

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended September 30, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-34079

Ocuphire Pharma, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

11-3516358

(I.R.S. Employer Identification Number)

37000 Grand River Avenue, Suite 120
Farmington Hills, MI

(Address of Principal Executive Offices)

48335

(Zip Code)

Registrant's Telephone Number, Including Area Code: (248) 957-9024

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, \$0.0001 par value per share	OCUP	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	<input type="checkbox"/>	Non-accelerated filer	<input checked="" type="checkbox"/>
Accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of outstanding shares of the registrant's common stock as of November 7, 2023 was 22,637,600.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Ocuphire Pharma, Inc. **Condensed Balance Sheets** (in thousands, except share amounts and par value)

	As of	
	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 42,350	\$ 42,634
Accounts receivable (Note 9)	10,132	1,298
Contract assets and unbilled receivables (Note 9)	1,211	3,552
Prepays and other current assets	484	1,453
Short-term investments	11	49
Total current assets	54,188	48,986
Property and equipment, net	3	6
Total assets	\$ 54,191	\$ 48,992
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,890	\$ 1,069
Accrued expenses	1,926	1,684
Derivative liability	93	—
Total current liabilities	3,909	2,753
Total liabilities	3,909	2,753
Commitments and contingencies (Note 3 and Note 8)		
Stockholders' equity		
Preferred stock, par value \$0.0001; 10,000,000 shares authorized as of September 30, 2023 and December 31, 2022; no shares issued and outstanding at September 30, 2023 and December 31, 2022.	—	—
Common stock, par value \$0.0001; 75,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 22,610,131 and 20,861,315 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively.	2	2
Additional paid-in capital	126,951	117,717
Accumulated deficit	(76,671)	(71,480)
Total stockholders' equity	50,282	46,239
Total liabilities and stockholders' equity	\$ 54,191	\$ 48,992

See accompanying notes.

Ocuphire Pharma, Inc.
Condensed Statements of Comprehensive Income (Loss)
(in thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
License and collaborations revenue	\$ 11,935	\$ —	\$ 17,358	\$ —
Operating expenses:				
General and administrative	2,055	1,703	8,680	5,215
Research and development	3,494	2,835	13,812	10,769
Total operating expenses	5,549	4,538	22,492	15,984
Income (loss) from operations	6,386	(4,538)	(5,134)	(15,984)
Financing costs (Note 6)	(1,328)	—	(1,328)	—
Interest expense (Note 4)	—	—	—	(9)
Fair value change in derivative liability	61	—	61	—
Other income (expense), net	456	7	1,224	(60)
Income (loss) before income taxes	5,575	(4,531)	(5,177)	(16,053)
Provision for income taxes	(14)	—	(14)	—
Net income (loss)	5,561	(4,531)	(5,191)	(16,053)
Other comprehensive income (loss), net of tax	—	—	—	—
Comprehensive income (loss)	\$ 5,561	\$ (4,531)	\$ (5,191)	\$ (16,053)
Net income (loss) per share (Note 10):				
Basic	\$ 0.26	\$ (0.22)	\$ (0.25)	\$ (0.82)
Diluted	\$ 0.25	\$ (0.22)	\$ (0.25)	\$ (0.82)
Number of shares used in per share calculations:				
Basic	21,446,648	20,498,229	21,117,211	19,635,651
Diluted	22,405,995	20,498,229	21,117,211	19,635,651

See accompanying notes.

Ocuphire Pharma, Inc.
Condensed Statements of Changes in Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Equity
Balance at December 31, 2021	18,845,828	\$ 2	\$ 111,588	\$ (89,368)	\$ 22,222
Issuance of common stock in connection with the at-the-market program	336,544	—	1,208	—	1,208
Issuance costs	—	—	(35)	—	(35)
Stock-based compensation	6,970	—	445	—	445
Exercise of stock options	24,309	—	27	—	27
Net and comprehensive loss	—	—	—	(6,595)	(6,595)
Balance at March 31, 2022	19,213,651	2	113,233	(95,963)	17,272
Issuance of common stock in connection with the at-the-market program	877,927	—	1,858	—	1,858
Issuance costs	—	—	(53)	—	(53)
Stock-based compensation	8,024	—	445	—	445
Net and comprehensive loss	—	—	—	(4,927)	(4,927)
Balance at June 30, 2022	20,099,602	2	115,483	(100,890)	14,595
Issuance of common stock in connection with the at-the-market program	634,509	—	1,362	—	1,362
Issuance costs	—	—	(42)	—	(42)
Stock-based compensation	66,372	—	493	—	493
Exercise of Series B warrants	1,023	—	—	—	—
Net and comprehensive loss	—	—	—	(4,531)	(4,531)
Balance at September 30, 2022	20,801,506	2	117,296	(105,421)	11,877
Balance at December 31, 2022	20,861,315	2	117,717	(71,480)	46,239
Issuance costs	—	—	(2)	—	(2)
Stock-based compensation	68,646	—	804	—	804
Exercise of warrants	17,869	—	—	—	—
Net and comprehensive loss	—	—	—	(5,791)	(5,791)
Balance at March 31, 2023	20,947,830	2	118,519	(77,271)	41,250
Issuance costs	—	—	(7)	—	(7)
Stock-based compensation	37,954	—	1,422	—	1,422
Net and comprehensive loss	—	—	—	(4,961)	(4,961)
Balance at June 30, 2023	20,985,784	2	119,934	(82,232)	37,704
Issuance of common stock in connection with the at-the-market program and purchase agreement	1,624,347	—	6,504	—	6,504
Issuance costs	—	—	(60)	—	(60)
Stock-based compensation	—	—	573	—	573
Net and comprehensive income	—	—	—	5,561	5,561
Balance at September 30, 2023	22,610,131	2	126,951	(76,671)	50,282

See accompanying notes.

Ocuphire Pharma, Inc.
Condensed Statements of Cash Flows
(in thousands)
(Unaudited)

	For the Nine Months Ended September 30,	
	2023	2022
Operating activities		
Net loss	\$ (5,191)	\$ (16,053)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,799	1,383
Depreciation	3	3
Unrealized loss from short-term investments	38	118
Financing costs	1,328	—
Fair value change in derivative liability	(61)	—
Change in assets and liabilities:		
Accounts receivable	(8,834)	—
Contract assets and unbilled receivables	2,341	—
Prepaid and other assets	969	709
Accounts payable	709	(125)
Accrued and other liabilities	239	(512)
Net cash used in operating activities	<u>(5,660)</u>	<u>(14,477)</u>
Investing activities		
Net cash used in investing activities	<u>—</u>	<u>—</u>
Financing activities		
Proceeds from issuance of common stock in connection with the at-the-market program and purchase agreement	5,482	4,428
Issuance costs	(106)	(119)
Payments made in connection with short-term loan	—	(538)
Exercise of Series B warrants	—	—
Exercise of stock options	—	27
Net cash provided by financing activities	<u>5,376</u>	<u>3,798</u>
Net decrease in cash and cash equivalents	(284)	(10,679)
Cash and cash equivalents at beginning of period	42,634	24,534
Cash and cash equivalents at end of period	<u>\$ 42,350</u>	<u>\$ 13,855</u>
<i>Supplemental disclosure of cash flow information:</i>		
Cash paid for income taxes	\$ 318	\$ —
Cash paid for interest	\$ —	\$ 9
<i>Supplemental non-cash financing transactions:</i>		
Unpaid issuance costs	\$ 115	\$ 11
Non-cash issuance of common stock in connection with equity purchase agreement	\$ 1,022	\$ —
Value of derivative established in connection with the equity purchase agreement	<u>\$ 154</u>	<u>\$ —</u>

See accompanying notes.

Notes to Condensed Financial Statements

1. Company Description and Summary of Significant Accounting Policies

Nature of Business

Ocuphire Pharma, Inc. (the “Company” or “Ocuphire”) is a clinical-stage ophthalmic biopharmaceutical company focused on developing novel therapies for the treatment of unmet needs of patients with retinal and refractive eye disorders.

The Company’s lead retinal product candidate, APX3330, is a first-in-class small-molecule inhibitor of Ref-1 (reduction oxidation effector factor-1 protein). Ref-1 is a regulator of transcription factors such as HIF-1 α and NF- κ B. Inhibiting REF-1 reduces levels of vascular endothelial growth factor (“VEGF”) and inflammatory cytokines which are known to play key roles in ocular angiogenesis and inflammation. Through inhibition of Ref-1, APX3330 normalizes the levels of VEGF to physiologic levels, unlike biologics that deplete VEGF below the levels required for normal function. APX3330 is an oral tablet administered twice per day for the treatment of diabetic retinopathy (“DR”). A Phase 2 study in subjects with DR or diabetic macular edema has recently been completed. A successful End-of-Phase 2 (“EOP2”) meeting with the U.S. Food and Drug Administration (the “FDA”) was held in October 2023 at which the Company obtained agreement on the registration endpoint supporting the advancement of APX3330 into Phase 3 clinical trials.

DR affects approximately 10 million people with diabetes and is projected to impact over 14 million Americans by 2050. DR is classified as Non-Proliferative Diabetic Retinopathy (“NPDR”), the early stage of the disease in which symptoms may be mild or nonexistent or Proliferative Diabetic Retinopathy (“PDR”) which is the more advanced stage of diabetic eye disease that can be highly symptomatic with loss of vision. Approximately 80% of DR patients have NPDR that will progress to PDR if left untreated. Despite the risk for visual loss associated with this disease, over 90% of NPDR patients currently receive no course of treatment apart from observation by their eye care specialist until they develop sight-threatening complications. This is due to the treatment burden of the frequent eye injections required with currently approved therapies for this disease. APX3330, as an oral tablet, has the potential to be an early, non-invasive treatment for the 8 million NPDR patients in the US.

The Company has also in-licensed APX2009 and APX2014, which are second-generation analogs of APX3330. The unique mechanism of action of these Ref-1 inhibitors of reducing angiogenesis and inflammation could potentially be beneficial in treating other retinal diseases such as age-related macular degeneration, and geographic atrophy.

In November 2022, the Company entered into a license and collaboration agreement (the “Nyxol License Agreement”) with FamyGen Life Sciences, Inc. (“Famy”) (acquired by Viatris, Inc. (“Viatris”) in January 2023) pursuant to which it granted Viatris an exclusive license to develop, manufacture, import, export and commercialize its refractive product candidate Phentolamine Ophthalmic Solution 0.75%, formerly known as Nyxol (“POS”). POS is a once-daily eye drop formulation of phentolamine mesylate designed to reduce pupil diameter and improve visual acuity. POS was approved by the FDA for the treatment for pharmacologically-induced mydriasis under the brand name RYZUMVI™ in September 2023. POS is currently in Phase 3 clinical trials for presbyopia (age-related blurry near vision). The VEGA-2 Phase 3 study in presbyopia achieved its primary endpoint. POS is also in Phase 3 for night vision disturbances or dim light vision (“DLD”) (halos, glares and starbursts) and a Special Protocol Assessment (“SPA”) has been submitted in DLD with the FDA.

The Company’s headquarters is located in Farmington Hills, Michigan.

Reverse Merger with Rexahn

On June 17, 2020, Ocuphire, Rexahn Pharmaceuticals, Inc. (“Rexahn”) and Razor Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Rexahn (“Merger Sub”), entered into an Agreement and Plan of Merger and Reorganization, as amended on June 29, 2020 (as amended, the “Merger Agreement”), pursuant to which, among other things, and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, Merger Sub would merge with and into Ocuphire, with Ocuphire continuing as a wholly-owned subsidiary of Rexahn and the surviving corporation of the merger (the “Merger”). The Merger closed on November 5, 2020. Upon completion of the Merger, Rexahn changed its name to Ocuphire Pharma, Inc. and changed its ticker symbol on the Nasdaq Capital Market (“Nasdaq”) to “OCUP”.

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the effects of the conflict between Russia and Ukraine and potentially between Israel and Hamas, disruptions in the banking system and financial markets, lingering COVID-19 pandemic, increased inflation and rising interest rates. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected the Company's access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, the Company's future cost of equity or debt capital and access to the capital markets could be adversely affected.

Additionally, the Company's operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, conflicts in Ukraine and the Middle East, disruptions in the banking system and financial markets, and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates.

Basis of Presentation

The accompanying condensed financial statements have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP") have been condensed or omitted pursuant to such rules and regulations.

The December 31, 2022 condensed balance sheet was derived from audited financial statements and may not include all disclosures required by GAAP; however, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the fiscal year ended December 31, 2022.

In the opinion of management, all adjustments, consisting of only normal recurring adjustments that are necessary to present fairly the financial position, results of operations, and cash flows for the interim periods, have been made. The results of operations for the interim periods are not necessarily indicative of the operating results for the full fiscal year or any future periods.

On December 31, 2021, the Company merged its wholly-owned subsidiary, OcuSub Inc, with and into the Company, with the Company remaining as the surviving entity. The merger of the Company's wholly-owned subsidiary did not have a financial impact in the periods presented. Upon closing of this merger, the Company did not have any remaining entities that required consolidation for financial statement reporting purposes. All significant intercompany accounts and transactions were eliminated in the preparation of the condensed financial statements prior to the December 31, 2021 merger with OcuSub Inc.

Liquidity

The accompanying condensed financial statements have been prepared on the basis that the Company will continue as a going concern. From its inception, the Company has devoted substantially all of its efforts to drug development and conducting clinical trials.

As of September 30, 2023, the Company had \$42.4 million in cash and cash equivalents. The Company believes its current available cash and cash equivalents will be sufficient to fund the Company's planned expenditures and meet its obligations for at least 12 months following November 13, 2023, which is the date that these condensed financial statements are available to be issued.

Notes to Condensed Financial Statements

In the future, the Company may need to raise additional funds until it is able to generate sufficient revenues to fund its development activities. The Company's future operating activities, coupled with its plans to raise capital or issue debt financing, may provide additional liquidity in the future, however these actions are not solely within the control of the Company and the Company is unable to predict the outcome of these actions to generate the liquidity ultimately required.

Use of Estimates

The preparation of condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed financial statements and accompanying notes. Actual results could differ from those estimates.

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer or such person functioning in such role. The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is the business of development of products related to vision performance and health. Accordingly, the Company has a single reporting segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of deposit to be cash equivalents.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. Management follows approved policies established by its Board of Directors to reduce credit risk associated with the Company's cash deposit and investment accounts. Pursuant to these policies, the Company limits its exposure through the kind, quality and concentration of its investments. The Company's cash and cash equivalents are held or managed by two financial institutions in the United States. As of September 30, 2023, the Company had cash equivalents of \$42.0 million that were not eligible for coverage by Federal Deposit Insurance Corporation ("FDIC"). These balances are invested in funds whose assets consist almost entirely of securities issued by the U.S. Treasury or guaranteed by the U.S. government.

Short-term Investments

The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase and records them on a settlement date basis. The Company's short-term investments are comprised of equity securities, which in accordance with the fair value hierarchy described below are recorded at fair value using Level 1 inputs on the balance sheets. Subsequent changes in fair values are recorded in other income (expense), net on the condensed statements of comprehensive income (loss). The Company classifies investments available to fund current operations as current assets on its balance sheets. The Company did not recognize any impairments on its investments to date through September 30, 2023.

Revenue Recognition

The Company follows the provisions of Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers. The guidance provides a five-step model to determine how revenue is recognized. The Company has entered into license agreements which have revenue recognition implications (See Note 9 – License and Collaboration Agreements).

In determining the appropriate amount of revenue to be recognized, the Company performs the following steps: (i) identification of the contracts with a customer; (ii) determination of the performance obligations in the contract; (iii) measurement of the transaction price, including potential constraints on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated stand-alone selling prices; and (v) recognition of revenue when (or as) the Company satisfies a performance obligation.

Notes to Condensed Financial Statements

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606. Performance obligations may include license rights, development and other services. Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations are either completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. The Company allocates the total transaction price to each performance obligation based on the relative standalone selling prices of the promised goods or service underlying each performance obligation.

Licenses of intellectual property and research and development services: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license. For licenses that are bundled with other obligations, such as research and development services, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. For research and development services that are distinct from a license transfer obligation, the Company determines whether the services are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from such services. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission) is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until such contingency occurs (such as receipt of those approvals).

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Contract Assets and Unbilled Receivables

The Company recognizes contract assets and unbilled receivables when goods or services are transferred to the customer before the customer pays or before reimbursement for payment is billed or due, excluding any amounts presented as an account receivable. The Company recorded contract assets and unbilled receivables in connection with a license and collaboration agreement in the amount of \$1.2 million as of September 30, 2023. See Note 9- License and Collaboration Agreements.

Accounts Receivable and Allowances for Doubtful Accounts

The Company records a provision for doubtful accounts, when appropriate, based on historical experience and a detailed assessment of the collectability of its accounts receivable. In estimating the allowance for doubtful accounts, the Company considers, among other factors, the aging of the accounts receivable, its historical write-offs, the credit worthiness of each customer, and economic conditions that could affect the collectability of the balances in the future. Account balances are charged off against the allowance when the Company believes that it is probable that the receivable will not be recovered. Actual write-offs may be in excess of the Company's estimated allowance. The Company has not incurred any bad debt expense to date and no allowance for doubtful accounts has been recorded during the periods presented.

Notes to Condensed Financial Statements

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries and stock-based compensation costs, for personnel in functions not directly associated with research and development activities. Other significant costs include legal fees relating to intellectual property and corporate matters, professional fees for accounting and tax services, settlement costs with third parties and other services provided by business consultants.

Research and Development

Research and development expenses (“R&D”) consist of costs incurred in performing research and development activities, including compensation for research and development employees and consultants, costs associated with nonclinical studies and clinical trials, regulatory activities, manufacturing activities to support clinical activities, license fees, fees paid to external service providers that conduct certain research and development, and an allocation of R&D related overhead expenses. R&D costs include costs that are reimbursed under the Nyxol License Agreement.

Financing costs

Financing costs consist of issuance costs attributed to an equity line financing facility with Lincoln Park (See Note 6 – Stockholders’ Equity).

Interest Expense

Interest expense is attributed to interest on principal related to a short-term loan during the period it was outstanding. The short-term loan was fully repaid in May 2022.

Other Income (Expense), net

Other income (expense), net reflected in this line item includes payments made by the Company in connection with the Contingent Value Rights Agreement discussed further below with former Rexahn shareholders. In addition, other income (expense), net includes interest earned from cash and cash equivalent investments, realized and unrealized gains (losses) from equity investments and reimbursements in connection with grants and other sources when they occur.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of the Financial Accounting Standards Board (“FASB”) ASC 718, *Compensation — Stock Compensation*. Accordingly, compensation costs related to equity instruments granted are recognized at the grant date fair value. The Company records forfeitures when they occur. Stock-based compensation arrangements to non-employees are accounted for in accordance with the applicable provisions of ASC 718.

Derivative Liability

The Company evaluates all features contained in financing agreements to determine if there are any embedded derivatives that require separation from the underlying agreement under ASC 815 – *Derivatives and Hedging*. An embedded derivative that requires separation is accounted for as a separate liability from the host agreement. The separated embedded derivative is accounted for separately on a fair market value basis. The Company records the fair value changes of a separated embedded derivative at each reporting period in the condensed statements of comprehensive income (loss) under the fair value change in derivative liability line item. The Company determined that certain features under an equity line financing (See Note 6 — Stockholders’ Equity) collectively qualified as an embedded derivative. The derivative was accounted for separately from the underlying equity line financing agreement.

Notes to Condensed Financial Statements

Fair Value Measurements

The Company follows accounting guidance that emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Fair value is defined as “the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.” Fair value measurements are defined on a three-level hierarchy:

- Level 1 inputs: Unadjusted quoted prices for identical assets or liabilities in active markets;
- Level 2 inputs: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, whether directly or indirectly, for substantially the full term of the asset or liability; and
- Level 3 inputs: Unobservable inputs that reflect the Company’s own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

As of September 30, 2023 and December 31, 2022, the fair values of cash and cash equivalents, accounts receivable, contract assets, unbilled receivables, prepaid and other assets, accounts payable, accrued expenses approximated their carrying values because of the short-term nature of these assets or liabilities. The fair value of the short-term investments, while outstanding, were based on observable Level 1 inputs in the form of quoted market prices from a major stock exchange. The fair value of the derivative liability associated with the equity line financing facility (See Note 6 – Stockholders’ Equity) was based on cash flow models discounted at current implied market rates representing expected returns by market participants for similar instruments and are based on Level 3 inputs. The fair value of the warrant liabilities, while outstanding, were based on a Black-Scholes option model using Level 3 inputs. There were no transfers between fair value hierarchy levels during the three and nine months ended September 30, 2023 and 2022.

The fair value of financial instruments measured on a recurring basis is as follows (in thousands):

Description	As of September 30, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Short-term investments	\$ 11	\$ 11	\$ —	\$ —
Total assets at fair value	\$ 11	\$ 11	\$ —	\$ —
Liabilities:				
Derivative liability	\$ 93	\$ —	\$ —	\$ 93
Total liabilities at fair value	\$ 93	\$ —	\$ —	\$ 93

Description	As of December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Short-term investments	\$ 49	\$ 49	\$ —	\$ —
Total assets at fair value	\$ 49	\$ 49	\$ —	\$ —

The following table provides a roll-forward of short-term investments and derivative liabilities measured at fair value on a recurring basis using observable Level 1 and Level 3 inputs, as applicable, for the nine months ended September 30, 2023 and 2022 (in thousands):

	2023	2022
Short-term investments		
Balance as of beginning of period	\$ 49	\$ 219
Unrealized loss	(38)	(118)
Balance as of end of period	\$ 11	\$ 101

Notes to Condensed Financial Statements

	2023	2022
Derivative liability		
Balance as of beginning of period	\$ —	\$ —
Purchase agreement execution	154	—
Unrealized gain	(61)	—
Balance as of end of period	<u>\$ 93</u>	<u>\$ —</u>

Rexahn Warrants

The fair value of the warrant liabilities associated with the Rexahn warrants was de minimis during the periods presented. The last of the Rexahn warrants classified as liabilities expired in April 2023 unexercised. See Note 2 – Merger for additional background.

There were no financial instruments measured on a non-recurring basis for any of the periods presented.

Recent Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update (“ASU”) 2016-13, “Financial Instruments – Credit Losses”. The ASU sets forth a current expected credit loss (CECL) model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. The Company adopted this ASU on January 1, 2023 and it did not have a significant impact on its condensed financial statements.

In August 2020, FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*, which, among other things, provides guidance on how to account for contracts on an entity’s own equity. This ASU eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity’s own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, this ASU modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted earnings per share computation. The amendments in this ASU are effective for public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. The Company adopted this ASU on January 1, 2023 and the adoption did not have a material impact on its condensed financial statements.

In November 2021, the FASB issued ASU 2021-10, Government Assistance (Topic 832) - Disclosures by Business Entities about Government Assistance, to increase the transparency of government assistance including the disclosure of the types of assistance, an entity’s accounting for the assistance, and the effect of the assistance on an entity’s financial statements. The amendments in this ASU are effective for all entities within their scope for financial statements issued for annual periods beginning after December 15, 2021. The Company adopted this guidance on January 1, 2022 and it did not have a material impact to the condensed financial statements.

2. Merger

On November 5, 2020, the Company completed the Merger transaction with Rexahn. In connection with the Merger, the Company, Shareholder Representatives Services LLC, as representative of the Rexahn stockholders prior to the Merger, and Olde Monmouth Stock Transfer Co., Inc., as the rights agent, entered into a Contingent Value Rights Agreement (the “CVR Agreement”).

Notes to Condensed Financial Statements

Pursuant to the terms of the Merger and the CVR Agreement, Rexahn stockholders of record as of immediately prior to the effective time of the Merger received one contingent value right (“CVR”) for each share of Rexahn common stock held.

Each CVR entitles such holders to receive, for each calendar quarter (each, a “CVR Payment Period”) during the 15-year period after the closing (the “CVR Term”), an amount equal to the following:

- 90% of all payments received by Rexahn or its affiliates during such CVR Payment Period from or on behalf of BioSense Global LLC (“BioSense”) pursuant to that certain License and Assignment Agreement, dated as of February 25, 2019, by and between BioSense and Rexahn, as amended by Amendment No. 1, dated August 24, 2019, and as further amended by Amendment No. 2, dated March 10, 2020, minus certain permitted deductions;
- 90% of all payments received by Rexahn or its affiliates during such CVR Payment Period from or on behalf of Zhejiang HaiChang Biotechnology Co., Ltd. (“HaiChang”) pursuant to that certain Exclusive License Agreement, dated as of February 8, 2020, by and between HaiChang and Rexahn, minus certain permitted deductions; and
- 75% of the sum of (i) all cash consideration paid by a third party to Rexahn or its affiliates during the applicable CVR Payment Period in connection with the grant, sale or transfer of rights to Rexahn’s pre-closing intellectual property (other than a grant, sale or transfer of rights involving a sale or disposition of the post-Merger combined company) that is entered into during the 10-year period after the closing (“Parent IP Deal”), plus (ii) with respect to any non-cash consideration received by Rexahn or its affiliates from a third party during the applicable CVR Payment Period in connection with any Parent IP Deal, all amounts received by Rexahn or its affiliates for such non-cash consideration at the time such non-cash consideration is monetized by Rexahn or its affiliates, minus (iii) certain permitted deductions.

The CVRs are not transferable, except in certain limited circumstances, will not be certificated or evidenced by any instrument, will not accrue interest and will not be registered with the SEC or listed for trading on any exchange. The CVR Agreement will continue in effect until the later of the end of the CVR Term and the payment of all amounts payable thereunder. As of September 30, 2023, no payments subject to the CVR had been received beyond those previously reported in the second and third quarters of calendar year 2021. In addition, no milestones had been accrued as there were no potential milestones yet considered probable beyond those previously reported.

Former Rexahn Warrants

Following the closing of the Merger, 231,433 outstanding, unexercised Rexahn warrants to purchase common stock remained outstanding, the majority of which were subsequently repurchased according to the terms of the original warrant agreements. As of September 30, 2023, 58,597 of the Rexahn warrants remained outstanding with an exercise price of \$38.40 per share with an average remaining contractual life of 0.3 years and were accounted for and classified as equity.

3. Commitments and Contingencies

Apexian Sublicense Agreement

On January 21, 2020, the Company entered into a sublicense agreement with Apexian Pharmaceuticals, Inc., pursuant to which it obtained exclusive worldwide patent and other intellectual property rights. In exchange for the patent and other intellectual rights, the Company agreed to certain milestone payments and royalty payments on future sales (See Note 8 — Apexian Sublicense Agreement). As of September 30, 2023, there was sufficient uncertainty with regard to any future cash milestone payments under the sublicense agreement that no liabilities were recorded related to the sublicense agreement.

Notes to Condensed Financial Statements

Facility Leases

The Company has a short-term, non-cancellable facility lease (the “HQ Lease”) for its headquarters. The HQ Lease qualified for the short-term lease exception under ASC 842, Leases. The monthly base rent, as amended, for the HQ Lease is approximately \$3,000. The rent expense associated with the HQ Lease amounted to \$9,000 during each of the three months ended September 30, 2023 and 2022. The rent expense associated with the HQ Lease amounted to \$27,000 and \$30,000 during the nine months ended September 30, 2023 and 2022, respectively. The total remaining expected rental payments under the HQ Lease amount to \$9,000 through its current expiration date of December 31, 2023.

Other

In the ordinary course of business, from time to time, the Company may be subject to a broad range of claims and legal proceedings that relate to contractual allegations, patent infringement and other claims. In addition, the Company from time to time may be potentially committed to reimburse third parties for costs incurred associated with business development related transactions upon the achievement of certain milestones. The Company establishes accruals when applicable for matters and commitments which it believes losses are probable and can be reasonably estimated. To date, no loss contingency for such matters and potential commitments have been recorded. Although it is not possible to predict with certainty the outcome of these matters or potential commitments, the Company is of the opinion that the ultimate resolution of these matters and potential commitments will not have a material adverse effect on its results of operations or financial position.

4. Supplemental Balance Sheet Information**Prepaid and Other Assets**

Prepaid and other assets consist of the following as of (in thousands):

	September 30, 2023	December 31, 2022
Prepays	\$ 433	\$ 1,373
Other	51	80
Total prepaids and other assets	<u>\$ 484</u>	<u>\$ 1,453</u>

Property and Equipment, net

Property and equipment held for use by category are presented in the following table as of (in thousands):

	September 30, 2023	December 31, 2022
Equipment	\$ 20	\$ 20
Furniture	5	5
Total property and equipment	25	25
Less accumulated depreciation	(22)	(19)
Property and equipment, net	<u>\$ 3</u>	<u>\$ 6</u>

Depreciation expense was \$1,000 during each of the three months ended September 30, 2023 and 2022. Depreciation expense was \$3,000 during each of the nine months ended September 30, 2023 and 2022.

Accrued Expenses

Accrued expenses consist of the following as of (in thousands):

	September 30, 2023	December 31, 2022
Income taxes	\$ 11	\$ 315
Payroll	470	782
Professional services	262	208
R&D services and supplies	634	212
Severance	500	—
Other	49	167
Total	<u>\$ 1,926</u>	<u>\$ 1,684</u>

Notes to Condensed Financial Statements

On April 19, 2023, the Company terminated the employment of Mina Sooch, the President and Chief Executive Officer of the Company.

Short-Term Loan

The Company entered into an unsecured short-term loan (the “Loan”) agreement in the amount of \$0.6 million in November 2021 related to financing an insurance policy. The Loan was payable in six monthly installments of \$108,000 beginning in December 2021. The Loan had an annual interest rate of 5.5% per annum. Interest expense in the amount of \$9,000 was recognized in connection with the Loan during the nine months ended September 30, 2022. No interest expense under the Loan was recognized during the three and nine months ended September 30, 2023.

5. Related Party Transactions

On April 8, 2022, Ocuphire entered into a consulting agreement with Jay Pepose, a director of the Company. The consulting agreement provided for \$10,000 a month in cash payments, effective as of April 1, 2022. Additionally, on April 8, 2022, in connection with the consulting arrangement, Dr. Pepose received a stock option grant for 50,000 options, of which 25% vested on March 31, 2023, with the remainder vesting in equal monthly installments over 36 months. The consulting agreement was amended on September 19, 2022 to provide for vesting acceleration for stock-based awards in the event of a change in control. The consulting agreement was also amended effective December 1, 2022 to increase the cash payment to \$25,000 per month.

The Company incurred related consulting expenses of \$75,000 and \$225,000 during the three and nine months ended September 30, 2023, respectively. The Company incurred related consulting expenses of \$30,000 and \$60,000 during the three and nine months ended September 30, 2022, respectively. As of September 30, 2023 and December 31, 2022, \$25,000 of the related consulting expenses were unpaid.

On April 19, 2023, Ocuphire appointed Richard Rodgers, a director of the Company, as interim President and Chief Executive Officer. In connection with his appointment, Ocuphire and Mr. Rodgers entered into a letter agreement concerning Mr. Rodgers’s services (the “Letter Agreement”). The Letter Agreement provides that Mr. Rodgers will receive (i) a \$40,000 monthly salary, and (ii) is eligible for a potential prorated bonus at the discretion of Ocuphire’s Board of Directors, at the end of his term as interim President and Chief Executive Officer. Mr. Rodgers also received 50,000 restricted stock units under the Company’s 2020 Equity Incentive Plan which will vest 12 months following the grant date. The Company incurred related consulting expenses of \$120,000 and \$215,000 during the three and nine months ended September 30, 2023, respectively. As of September 30, 2023, \$80,000 of the related consulting expenses were unpaid.

6. Stockholders’ Equity

Lincoln Park Purchase Agreement

On August 10, 2023, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC (“Lincoln Park”) for an equity line financing (the “Purchase Agreement”). The Purchase Agreement provides that, subject to the terms and conditions set forth therein, the Company has the sole right, but not the obligation, to direct Lincoln Park to purchase up to \$50 million of shares of the Company’s common stock from time to time over the 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park (the “Registration Rights Agreement”), pursuant to which the Company agreed to register the resale of the shares of the Company’s common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to a registration statement. Upon the execution of the Purchase Agreement, the Company issued 246,792 shares of the Company’s common stock to Lincoln Park with a fair value of \$1.0 million as consideration for its commitment to purchase shares of the Company’s common stock under the Purchase Agreement which was recorded as a component of financing costs in the accompanying statements of comprehensive income (loss) during the three and nine month periods ended September 30, 2023. Lincoln Park has agreed not to cause or engage in any manner whatsoever in any direct or indirect short selling or hedging of the Company’s common stock.

Notes to Condensed Financial Statements

In addition to the commitment shares referenced above, a total of 800,000 shares of the Company's common stock were sold under the Purchase Agreement for net proceeds through September 30, 2023 in the amount of \$3.1 million. Lastly, the Company incurred issuance costs of \$0.2 million, consisting of investor expense reimbursement and legal costs, during the three- and nine-months periods ended September 30, 2023 which were recorded as a component of financing costs in the accompanying statements of comprehensive income (loss) during the three and nine month periods ended September 30, 2023. No shares of the Company's common stock were sold under the Purchase Agreement prior to the third quarter of 2023.

Under the Purchase Agreement on any business day selected by the Company, the Company may direct Lincoln Park to purchase up to 50,000 shares of its common stock on such business day (or the purchase date) (a "Regular Purchase"), provided that the closing sale price of the Company's common stock on Nasdaq on the applicable purchase date is not below \$0.25 and subject to other adjustments. A Regular Purchase may be increased to up to (i) 60,000 shares if the closing sale price of the Company's common stock on Nasdaq is not below \$5.00 on the applicable purchase date and (ii) 70,000 shares if the closing sale price of the Company's common stock on Nasdaq is not below \$7.50 on the applicable purchase date. The Company may direct Lincoln Park to purchase shares in Regular Purchases as often as every business day. The purchase price per share for each such Regular Purchase will be equal to the lesser of:

- the lowest sale price for the Company's common stock on Nasdaq on the purchase date of such shares; and
- the average of the three (3) lowest closing sale prices for the Company's common stock on Nasdaq during the ten (10) consecutive business days prior to the purchase date of such shares.

In addition, the Company may also direct Lincoln Park, on any business day on which the Company has submitted a Regular Purchase notice for the maximum amount allowed for such Regular Purchase, to purchase an additional amount of the Company's common stock (an "Accelerated Purchase") of up to the lesser of:

- three (3) times the number of shares purchased pursuant to such Regular Purchase; and
- 30% of the aggregate shares of the Company's common stock traded on Nasdaq during all or, if certain trading volume or market price thresholds specified in the Purchase Agreement are crossed on the applicable Accelerated Purchase date, the portion of the normal trading hours on the applicable Accelerated Purchase date prior to such time that any one of such thresholds is crossed (the "Accelerated Purchase Measurement Period").

The purchase price per share for each such Accelerated Purchase will be equal to 96.5% of the lower of:

- the closing sale price of the Company's common stock on Nasdaq on the applicable Accelerated Purchase date; and
- the volume-weighted average price of the Company's common stock on Nasdaq during the applicable Accelerated Purchase Measurement Period on the applicable Accelerated Purchase date.

The Company may also direct Lincoln Park, on any business day on which an Accelerated Purchase has been completed and all of the shares to be purchased thereunder have been delivered to Lincoln Park in accordance with the Purchase Agreement, to purchase an additional amount of the Company's common stock (an "Additional Accelerated Purchase") as described in the Purchase Agreement.

The pricing and settlement provisions in the Purchase Agreement result in the recognition of a derivative liability under the Purchase Agreement were accounted for as a derivative liability on a fair value basis under the provisions of ASC 815 - Derivatives and Hedging. A Monte Carlo simulation model was used to estimate future stock pricing and purchase activity to determine the fair value of the derivative liability as of the August 10, 2023 commencement date and again as of September 30, 2023. As of August 10, 2023 and September 30, 2023, the inputs used to determine fair value of the derivative liability included the Company's Nasdaq closing stock price of \$4.14 and \$3.35 per share, respectively, a stock volatility rate of 82.5% and 87.5%, respectively, an expected term of 2.5 years and 2.4 years, respectively, and a risk-free interest rate of 4.6% and 4.9%, respectively. Lastly, the fair value of the derivative liability took into account future purchase decisions based on economic considerations and relevant stock issuance rules/limitations. The fair value change in the derivative liability was recorded in the fair value change in derivative liability line item in the accompanying statements of comprehensive income (loss) during the three- and nine-month periods ended September 30, 2023.

At-The-Market Program

On February 4, 2021, Ocuphire filed a Form S-3 shelf registration under the Securities Act of 1933 which was declared effective by the SEC on February 12, 2021 (the “2021 Shelf”) under which the Company may offer and sell, from time to time in its sole discretion, securities having an aggregate offering price of up to \$125 million. In connection with the 2021 Shelf, on March 11, 2021, Ocuphire entered into a sales agreement with JonesTrading Institutional Services LLC (“JonesTrading”) under which the Company may offer and sell, from time to time at its sole discretion, to or through JonesTrading, acting as agent and/or principal, shares of its common stock having an aggregate offering price of up to \$40 million (the “2021 ATM”). During the three and nine months ended September 30, 2023, 577,555 shares of common stock were sold under the 2021 ATM for aggregate gross proceeds in the amount of \$2.4 million before deducting issuance expenses, including the placement agent’s fees, legal and accounting expenses, in the amount of \$69,000.

During the three and nine months ended September 30, 2022, 634,509 and 1,848,980 shares of common stock were sold under the 2021 ATM, respectively, for aggregate gross proceeds in the amount of \$1.4 million and \$4.4 million, respectively, before deducting issuance expenses, including the placement agent’s fees, legal and accounting expenses, in the amount of \$42,000 and \$130,000, respectively.

Registered Direct Offering

On June 4, 2021, the Company entered into a placement agency agreement with A.G.P./Alliance Global Partners (“AGP”). Pursuant to the terms of the placement agency agreement, AGP on June 8, 2021 sold an aggregate of 3,076,923 shares of the Company’s common stock and warrants to purchase 1,538,461 shares of the Company’s common stock (the “RDO Warrants”). The RDO Warrants are equity classified, have an exercise price of \$6.09 per share, are exercisable from the initial issuance date of June 8, 2021, and will expire five years following the initial issuance date. As of September 30, 2023, 1,538,461 RDO Warrants were outstanding.

Pre-Merger Financing

On June 17, 2020, Ocuphire, Rexahn and certain investors entered into a Securities Purchase Agreement, which was amended and restated in its entirety on June 29, 2020 (as amended and restated, the “Securities Purchase Agreement”). Pursuant to the Securities Purchase Agreement, the investors invested a total of \$21.15 million in cash, including \$300,000 invested by five directors of Ocuphire Pharma, Inc., prior to the Merger and one director of Rexahn upon closing of the Merger (the “Pre-Merger Financing”). The Pre-Merger Financing also included the issuance of Series A Warrants and Series B Warrants discussed further below.

Series A Warrants

The Series A Warrants were issued on November 19, 2020 at an initial exercise price of \$4.4795 per share, were immediately exercisable upon issuance and have a term of five years from the date of issuance. The Series A Warrants are exercisable for 5,665,838 shares of common stock in the aggregate (without giving effect to any limitation on exercise contained therein) and were outstanding as of September 30, 2023. The Series A Warrants were accounted for and classified as equity on the accompanying condensed balance sheets.

Series B Warrants

The Series B Warrants had an exercise price of \$0.0001, were exercisable upon issuance and would have expired on the day following the later to occur of (i) the Reservation Date (as defined therein) or (ii) the date on which the investor’s Series B Warrants would have been exercised in full (without giving effect to any limitation on exercise contained therein). None of the Series B Warrants were outstanding as of September 30, 2023. During the nine months ended September 30, 2023, 17,869 warrants were exercised for shares of common stock. The Series B Warrants were accounted for and classified as equity on the accompanying condensed balance sheets while outstanding.

7. Stock-based Compensation

Stock-based compensation expense was included in general and administrative and research and development costs as follows in the accompanying condensed statements of comprehensive income (loss) for the three and nine-month periods indicated below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
General and administrative	\$ 335	\$ 299	\$ 1,969	\$ 870
Research and development	238	194	830	513
Total stock-based compensation	<u>\$ 573</u>	<u>\$ 493</u>	<u>\$ 2,799</u>	<u>\$ 1,383</u>

Ocuphire Stock Options*Inducement Plan*

On February 22, 2021, the Company adopted the Ocuphire Pharma, Inc. Inducement Plan (the “Inducement Plan”), pursuant to which the Company reserved 325,258 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual’s entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules.

2020 Equity Incentive Plan

The stockholders of the Company approved the 2020 Equity Incentive Plan (the “2020 Plan”) for stock-based awards. The 2020 Plan became effective on November 5, 2020. Under the 2020 Plan, (i) 1,000,000 new shares of common stock were reserved for issuance and (ii) up to 70,325 additional shares of common stock may be issued, consisting of (A) shares that remain available for the issuance of awards under prior equity plans and (B) shares of common stock subject to outstanding stock options or other awards covered by prior equity plans that have been cancelled or expire on or after the date that the 2020 Plan became effective. The 2020 Plan permits the grant of incentive and non-statutory stock options, appreciation rights, restricted stock, restricted stock units, performance stock and net loss awards, and other stock-based awards.

2018 Equity Incentive Plan

Prior to the 2020 Plan, the Company had adopted a 2018 Equity Incentive Plan (the “2018 Plan”) in April 2018 under which 1,175,000 shares of the Company’s common stock were reserved for issuance to employees, directors and consultants. Upon the effective date of the 2020 Plan, no additional shares were available for issuance under the 2018 Plan.

2020 Plan Evergreen Provision

Under the 2020 Plan, the shares reserved automatically increase on January 1 of each year, for a period of not more than ten years from the date the 2020 Plan is approved by the stockholders of the Company, commencing on January 1, 2021 and ending on (and including) January 1, 2030, by an amount equal to 5% of the shares of common stock outstanding as of December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board of Directors may act prior to January 1st of a given year to provide that there will be no January 1 increase in the share reserve for such year or that the increase in the share reserve for such year will be a lesser number of shares of common stock than would otherwise occur pursuant to the preceding sentence. On January 1, 2023, 1,043,066 shares were added to the 2020 Plan as a result of the evergreen provision.

Notes to Condensed Financial Statements

Stock Options

During the three and nine months ended September 30, 2023, 30,000 and 793,578 stock options were granted to directors, officers, employees and consultants, respectively, generally vesting over a five (5) to forty-eight (48) month period. During the three and nine months ended September 30, 2022, 167,000 and 893,305 stock options were granted to directors, officers, employees and consultants, respectively, generally vesting over a ten (10) to forty-eight (48) month period.

The Company recognized \$400,000 and \$394,000 in stock-based compensation expense related to stock options during the three months ended September 30, 2023 and 2022, respectively, and \$2,087,000 and \$1,229,000 during the nine months ended September 30, 2023 and 2022, respectively. Stock-based compensation expense during the nine-month period ended September 30, 2023 included a one-time charge of \$0.4 million attributed to the modification of the Company's former Chief Executive Officer's stock options with respect to their exercisability provisions.

During the nine months ended September 30, 2022, 24,309 stock options were exercised with an intrinsic value of \$59,000. There were no exercises during the three and nine months ended September 30, 2023.

As of September 30, 2023 and December 31, 2022, 3,469,389 and 2,936,044 stock options were outstanding, respectively.

The weighted average fair value per share of options granted during the three and nine months ended September 30, 2023 was \$3.30 and \$2.85, respectively. The weighted average fair value per share of options granted during the three and nine months ended September 30, 2022 was \$1.65 and \$2.06, respectively. The Company measures the fair value of stock options with service-based vesting criteria to employees, directors, consultants and directors on the date of grant using the Black-Scholes option pricing model. The Company does not have sufficient share trading history to support an internal calculation of volatility and expected term. As such, the Company has used a weighted average volatility considering the volatilities of several guideline companies.

For purposes of identifying similar entities, the Company considered characteristics such as industry, length of trading history, and stage of life cycle. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The average expected life of the options was based on the contractual term for agreements that allow for exercise of vested options through the end of the contractual term upon termination of continuous service, and for all other agreements, was based on the midpoint between the vesting date and the end of the contractual term according to the "simplified method" as described in Staff Accounting Bulletin 110. The risk-free interest rate is determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. The Company records forfeitures when they occur.

The weighted average assumptions used in the Black-Scholes option pricing model are as follows during the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Expected stock price volatility	96.4%	91.2%	95.3%	97.4%
Expected life of options (years)	6.1	5.4	6.1	5.8
Expected dividend yield	0%	0%	0%	0%
Risk free interest rate	4.2%	3.4%	3.7%	2.3%

During the three and nine months ended September 30, 2023, 94,347 and 715,171 stock options vested, respectively, inclusive of the vesting acceleration of stock options attributed to the departure of the Company's former Chief Executive Officer in the amount of 145,418 during the second quarter of 2023. During the three and nine months ended September 30, 2022, 89,623 and 356,726 stock options vested, respectively.

Notes to Condensed Financial Statements

During the three and nine months ended September 30, 2023, 5,267 and 260,233 options were forfeited, respectively, inclusive of the stock option forfeited in connection with the departure of the Company's former Chief Executive Officer in the amount of 249,633 during the second quarter of 2023. During the three and nine months ended September 30, 2022, 13,500 and 27,788 options were forfeited, respectively.

Restricted Stock Units

During the three and nine months ended September 30, 2023, the Company granted an aggregate of zero and 416,464 restricted stock units ("RSUs"), respectively, to certain officers and employees under the 2020 Plan. The weighted average grant date per unit fair value of the RSUs granted during the nine months ended September 30, 2023 was \$3.98. The vesting period of the RSUs range from a one year period to a four year period where 25% of the RSUs vest annually on each anniversary of the grant date, subject to the recipient's continued service on such dates. There were no RSUs granted during the three and nine months ended September 30, 2022.

During the three and nine months ended September 30, 2023, zero and 33,614 RSUs vested, respectively, and zero and 100,842 RSUs were forfeited during the three and nine months ended September 30, 2023, respectively, attributed solely to the departure of the Company's former Chief Executive Officer. The total expense for the three and nine months ended September 30, 2023 related to these RSUs was \$173,000 and \$437,000, respectively.

Common Stock Issued for Services

The Company granted stock for services in the amount of zero and 72,986 common shares during the three and nine months ended September 30, 2023, respectively, to board members who elected to receive their board retainers in the form of stock for services with a weighted grant date fair value of \$3.77 per share. The Company granted stock for services in the amount of 52,225 and 74,396 common shares during the three and nine months ended September 30, 2022, respectively, to board members who elected to receive their board retainers in the form of stock for services with a weighted grant date fair value of \$1.89 and \$2.04 per share, respectively.

The stock-based compensation related to these services amounted to zero and \$99,000 during the three months ended September 30, 2023 and 2022, respectively, and \$275,000 and \$154,000 during the nine months ended September 30, 2023 and 2022, respectively.

General

As of September 30, 2023, 1,016,033 shares were available for future issuance under the 2020 Plan and Inducement Plan, in the aggregate. No shares were available for future issuance under the 2018 Plan. Unrecognized stock-based compensation cost was \$3.4 million as of September 30, 2023. The unrecognized stock-based expense is expected to be recognized over a weighted average period of 1.2 years.

8. Apexian Sublicense Agreement

On January 21, 2020, the Company entered into a sublicense agreement (as amended on June 4, 2020, the "Apexian Sublicense Agreement") with Apexian, pursuant to which it obtained exclusive worldwide patent and other intellectual property rights that constitute a Ref-1 Inhibitor program relating to therapeutic applications to treat disorders related to ophthalmic and diabetes mellitus conditions. The lead compound in the Ref-1 Inhibitor program is APX3330, which the Company intends to develop as an oral tablet therapeutic to treat diabetic retinopathy initially, and potentially later to treat diabetic macular edema, geographic atrophy and age-related macular degeneration. In connection with the Apexian Sublicense Agreement, the Company issued a total of 891,422 shares of its common stock to Apexian and to certain affiliates of Apexian in calendar year 2020. As a result of the common stock issued pursuant to the Apexian Sublicense Agreement, Apexian is considered by Ocuphire to be a related party.

Notes to Condensed Financial Statements

The Company also agreed to make one-time milestone payments under the Apexian Sublicense Agreement for each of the first ophthalmic indication and the first diabetes mellitus indication for the development and regulatory milestones, and once for each of several sales milestones. These milestone payments include (i) payments for specified developmental and regulatory milestones (including completion of the first Phase 2 trial and the first Phase 3 pivotal trial in the United States, and filing and achieving regulatory approval from the FDA for the first New Drug Application for a compound) totaling up to \$11 million in the aggregate and (ii) payments for specified sales milestones of up to \$20 million in the aggregate, which net sales milestone payments are payable once, upon the first achievement of such milestone. Lastly, the Company also agreed to make a royalty payment equal to a single-digit percentage of its net sales of products associated with the covered patents under the Apexian Sublicense Agreement. If it is not terminated pursuant to its terms, the Apexian Sublicense Agreement shall remain in effect until expiration of the last to expire of the covered patents.

None of the milestone or royalty payments were triggered or deemed probable as of September 30, 2023 or December 31, 2022.

9. License and Collaboration Agreements

Nyxol License Agreement

On November 6, 2022, the Company entered into the Nyxol License Agreement, pursuant to which it granted Famy an exclusive, perpetual, sub-licensable license to develop, manufacture, import, export and commercialize (i) POS, for treating (a) reversal of mydriasis, (b) night vision disturbances or dim light vision, and (c) presbyopia, and (ii) POS and low dose pilocarpine for treating presbyopia (together, the “Nyxol Products”) worldwide except for certain countries and jurisdictions in Asia (the “Viatriis Territory”). The Company retains the exclusive right to develop, manufacture, have manufactured, import, export and commercialize the Nyxol Products outside of the Viatriis Territory. In January 2023, Famy was acquired by Viatriis Inc., and Viatriis has assumed all of Famy’s obligations under the Nyxol License Agreement.

Under the terms of the Nyxol License Agreement, the Company in partnership with Viatriis, will develop the Nyxol Products in the United States. Viatriis will reimburse the Company for budgeted costs related to the development of the Nyxol Products through FDA approval. Viatriis will be responsible for developing the Nyxol Products in countries and jurisdictions in the Viatriis Territory outside of the United States. The parties established a joint steering committee, which oversees and makes decisions regarding the development of the Nyxol Products. The committee is composed of an equal number of representatives of Viatriis and Ocuphire. Viatriis will commercialize the Nyxol Products in the Viatriis Territory for each indication that receives regulatory approval.

Pursuant to the Nyxol License Agreement, the Company received a one-time non-refundable cash payment of \$35 million in November 2022 for the exclusive, perpetual, sub-licensable license to develop, manufacture, import, export and commercialize the Nyxol Products in the Viatriis Territory. In addition, with respect to the Nyxol Products, the Company will be eligible to receive potential additional payments of up to \$130 million in the aggregate upon achieving certain specified regulatory or net sales milestones, with the first milestone payment of \$10 million to be made following approval by the FDA of POS, for reversal of mydriasis which occurred during the third quarter of 2023. The Company will also receive tiered royalties, starting at low double-digit royalties up to low 20% royalties, based on the aggregate annual net sales of all Nyxol Products in the United States, and will receive low double-digit royalties based on all annual net sales in the Viatriis Territory outside of the United States. The royalty payments will continue on a country-by-country basis from the date of the first commercial sale of the first Nyxol Product in a country of the Viatriis Territory until December 31, 2040.

Either party may terminate the Nyxol License Agreement upon written notice in the case of the other party’s material breach (subject to applicable cure periods) or if the other party becomes subject to an insolvency event. In addition, the Company may terminate the agreement in its entirety if Viatriis or its affiliates commences an action challenging the validity, enforceability or scope of any of Ocuphire’s patents that are exclusively licensed under the Nyxol License Agreement. Additionally, if Viatriis determines not to pursue development or commercialization of a Nyxol Product in a country or jurisdiction in the Viatriis Territory, Viatriis may terminate the license with respect to such Nyxol Product in such country or jurisdiction.

Both Ocuphire and Viatriis have agreed to indemnify the other party against certain losses and expenses relating to any breach of the indemnifying party’s obligations, representations, warranties or covenants under the Nyxol License Agreement.

Notes to Condensed Financial Statements

The Nyxol License Agreement was accounted for under the provisions of ASC 606. In accordance with the provisions under ASC 606, the Company identified two distinct performance obligations at the effective date: (1) the license to its intellectual property (“license transfer”) and (2) research and development services.

The aggregate transaction price associated with the Nyxol License Agreement, as adjusted for variable consideration subsequent to December 31, 2022, was \$40.0 million which comprised the initial license transfer fee of \$35.0 million and the \$5.0 million payment anticipated under the research and development services that were not subject to cancellation. The transaction price was allocated between performance obligations based on their relative standalone selling price (“SSP”). The performance obligations for research and development services through the non-cancellation period were fully met by the Company as of the first quarter of 2023.

The SSP for the license transfer and for the research and development services was determined to be \$287.8 million and \$5.0 million, respectively. The SSP for the license transfer was determined based on a discounted royalty cash flow approach, taking into consideration assumptions, including projected worldwide net profit for each of the respective programs based on probability assessments, projections based on internal forecasts, industry data, and information from other guideline companies within the same industry and other relevant factors. The SSP for the research and development services was determined using a cost-plus margin approach, based on anticipated expenditure outlays within the first 120-day non-cancellation window. On a relative SSP basis, \$39.3 million and \$0.7 million of the transaction price was allocated to the license transfer and to the research and development services obligations, respectively.

The Company determined that the licenses transferred represented functional intellectual property. As such, the revenue related to the licenses was recognized at the point in time in which the license/know-how was delivered to Viatris (as successor to Famy) which occurred during the fourth quarter of 2022. The Company determined that revenue related to the research and development services constrained to the 120-day non-cancellation period was to be recognized over time as the services are rendered based on an estimated percentage of completion input model.

Recognition of Revenue

On September 25, 2023, the Company met the \$10 million milestone payment requirements attributed to the FDA’s approval of POS, for reversal of mydriasis, and the \$10 million milestone payment was included in the revenue recognized during the three and nine months ended September 30, 2023. The \$10 million milestone payment was reflected as an account receivable as of September 30, 2023 and was subsequently paid in October 2023. The \$10 million milestone payment was previously constrained by the Company with regard to its inclusion in the initial aggregate transaction price associated with the Nyxol License Agreement. Lastly, the balance of the revenue recognized during the three and nine months ended September 30, 2023 related to the output of research and development services.

Revenue recognized under the Nyxol License Agreement during the three and nine months ended September 30, 2023 was \$11.9 million and \$17.4 million, respectively.

Regulatory Milestones under the Nyxol License Agreement

The Company has evaluated the regulatory milestones that may be received in connection with the Nyxol License Agreement. There is uncertainty that the events to obtain the remaining regulatory milestones (aside from the approval by the FDA of POS, for reversal of mydriasis) will be achieved given the nature of clinical development and the stage of the development of the Nyxol Products. These remaining regulatory milestones will be constrained until it is probable that a significant revenue reversal will not occur.

Sales Milestone and Royalty Payments

Sales milestones and royalties relate predominantly to a license of intellectual property granted to Viatris and are determined by sales or usage-based thresholds. The sales milestones and royalties are accounted for under the royalty recognition constraint and will be accounted for as constrained variable consideration. The Company applies the royalty recognition constraint for each commercial milestone and will not recognize revenue for each until the subsequent sale of a licensed product (achievement of each) occurs.

Notes to Condensed Financial Statements

Each of the remaining regulatory and sales milestone performance obligations (aside from the \$10 million milestone payment related to the FDA's approval of POS, for reversal of mydriasis) and the royalty payments were fully constrained as of September 30, 2023 and no revenue was recognized.

A reconciliation of the closing balance of the contract assets and unbilled receivables associated with the Nyxol License Agreement is as follows as of September 30, 2023 (in thousands):

Contract Assets and Unbilled Receivables

Balance as of December 31, 2022	\$ 3,552
Revenue recognized	17,358
Reclassification to accounts receivable related to costs billed under the Nyxol License Agreement	(19,699)
Balance as of September 30, 2023	<u>\$ 1,211</u>

The remaining amounts in contract assets and unbilled receivables as of September 30, 2023 attributed to the research and development services are expected to be settled during the fourth quarter of 2023.

BioSense License and Assignment Agreement

On March 10, 2020, pre-Merger, Rexahn entered into an amendment to its collaboration and license agreement, (as amended, the "BioSense License and Assignment Agreement") with BioSense to advance the development and commercialization of RX-3117 for all human uses in the Republic of Singapore, China, Hong Kong, Macau, and Taiwan (the "BioSense Territory"). Under the terms of the BioSense License and Assignment Agreement, the Company (i) granted BioSense an exclusive license to develop and commercialize pharmaceutical products containing RX-3117 as a single agent for all human uses in the BioSense Territory and (ii) assigned and transferred all of the former Rexahn patents and patent applications related to RX-3117 in the BioSense Territory. The upfront payment consisted of an aggregate of \$1,650,000, of which \$1,550,000 was paid to Rexahn prior to the Merger and the remaining \$100,000 during calendar year 2021.

Under the BioSense License and Assignment Agreement, the Company is eligible to receive additional milestone payments in an aggregate of up to \$84,500,000 upon the achievement of development, regulatory and commercial goals and will also be eligible to receive tiered royalties at low double-digit rates on annual net sales in the BioSense Territory. The Company determined that none of the milestone payments under the BioSense License and Assignment Agreement were probable of payment as of September 30, 2023, and as a result, no revenue related to the milestones was recognized as the achievement of events entitling the Company to any milestone payments were highly susceptible to factors outside of the Company's control. Future sales-based royalties related to the exclusive license to develop RX-3117 will be recognized in the period the underlying sales transaction occurs.

Payments received under the BioSense License and Assignment Agreement are subject to the CVR Agreement described in Note 2 – Merger.

Processa License Agreement

On June 16, 2021, the Company entered into a license agreement (the "Processa License Agreement") with Processa Pharmaceuticals, Inc. ("Processa"), pursuant to which the Company has agreed to grant Processa an exclusive license to develop, manufacture and commercialize RX-3117 globally, excluding the BioSense Territory.

Processa will make future payments to the Company upon the achievement of certain development and regulatory milestones, which primarily consist of dosing a patient in pivotal trials or having a drug indication approved by a regulatory authority in the United States or another country. In addition, Processa will pay the Company mid-single-digit royalties based on annual sales under the license and will make one-time sales milestone payments based on the achievement during a calendar year of certain thresholds for annual sales. Processa is also required to give the Company 32% of any milestone payments received based on any sub-license agreement Processa may enter into with respect to the Processa License Agreement. The Company determined that none of the milestone payments under the Processa License Agreement were probable of payment as of September 30, 2023, and as a result, no revenue related to the milestones was recognized, as the achievement of events entitling the Company to any milestone payments were highly susceptible to factors outside of the Company's control.

Notes to Condensed Financial Statements

Processa is required to use commercially reasonable efforts, at its sole cost and expense, to conduct development activities in one or more countries, including meeting specific diligence milestones that consist of: (i) first patient administered drug in a clinical trial of a licensed product prior to the three (3) year anniversary of the effective date; and (ii) first patient administered drug in a pivotal clinical trial of a licensed product or first patient administered drug in a clinical trial for a second indication of a licensed product prior to the five (5) year anniversary of the effective date. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 120-day opportunity to cure such breach, and Processa may terminate the agreement for any reason upon 120 days prior written notice to Ocuphire.

Future payments received under the Processa License Agreement will be subject to the CVR Agreement described in Note 2– Merger.

10. Net Income (Loss) per Share

Basic net income (loss) per share of common stock is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted earnings or loss per share of common stock is computed similarly to basic earnings or loss per share except the weighted average shares outstanding are increased to include additional shares from the assumed exercise of any common stock equivalents, if dilutive. The Company's warrants, stock options, RSUs and any unissued common stock for services, while outstanding, are considered common stock equivalents for this purpose. Diluted earnings is computed utilizing the treasury method for the warrants, stock options, RSUs and any unissued common stock for services. With the exception of the third quarter of 2023, no incremental common stock equivalents were included in calculating diluted loss per share because such inclusion would be anti-dilutive given the net loss reported for the other periods presented.

The following table presents the computation of weighted average common shares considered in the computation of diluted net income (loss) per share during the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Basic	21,446,648	20,498,229	21,117,211	19,635,651
Dilutive stock options	914,583	—	—	—
Dilutive RSUs	44,764	—	—	—
Dilutive warrants	—	—	—	—
Diluted common shares outstanding	<u>22,405,995</u>	<u>20,498,229</u>	<u>21,117,211</u>	<u>19,635,651</u>

The following potential common shares were not considered in the computation of diluted net income (loss) per share as their effect would have been anti-dilutive for the three and nine-month periods presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Series A, Series B, and RDO warrants	7,204,299	7,281,977	7,204,299	7,281,977
Stock options	2,554,806	2,938,044	3,469,389	2,938,044
RSUs	237,244	—	282,008	—
Former Rexahn warrants	58,597	63,734	58,597	63,734

11. Income Taxes

The effective tax rate for the nine months ended September 30, 2023 and 2022 was nominal and 0%, respectively. As of September 30, 2023, a full valuation allowance has been established to reduce the Company's net deferred income tax assets. As such, no tax benefit related to the Company's pre-tax loss was recognized for any of the periods presented.

The Company's corporate returns are subject to examination for tax years beginning in 2019 for federal income tax purposes and subject to examination in various state jurisdictions. The Company does not have any reserves for income taxes that represent the Company's potential liability for uncertain tax positions.

12. Deferred Compensation Plan

Effective October 1st, 2021, the Company began offering a 401(k) plan ("401K Plan") to its employees. All employees are eligible to participate in the 401K Plan. The Company makes matching contributions equal to 100% on the first 3% of compensation that is deferred as an elective deferral and an additional 50% on the next 2% of compensation. The Company's matching contributions are made on a payroll-by-payroll basis. During the three months ended September 30, 2023 and 2022, the Company contributed \$21,000 and \$17,000 to the 401K Plan, respectively. During the nine months ended September 30, 2023 and 2022, the Company contributed \$77,000 and \$62,000 to the 401K Plan, respectively.

13. Subsequent Events

On November 1, 2023, the Company announced the appointment of George Magrath, M.D., M.B.A., M.S., as Chief Executive Officer and member of the Board of Directors. As a result of such appointment, Richard Rodgers, who was serving as Interim President and Chief Executive Officer, resigned from such positions and remains on the Board.

Effective as of November 1, 2023, the Company amended the 2021 Inducement Plan reserve to 2,325,258 shares of its common stock.

On November 1, 2023, the Company granted, from the 2021 Inducement Plan, Dr. George Magrath an option to purchase 600,000 shares of the Company's common stock at an exercise price of \$2.87 and 400,000 restricted stock units. The option vests over a period of four years, with 25% vesting one year after the date of grant and the remaining 75% vesting in 36 approximately equal monthly increments, and the restricted stock units vest in four equal consecutive annual installments of 25% beginning on the first anniversary of the grant date, provided in each case that the new hire's employment is continuing on each such date, and subject to acceleration or forfeiture upon the occurrence of certain events as set forth in the new hire's award agreements.

Ocuphire Pharma, Inc.
Form 10-Q

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the unaudited financial statements and notes included in Part I "Financial Information", Item 1 "Financial Statements" of this Quarterly Report on Form 10-Q (the "Report") and the audited financial statements and related footnotes included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Forward-Looking Statements

Certain statements contained in this Report are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements give current expectations or forecasts of future events or our future financial or operating performance. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "we expect," "we anticipate," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements.

These forward-looking statements reflect our management's beliefs and views with respect to future events, are based on estimates and assumptions as of the date of this Report and are subject to risks and uncertainties, many of which are beyond our control, that could cause our actual results to differ materially from those in these forward-looking statements. We discuss many of these risks in greater detail under Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent reports filed with or furnished to the Securities and Exchange Commission (the "SEC"). Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Any forward-looking statement made by us in this Report speaks only as of the date hereof or as of the date specified herein. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable laws or regulations.

Overview

We are a clinical-stage ophthalmic biopharmaceutical company focused on developing novel therapies for the treatment of unmet needs of patients with retinal and refractive eye disorders.

APX3330

Our lead retinal product candidate, APX3330, is a first-in-class small-molecule inhibitor of Ref-1 (reduction oxidation effector factor-1 protein). Ref-1 is a regulator of transcription factors such as HIF-1 α and NF- κ B. Inhibiting REF-1 reduces levels of vascular endothelial growth factor ("VEGF") and inflammatory cytokines which are known to play key roles in ocular angiogenesis and inflammation. Through inhibition of Ref-1, APX3330 normalizes the levels of VEGF to physiologic levels, unlike biologics that deplete VEGF below the levels required for normal function. APX3330 is an oral tablet administered twice per day for the treatment of diabetic retinopathy ("DR").

DR affects approximately 10 million people with diabetes and is projected to impact over 14 million Americans by 2050. DR is classified as Non-Proliferative Diabetic Retinopathy ("NPDR"), the early stage of the disease in which symptoms may be mild or nonexistent or Proliferative Diabetic Retinopathy ("PDR") which is the more advanced stage of diabetic eye disease that can be highly symptomatic with loss of vision. Approximately 80% of the DR patients have NPDR that will progress to PDR if left untreated. Despite the risk for visual loss associated with this disease, over 90% of NPDR patients currently receive no course of treatment apart from observation by their eye care specialist until they develop sight-threatening complications. This is due to the treatment burden of the frequent eye injections required with currently approved therapies for this disease. APX3330 as an oral tablet has the potential to be an early, non-invasive treatment for the 8 million NPDR patients in the US.

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In January 2023, we reported top-line efficacy and safety results from the ZETA-1 Phase 2 trial conducted in 103 subjects (51 treated with 600 mg daily dose of APX3330) in DR, including moderately severe and severe NPDR and mild PDR, as well as patients with diabetic macular edema without loss of central vision. Although administration of APX3330 daily did not meet the study's primary endpoint of percentage of patients with a ≥ 2 -step improvement in Early Treatment of Diabetic Retinopathy Study ("ETDRS") diabetic retinopathy severity scale ("DRSS") in the study eye at week 24 compared to placebo, efficacy was seen on the FDA agreed upon registration endpoint of ≥ 3 -step worsening on a binocular DRSS Person Scale. Prevention or slowing of progression of DR to vision-threatening complication such as PDR is a clinically meaningful endpoint. APX3330 also demonstrated favorable safety and tolerability in diabetic patients. A successful End-of-Phase 2 ("EOP2") meeting with the U.S. Food and Drug Administration (the "FDA") was held in October 2023 at which we obtained agreement on the Phase 3 registration endpoint supporting the advancement of APX3330 into Phase 3. Ocuphire plans to submit a Special Protocol Assessment ("SPA") to agree on the clinical trial protocol and statistical analysis plan for the Phase 3 trials.

Prior to Ocuphire in-licensing the APX3330 product candidate, it had been studied by other sponsors in a total of 11 clinical trials (6 Phase 1 and 5 Phase 2) in a total of over 420 healthy volunteers or patients (with over 340 APX3330-treated) for inflammatory (hepatic) and oncology indications, and had demonstrated evidence of target engagement, consistent pharmacokinetics, durability, and favorable safety and tolerability. Treatment-related adverse events were uncommon, and most were mild in severity. No clinically significant changes were observed in liver, kidney, or heart function. There were no treatment-related effects on hematologic or blood chemistry evaluations. APX3330 demonstrated favorable safety and tolerability in the ZETA-1 trial, consistent with the safety data from the prior 11 clinical trials.

We also in-licensed APX2009 and APX2014, which are second-generation analogs of APX3330. The unique mechanism of action of these Ref-1 inhibitors of reducing angiogenesis and inflammation could potentially be beneficial in treating other retinal diseases such as age-related macular degeneration ("AMD"), and geographic atrophy ("GA").

We are currently evaluating local delivery routes of APX3330 and its second-generation analogs in addition to the systemic (oral) route as part of its pipeline expansion in retinal therapies.

Phentolamine Ophthalmic Solution 0.75% (POS)

In November 2022, we entered into a license and collaboration agreement (the "Nyxol License Agreement") with FamyGen_Life Sciences, Inc. (acquired by Viatris, Inc. ("Viatris") in January 2023) pursuant to which we granted Viatris an exclusive license to develop, manufacture, import, export and commercialize our refractive product candidate Phentolamine Ophthalmic Solution 0.75%, formerly known as Nyxol ("POS") for treating (a) reversal of pharmacologically-induced mydriasis, (b) night vision disturbances or dim light vision ("DLD"), and (c) presbyopia, and (ii) POS and low dose pilocarpine for treating presbyopia (together, the "Nyxol Products") worldwide except for certain countries and jurisdictions in Asia (the "Viatris Territory").

Under the terms of the Nyxol License Agreement, Ocuphire in partnership with Viatris, will develop the Nyxol Products in the United States. Viatris will reimburse us for budgeted costs related to the development of the Nyxol Products through FDA approval. Viatris will be responsible for developing the Nyxol Products in countries and jurisdictions in the Viatris Territory outside of the United States.

POS is a once-daily eye drop formulation of phentolamine mesylate designed to reduce pupil diameter and improve visual acuity. POS can potentially be used across multiple indications such as treatment of pharmacologically-induced mydriasis ("RM") (dilation of the pupil), presbyopia (age-related blurry near vision) and DLD (halos, glares and starbursts). Our management believes these multiple indications potentially represent a significant market opportunity. POS has been studied in a total of 12 clinical trials (3 Phase 1, 5 Phase 2 and 4 Phase 3) in a total of over 1100 patients (with over 650 POS-treated) and has demonstrated promising clinical data across the three targeted refractive indications.

We submitted a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") in November 2022 under the 505(b)(2) pathway for POS for RM; the FDA approved the NDA in September 2023 under the brand name RYZUMVI™, which triggered a \$10 million milestone payment under the Nyxol License Agreement.

Ocuphire Pharma, Inc.
Form 10-Q

We reported positive top-line data from multiple late-stage clinical trials for POS in RM, presbyopia and DLD. We reported positive top-line data from Phase 3 trials in RM: MIRA-2 in March 2021, MIRA-3 in March 2022 and MIRA-4 in April 2022. We also reported positive top-line data from a Phase 2 trial of POS for treatment of presbyopia, both as monotherapy and with low-dose pilocarpine (pilocarpine hydrochloride ophthalmic solution 0.4%, “LDP”) as adjunctive therapy (VEGA-1). We reported top-line data from a Phase 3 trial in DLD in May 2022 (LYNX-1). The VEGA-2 Phase 3 study in presbyopia achieved its primary endpoint and Viatriis, our development and commercial partner, is expected to continue Phase 3 development in the first half of 2024. For DLD, a SPA has been submitted and Viatriis is also expected to continue Phase 3 development in the first half of 2024 following FDA agreement.

Strategic Outlook

We will continue to explore opportunities to acquire additional ophthalmic assets, expand current pipeline to other retinal indications with APX3330, APX2009 and APX2014, and to seek strategic partners for late-stage development, regulatory preparation and commercialization of APX3330 in key global markets. To date, our primary activities have been conducting research and development activities, planning clinical trials, performing business and financial planning, recruiting personnel and raising capital. We have only one product, RYZUMVI™, approved for sale that may generate royalties based on sales by Viatriis, and we do not expect to consistently generate significant revenues, other than license and collaborations revenue, until, and unless, the FDA or other regulatory authorities approve, and we successfully commercialize, APX3330. Until such time, if ever, as we can consistently generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings as well as through collaborations, strategic alliances and licensing arrangements.

Through September 30, 2023, we have funded our operations primarily through equity financings that totaled \$59.6 million in gross proceeds, of which \$21.15 million was received in connection with the merger (“Merger”) with Rexahn Pharmaceuticals, Inc. (“Rexahn”) and through the issuance of convertible notes in private placements that totaled \$8.5 million in gross proceeds net cash. In addition, we have received license fee and milestone payments of \$45.0 million in the aggregate and reimbursement for costs related to development, all in connection with the Nyxol License Agreement.

Our net loss was \$5.2 million for the nine months ended September 30, 2023 as compared to a net loss of \$16.1 million for the nine months ended September 30, 2022. As of September 30, 2023, we had an accumulated deficit of \$76.7 million. Furthermore, we anticipate that our expenses will increase as we:

- continue clinical trials for APX3330, POS and for any other product candidate in our future pipeline;
- continue nonclinical studies for APX3330, APX2009 and APX2014, POS and for any other product candidate in our future pipeline;
- develop additional product candidates that we identify, in-license or acquire;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- contract to manufacture our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, operational and financial personnel, to execute our business plan;
- add operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts;
- continue to operate as a public company; and
- establish on our own or with partners, a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval.

Our net income (loss) will likely continue to fluctuate significantly from quarter to quarter and year to year, depending on the timing of our nonclinical studies, clinical trials, expenditures on other research and development activities (and reimbursement thereof), and from potential milestone payments received from and revenue earned under the Nyxol License Agreement or any other license and collaboration agreements that we enter into, and potential payments that may become payable from time to time under the Apexian Sublicense Agreement.

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Form 10-Q

Recent Developments

Clinical Milestones

APX3330

In January 2023, we announced top-line efficacy and safety results from ZETA-1, a Phase 2b trial of APX3330 in diabetic retinopathy patients. In ZETA-1, APX3330 demonstrated favorable safety and tolerability and exhibited efficacy in slowing or prevention of DR worsening on a binocular DRSS Person Scale. The FDA agreed this was an approvable registration endpoint at our EOP2 meeting.

Phentolamine Ophthalmic Solution 0.75% (POS)

In January 2023, we announced the initiation of the VEGA-2 Phase 3 pivotal trial, the first of two Phase 3 registration trials intended to support a presbyopia indication for POS alone and POS with LDP. The VEGA-2 Phase 3 study achieved its primary endpoint and Viatriis, our development and commercial partner, is expected to continue Phase 3 development in the first half of 2024.

Regulatory Update

In September 2023, we announced FDA approval of POS under the brand name RYZUMVI™ for the treatment of RM; for this approval we received a \$10 million milestone payment under the Nyxol License Agreement.

In October 2023, a SPA was submitted to the FDA for DLD and Viatriis, our development and commercial partner, is expected to continue Phase 3 development in the first half of 2024 following FDA agreement.

In November 2023, we announced the successful outcome of the EOP2 meeting with the FDA, at which we obtained agreement on the registration endpoint supporting the advancement of APX3330 into Phase 3. Ocuphire plans to submit a SPA to agree on the clinical trial protocol and statistical analysis plan for the Phase 3 trials and will share specifics on the study design parameters and anticipated timing once agreed with the FDA.

CEO Transition

On April 19, 2023, the Company terminated the employment of Mina Sooch, the former President and Chief Executive Officer of the Company, and appointed Richard Rodgers as the Company's interim President and Chief Executive Officer. On June 8, 2023, the Company entered into a Separation and Release Agreement with Ms. Sooch.

On November 1, 2023, the Company announced the appointment of George Magrath, M.D., M.B.A., M.S., as Chief Executive Officer and member of the Board of Directors. As a result of such appointment, Richard Rodgers, who was serving as Interim President and Chief Executive Officer, resigned from such positions and remains on the Board.

Purchase Agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park")

On August 10, 2023, we entered into a common stock purchase agreement (the "Purchase Agreement") with Lincoln Park, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Ocuphire has the sole right, but not the obligation, to direct Lincoln Park to purchase up to \$50 million of shares of our common stock, par value \$0.0001 (the "Common Stock"), from time to time over the 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, Ocuphire also entered into a registration rights agreement with Lincoln Park (the "Registration Rights Agreement"), pursuant to which we agreed to register the resale of the shares of our Common Stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to a registration statement. Upon the execution of the Purchase Agreement, we issued 246,792 shares of Common Stock to Lincoln Park as consideration for its commitment to purchase shares of our Common Stock under the Purchase Agreement. Lincoln Park has agreed not to cause or engage in any manner whatsoever in any direct or indirect short selling or hedging of our Common Stock.

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Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the effects of the conflict between Russia and Ukraine and potentially between Israel and Hamas, disruptions in the banking system and financial markets, lingering COVID-19 pandemic, increased inflation and increased interest rates. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

Additionally, our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the conflicts in Ukraine and the Middle East, disruptions in the banking system and financial markets, and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates.

Financial Operations Overview

License and Collaborations Revenue

License and collaborations revenue to date was derived from a one-time non-refundable payment related to a license transfer, an additional milestone payment and reimbursement of expenses earned under the Nyxol License Agreement, and to a much lesser degree, from license agreements with BioSense Global LLC (“BioSense”) and Processa Pharmaceuticals, Inc. (“Processa”) in connection with the Rexahn RX-3117 drug compound. We anticipate that we will recognize revenue as we earn reimbursement for research and development services in connection with the Nyxol License Agreement and we may earn additional revenues from potential milestone and royalty payments from the agreements with Viartis, BioSense, Processa, or from other license agreements entered into the future; however, the attainment of milestones or level of sales required to earn royalty payments is highly uncertain for the reasons explained below.

To date, outside of the license and collaborations revenue referenced above, we do not expect to generate significant revenue unless or until our partner, Viartis, commercializes RYZUMVI™, or regulatory approval is obtained and commercialization begins for APX3330 or POS for indications other than RM. If we fail to complete the development of APX3330, POS, or any other product candidate we may pursue in the future, in a timely manner, or fail to obtain regulatory approval, our ability to generate significant revenue would be compromised.

Operating Expenses

Ocuphire’s operating expenses are classified into two categories: general and administrative and research and development.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, benefits and stock-based compensation costs, for personnel in functions not directly associated with research and administrative activities. Other significant costs include insurance coverage for directors and officers and other property and liability exposures, legal fees relating to intellectual property and corporate matters, professional fees for accounting and tax services, other services provided by business consultants and legal settlements.

Research and Development Expenses

To date, our research and development expenses have related primarily to the clinical stage development of APX3330 and POS. Research and development expenses consist of costs incurred in performing research and development activities, including compensation and benefits for research and development employees and costs for consultants, costs associated with nonclinical studies and clinical trials, regulatory activities, manufacturing activities to support clinical activities, license fees, nonlegal patent costs, fees paid to external service providers that conduct certain research and development, and an allocation of overhead expenses.

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Pursuant to the Nyxol License Agreement, our budgeted research and development expenses related to the development of POS are fully reimbursed by Viatrix. However, all research and development costs, including those related to POS, are expensed as incurred, and costs incurred by third parties are expensed as the contracted work is performed. We accrue for costs incurred as the services are being provided by monitoring the status of the study or project, and as the invoices are received from our external service providers. We adjust our accrual as actual costs become known. Research and development activities are central to our business model.

We expect that APX3330 and POS will have higher development costs during the later stages of clinical development, as compared to costs incurred during their earlier stages of development, primarily due to the increased size and duration of the later-stage clinical trials and associated nonclinical studies. We expect our research and development expenses to increase over the next several years. However, it is difficult for us to determine with certainty the duration, costs and timing to complete our current or future nonclinical programs and clinical trials of APX3330, POS, and other product candidates. The duration, costs and timing of clinical trials and development of APX3330, POS and other product candidates will depend on a variety of factors that include, but are not limited to, the following:

- the conduct of nonclinical studies;
- the design of clinical studies;
- per-patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the phase of development of the product candidate;
- arrangements with contract research organizations and other service providers; and
- the efficacy and safety profile of the product candidates.

Financing costs

Financing costs consist of issuance costs attributed to an equity line financing with Lincoln Park discussed further below.

Interest Expense

Interest expense consists of interest costs on principal related to a short-term loan (related to financing an insurance policy) during the period it was outstanding. The short-term loan had an annual interest rate of 5.5%. The short-term loan was fully repaid in May 2022.

Fair value change in derivative liability

The fair value change in derivative liability consists of the fair value change of the derivative liability associated with our equity line financing during the periods the derivative liability is outstanding.

Other Income (Expense), net

Other income (expense), net reflected in this line item includes interest earned from cash and cash equivalent investments, realized and unrealized gains (losses) from equity investments and reimbursements in connection with grants and other sources when they occur. In addition, other income (expense), net also includes payments when made by us in connection with the Contingent Value Rights Agreement (the “CVR Agreement”) with former Rexahn shareholders.

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Provision for Income Taxes

Provision for income taxes consists of federal and state income taxes in the United States, as well as deferred income taxes and changes in related valuation allowance reflecting the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. A full valuation allowance has been provided on the net deferred tax assets as of September 30, 2023 and December 31, 2022.

Results of Operations

Comparison of Three Months Ended September 30, 2023 and 2022

The following table summarizes Ocuphire's operating results for the periods indicated (in thousands):

	For the Three Months Ended September 30,		
	2023	2022	Change
License and collaborations revenue	\$ 11,935	\$ —	\$ 11,935
Operating expenses:			
General and administrative	2,055	1,703	352
Research and development	3,494	2,835	659
Total operating expenses	5,549	4,538	1,011
Income (loss) from operations	6,386	(4,538)	10,924
Financing costs	(1,328)	—	(1,328)
Fair value change in derivative liability	61	—	61
Other income, net	456	7	449
Income (loss) before income taxes	5,575	(4,531)	10,106
Provision for income taxes	(14)	—	(14)
Net income (loss)	\$ 5,561	\$ (4,531)	\$ 10,092

License and Collaborations Revenue

License and collaborations revenue was 11.9 million for the three months ended September 30, 2023. There was no license and collaborations revenue during the three months ended September 30, 2022. Revenue during the third quarter of 2023 was derived from the achievement of a \$10.0 million milestone attributed to the FDA's approval of POS, for reversal of mydriasis, and from the reimbursement of research and development services under the Nyxol License Agreement in the amount of \$1.9 million.

General and Administrative

General and administrative expenses for the three months ended September 30, 2023 were \$2.1 million compared to \$1.7 million for the three months ended September 30, 2022. The increase period over period of \$0.4 million was primarily attributable to professional services of \$0.2 million, personnel related and other costs of \$0.2 million on a net basis. General and administrative expenses included \$0.3 million in stock-based compensation expense during both three months ended September 30, 2023 and 2022.

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Research and Development

The following table illustrates the components of our research and development expenses for the periods presented (in thousands):

	For the Three Months Ended September 30,		
	2023	2022	Change
External costs:			
Phentolamine Ophthalmic Solution 0.75% ("POS")	\$ 1,561	\$ 1,637	\$ (76)
APX3330	1,294	692	602
Unallocated	158	173	(15)
Total external cost	3,013	2,502	511
Internal costs:			
Employee related expenses	469	324	145
Facilities, supplies and other	12	9	3
Total internal costs	481	333	148
Total research and development expenses	\$ 3,494	\$ 2,835	\$ 659

Research and development expenses for the three months ended September 30, 2023 were \$3.5 million compared to \$2.8 million for the three months ended September 30, 2022. The \$0.7 million increase in the current period was primarily attributable to increased drug manufacturing of \$0.4 million and toxicology services of \$0.3 million related to APX3330 and increased payroll and consulting related costs of \$0.2 million, offset partially by decreases in regulatory and clinical activities of approximately \$0.3 million on a net basis. Pursuant to the Nyxol License Agreement, our budgeted research and development expenses related to the development of POS, are fully reimbursed by Viatrix. Research and development expenses also included \$0.2 million in stock-based compensation expense during both three months ended September 30, 2023 and 2022.

Financing costs

Financing costs for the three months ended September 30, 2023 of \$1.3 million was comprised of issuance costs attributed to the equity line financing with Lincoln Park described further below. We did not incur any financing costs during the three months ended September 30, 2022.

Fair value change in derivative liability

The fair value change in derivative liability attributed to the equity line financing with Lincoln Park, described further below, was a gain of \$0.1 million for the three months ended September 30, 2023 attributed to the fluctuations in our common stock fair value and the number of potential shares of common stock issuable at the various discount tiers under the equity line financing.

Other Income, net

During the three months ended September 30, 2023, Ocuphire had other income, net of \$0.5 million related primarily to interest income in connection with our cash and cash equivalents on-hand.

During the three months ended September 30, 2022, Ocuphire had other income, net of \$7,000 which consisted of interest income related to cash and cash equivalents of \$34,000, offset in part by unrealized losses from our short-term investments of \$25,000 and from realized foreign currency exchange losses of \$2,000.

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Comparison of Nine Months Ended September 30, 2023 and 2022

The following table summarizes Ocuphire's operating results for the periods indicated (in thousands):

	For the Nine Months Ended September 30,		
	2023	2022	Change
License and collaborations revenue	\$ 17,358	\$ —	\$ 17,358
Operating expenses:			
General and administrative	8,680	5,215	3,465
Research and development	13,812	10,769	3,043
Total operating expenses	22,492	15,984	6,508
Loss from operations	(5,134)	(15,984)	10,850
Financing costs	(1,328)	—	(1,328)
Interest expense	—	(9)	9
Fair value change in derivative liability	61	—	61
Other income (expense), net	1,224	(60)	1,284
Loss before income taxes	(5,177)	(16,053)	10,876
Provision for income taxes	(14)	—	(14)
Net loss	\$ (5,191)	\$ (16,053)	\$ 10,862

License and Collaborations Revenue

License and collaborations revenue was \$17.4 million for the nine months ended September 30, 2023. There was no license and collaboration revenue during the nine months ended September 30, 2022. Revenue during the nine month period ended September 30, 2023 was derived from the achievement of a \$10.0 million milestone attributed to the FDA's approval of POS, for reversal of mydriasis, and from the reimbursement of research and development services under the Nyxol License Agreement in the amount of \$7.4 million.

General and Administrative

General and administrative expenses for the nine months ended September 30, 2023 were \$8.7 million compared to \$5.2 million for the nine months ended September 30, 2022. The increase period over period of \$3.5 million was primarily attributable to severance costs associated with the departure of our former Chief Executive Officer in the amount of \$1.2 million, stock-based compensation of \$1.1 million, professional services of \$0.4 million, legal support of \$0.2 million, other personnel related costs of \$0.3 million and business development activities and other costs of \$0.3 million on a net basis. General and administrative expenses totaled \$2.0 million and \$0.9 million in stock-based compensation expense during the nine months ended September 30, 2023 and 2022, respectively.

Research and Development

The following table illustrates the components of our research and development expenses for the periods presented (in thousands):

	For the Nine Months Ended September 30,		
	2023	2022	Change
External costs:			
Phentolamine Ophthalmic Solution 0.75% ("POS")	\$ 8,732	6,516	2,216
APX 3330	2,947	2,631	316
Unallocated	536	446	90
Total external cost	12,215	9,593	2,622
Internal costs:			
Employee related expenses	1,578	1,099	479
Facilities, supplies and other	19	77	(58)
Total internal costs	1,597	1,176	421
Total research and development expenses	\$ 13,812	10,769	3,043

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Research and development expenses for the nine months ended September 30, 2023 were \$13.8 million compared to \$10.8 million for the nine months ended September 30, 2022. The \$3.0 million increase was primarily attributable to increased clinical costs of \$2.6 million for the POS VEGA-2 trial, increased manufacturing and toxicology activities of approximately \$1.3 million for APX3330, offset by decreased clinical costs for the APX3330 ZETA-1 trial and other research and development activities period over period. Additionally, higher payroll, including stock-based compensation, and consulting costs of \$0.8 million and other operating expenses of \$0.1 million, on net basis, contributed to the expense increase during the current nine-month period. Pursuant to the Nyxol License Agreement, our budgeted research and development expenses related to the development of POS are fully reimbursed by Viatris. Research and development expenses also included \$0.8 million and \$0.5 million in stock-based compensation expense during the nine months ended September 30, 2023 and 2022, respectively.

Financing costs

Financing costs for the nine months ended September 30, 2023 of \$1.3 million was comprised of issuance costs attributed to the equity line financing with Lincoln Park described further below. We did not have any financing costs during the nine months ended September 30, 2022.

Interest Expense

Interest expense for the nine months ended September 30, 2022 of \$9,000 was comprised of interest on principal related to a short-term loan (related to financing an insurance policy). We did not have any interest expense during the nine months ended September 30, 2023.

Fair value change in derivative liability

The fair value change in derivative liability attributed to the equity line financing, described further below, was a gain of \$0.1 million for the nine months ended September 30, 2023 attributed to the fluctuations in our common stock fair value and the number of potential shares of common stock issuable at the various discount tiers under the equity line financing.

Other Income (Expense), net

During the nine months ended September 30, 2023, Ocuphire had other income (expense), net of \$1.2 million related primarily to interest income in connection with our cash and cash equivalents on-hand.

During the nine months ended September 30, 2022, Ocuphire had other expense, net of \$60,000 stemming from net unrealized losses from our short-term investments of \$118,000 and realized currency losses of approximately \$1,000, offset in part by interest income of \$59,000 related to cash and cash equivalents.

Liquidity and Capital Resources

Capital Resources

As of September 30, 2023, our principal sources of liquidity consisted of cash and cash equivalents of \$42.4 million. We believe that our cash on hand will be sufficient to fund our operations for at least twelve months beyond the date of this filing. As of September 30, 2023, our cash and cash equivalents on-hand were held at two large financial institutions.

Historical Capital Resources

Our primary source of cash to fund our operations has been various equity offerings in the amount of \$59.6 million and the issuance of convertible notes in the amount of \$8.5 million, inclusive of the promissory notes exchanged for Ocuphire convertible notes (the "Ocuphire Convertible Notes"). In addition, we received a one-time non-refundable cash payment of \$35.0 million during the fourth quarter of 2022, a \$10.0 million milestone payment during the third quarter of 2023, and have received reimbursement for costs related to development since the fourth quarter of 2022, all in connection with the Nyxol License Agreement.

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Lincoln Park Purchase Agreement

On August 10, 2023, we entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC (“Lincoln Park”) for an equity line financing (the “Purchase Agreement”). The Purchase Agreement provides that, subject to the terms and conditions set forth therein, we have the sole right, but not the obligation, to direct Lincoln Park to purchase up to \$50 million of shares of the Company’s common stock from time to time over the 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a Registration Rights Agreement, pursuant to which we agreed to register the resale of the shares of our common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to a registration statement. Upon the execution of the Purchase Agreement, we issued 246,792 shares of the Company’s common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement. Lincoln Park has agreed not to cause or engage in any manner whatsoever in any direct or indirect short selling or hedging of our common stock. In addition to the commitment shares referenced above, a total of 800,000 shares of common stock were sold under the Purchase Agreement for net proceeds through September 30, 2023 in the amount of \$3.1 million. No shares of common stock were sold under the Purchase Agreement prior to the third quarter of 2023.

At-The-Market Program

On February 4, 2021, we filed a Form S-3 shelf registration under the Securities Act which was declared effective by the SEC on February 12, 2021 (the “2021 Shelf”) under which the Company may offer and sell, from time to time in our sole discretion, securities having an aggregate offering price of up to \$125 million. In connection with the 2021 Shelf, on March 11, 2021, we entered into a sales agreement with JonesTrading Institutional Services LLC (“JonesTrading”) under which we may offer and sell, from time to time at our sole discretion, to or through JonesTrading, acting as agent and/or principal, shares of our common stock having an aggregate offering price of up to \$40 million (the “ATM”). A total of 5,205,425 shares of common stock were sold under the ATM since its inception for net proceeds through September 30, 2023 in the amount of \$19.6 million.

Registered Direct Offering

On June 4, 2021, we entered into a placement agency agreement with A.G.P./Alliance Global Partners (“AGP”). Pursuant to the terms of the placement agency agreement, AGP on June 8, 2021, sold an aggregate of 3,076,923 shares of our common stock and warrants to purchase 1,538,461 shares of our common stock (the “RDO Warrants”) at an offering price of \$4.875 per share and 0.50 RDO Warrants, for gross proceeds of \$15.0 million, before deducting AGP’s fees and related offering expenses in the amount of \$1.1 million. The purchase agreement contains customary representations, warranties and agreements by Ocuphire, customary conditions to closing, indemnification obligations of Ocuphire, other obligations of the parties and termination provisions.

The RDO Warrants have an exercise price of \$6.09 per share, are exercisable upon the initial issuance date of June 8, 2021, and will expire five years following the initial exercise date. Subject to limited exceptions, a holder of a RDO Warrant will not have the right to exercise any portion of its RDO Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of a holder prior to the date of issuance, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise; provided, however, that upon prior notice to us, the holder may increase or decrease the beneficial ownership limitation, provided further that in no event shall the beneficial ownership limitation exceed 9.99%. As of September 30, 2023, 1,538,461 RDO Warrants were still outstanding. The offering of the securities was made pursuant to our effective shelf registration statement on Form S-3.

Pre-Merger Financing

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Securities Purchase Agreement

On June 17, 2020, Ocuphire, Rexahn and certain investors entered into a Securities Purchase Agreement, which was amended and restated in its entirety on June 29, 2020 (as amended and restated, the “Securities Purchase Agreement”). Pursuant to the Securities Purchase Agreement, the investors invested a total of \$21.15 million in cash, including \$300,000 invested by directors of Ocuphire Pharma, Inc. prior to the Merger, and one director of Rexahn, upon closing of the Merger (the “Pre-Merger Financing”). Pursuant to the Pre-Merger Financing, (i) Ocuphire issued and sold to the investors shares of common stock of Ocuphire Pharma, Inc. prior to the Merger (the “Initial Shares”) which converted pursuant to the exchange ratio in the Merger into an aggregate of 1,249,996 shares (the “Converted Initial Shares”) of common stock, (ii) Ocuphire deposited into escrow, for the benefit of the investors, additional shares of common stock of Ocuphire Pharma, Inc. prior to the Merger (the “Additional Shares”) which converted pursuant to the exchange ratio in the Merger into an aggregate of 3,749,992 shares of common stock (the “Converted Additional Shares”), which Converted Additional Shares were delivered (or became deliverable) to the investors on November 19, 2020, and (iii) we agreed to issue to each investor on the tenth trading day following the consummation of the Merger (x) Series A Warrants representing the right to acquire shares of common stock equal to the sum of (A) the Converted Initial Shares purchased by the investor, (B) the Converted Additional Shares delivered or deliverable to the investor, without giving effect to any limitation on delivery contained in the Securities Purchase Agreement and (C) the initial number of shares of common stock, if any, underlying the Series B Warrants issued to the investor and (y) additional warrants to purchase shares of common stock.

Waiver Agreements

Effective February 3, 2021, each investor that invested in the Pre-Merger Financing (each, a “Holder”) entered into a Waiver Agreement with the Company (collectively, the “Waiver Agreements”). Pursuant to the Waiver Agreements, the Holders and Ocuphire agreed to waive certain rights, finalize the exercise price and number of Series A Warrants and Series B Warrants, eliminate certain financing restrictions, extend the term of certain leak-out agreements, and, in the case of certain Holders, grant certain registration rights for the shares underlying the warrants.

The Waiver Agreements provide for the permanent waiver of the full ratchet anti-dilution provisions, contained in the Series A Warrants (as certain of the anti-dilution provisions had previously caused liability accounting treatment for the Series A Warrants). Upon the effective date of the Waiver Agreement, the Series A Warrants were reclassified to equity.

Pursuant to the Waiver Agreements, the number of shares underlying all of the Series B Warrants was fixed to 1,708,335 in the aggregate with respect to all Holders.

Series A Warrants

The Series A Warrants were issued on November 19, 2020 at an initial exercise price of \$4.4795 per share, were immediately exercisable upon issuance and have a term of five years from the date of issuance. The Series A Warrants are exercisable for 5,665,838 shares of common stock in the aggregate (without giving effect to any limitation on exercise contained therein). As of September 30, 2023, 5,665,838 Series A Warrants were still outstanding.

At issuance, the Series A Warrants contained certain provisions that could have resulted in a downward adjustment of the initial exercise price and an upward adjustment in the number of shares underlying the warrants if Ocuphire were to have issued or sold, or made an agreement to issue or sell, any shares of common stock for a price lower than the exercise price then in effect. Pursuant to the terms of the Waiver Agreements, these provisions are no longer in effect.

Series B Warrants

The Series B Warrants had an exercise price of \$0.0001, were exercisable upon issuance and would have expired on the day following the later to occur of (i) the Reservation Date (as defined therein) or (ii) the date on which the investor’s Series B Warrants would have been exercised in full (without giving effect to any limitation on exercise contained therein). The Series B Warrants were initially exercisable for 665,836 shares of common stock in the aggregate (without giving effect to any limitation on exercise contained therein) and ultimately became exercisable for 1,708,335 shares of common stock upon execution of the Waiver Agreements. As of September 30, 2023, none of the Series B Warrants remained outstanding.

At issuance, the Series B Warrants contained certain provisions that could have resulted in the issuance of additional Series B Warrants depending on the dollar volume-weighted average prices of a share of Common Stock during a 45-trading day reset period. Pursuant to the terms of the Waiver Agreements, those provisions were no longer in effect.

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Ocuphire Convertible Notes

From May 2018 through March 2020, we issued the Ocuphire Convertible Notes for aggregate gross proceeds of \$8.5 million, inclusive of the promissory notes exchanged for Ocuphire Convertible Notes. The final closing of the Ocuphire Convertible Notes occurred on March 10, 2020. The Ocuphire Convertible Notes had an interest rate of 8% per annum. On November 4, 2020, all of Ocuphire's outstanding notes were converted into 977,128 shares of Ocuphire common stock in connection with the completion of the Merger.

Cash Flows

The following table summarizes Ocuphire's cash flows for the periods indicated (in thousands):

	For the Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	\$ (5,660)	\$ (14,477)
Net cash provided by (used in) investing activities	—	—
Net cash provided by financing activities	5,376	3,798
Net decrease in cash and cash equivalents	<u>\$ (284)</u>	<u>\$ (10,679)</u>

Cash Flow from Operating Activities

For the nine months ended September 30, 2023, cash used in operating activities of \$5.7 million was attributable to a net loss of \$5.2 million, partially offset by \$4.1 million in non-cash operating expenses and a net change cash use of \$4.6 million in Ocuphire's net operating assets and liabilities. The non-cash expenses consisted principally of stock-based compensation of \$2.8 million, non-cash financing costs of \$1.2 million in connection with the equity line financing and \$0.2 million of issuance costs reclassified to financing activities, offset by a fair value gain attributed to the derivative liability of \$0.1 million. The change in operating assets and liabilities was primarily attributable to an overall net increase in Ocuphire's accounts receivable attributed to the milestone receivable associated with the FDA's approval of POS, for reversal of mydriasis. Net cash used for the period was partially offset by decreases in our contract assets/unbilled receivables, prepaid expenses and increases in our accounts payable, all associated with Ocuphire's operating expenses under the normal course of business.

For the nine months ended September 30, 2022, cash used in operating activities of \$14.5 million was attributable to a net loss of \$16.1 million, partially offset by \$1.5 million in non-cash operating expenses, and attributable to a net cash increase of approximately \$0.1 million stemming from the change in Ocuphire's net operating assets and liabilities. The non-cash expenses consisted principally of stock-based compensation of \$1.4 million and unrealized loss on short-term investments of \$0.1 million. The change in operating assets and liabilities was primarily attributable to a net cash source of \$0.7 million attributed to a decrease in prepaid expenses, offset largely by a decrease in accounts payable and accrued expense associated with the fluctuations of Ocuphire's operating expenses.

Cash Flow from Investing Activities

There were no sources or uses from investing activities during the periods presented.

Cash Flow from Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2023 was \$5.4 million that consisted of net proceeds received from both the 2021 ATM and the equity line financing in the aggregate of \$5.4 million.

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Net cash provided by financing activities during the nine months ended September 30, 2022 was \$3.8 million that consisted principally of proceeds received from the 2021 ATM net of issuance costs in the amount of \$4.3 million, offset in part by payments made on the short-term loan of \$0.5 million.

Liquidity and Capital Resource Requirements

As of September 30, 2023, we had cash and cash equivalents of \$42.4 million. This does not include the \$10 million license agreement milestone payment received in October 2023 under the Nyxol License Agreement for the NDA approval of RYZUMVI™ for the treatment of RM. License and collaborations revenue inception to date was derived from a one-time non-refundable payment of \$35 million, a milestone payment of \$10 million and reimbursement and expected reimbursement of expenses earned under the Nyxol License Agreement, and to a much lesser degree, from license agreements with BioSense Global LLC (“BioSense”) and Processa Pharmaceuticals, Inc. (“Processa”) in connection with the Rexahn RX-3117 drug compound. We anticipate that we will recognize revenue as we earn reimbursement for research and development services in connection with the Nyxol License Agreement and we may earn additional revenues from future potential milestone and royalty payments from the agreements with Viatriis, BioSense, Processa, or from other license agreements entered into the future; however, the attainment of milestones or level of sales required to earn royalty payments is highly uncertain for the reasons explained below.

To date, outside of the license and collaborations revenue referenced above, we do not expect to generate significant revenue unless or until our partner, Viatriis, commercializes RYZUMVI™, or regulatory approval is obtained and commercialization begins for APX3330 or POS for indications other than RM. If we fail to complete the development of APX3330, POS, or any other product candidate we may pursue in the future, in a timely manner, or fail to obtain regulatory approval, our ability to generate significant revenue would be compromised.

In addition, on August 10, 2023, we entered into the Purchase Agreement with Lincoln Park, which provides that we have the sole right, but not the obligation, to direct Lincoln Park to purchase up to \$50 million of shares of our common stock, from time to time over the 30-month term of the Purchase Agreement. The Purchase Agreement was executed to compliment the ATM. Concurrently with entering into the Purchase Agreement, we also entered into a Registration Rights Agreement with Lincoln Park, pursuant to which we agreed to register the resale of the shares of our common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to a registration statement. We filed a prospectus supplement to our Registration Statement (File No. 333-252715) on August 11, 2023 with the SEC. Per the terms of the Purchase Agreement, we will be unable to sell shares of our common stock to Lincoln Park if the sale price falls below \$0.25 per share. Therefore, there is no assurance that we will have full access to the facility during the term of the Purchase Agreement.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation, warrants or other preferences that adversely affect your rights as a common stockholder. Debt 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. If we raise additional funds through future collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development, future commercialization efforts, or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

Future Capital Requirements

Pursuant to the Nyxol License Agreement, our budgeted research and development expenses related to the development of POS are fully reimbursed by Viatriis. The development of APX3330 is subject to numerous uncertainties, and we have based these estimates on assumptions that may prove to be substantially different than what we currently anticipate and could result in cash resources being used sooner than what we currently expect. Additionally, the process of advancing early-stage product candidates and testing product candidates in clinical trials is costly, and the timing of progress in these clinical trials is uncertain. Our ability to successfully transition to profitability will be dependent upon achieving a level of product sales adequate to support our cost structure. We cannot give any assurance that we will ever be profitable or generate positive cash flow from operating activities.

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Contractual Obligations and Commitments

Facility Lease

We lease a facility under a non-cancellable operating lease that expires on December 31, 2023, as amended, for a base rent in the amount of \$3,000 per month.

Apexian Sublicense Agreement

On January 21, 2020, we entered into the Apexian Sublicense Agreement, pursuant to which we obtained exclusive worldwide patent and other intellectual property rights that constitute a Ref-1 Inhibitor program relating to therapeutic applications to treat disorders related to ophthalmic and diabetes mellitus conditions. The lead compound in the Ref-1 Inhibitor program is APX3330, which we intend to develop as an oral tablet therapeutic to treat NPDR. The unique, dual mechanism of action of Ref-1 inhibitors (e.g., APX3330, APX2009 and APX2014) of reducing angiogenesis and inflammation could potentially be beneficial in treating other retinal diseases such as AMD and GA. Ocuphire is currently evaluating local delivery routes in addition to the systemic (oral) route as part of its pipeline expansion into retina.

In connection with the Apexian Sublicense Agreement, we issued 843,751 shares of our common stock to Apexian and certain of Apexian's affiliates.

We agreed to make one-time milestone payments under the Apexian Sublicense Agreement for each of the first ophthalmic indication and the first diabetes mellitus indication. These milestone payments include (i) payments for specified developmental and regulatory milestones (including completion of the first Phase 2 trial (if such trial meets a primary endpoint) and the first Phase 3 pivotal trial in the United States, and filing and achieving regulatory approval from the FDA for the first New Drug Application for a compound) totaling up to \$11 million in the aggregate and (ii) payments for specified sales milestones of up to \$20 million in the aggregate, each of which net sales milestone payments is payable once, upon the first achievement of such milestone.

Lastly, we also agreed to make royalty payments equal to a single-digit percentage of our net sales of products covered by the patents under the Apexian Sublicense Agreement. None of the milestone or royalty payments were triggered as of the date of this Report.

Other Commitments

In the course of normal operations, we entered into cancellable purchase commitments with our suppliers for various key research, clinical and manufacturing services. The purchase commitments covered by these arrangements are subject to change based on our research and development efforts.

Other Funding Requirements

As noted above, certain of our cash requirements relate to the funding of our ongoing research and development of APX3330, inclusive of any potential milestone and royalty obligations under our intellectual property licenses. See "Part I, Item 1— Business—APX3330 Clinical Experience Summary —Ocuphire Clinical Development Plan —Potential Clinical Plans for APX3330—Future In-Licensing and Acquisition Opportunities—Manufacturing—Apexian Sublicense Agreement— Review and Approval of Drugs in the United States" in our Annual Report on Form 10-K for the year ended December 31, 2022 for a discussion of design, development, pre-clinical and clinical activities that we may conduct in the future, including expected cash expenditures required for some of those activities, to the extent we are able to estimate such costs.

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Our other cash requirements within the next twelve months include accounts payable, accrued expenses, purchase commitments and other current liabilities. Our other cash requirements greater than twelve months from various contractual obligations and commitments may include operating leases and contractual agreements with third-party service providers for clinical research, product development, manufacturing, commercialization, supplies, payroll, equipment maintenance, and audits for periods into calendar year 2024. Refer to Note 3 – Commitments and Contingencies included in “Part 1, Item 1 – Financial Statements” of this Report for further detail of our lease obligation and license agreements with regard to the timing of expected future payments.

We expect to satisfy our short-term and long-term obligations through cash on hand, from future equity and debt financings, and from reimbursement payments, potential milestone and royalty payments under the Nyxol License Agreement and any future collaborations and license agreements, until we generate an adequate level of revenue from commercial sales to cover expenses, if ever.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with U.S. GAAP. These accounting principles require us to make estimates and judgments that can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenue and expense during the periods presented. We believe that the estimates and judgments upon which we rely are reasonably based upon information available to us at the time that we make these estimates and judgments. To the extent that there are material differences between these estimates and actual results, our financial results will be affected. The accounting policies that reflect our more significant estimates and judgments and which we believe are the most critical to aid in fully understanding and evaluating our reported financial results are described below.

Our significant accounting policies are discussed in Note 1 — Company Description and Summary of Significant Accounting Policies, included in “Part I, Item 1 – Financial Statements” of this Report. We believe that the following accounting policies and estimates are the most critical to aid in fully understanding and evaluating our reported financial results. These estimates require our most difficult, subjective, or complex judgments because they relate to matters that are inherently uncertain. We have reviewed these critical accounting policies and estimates and related disclosures with the Audit Committee of our Board of Directors. We have not made any material changes to date, nor do we believe there is a reasonable likelihood of a material future change to the accounting methodologies for the areas described below.

License and Collaborations Revenue

We account for license and collaborations revenue in accordance with the provisions of the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 606, *Revenue from Contracts with Customers*. The guidance provides a unified model to determine how revenue is recognized. We have entered into license and collaboration agreements which have revenue recognition implications. We recognize license and collaborations revenue by first allocating the transaction price of a contract to each performance obligation under the contract based on its stand-alone price. The stand-alone price of each performance obligation is based on its fair value utilizing a discounted cash flow approach, taking into consideration assumptions, including projected worldwide net profit for each of the respective programs based on probability assessments, projections based on internal forecasts, industry data, and information from other guideline companies within the same industry and other relevant factors. We do not expect to have in the future, significant variable consideration adjustments related to our existing license and collaborations revenue recognized. For discussion about the determination of license and collaborations revenue, see Note 9 — License and Collaboration Agreements included in “Part 1, Item 1 – Financial Statements” of this Report.

Stock-based Compensation

Ocuphire accounts for stock-based compensation in accordance with the provisions of ASC 718, *Compensation — Stock Compensation*. Accordingly, compensation costs related to equity instruments granted are recognized at the grant date fair value which is not subject to remeasurement. We record equity instrument forfeitures when they occur. For discussions about the application of grant date fair value associated with our stock-based compensation, see Note 7 — Stock-based Compensation included in “Part 1, Item 1 – Financial Statements” of this Report.

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Income Tax Assets and Liabilities

A full valuation allowance has been provided on our net deferred tax assets given the uncertainty of future taxable income and other related factors impacting the realizability of our remaining net deferred tax assets. For additional information, see Note 12 — Income Taxes included in “Part II, Item 8 – Consolidated Financial Statements and Supplementary Data” in our Annual Report filed on Form 10-K for the year ended December 31, 2022, and see Note 11 — Income Taxes included in “Part 1, Item 1 – Financial Statements” of this Report.

Contingencies

We are subject to numerous contingencies arising in the ordinary course of business, including obligations related to certain license agreements. For additional information, see Note 3 — Commitments and Contingencies included in “Part 1, Item 1 – Financial Statements” of this Report.

Recent Accounting Pronouncements

Refer to Note 1— “Company Description and Summary of Significant Accounting Policies” to our condensed financial statements included in “Part 1, Item 1 – Financial Statements” in this Report for a discussion of recently issued accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information we are required to disclose in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

We designed and evaluated our disclosure controls and procedures recognizing that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance and not absolute assurance of achieving the desired control objectives. Also, the design of a control system must reflect the fact that there are resource constraints and that the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Under the supervision of and with the participation of our management, including our principal executive officer and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15(d)- 15(e) promulgated under the Exchange Act as of September 30, 2023. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2023.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended September 30, 2023, that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

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PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

There have been no material changes in our risk factors previously disclosed in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022. You should carefully read and consider the risks and uncertainties described therein.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable to our Company.

Item 5. Other Information

None.

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Item 6. Exhibits

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Appendix G to the Registrant's Definitive Proxy Statement on Schedule 14A, filed on April 29, 2005).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on May 5, 2017).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on August 30, 2018).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on April 12, 2019).
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on November 6, 2020).
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on November 6, 2020).
3.7	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K, filed on November 6, 2020).
3.8	First Amendment to Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 10, 2022).
3.9	Second Amendment to Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 17, 2022).
3.10	Third Amendment to Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 2, 2023).
10.1	Purchase Agreement, dated as of August 10, 2023, by and between Ocuphire Pharma, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on August 11, 2023).
10.2	Registration Rights Agreement, dated as of August 10, 2023, by and between Ocuphire Pharma, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on August 11, 2023).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

+ Indicates management contract or compensatory plan.

* Documents are furnished not filed.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 13, 2023

Ocuphire Pharma, Inc.

By: /s/ George Magrath

George Magrath
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Amy Rabourn

Amy Rabourn
Senior Vice President of Finance
(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a), AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002**

I, George Magrath, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2023 of Ocuphire Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ George Magrath

Name: George Magrath

Title: Chief Executive Officer

(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a), AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002**

I, Amy Rabourn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2023 of Ocuphire Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ Amy Rabourn

Name: Amy Rabourn

Title: Senior Vice President of Finance
(Principal Financial Officer)

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 (the “Report”) of Ocuphire Pharma, Inc., a Delaware corporation (the “Company”) as filed with the Securities and Exchange Commission, George Magrath, as Chief Executive Officer of the Company, and Amy Rabourn, as Senior Vice President of Finance of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of his and her knowledge and belief:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ George Magrath

George Magrath
Chief Executive Officer
(Principal Executive Officer)

/s/ Amy Rabourn

Amy Rabourn
Senior Vice President of Finance
(Principal Accounting Officer)

Dated: November 13, 2023
