product candidates must be inspected by the FDA and other comparable foreign regulatory agencies in connection with our submission of an NDA or relevant foreign regulatory submission to the applicable regulatory agency. In addition, the manufacturing of drug substance or product is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, or vendor or operator error. Moreover, the manufacturing facilities in which product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures, or other factors. Manufacturing timelines may be negatively affected by material shortages, construction delays and supply chain challenges due to, among other factors, global supply chain shortages **. Ocuphire Pharma, Inc. Form 10- KFurther, requirements related to the manufacturing of ophthalmic products may evolve, which may require modifications to our current manufacturing processes. In December 2023, FDA published a revised draft guidance, Quality Considerations for Topical Ophthalmic Drug Products, which focuses on quality considerations for ophthalmic drug products intended for topical delivery in and around the eye. Updated quality considerations may cause delay to adapt to new requirements and may also increase costs associated with manufacturing** . We do not control the manufacturing and testing processes of our contract manufacturers and analytical labs, and are completely dependent on them to comply with current good manufacturing practices (" cGMP ") for manufacture

and good lab practices (“ GLP ”) of both active drug substances and finished drug products. If our contract manufacturers and analytical labs cannot successfully manufacture and test materials that conform to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, we will not be able to secure and / or maintain regulatory approval for our products. In addition, we have no control over our contract manufacturers’ and analytical labs’ ability to maintain adequate quality control, quality assurance, and qualified personnel. Failure to satisfy the regulatory requirements for the production and testing of those materials and products may affect the regulatory clearance of our contract manufacturers’ and analytical labs’ facilities generally. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture and testing of product candidates, or if it withdraws its approval in the future, we may need to find alternative manufacturing and testing facilities, which would adversely impact our ability to develop, obtain regulatory approval for, or market product candidates. Furthermore, all of our contract manufacturers and analytical labs are engaged with other companies to supply and / or manufacture and / or test materials or products for such companies, which exposes our manufacturers to regulatory and sourcing risks for the production of such materials and products. To the extent practicable, ~~our~~ **we have** ~~attempts~~ **attempted** to identify more than one supplier. However, some raw materials are available only from a single source or only one supplier has been identified, even in instances where multiple sources exist. ~~Ocuphire Pharma, Inc. Form 10- KWe~~ - **We** have relied and will rely upon third- party manufacturers and testing labs in the United States and overseas for the manufacture and testing of ~~Nyxol and~~ APX3330 **and PS** for ~~preclinical~~ **nonclinical** and clinical testing purposes and intend to continue to do so in the future for ~~Nyxol,~~ APX3330, **PS** ~~Nyxol with adjunctive low- dose pilocarpine~~ , and any other product candidates, including for commercial purposes. If our third- party manufacturers and analytical labs are unable to supply or test drug substance and / or drug product on a commercial basis, we may not be able to successfully produce and market product candidates, if approved, or we could be delayed in doing so. For instance, we presently rely on one supplier in Italy for the drug substance for ~~Nyxol~~ **PS** , and one manufacturer in India for APX3330 drug substance. If there is any delay or problem with the manufacture of these drug substances or if there is a delay in producing finished drug product from these drug substances, the development and **PS, the** possible approval of our product candidates and potential commercial launch may be delayed or otherwise adversely affected. We will rely on comparison of product specifications (identity, strength, quality, and potency) to demonstrate equivalence of the current drug substance and / or drug product to the drug substance and / or drug product used in previously completed ~~preclinical~~ **nonclinical** and clinical testing. If we are unable to demonstrate such equivalence, we may be required to conduct additional ~~preclinical~~ **nonclinical** and / or clinical testing of our product candidates ~~. The formulation of the low- dose pilocarpine as adjunctive product candidate with Nyxol is still in development. We have already experienced a few interruptions in our manufacturing, supply chain, research and development operations, regulatory and financial position, including, for example, the shipment of active pharmaceutical ingredient supply from overseas~~ . Due to these and other potential problems, we are exploring the possibility of establishing additional sources of supply, with U. S. manufacturers, for the active pharmaceutical ingredients of both ~~Nyxol and~~ APX3330 **and PS** . Establishing these additional sources, including qualifying their manufacturing processes and demonstrating the equivalence of their products, may be costly, time- consuming, and difficult to effectuate, and may delay our research and development activities **. Even if we could transfer manufacturing to a different third party, any shift would likely be expensive and time consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before using or selling any products manufactured at that facility** . If we must replace any manufacturer, our research and development activities may have to be suspended until we find another manufacturer that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the development and commercialization of product candidates. **Ocuphire Pharma, Inc. Form 10- K We have entered and may enter into licensing arrangements for the development or sale of product candidates (such as the Viatris License Agreement) and may form or seek additional strategic alliances or enter into licensing arrangements in the future. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be harmed.** We have entered into ~~the Nyxol License Agreement and may form or seek additional strategic alliances or enter into licensing arrangements in the future, and may not realize benefits from such alliances or licensing arrangements. We have entered into the Nyxol License Agreement,~~ and may form or seek additional strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates **(such as the Viatris License Agreement)** . Any of these relationships may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, or issue securities that dilute our existing stockholders, which may disrupt our management and business. Our likely collaborators include large, mid- size, regional, or national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators’ abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Collaborations involving product candidates pose the following risks to us: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may not pursue development and commercialization or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator’ s strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities; ~~Ocuphire Pharma, Inc. Form 10- K~~ • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidate if

the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more attractive than ours; • a collaborator with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing or distribution of any such product candidate; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • disputes may arise between us and collaborators that result in the delay or termination of research, development, or commercialization of our product candidates, or in litigation or arbitration that diverts management attention and resources; • we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control; • collaborations may be terminated and such terminations may create a need for additional capital to pursue further development or commercialization of the applicable product candidates; **Ocuphire Pharma, Inc. Form 10- K** • collaborators may learn about our discoveries and use this knowledge to compete with us in the future; • the results of collaborators' ~~preclinical~~ **nonclinical** or clinical studies could harm or impair other development programs; • there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others; • the number and nature of our collaborations could adversely affect our attractiveness to potential future collaborators or acquirers; • collaboration agreements may not lead to development or commercialization of our product candidate in the most efficient manner or at all. If a present or future collaborator of us were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated; and • collaborators may be unable to obtain the necessary marketing approvals. ~~Ocuphire Pharma, Inc. Form 10- KIF~~ **If** future collaboration partners fail to develop or effectively commercialize product candidates for any of these reasons, such product candidates may not be approved for sale and our sales of such product candidates, if approved, may be limited, which would have an adverse effect on our operating results and financial condition. If we are not able to establish new collaborations for APX3330 on commercially reasonable terms, we may have to alter our development, manufacturing, and commercialization plans. We face significant competition in attracting collaborators for development, manufacturing or commercialization plans **. We already have a collaboration with Viatris for the development and commercialization of RYZUMVI and PS** . Whether we reach a definitive agreement for collaboration for APX3330 will depend, among other things, upon our assessment of the proposed collaborator' s resources, expertise, and evaluation of a number of factors related to the associated product candidate, as well as the terms and conditions of the proposed collaboration. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which may exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaborations and whether such a collaboration could be more attractive than one with us. We may not be able to enter into these agreements on commercially reasonable terms, or at all. Much of the potential revenue from future commercial collaborations may consist of contingent payments, such as payments for achieving regulatory milestones or royalties payable on sales of our product candidate, if approved. The milestone and royalty revenue that we may receive under these collaborations would depend upon our collaborators' ability to successfully develop, introduce, market and sell our product candidate, if approved. In addition, collaborators may decide to enter into arrangements with third parties to commercialize products developed under collaborations related to our product candidates, which could reduce the milestone and royalty revenue received, if any. We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. **Ocuphire Pharma, Inc. Form 10-** ~~We~~ **KWe** may not be able to negotiate collaborations on a timely basis and on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or that of one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or bring us to market and generate product revenue. If we engage in acquisitions, in- licensing or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks. We may engage in various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership may entail numerous risks, including: • increased operating expenses and cash requirements; • the assumption of indebtedness or contingent liabilities; ~~Ocuphire Pharma, Inc. Form 10- K~~ • the issuance of our equity securities which would result in dilution to our stockholders; • assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel; • the diversion of management' s attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership; • retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and • our inability to generate revenue from acquired intellectual property, technology and / or products

sufficient to meet our objectives or even to offset the associated transaction and maintenance costs. In addition, if we undertake such a transaction, we may incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. Risks Related to Our Intellectual Property If we are unable to obtain and maintain sufficient patent protection for our product candidates, our competitors could develop and commercialize products or technology similar or identical to those of us, which would adversely affect our ability to successfully commercialize any product candidates we may develop, our business, results of operations, financial condition and prospects. We ~~primarily~~ **and our licensors have sought to** protect our **proprietary position by filing** ~~intellectual property through a combination of patents and~~ patent applications **in** ~~on inventions, trademark protection on our product name, and trade secret protection as we deem appropriate. As of February 10, 2023, our patent estate relating to~~ the ~~Nyxol contains ten~~ U. S. ~~patents, eight~~ **and abroad related to our novel technologies and product candidates. Our** pending **and future** ~~U. S. non- provisional~~ patent applications ~~, as well as~~ **may not result in patents being** issued ~~patents in Australia, Canada, Europe, Japan, and Mexico and pending patent applications in Australia, Canada, Europe, Japan, China, and other foreign countries, all of~~ which **protect our technology or products** ~~are owned by us. Our U. S. Patents 9~~ , ~~795, 560; 10, 278, 918; 10, 772, 829, 11, 090, 261, 11, 566, 005 and counterpart Australian, Canadian, European, and Japanese patents each contain composition of matter claims to aqueous phentolamine mesylate formulations and are scheduled to expire~~ in ~~year 2034~~ **whole or in part, or which effectively prevent others from commercializing competitive technologies and products** . In **particular** ~~the same patent family~~ , **during prosecution of any** ~~we also have 1 pending U. S.~~ patent application ~~with additional claims to aqueous phentolamine mesylate formulations~~ , ~~whereby a patent, if granted, based on this patent application would expire in year 2034. The patents and patent applications cover the current clinical formulation for the Nyxol product. Our U. S. Patent Nos. 9, 089, 560; 9, 789, 088; and 11, 000, 509 contain claims directed to methods of improving visual performance using, for example, phentolamine mesylate and are scheduled to expire in year 2034. Counterpart patents have issued in Australia, Canada, Europe and Japan, which are scheduled to expire in year 2034. In the same patent family, we also have 1 pending U. S. patent application with additional claims to methods of improving visual performance using, for example, phentolamine mesylate, whereby a patent, if granted from this pending patent application, would expire in year 2034. The patents and patent applications cover uses of the current clinical formulation for the Nyxol product. We have patent applications pending in the U. S., Australia, Canada, China, Europe, and Japan directed to treating glaucoma and other~~ -- **the issuance** ~~medical disorders using phentolamine mesylate. Patents, if granted, based on these pending applications would expire in year 2039. Oeuphire Pharma, Inc. Form 10- KOur U. S. Patent 10, 993, 932 contains claims directed to methods~~ of **any** ~~treating presbyopia using phentolamine mesylate in combination with pilocarpine and is scheduled to expire in year 2039. Our U. S. Patent 11, 400, 077 contains claims directed to methods of treating mydriasis using phentolamine mesylate and is scheduled to expire in year 2039. In the same patent family as U. S. Patent Nos. 10, 993, 932 and 11, 400, 077, we have four pending U. S. patent applications, two of which have claims to treating presbyopia and the other two U. S. application have claims to treating mydriasis. Counterpart patent applications are pending in Australia, Canada, China, Europe, Japan, and other foreign countries, whereby a patent, if granted, based on these pending U. S. and foreign patent applications would expire in year 2039. We have one U. S. Patent 11, 566, 005, a pending U. S. patent application, and a pending international patent application directed to phentolamine mesylate composition of matter and methods of making high- purity phentolamine mesylate, and compositions with claimed phentolamine mesylate for the treatment of presbyopia, dim light or night vision disturbances and others. Our U. S. patent 11, 566, 005 claims include phentolamine mesylate composition of matter, topical ophthalmic composition containing 1 % of the claimed phentolamine mesylate composition of matter and methods of use for the claimed composition in presbyopia, dim light and night vision disturbances and treatment of pharmacologically induced mydriasis. This patent and other~~ patents based on the ~~foregoing patent applications~~ - **application may depend upon our ability** ~~in its class if granted, are scheduled~~ to ~~expire in year 2042~~ **generate additional pre- clinical or clinical data that support the patentability of our proposed claims** . We **may not be able** ~~also have one pending patent application in China directed~~ to **generate sufficient** ~~methods of making high- purity phentolamine mesylate and compositions resulting from such methods, whereby any patents, if granted, based on this patent application in China would expire in year 2041. We also have a pending international patent application directed to~~ additional **data** ~~methods for treating mydriasis and glaucoma, whereby any U. S. or foreign patents, if granted, from~~ on a **timely basis** ~~patent application filed based on this international patent application would expire in year 2042 We also own an issued patent in Mexico that is scheduled to expire in year 2025 and has claims to ophthalmic formulations. We have in- licensed a patent estate directed to APX3330 and related compounds that~~ , ~~as of February 10, 2023, contains seven U. S. patents, two pending U. S. non- provisional patent applications, as well as issued patents in Europe, Japan, Canada, and Australia, and pending patent applications in Europe, Japan, Canada, China, South Korea and Australia. Our in- licensed U. S. patent 9, 040, 505 has claims to methods of treating diabetic retinopathy and other diseases using, for~~ - **or at all** ~~example, APX3330 and is scheduled to expire in year 2030. Counterpart patents have issued in Europe, Japan, Australia, and Canada, which are scheduled to expire in year 2028, and there is a related pending U. S. patent application with method of treatment claims that, if issued as a patent, would expire in year 2028. Our in- licensed pending U. S. patent application 16, 968, 009 and pending applications in Europe, Japan, Canada, South Korea and Australia have claims to methods of treating wAMD and other diseases using, for example, APX3330, whereby patents, if granted based on these pending patent applications, would expire in year 2039. Our in- licensed patent applications directed to a combination therapy composition comprising an APE1 / REF- 1 inhibitor, such as APX3330, and a second therapeutic agent, and are pending in the U. S. and Canada, whereby patents, if granted based on these pending patent applications, would expire in year 2038. In- licensed patent applications directed to use of an APE1 / REF- 1 inhibitor, such as APX3330, in monotherapy or combination therapy to reduce neuronal sensitivity and / or treat other indications are pending in Europe, Japan, and Canada, whereby patents, if granted based on these applications, would expire in year 2038. This same patent family includes one in- licensed U. S. patent directed to methods using APX3330 to treat inflammation and pain as part of a combination therapy.~~

~~Patents to derivatives of APX3330 have been issued in the U. S., Europe, and other countries that are scheduled to expire from year 2028 to 2032. In addition to patents and patent applications that we have in- licensed, as of February 10, 2023, we own one pending international patent application directed to methods of treating diabetic retinal diseases using APX3330. Patents, if granted, from an application filed based on this pending international patent applications would expire in year 2042. Additionally, we own one pending U. S. provisional patent application directed to certain salt forms of APX3330 and methods of use, whereby any patents, if granted, from an application filed based on this provisional patent application would expire in year 2043, and we own one pending U. S. provisional patent application directed to additional therapeutic methods using APX3330 in patients with diabetic retinal disease, whereby any patents, if granted, from an application filed based on this provisional patent application would expire in year 2044~~ . Ocuphire Pharma, Inc. Form 10- KThe patent prosecution process is expensive and time- consuming, and we and our future licensors, licensees, or collaboration partners may not be able to prepare, file, and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or any future licensors, licensees, or collaboration partners may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. We and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued from such applications, and then only to the extent the issued claims cover the technology. We cannot assure you that any of our patents have matured, or that any of our pending patent applications will mature, into issued patents that will include, claims with a scope sufficient to protect our product candidates. Others have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, for example by claiming the same compounds, methods or formulations or by claiming subject matter that could dominate the patents that we owns or in- licenses. The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity, and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U. S. patents and patent applications may also be subject to interference proceedings, ex parte reexamination, or inter partes review proceedings, supplemental examination and challenges in district court. Patents may be subjected to opposition, post- grant review, or comparable proceedings in various national and regional patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, re- examination, opposition, post- grant review, inter partes review, supplemental examination, or revocation proceedings may be costly or time- consuming. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. Furthermore, the issuance of a patent, while presumed valid, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs, or methods. We may not be able to prevent the unauthorized disclosure or use of any technical knowledge or trade secrets by consultants, vendors, former employees, or current employees. The laws of some foreign countries do not protect proprietary rights to the same extent as do the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales. Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time- consuming and would divert the attention of management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If, in any proceeding, a court invalidated or found unenforceable our patents covering our product candidates, our financial position and results of operations would be adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered our product candidates, our financial position and results of operations would also be adversely impacted. **Ocuphire Pharma, Inc. Form 10-** ~~The~~ **KThe** degree of future protection for our proprietary rights is uncertain, and we cannot ensure that: ~~Ocuphire Pharma, Inc. Form 10- K~~ • any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our product candidates; • any of our pending patent applications will result in issued patents; • we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire; • we were the first to make the inventions covered by each of our patents and pending patent applications; • we were the first to file patent applications for these inventions; • others will not develop similar or alternative technologies that do not infringe our patents; • any of our patents will be valid and enforceable; • any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; • we will develop additional proprietary technologies or product candidates that are separately patentable; or • our commercial activities or products will not infringe upon the patents of others. Patents have a limited lifespan. The natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the extensive period of time between patent filing and regulatory approval for a product candidate, the time during which we can market a product candidate under patent

protection is ~~limited~~ **listed** , and our patent may expire before we obtain such approval. Without patent protection for our product candidates, we may be vulnerable to competition from generic versions of our product candidates, which may affect the profitability of our product candidates. **Furthermore, obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment or other provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have an adverse effect on our business. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Maintaining patents in the U. S. is an expensive process and it is even more expensive to maintain patents and patent applications in foreign countries. As a result, it is possible that we and our licensors will fail to maintain such patents thereby reducing the rights of our portfolio. The patent position of pharmaceutical, biotechnology, and medical device companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, or which effectively prevent others from commercializing competitive technologies and products. Ocuphire Pharma, Inc. Form 10-** ~~If~~ **KIf** we do not obtain protection under the Hatch- Waxman Act and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidate, our business may be materially harmed. Depending upon the timing, duration of regulatory review, and date of FDA marketing approval of our ~~APX3330~~ or other product candidates, if any, one of such U. S. patents may be eligible for patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Act. The Hatch- Waxman Act provides for a patent restoration term, or patent term extension, of up to five years as compensation for the time the product is under FDA regulatory review. The duration of patent term extension is calculated based on the time spent in the regulatory review process. In the future, we may plan to seek patent term extension for one or more of our patents related to our ~~APX3330~~ **RYZUMVI** or other product candidates. However, we may not be granted an extension because of, for example, failing to apply within the applicable deadline, expiration of relevant patents prior to obtaining approval, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be shorter or less than what we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our revenue could be reduced, possibly materially. ~~Ocuphire Pharma, Inc. Form 10- KChanges~~ **Changes** in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. In 2011, the United States enacted wide- ranging patent reform legislation with the America Invents Act (" AIA "). An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before we could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Additionally, the U. S. Supreme Court' s holdings in several patent cases in recent years, such as Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I), Mayo Collaborative Services v. Prometheus Laboratories, Inc., and Alice Corporation Pty. Ltd. v. CLS Bank International, have narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty about our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. **Ocuphire Pharma, Inc. Form 10-** ~~We~~ **KWe** may not be able to protect or practice our intellectual property rights throughout the world. In jurisdictions where we have not obtained patent protection, competitors may use our intellectual property to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our product candidates in jurisdictions where we do not have issued or granted patents or where our issued or granted patent claims or other intellectual property rights are not sufficient to prevent

competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly that relating to pharmaceuticals. This could make it difficult for us to prevent the infringement of our patents or marketing of competing products in violation of our proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we, or any future licensor, encounters difficulties in protecting, or is otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we, or any licensor, is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business and results of operations may be adversely affected. ~~Ocuphire Pharma, Inc. Form 10- KWe-~~ **We** may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming, and unsuccessful. Competitors may infringe on our patents, the patents of our licensing partners, or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that our patent is invalid or unenforceable, or may refuse to stop the other party from using the technology on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Litigation proceedings may fail and, even if successful, may be costly and a distraction to our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, we could have a substantial adverse effect on the price of our common stock. **Ocuphire Pharma, Inc. Form 10-** ~~Third~~ **KThird** parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have an adverse effect on the success of our business. Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our medicines and technology, including interference or derivation proceedings, post- grant reviews, inter partes reviews, or other procedures before the USPTO or other similar procedures in foreign jurisdictions. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our medicines and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, we could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. We could be forced, including by court order, to cease developing and commercializing the infringing technology or medicine. In addition, we could be held liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if found to have willfully infringed. A finding of infringement could prevent us from commercializing a product candidate or force us to cease some of our business operations, which could harm our business. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. The cost to us of any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial and may result in substantial costs and distraction to our management and other employees. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations. ~~Ocuphire Pharma, Inc. Form 10- KWe-~~ **We** may be subject to damages resulting from claims that our employees or we have wrongfully **misappropriated their intellectual property** ~~used or disclosed alleged trade secrets~~ of their former employers. Our employees and consultants have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information or intellectual property of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could detract from our ability to develop or commercialize our product candidates. If we are not able to adequately

prevent disclosure of trade secrets and other proprietary information, the value of any product we may pursue could be significantly diminished. **While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.** We may rely upon trade secrets, know- how, and continuing technological innovation to develop and maintain our competitive position. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or has had access to trade secrets. If a party breaches an agreement and discloses our proprietary information, including our trade secrets, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, some courts in and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be harmed. **Ocuphire Pharma, Inc. Form 10-** ~~Obtaining~~ **KObtaining** and maintaining our trademark protection depends on approval from the USPTO and other foreign government agencies, and third parties may challenge, infringe, or otherwise weaken our trademark rights. We have obtained registration of the " ~~Nyxol~~ **RYZUMVI** " trademark in the United States. We have not yet registered trademarks for any other product candidates in any jurisdiction **(other than " Nyxol ", which we are no longer using)** . If we do not secure and maintain registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could affect our business. When we file trademark applications for a product candidate, those applications may not be allowed for registration, and registered trademarks may not be obtained, maintained, or enforced. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but may not be able to overcome such rejections. In addition, the ~~USPTO~~ **SPTO** and comparable agencies in many foreign jurisdictions allow third parties opportunities to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings. In addition, any proprietary name we propose to use with a future product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed drug names, including an evaluation of potential for confusion with other drug names. If the FDA objects to any proposed proprietary drug name for any product candidate, we may be required to expend significant additional resources in an effort to identify a suitable substitute proprietary drug name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. ~~Ocuphire Pharma, Inc. Form 10- KIf~~ **If** we register any of our trademarks, our trademarks or trade names may be challenged, infringed, circumvented, declared generic, or determined to infringe on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. ~~Obtaining and maintaining~~ **We may enter into collaborations, in- licensing arrangements, joint ventures, strategic alliances** ~~our results of operations and prospects.We may enter into collaborations,in- licensing arrangements,joint ventures,strategic alliances~~ or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.We may enter into certain license or other collaboration agreements in the future.Such agreements may impose various diligence,milestone payment,royalty,insurance or other obligations on us.If we fail to comply with such obligations,our licensor or collaboration partners may have the right to terminate the relevant agreement,in which event we would not be able to develop or market the products covered by such licensed intellectual property.Moreover,disputes may arise regarding intellectual property subject to a licensing agreement,including:• the scope of rights granted under the license agreement and other interpretation- related issues;• the extent to which our product candidates,technology **and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;• the sublicensing of** patent ~~protection depends on compliance with various procedural, document submission, fee payment,~~ and other ~~requirements imposed by governmental agencies,~~ **rights under our collaborative development relationships; • our diligence obligations under the license agreement** and **what activities satisfy those diligence obligations; Ocuphire Pharma, Inc. Form 10- K • the inventorship and ownership of inventions and know- how resulting from the joint creation** ~~our~~ **or use of intellectual property; and • the priority of invention of** ~~patent~~ **patented technology** ~~protection could be reduced or eliminated for noncompliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment or other provisions during the patent application process~~ . In addition, ~~periodic maintenance~~ **the agreements under which intellectual property or technology is licensed from third parties are complex,** and ~~annuity fees on~~ **certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of** any **contract interpretation disagreement that** ~~issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. While an inadvertent lapse can in many~~ **may** ~~cases~~ **arise could narrow what we believe to** be **the scope** ~~cured by payment~~ of

our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a **material** ~~late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have an~~ adverse effect on our business **, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In addition, we cannot be certain that the preparation, filing, prosecution and maintenance activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights** . We depend on intellectual property sublicensed from **third parties (such as** Apexian Pharmaceuticals, Inc. **for product candidates** (" Apexian ") for our APX3330 product candidate under development **)** and our additional pipeline candidates, and the termination of, or reduction or loss of rights under, this sublicense would harm our business. We entered into a sublicense agreement with Apexian (as amended, the " Apexian Sublicense Agreement ") to in- license patents and other intellectual property relating to the APX3330 product candidate and second- generation product candidates owned by Apexian, and intellectual property that Apexian in- licensed from Eisai Co., Ltd. (" Eisai ") including certain study reports, manufacturing and analytical records, data, know- how, technical and other proprietary information relating to APX3330. **We may, in the future, enter into additional sublicense agreements of the same or a similar nature for APX3330 or other product candidates.** The rights granted under **sublicense agreements, such as** the Apexian Sublicense Agreement **,** are **and may be** subject to various milestone payment, royalty, insurance or other obligations on us, and may be revocable under certain circumstances including if we cease to do business, fail to make the payments due thereunder, commit a material breach of the agreement that is not cured within a certain time period after receiving written notice or fail to meet certain specified development and commercial timelines. Termination of **sublicense agreements, such as** the Apexian Sublicense Agreement **,** may result in us having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, which may mean we are unable to develop or commercialize APX3330 and second- generation assets. We do not have total control over the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license under **sublicense agreements, including** the Apexian Sublicense Agreement. Under the Sublicense Agreement, Indiana University Research and Technology Corp. (" IURTC "), the owner of the patents licensed to Apexian and sublicensed to us, maintains the right to control all prosecution and maintenance of such patents. Therefore, we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business. Although we have a right to have our comments considered in connection with, and have agreed to bear the costs of, the prosecution and maintenance of the licensed patents, if IURTC fails to prosecute and maintain such patents, or loses rights to those patents or patent applications as a result of its control of the prosecution activities, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. ~~Ocuphire Pharma, Inc~~ **Similar reductions of rights or terminations may occur with regards to future sublicense agreements** . ~~Form 10- KFurther~~ - **Further** , if Apexian breaches its license agreement with IURTC and fails to cure such breach within a 60- day cure period, IURTC may terminate such license agreement with Apexian, in which case, our license shall also terminate and we will lose all rights under the license agreement with Apexian. **Ocuphire Pharma, Inc. Form 10-** ~~While~~ **KWhile** the Apexian Sublicense Agreement provides that Apexian must cooperate with us to remedy and cure Apexian' s breach of the license agreement with IURTC in order to prevent the termination of such license agreement, we cannot guarantee that such efforts will be successful in preventing the termination of the license agreement between Apexian and IURTC. Similarly, if Apexian breaches its license agreement with Eisai and fails to cure such breach within a 60- day cure period, Eisai may terminate such license agreement with Apexian, in which case, our sublicense rights under such license shall also terminate. While we do not have any material obligations under the license agreement between Eisai and Apexian, Apexian has certain confidentiality and payment obligations that, if not met, could result in breach of the Eisai license ~~agreement~~ **agreements** . Under Apexian' s license agreement with IURTC, any act or omission by us that would be a breach of the license agreement with IURTC if imputed to Apexian is deemed to be a breach by Apexian of such license agreement and cause for termination, including, in particular, any breach by us of our payment, reporting, audit, and indemnification obligations. **Expansion through obtaining rights to product candidates and approved products through acquisitions may not be successful. We may acquire the rights to other products, product candidates, or technologies in the future.** The **future growth** ~~Apexian Sublicense Agreement obligates us to make certain milestone payments. We are obligated to pay certain milestone payments to Apexian pursuant to the Apexian Sublicense Agreement. These milestone payments include (i) payments for specified developmental and regulatory milestones totaling up to $ 11 million in the aggregate and (ii) payments for specified sales milestones~~ of **our business may depend** ~~up to $ 20 million~~ in **part on our ability** ~~the aggregate. Because certain milestone payments payable by us are due upon certain events related~~ to **acquire** the **rights to** ~~development and regulatory approval~~ **approved** ~~of our~~ **products, additional** product candidates, **or technologies. However,** we may be ~~required~~ **unable** to ~~make~~ **acquire the rights to any** such **products** ~~payments prior to the time at which we are able to generate revenue~~ , ~~if any, from sales any of our~~ product candidates, ~~if approved. There can be no assurance that we will have the funds necessary to make such payments, or be able to raise such funds when needed, on terms acceptable to us, or at all. Furthermore, if we are forced to raise additional funds, we may be required to delay, limit, reduce or terminate our~~ - **or** product development or future commercialization efforts,..... to which our product candidates, technology **technologies** ~~and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of~~

~~patent and other rights under our collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; Ocuphire Pharma, Inc. Form 10- K • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property; and • the priority of invention of patented technology. In addition, the agreements under which intellectual property or technology is licensed~~ from third parties **. The acquisition of pharmaceutical products is a competitive area, and a number of more established companies** are **also pursuing strategies** ~~complex, and certain provisions in such agreements may be susceptible~~ to ~~multiple interpretations. The resolution of any contract interpretation disagreement~~ **license or acquire products, product candidates, or technologies** that ~~may arise could narrow what~~ we **may consider attractive. These established companies may** ~~believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could~~ have a **competitive advantage** ~~material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes~~ over **us due** ~~intellectual property that we have licensed prevent or impair our ability~~ to **their size** ~~maintain our licensing arrangements on commercially acceptable terms~~, ~~we may be unable to successfully~~ **cash resources, and greater clinical** ~~develop~~ **development** and ~~commercialize~~ **commercialization capabilities** ~~the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects~~. In addition, **companies** ~~we cannot be certain~~ that ~~the preparation, filing, prosecution and maintenance activities by any future~~ **perceive us to be a competitor may be unwilling to assign or** ~~licensors~~ **license** ~~have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property~~ rights **to us. We also may be unable to acquire the rights to the relevant product, product candidate, or technology on terms that would allow us to make an appropriate return on our investment. Furthermore, we may be unable to identify suitable products, product candidates, or technologies within our area of focus. If we are unable to successfully obtain rights to suitable products, product candidates or technologies, our ability to pursue this element of our strategy could be impaired** . Risks Related to Our Employee Matters and Managing Growth We are dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. We are highly dependent on our management, scientific, and medical personnel, including ~~Mina Sooch~~ **George Magrath** , ~~our President~~ **MD, MBA, MS** , Chief Executive Officer and Board **Director** ~~Vice Chair~~ . We have entered into employment agreements with our executive officers, but any employee may terminate his or her employment with us. The loss of the services of any of our executive officers, other key employees or consultants, or other scientific and medical advisors in the foreseeable future might impede the achievement of our research, development, and commercialization objectives. If we fail to retain key personnel and are unable to hire highly qualified replacements, we may not be able to meet key objectives, such as meeting financial goals, and maintaining or expanding our business. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Recruiting and retaining qualified scientific personnel and business and commercial personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical trials may also make it more challenging to recruit and retain qualified scientific personnel. **Ocuphire Pharma, Inc. Form 10-** ~~We~~ **KWe expect that we** will need to develop and expand **a number of corporate functions in** our company **(including sales, marketing,** and **distribution teams), and, as a result, we** may encounter difficulties in managing this development and expansion, which could disrupt our operations. As of March 1, ~~2023~~ **2024** , we had ~~ten~~ **17** full- time employees, and we expect to increase our number of employees and the scope of our operations as we further the clinical development of our product candidates. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of our attention away from our day- to- day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees, or reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage our future development and expansion. **A** ~~Ocuphire Pharma, Inc. Form 10- KA~~ variety of risks associated with operating internationally for us and our collaborators could adversely affect our business. In addition to our U. S. operations, we may pursue international operations in the future and would face risks associated with such global operations, including possible unfavorable regulatory, pricing and reimbursement, legal, political, tax, and labor conditions, which could harm our business. We plan to conduct clinical trials outside of the United States. We are subject to numerous risks associated with international business activities, including: • compliance with differing or unexpected regulatory requirements for our product candidates; • different medical practices and customs affecting acceptance of our product candidates, if approved, or any other approved product in the marketplace; • language barriers; • the interpretation of contractual provisions governed by foreign law in the event of a contract dispute; • difficulties in staffing and managing foreign operations, and an inability to control commercial or other activities where it is relying on third parties; • workforce uncertainty in countries where labor unrest

is more common than in the United States; • potential liability under the Foreign Corrupt Practice Act of 1977 or comparable foreign regulations; • production shortages resulting from any events affecting raw material supply or manufacturing capability abroad; • foreign government taxes, regulations, and permit requirements; • U. S. and foreign government tariffs, trade restrictions, price and exchange controls, and other regulatory requirements; **Ocuphire Pharma, Inc. Form 10- K** • economic weakness, including inflation, natural disasters, war, events of terrorism, or political instability in particular foreign countries; • fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues; • compliance with tax, employment, immigration, and labor laws, regulations, and restrictions for employees living or traveling abroad; • changes in diplomatic and trade relationships; **and** ~~andOcuphire Pharma, Inc. Form 10- K~~ • challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States. ~~Our business and~~ **If we experience any of these risks, our sales in non-U. S. jurisdictions may be harmed, our results of** operations would suffer **, and our reputation and business prospects would be negatively impacted. Our business and operations would suffer** in the event of system failures or unplanned events **, including cyber incidents, network security breaches, service interruptions, or data corruption** . Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunications and electrical failures. In March 2021, we were the victim of a business email compromise. This fraud did not cause any losses to us. If another such event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to mitigate, detect and remediate actual or potential vulnerabilities. Furthermore, **failure to protect our information technology infrastructure against cyber incidents, network security breaches, service interruptions, or data corruption could materially disrupt our operations and adversely affect our business, operating results, or the effectiveness of our internal controls over financial reporting. Furthermore,** any unplanned event, such as flood, fire, explosion, tornadoes, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunications failure, **cybersecurity incidents, network security breaches, service interruptions, or data corruption** other natural or manmade accidents or incidents, or pandemics, that result in us being unable to fully utilize the facilities, may have an adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on its financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates, or interruption of our business operations. **Risks Related to Ownership of** Our **Common Stock** ~~insurance policies are expensive and protect only from some business risk, which leaves us exposed to significant uninsured liabilities.~~ We ~~do not carry~~ **currently have a substantial number of shares of common stock subject to potential** ~~insurance~~ **issuance associated with our Equity Line of Credit arrangement. The issuance** ~~for~~ **or sale** ~~all categories~~ of ~~risks~~ **shares under our ELOC arrangement would substantially increase the number of shares outstanding and result in dilution to our security holders. This might substantially decrease the market price of the common stock. We have a substantial number of shares of our common stock** that ~~our business~~ may ~~encounter, and insurance coverage is becoming increasingly expensive. We do not know if we will~~ be **issued** ~~able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire~~ in the future ~~may not be sufficient to reimburse the company for any expenses or losses we may suffer. If we obtain marketing approval for any product candidates that we may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. Required coverage limits for such insurances are difficult to predict and may not be sufficient. If potential losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that the company or our collaborators may develop. In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers~~ . Ocuphire Pharma, Inc. Form 10- ~~KEnvironmental~~ **K • In connection with our equity line of credit** , ~~social and governance matters and any related reporting obligations may impact our~~ **or ELOC** businesses. U. S. and international regulators ~~investors and other stakeholders are increasingly focused on environmental~~ , **arrangement** ~~social, and governance (ESG) matters. For example, new domestic and international laws and regulations relating to ESG matters, including human capital~~ **we issued Lincoln Park Capital Fund** , ~~diversity~~ **LLC 246** , **792 shares of** ~~sustainability, climate change and cybersecurity, are under consideration or~~ **our common stock. • Under** ~~being adopted, which may include specific, target- driven disclosure requirements or~~ **our ELOC arrangement** ~~obligations. Our response will require additional investments and implementation of new practices and reporting processes~~ , **we can sell up** ~~all entailing additional compliance risk. Our aspirations and disclosures related~~ to ~~environmental~~ **$ 50** , ~~social~~ **000** , **000 worth** ~~and governance (" ESG ") matters expose us to risks that could adversely affect our reputation and performance. Risks Related to Ownership~~ of ~~Our~~ **our** Common Stock **over the thirty- six month term**

of the ELOC arrangement, to Lincoln Park Capital, LLC, beginning only after certain conditions set forth in the Purchase Agreement have been satisfied. To the extent that shares of common stock are issued or sold under our ELOC arrangement, dilution to our security holders may occur. The issuance of these additional securities may have an adverse effect on the market price of our securities. We do not anticipate paying any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain, if any, for the foreseeable future. If we fail to comply with the continued listing standards of the Nasdaq Capital Market, our common stock could be delisted. If it is delisted, the liquidity of our common stock would be impacted. The continued listing of our common stock on Nasdaq is contingent on our continued compliance with a number of listing standards. There is no assurance that we will remain in compliance with these standards. Delisting from Nasdaq would adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our securities and negatively affect the value and liquidity of our common stock. Delisting also could limit our strategic alternatives and attractiveness to potential counterparties and have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities. In addition, if our common stock is delisted from the Nasdaq Capital Market and the trading price remains below $ 5. 00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a " penny stock " (generally, any equity security not listed on a national securities exchange or quoted on Nasdaq that has a market price of less than $ 5. 00 per share, subject to certain exceptions). The market price of our common stock may fluctuate significantly. The market price of our common stock may fluctuate significantly in response to factors, some of which are beyond our control, such as: • the announcement of new products or product enhancements by us or our competitors; • changes in our relationships with our licensors or other strategic partners; • developments concerning intellectual property rights and regulatory approvals; • variations in ours and our competitors' results of operations; • substantial sales of shares of our common stock due to the release of lock- up agreements; • the announcement of clinical trial results; • the announcement of potentially dilutive financings; • changes in earnings estimates or recommendations by securities analysts; Ocuphire Pharma, Inc. Form 10- K • changes in the structure of healthcare payment systems; ~~and~~ • developments and market conditions in the pharmaceutical and biotechnology industries, including due to the COVID- 19 pandemic **; and • the results of clinical trials of APX3330, PS, or any other product candidate that we may develop** . Further, the stock market, in general, and the market for biotechnology companies, in particular, have experienced extreme price and volume fluctuations **. As a result of this volatility, investors may not be able to sell their securities at a profit** . Continued market fluctuations could result in extreme volatility in the price of our common stock, which may be unrelated or disproportionate to our operating performance and which could cause a decline in the value **of our common stock and result in substantial losses for purchasers** of our common stock. We may be subject to securities litigation, which is expensive and could divert management attention. The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and direct our management' s attention from other business concerns, which could seriously harm our business. ITEM 1B. UNRESOLVED STAFF COMMENTS