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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended: June 30, 2024

OR

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

For the transition period from to

COMMISSION FILE NUMBER: 001-38365

EYENOVIA, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE	**47-1178401**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
295 Madison Avenue, Suite 2400 NEW YORK, NY	**10017**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (833) 393-6684

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, par value $0.0001 per share	EYEN	Nasdaq Capital Market

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 (§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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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 news 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 Act). Yes ☐ No ☒

The number of outstanding shares of the registrant's common stock was 64,059,440 as of August 9, 2024 .

EYENOVIA, INC.

FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2024

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

EYENOVIA, INC.

Condensed Balance Sheets

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current Assets		
Cash and cash equivalents	$ 2,300,852	$ 14,849,057
Inventories	3,052,142	109,798
Deferred clinical supply costs	412,140	4,256,793
License fee and expense reimbursements receivable	124,173	123,833
Security deposits, current	—	1,506
Prepaid expenses and other current assets	1,394,313	1,365,731
Total Current Assets	7,283,620	20,706,718
Property and equipment, net	3,041,462	3,374,384
Deferred offering costs	170,632	—
Security deposits, non-current	197,168	197,168
Intangible assets	6,122,945	2,122,945
Prepaid expenses, non-current	58,693	—
Operating lease right-of-use asset	1,408,999	1,666,718
Equipment deposits	711,441	711,441
Total Assets	$ 18,994,960	$ 28,779,374
Liabilities and Stockholders' (Deficiency) Equity		
Current Liabilities:		
Accounts payable	$ 1,436,665	$ 1,753,172
Accrued compensation	1,278,178	1,658,613
Accrued expenses and other current liabilities	2,988,128	287,928
Operating lease liabilities - current portion	600,379	501,250
Notes payable - current portion, net of debt discount of $692,567 and $503,914 as of June 30, 2024 and December 31, 2023, respectively	8,730,043	5,329,419
Convertible notes payable - current portion, net of debt discount of $18,117 and $0 as of June 30, 2024 and December 31, 2023, respectively	815,216	—
Total Current Liabilities	15,848,609	9,530,382
Operating lease liabilities - non-current portion	983,839	1,292,667
Notes payable - non-current portion, net of debt discount of $0 and $448,367 as of June 30, 2024 and December 31, 2023, respectively	637,500	4,355,800
Convertible notes payable - net of debt discount of $271,752 and $398,569 as of June 30, 2024 and December 31, 2023, respectively	3,894,915	4,601,431
Total Liabilities	21,364,863	19,780,280
Commitments and contingencies (Note 8)		
Stockholders' (Deficiency) Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized; 55,817,921 and 45,553,026 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	5,582	4,555
Additional paid-in capital	165,091,874	154,486,098
Accumulated deficit	(167,467,359)	(145,491,559)
Total Stockholders' (Deficiency) Equity	(2,369,903)	8,999,094
Total Liabilities and Stockholders' (Deficiency) Equity	$ 18,994,960	$ 28,779,374

The accompanying notes are an integral part of these condensed financial statements.

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Operating Income				
Revenue	$ 22,625	$ —	$ 27,618	$ —
Cost of revenue	(490,361)	—	(693,388)	—
Gross Loss	(467,736)	—	(665,770)	—
Operating Expenses:				
Research and development	4,597,173	2,811,061	9,028,774	5,333,011
General and administrative	3,758,835	3,149,809	7,396,024	6,086,695
Reacquisition of license rights	2,864,600	—	4,864,600	—
Total Operating Expenses	11,220,608	5,960,870	21,289,398	11,419,706
Loss From Operations	(11,688,344)	(5,960,870)	(21,955,168)	(11,419,706)
Other Income (Expense):				
Other income (expense), net	2,980	119,450	(94,578)	190,443
Change in fair value of equity consideration payable	1,240,800	—	1,240,800	—
Interest expense	(674,001)	(558,003)	(1,352,659)	(1,012,006)
Interest income	64,866	183,563	185,805	286,043
Total Other Income (Expense)	634,645	(254,990)	(20,632)	(535,520)
Net Loss	$ (11,053,699)	$ (6,215,860)	$ (21,975,800)	$ (11,955,226)
Net Loss Per Share - Basic and Diluted	$ (0.21)	$ (0.16)	$ (0.44)	$ (0.32)
Shares Outstanding - Basic and Diluted	53,121,760	38,093,826	49,864,275	37,753,694

The accompanying notes are an integral part of these condensed financial statements.

EYENOVIA, INC.

Condensed Statements of Changes in Stockholders' (Deficiency) Equity
(unaudited)

	For the Three and Six Months Ended June 30, 2024				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	(Deficiency) Equity
Balance - January 1, 2024	45,553,026	$ 4,555	$ 154,486,098	$ (145,491,559)	$ 8,999,094
Issuance of common stock in At the Market offering [1]	1,833,323	183	3,194,364	—	3,194,547
Stock-based compensation	—	—	546,232	—	546,232
Net loss	—	—	—	(10,922,101)	(10,922,101)
Balance - March 31, 2024	47,386,349	4,738	158,226,694	(156,413,660)	1,817,772
Issuance of common stock in registered direct offering [2]	3,223,726	322	1,888,507	—	1,888,829
Issuance of common stock as consideration for licensing agreement [3]	613,496	62	436,747	—	436,809
Issuance of common stock as consideration for reacquisition of licensing agreement [4]	2,299,397	230	2,322,161	—	2,322,391
Issuance of common stock in At the Market offering [5]	2,294,953	230	1,676,709	—	1,676,939
Stock-based compensation	—	—	541,056	—	541,056
Net loss	—	—	—	(11,053,699)	(11,053,699)
Balance - June 30, 2024	55,817,921	$ 5,582	$ 165,091,874	$ (167,467,359)	$ (2,369,903)

[1] Includes gross proceeds of $3,293,347 less total issuance costs of $98,800.
[2] Includes gross proceeds of $2,000,000, less total issuance costs of $111,171.
[3] Shares issued as partial consideration for License Agreement with Formosa Pharmaceuticals Inc.
[4] Shares issued as partial consideration for reversion of License Agreement with Bausch & Lomb Ireland Limited.
[5] Includes gross proceeds of $1,728,804 less total issuance costs of $51,865.

	For the Three and Six Months Ended June 30, 2023				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance - January 1, 2023	36,668,980	$ 3,667	$ 135,461,361	$ (118,230,463)	$ 17,234,565
Issuance of common stock in At the Market offering [1]	1,299,947	130	3,499,462	—	3,499,592
Cashless exercise of stock options	19,530	2	(2)	—	—
Stock-based compensation	—	—	819,064	—	819,064
Issuance of common stock related to vested restricted stock units	3,289	—	—	—	—
Net loss	—	—	—	(5,739,366)	(5,739,366)
Balance - March 31, 2023	37,991,746	3,799	139,779,885	(123,969,829)	15,813,855
Issuance of common stock in At the Market offering [2]	121,989	13	403,107	—	403,120
Cashless exercise of stock options	1,219	—	—	—	—
Exercise of stock options	10,000	1	27,199	—	27,200
Stock-based compensation	—	—	493,632	—	493,632
Issuance of common stock related to vested restricted stock units	44,444	4	(4)	—	—
Net loss	—	—	—	(6,215,860)	(6,215,860)
Balance -June 30, 2023	38,169,398	$ 3,817	$ 140,703,819	$ (130,185,689)	$ 10,521,947

[1] Includes gross proceeds of $3,607,827 less total issuance costs of $108,235.
[2] Includes gross proceeds of $415,588 less total issuance costs of $12,468.

The accompanying notes are an integral part of these condensed financial statements.

EYENOVIA, INC.

Condensed Statements of Cash Flows
(unaudited)

	For the Six Months Ended June 30,	
	2024	**2023**
Cash Flows From Operating Activities		
Net loss	$ (21,975,800)	$ (11,955,226)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,087,288	1,312,696
Change in fair value of equity consideration payable	(1,240,800)	—
Depreciation of property and equipment	543,124	187,267
Amortization of debt discount	368,414	313,446
Write-off of property and equipment	85,051	—
Write-down of inventories to net realizable value	665,770	—
Reacquisition of license rights	2,864,600	—
Non-cash rent expense	257,719	280,968
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	417,775	(1,514)
License fee and expense reimbursement receivables	(340)	754,780
Deferred clinical supply costs	377,365	(1,293,395)
Inventories	(140,826)	—
Security and equipment deposits	1,506	1,750
Accounts payable	(316,508)	(115,534)
Accrued compensation	(380,435)	(734,073)
Accrued expenses and other current liabilities	(470,432)	(139,645)
Lease liabilities	(209,699)	(284,996)
Net Cash Used In Operating Activities	(18,066,228)	(11,673,476)
	—	
Cash Flows From Investing Activities		
Purchases of property and equipment	(159,853)	(2,122,197)
Net Cash Used In Investing Activities	(159,853)	(2,122,197)
Cash Flows From Financing Activities		
Proceeds from sale of common stock and warrants in registered direct offering	2,000,000	—
Payment of registered direct offering issuance costs	(111,171)	—
Proceeds from sale of common stock in At the Market offering	5,022,151	4,023,414
Payment of issuance costs for At the Market offering	(150,665)	(120,702)
Proceeds from exercise of stock options	—	27,200
Proceeds from note payable and equity issued to Avenue	—	5,000,000
Payment of issuance costs for notes issued to Avenue	—	(125,982)
Repayments of notes payable	(1,082,439)	(403,689)
Net Cash Provided By Financing Activities	5,677,876	8,400,241
Net Decrease in Cash and Cash Equivalents	(12,548,205)	(5,395,432)
Cash and Cash Equivalents - Beginning of Period	14,849,057	22,863,520
Cash and Cash Equivalents - End of Period	$ 2,300,852	$ 17,468,088

The accompanying notes are an integral part of these condensed financial statements.

EYENOVIA, INC.

Condensed Statements of Cash Flows, continued
(unaudited)

	For the Six Months Ended June 30,	
	2024	**2023**
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ 984,246	$ 699,116
Supplemental Disclosure of Non-Cash Investing and Financing Activities		
Purchase of insurance policy financed by note payable	$ 505,050	$ 609,140
Accrual for intangible asset milestone obligation	$ 2,000,000	$ —
Reclassification of deferred clinical supply costs to inventories	$ 2,801,518	$ —
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ 904,437
Vendor deposits applied to purchases of property and equipment	$ —	$ 468,376
Original issue discount on notes payable	$ —	$ 212,500
Cashless exercise of stock options	$ —	$ 2
Common stock issued in consideration for licensing agreement	$ 436,809	$ —
Common stock issued in consideration for reacquisition of licensing agreement	$ 2,322,391	$ —
Issuance of common stock related to vested restricted stock units	$ —	$ 4

The accompanying notes are an integral part of these condensed financial statements.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

Note 1 – Business Organization, Nature of Operations and Basis of Presentation

Eyenovia, Inc. ("Eyenovia" or the "Company") is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics based on its Optejet platform. MicroPine, its leading late-stage candidate for the multi-billion dollar pediatric progressive myopia market has been licensed to Arctic Vision (Hong Kong) Limited ("Arctic Vision") in China and South Korea. In the United States, Eyenovia is also focused on the commercialization of its two Food and Drug Administration ("FDA")-approved products: Mydcombi (tropicamide and phenylephrine ophthalmic HCI spray) 1%/2.5% for mydriasis, as well as clobetasol propionate ophthalmic suspension 0.05% to reduce pain and inflammation following ocular surgery.

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, such statements include all adjustments (consisting only of normal recurring items) which are considered necessary for a fair presentation of the condensed financial statements of the Company as of June 30, 2024 and for the three and six months ended June 30, 2024 and 2023. The results of operations for the three and six months ended June 30, 2024 are not necessarily indicative of the operating results for the full year ending December 31, 2024 or any other period. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and related disclosures of the Company as of December 31, 2023 and for the year then ended, which were included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission ("SEC") on March 18, 2024 (the "2023 Form 10-K"), as amended by Amendment No. 1, filed with the SEC on April 26, 2024 (the "2023 Form 10-K Amendment").

Note 2 – Summary of Significant Accounting Policies

The Company disclosed its significant accounting policies in Note 2 – Summary of Significant Accounting Policies included in the 2023 Form 10-K. There have been no material changes to the Company's significant accounting policies during the six months ended June 30, 2024, except as disclosed below.

Liquidity and Going Concern

As of June 30, 2024, the Company had unrestricted cash and cash equivalents of approximately $ 2.3 million and an accumulated deficit of approximately $167.5 million. For the six months ended June 30, 2024 and 2023, the Company incurred net losses of approximately $22.0 million and $12.0 million, respectively, and used cash in operations of approximately $ 18.1 million and $11.7 million, respectively. The Company does not have recurring revenue and has not yet achieved profitability. The Company expects to continue to incur cash outflows from operations for the near future. The Company expects that its research and development and general and administrative expenses will continue to increase and, as a result, it will eventually need to generate significant product revenues to achieve profitability. These circumstances raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the date that these financial statements are issued. Implementation of the Company's plans and its ability to continue as a going concern will depend on many factors, including the Company's ability to successfully commercialize its products and services, competing technological and market developments, and the need to enter into collaborations with other companies, or acquire other companies or technologies to enhance or complement its product and service offerings. Additionally, the Company will need to raise further capital, through the sale of additional equity or debt securities. On July 1, 2024, the Company raised $5.0 million of gross proceeds from a registered direct offering of equity securities. Also, subsequent to June 30, 2024, the Company raised $0.8 million of gross proceeds from its ongoing "at-the-market" offering. See Note 11 – Subsequent Events for additional details. If the Company is unable to generate sufficient recurring revenues or secure additional capital, it may be required to curtail its research and development initiatives and take additional measures to reduce costs in order to conserve its cash.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents in the financial statements. As of June 30, 2024 and December 31, 2023, the Company had Treasury bills with original maturity dates of three months or less in the amounts of $0 and $5,450,118, respectively.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

The Company has cash deposits in financial institutions that, at times, may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits. The Company has not experienced losses in such accounts and periodically evaluates the creditworthiness of its financial institutions. As of June 30, 2024 and December 31, 2023, the Company had cash and cash equivalent balances in excess of FDIC insurance limits of $1,573,044 and $14,243,870, respectively.

Clinical Supply Arrangements

Bausch + Lomb Ireland Limited ("Bausch + Lomb") and Arctic Vision had contracted with the Company to manufacture and supply them with the appropriate drug-device combination products to conduct their clinical trials on a cost plus 10% mark-up basis. Pursuant to the Letter Agreement (as defined below) with Bausch + Lomb, as referenced in Note 8 – Commitments and Contingencies – Bausch License Agreements, the arrangement with Bausch + Lomb has been terminated, and all rights have been repurchased by Eyenovia. The arrangement with Arctic Vision is still in place. The Company's licensing agreement with Arctic Vision represents a collaborative arrangement and Arctic Vision is not a customer with respect to the clinical supply arrangements. The Company's policy is to (a) defer the materials and manufacturing costs in order to properly match them up against the income from the clinical supply arrangements; and (b) report the net income from the clinical supply arrangements as other income. Deferred clinical supply costs were $0.4 million and $4.3 million at June 30, 2024 and December 31, 2023, respectively. See Note 8 – Commitments and Contingencies –Defective Clinical Supply for additional information.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. The cost of inventory that is sold to third parties is included within cost of sales. The Company will periodically review for slow-moving, excess or obsolete inventories.

Inventory is primarily comprised of drug-device combination products, which are available for commercial sale, as follows:

	June 30, 2024	December 31, 2023
Finished goods	$ 286,236	$ 30,683
Raw materials	2,765,906	79,115
Total inventory	$ 3,052,142	$ 109,798

The Company has evaluated the net realizable value of the commercial inventory. The write-down of commercial inventory to net realizable value for the three months ended June 30, 2024 and 2023 was $0.5 million and $0.0 million, respectively. The write-down of commercial inventory for the six months ended June 30, 2024 and 2023 was $0.7 million and $0.0 million, respectively, which consisted of $0.2 million of inventory write down of adjustments to list price for the first quarter of 2024 and $ 0.5 million for the write-down of short dated inventory to net realizable value for the second quarter of 2024. The Company recorded the write-downs to cost of revenue as it relates to goods that were part of commercial inventory during 2024.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period, plus fully vested shares that are subject to issuance for little or no monetary consideration. Diluted loss per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock. The following table presents the computation of basic and diluted net loss per common share:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net loss attributable to common stockholders	$ (11,053,699)	$ (6,215,860)	$ (21,975,800)	$ (11,955,226)
Denominator (weighted average quantities):				
Common shares issued	52,965,044	38,064,215	49,718,045	37,724,083
Add: Undelivered vested restricted shares	156,716	29,611	146,230	29,611
Denominator for basic and diluted net loss per share	53,121,760	38,093,826	49,864,275	37,753,694
Basic and diluted net loss per common share	$ (0.21)	$ (0.16)	$ (0.44)	$ (0.32)

The following securities are excluded from the calculation of weighted average diluted shares of common stock because their inclusion would have been anti-dilutive:

	June 30,	
	2024	2023
Warrants	10,926,554	5,185,078
Options	6,599,389	6,087,845
Convertible notes	2,327,747	2,327,747
Restricted stock units	368,886	86,205
Total potentially dilutive shares	20,222,576	13,686,875

Subsequent Events

The Company has evaluated subsequent events through the date which the financial statements were issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the financial statements, except as disclosed.

Recently Issued Accounting Standards

In November 2023, the FASB issued ASU 2023-07, Improvements to Reportable Segments Disclosures (Topic 280), which updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses on both an annual and interim basis. The guidance becomes effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Since this new ASU addresses only disclosures, the Company does not expect the adoption of this ASU to have any material effects on its financial condition, results of operations or cash flows. The Company is currently evaluating any new disclosures that may be required upon adoption of ASU 2023-07.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The amendments in this update address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This update also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this standard, but does not expect it to have a material impact on its financial statements.

Note 3 – Prepaid Expenses and Other Current Assets

As of June 30, 2024 and December 31, 2023, prepaid expenses and other current assets consisted of the following:

	June 30, 2024	December 31, 2023
Prepaid insurance expenses	$ 568,997	$ 167,338
Payroll tax receivable	305,981	500,684
Prepaid research and development expenses	65,769	421,056
Prepaid conference expenses	36,765	123,556
Prepaid general and administrative expenses	270,401	85,938
Prepaid patent expenses	88,483	48,409
Prepaid rent and security deposit	18,750	18,750
Prepaid professional fees	6,667	—
Prepaid board of directors fees	32,500	—
Total prepaid expenses and other current assets	$ 1,394,313	$ 1,365,731

Note 4 - Intangible Assets

On August 15, 2023 (the “Effective Date”), the Company entered into a license agreement (the “License”) with Formosa Pharmaceuticals Inc. (“Formosa”), whereby the Company acquired the exclusive U.S. rights to commercialize any product related to a novel formulation of clobetasol propionate ophthalmic suspension, 0.05% (the “Licensed Product”), which was approved by the FDA for ophthalmic use for inflammation and pain after ocular surgery and supplemental disease indications, if any, associated with the New Drug Application for the Licensed Product. The License will remain in effect for ten years from the date of the first commercial sale of a Licensed Product, unless earlier terminated. The Company paid Formosa the aggregate amount of $2.0 million (the “Upfront Payment”), consisting of (a) cash in the amount of $1.0 million and (b) 487,805 shares of common stock, which is included in Intangible Assets on the accompanying balance sheet. The Company also capitalized $122,945 of transaction costs, which were primarily legal expenses. In addition to the Upfront Payment, the Company must pay Formosa up to $4.0 million upon the achievement of certain development milestones and up to $80.0 million upon the achievement of certain sales milestones. The trigger for the initial $ 2.0 million development milestone payments was FDA approval of the Licensed Product and the effective date of the acceptance by the Company of the transfer and assignment of the FDA approval. This occurred on March 14, 2024. Under the provisions of the License, the Company had 45 days from the effective date of acceptance of the transfer and assignment of FDA approval to make the payment half in cash and half in common stock, otherwise the payment due would revert to be fully in cash. The Company paid Formosa the aggregate amount of $2.0 million, consisting of (a) cash in the amount of $ 1.0 million on April 26, 2024 and (b) 613,496 shares of common stock on April 29, 2024 (calculated pursuant to the License using a five-day volume-weighted average price on March 14, 2024, but valued at $0.4 million on the April 29, 2024 settlement date, resulting in a $ 0.6 million change in fair value of the equity consideration payable), which is included in Intangible Assets on the accompanying balance sheet as of June 30, 2024. The second $2.0 million development milestone (to be fully paid in cash) was earned upon FDA approval of the Licensed Product and payment was triggered on the earlier of twelve months after FDA approval or six months following the first commercial sale of the Licensed Product. Because the payment became probable and estimable, the Company recorded an additional $2.0 million increase in the intangible asset and the related accrual on March 14, 2024.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

Note 5 – Accrued Compensation

As of June 30, 2024 and December 31, 2023, accrued compensation consisted of the following:

	June 30, 2024	December 31, 2023
Accrued bonus expenses	$ 808,787	$ 1,302,997
Accrued payroll expenses	469,391	355,616
Total accrued compensation	$ 1,278,178	$ 1,658,613

Note 6 – Accrued Expenses and Other Current Liabilities

As of June 30, 2024 and December 31, 2023, accrued expenses and other current liabilities consisted of the following:

	June 30, 2024	December 31, 2023
Accrued intangible asset milestone obligation	$ 2,000,000	$ —
Accrued defective clinical supply settlement, net	250,000	100,000
Accrued research and development expenses	455,520	89,872
Accrued professional services	239,201	63,028
Credit card payable	31,967	27,193
Accrued franchise tax	10,000	—
Other	1,440	7,835
Total accrued expenses and other current liabilities	$ 2,988,128	$ 287,928

Note 7 – Notes Payable and Convertible Notes Payable

As of June 30, 2024 and December 31, 2023, notes payable and convertible notes payable consisted of the following:

	June 30, 2024			December 31, 2023		
	Notes Payable	Debt Discount	Net	Notes Payable	Debt Discount	Net
Current portion:						
D&O insurance policy loan	$ 255,943	$ —	$ 255,943	$ —	$ —	$ —
Avenue - Note payable	9,166,667	(692,567)	8,474,100	5,833,333	(503,914)	5,329,419
Avenue - Convertible note payable	833,333	(18,117)	815,216	—	—	—
Total current portion	$ 10,255,943	$ (710,684)	$ 9,545,259	$ 5,833,333	$ (503,914)	$ 5,329,419
Non-Current portion:						
Avenue - Note payable	$ 637,500	$ —	$ 637,500	$ 4,804,167	$ (448,367)	$ 4,355,800
Avenue - Convertible note payable	4,166,667	(271,752)	3,894,915	5,000,000	(398,569)	4,601,431
Total non-current portion	$ 4,804,167	$ (271,752)	$ 4,532,415	$ 9,804,167	$ (846,936)	$ 8,957,231

On February 24, 2024, the Company issued a note payable in the amount of $ 505,050 for the purchase of a directors and officers' liability insurance policy (the "D&O Loan"). The note accrues interest at a rate of 8.15% per year and matures on October 24, 2024. The D&O Loan is payable in eight monthly payments of $65,076 consisting of principal and interest. During the six months ended June 30, 2024, the Company repaid $249,107 of principal owed on the D&O Loan.

In June 2024, the Company made its initial principal payment related to that certain loan and security agreement (the "Loan and Security Agreement") with Avenue Capital Management II, L.P. and related entities (together, "Avenue") in the amount of $ 833,333 plus interest.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

During the three months ended June 30, 2024, the Company recorded interest expense of $ 674,001, of which $666,235 (including amortization of debt discount of $184,207) was related to the Avenue loan and $ 7,767 was related to the D&O Loan. During the six months ended June 30, 2024, the Company recorded interest expense of $1,352,659, of which $1,341,462 was related to the Loan and Security Agreement (including amortization of debt discount of $368,414) and $11,197 was related to the D&O Loan.

Note 8 – Commitments and Contingencies

Defective Clinical Supply

During the third quarter of 2023, a certain portion of clinical supply product sold to Bausch + Lomb was determined to be defective. On April 23, 2024, the Company and Bausch + Lomb executed a letter agreement (the “Side Letter”) pursuant to which the Company and Bausch + Lomb agreed that the Company would pay approximately $0.5 million to Bausch + Lomb related to the defective clinical supply. Accordingly, the Company recorded an estimated charge equal to $ 0.4 million, which was included within other income (expense) during the year ended December 31, 2023, because the original sales to the licensee were recorded on that line item. During the three and six months ended June 30, 2024, the Company recorded no additional charge and a $ 0.1 million charge, respectively, to other income (expense).

Bausch License Agreements

On October 9, 2020, the Company entered into a license agreement (the Bausch License Agreement”), pursuant to which Bausch + Lomb was permitted to develop and commercialize the Bausch Licensed Product (as defined in the Bausch License Agreement) in the United States and Canada (the “Licensed Territory”). Bausch + Lomb could terminate the Bausch License Agreement, with respect to the Bausch Licensed Product to either country in the Licensed Territory, at any time for convenience upon 90 days’ written notice.

On January 12, 2024, the Company and Bausch + Lomb entered into a mutual termination and reassignment agreement (the “Letter Agreement”), pursuant to which Eyenovia reacquired the rights to the Bausch Licensed Product. The terms of the agreement include the immediate transfer of the rights and the subsequent transfer of certain assets relating to the Bausch Licensed Product from Bausch + Lomb to the Company in exchange for cash and common stock consideration. In addition, under the terms of the Letter Agreement, the Company agreed to pay Bausch + Lomb a low single-digit royalty on its net sales of the Bausch Licensed Product in the United States and Canada for a period of ten years from the date of the first commercial sale by the Company (or its affiliates or licensees) of the Bausch Licensed Product in the United States. Under the Letter Agreement, (i) the Company will re-acquire any and all licenses and other rights granted by the Company to Bausch + Lomb under the original Bausch License Agreement, (ii) any and all licenses and other rights granted by Bausch + Lomb to the Company under the License Agreement are terminated, other than as set forth in the Letter Agreement, and (iii) other than as set forth in the Letter Agreement, Bausch + Lomb is released from all of their ongoing obligations under the License Agreement, including development and commercialization obligations.

Pursuant to the Letter Agreement, the Company paid Bausch + Lomb an upfront payment of $ 2.0 million in cash on January 22, 2024. The Company has recorded this amount as an operating expense. In connection with the entry into the Letter Agreement, the Company also agreed to issue Bausch + Lomb $3.0 million in shares of the Company’s common stock, following the Regulatory Transfer Date (the “Transfer Date”). On April 11, 2024, the Transfer Date, the transfer of the rights and certain assets relating to the CHAPERONE trial from Bausch + Lomb to the Company, was completed. On May 3, 2024, the Company issued Bausch + Lomb 2,299,397 shares of the Company’s common stock (calculated pursuant to the Letter Agreement at $3.0 million using a thirty-day volume-weighted average price on April 11, 2024, but valued at $2.3 million on the May 3, 2024 settlement date, resulting in a $ 0.7 million change in fair value of the equity consideration payable), in satisfaction of its obligations pursuant to the Letter Agreement.

Pursuant to the Side Letter described above (see Defective Clinical Supply), the Company agreed to pay approximately $ 0.5 million to Bausch + Lomb related to the defective clinical supply. It was also agreed that the Company will receive approximately $0.25 million from Bausch + Lomb to fund the vendor hold back liability that will be due upon completion of the CHAPERONE study.The Company has recorded the payable to Bausch + Lomb in the amount of $0.25 million. In addition, the Company purchased $ 0.5 million of clinical supplies from Bausch + Lomb in April 2024.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

Operating Leases

A summary of the Company's right-of-use assets and liabilities is as follows:

	For the Six Months Ended June 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating activities	$ 209,699	$ 284,996
Right-of-use assets obtained in exchange for lease obligations		
Operating leases	$ —	$ 904,437
Weighted Average Remaining Lease Term (Years)		
Operating leases	2.59 years	3.50 years
Weighted Average Discount Rate		
Operating leases	10.0 %	10.0 %

Future minimum payments under the Company's operating lease agreements are as follows:

For the Years Ending December 31,	Minimum Lease Payments
2024	$ 364,928
2025	675,400
2026	560,996
2027	214,618
Total future minimum lease payments	1,815,942
Less: Imputed interest	(231,724)
Present value of lease liabilities	1,584,218
Less: current portion	(600,379)
Lease liabilities, non-current portion	$ 983,839

Litigations, Claims and Assessments

The Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

Note 9 – Stockholders' (Deficiency) Equity

Increase in Authorized Number of Shares of Common Stock

On June 12, 2024, at the Annual Shareholders' Meeting, the Company proposed and the shareholders approved an increase in authorized number of shares of common stock from 90,000,000 to 300,000,000 at the same par value of $ 0.0001 per share.

Common Stock Issuances

Pursuant to the License and certain milestone achievements, the Company issued 613,496 shares of common stock valued at $ 0.4 million on April 29, 2024 to Formosa (see Note 4 – Intangible Assets).

On May 3, 2024, the Company issued Bausch + Lomb 2,299,397 shares of the Company's common stock, valued at $ 2.3 million, in satisfaction of its obligations pursuant to the Letter Agreement (see Note 8 – Commitments and Contingencies).

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

At-The-Market Offering

During the six months ended June 30, 2024, the Company received approximately $ 4.9 million in net proceeds from the sale of 4,128,276 shares of its common stock pursuant to a sales agreement (the "Sales Agreement") with Leerink Partners, LLC, formerly known as SVB Securities LLC ("Leerink Partners") in an "at-the-market" offering.

Registered Direct Offering

On April 8, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") with a single fundamentals-based healthcare investor (the "Purchaser"), pursuant to which the Company agreed to sell, in a registered direct offering by the Company directly to the Purchaser (the "Offering"), 3,223,726 shares of common stock, par value $ 0.0001 per share. The price per share in the Offering was $0.6204. The aggregate gross proceeds to the Company from the Offering were $ 2.0 million, and net proceeds after offering costs were approximately $1.9 million.

Stock-Based Compensation Expense

The Company records stock-based compensation expense related to stock options and restricted stock units ("RSUs"). For the three months ended June 30, 2024 and 2023, the Company recorded stock-based compensation expense of $541,056 ($232,154 of which was included within research and development expenses and $308,902 was included within general and administrative expenses on the statements of operations) and $493,632 ($36,197 of which was included within research and development expenses and $ 457,435 of which was included within general and administrative expenses on the statements of operations), respectively. For the six months ended June 30, 2024 and 2023, the Company recorded stock-based compensation expense of $1,087,288 ($438,740 of which was included within research and development expenses and $648,548 of which was included within general and administrative expenses on the statements of operations) and $1,312,696 ($411,327 of which was included within research and development expenses and $901,369 of which was included within general and administrative expenses on the statements of operations), respectively.

Restricted Stock Units

A summary of the restricted stock units ("RSUs") activity during the six months ended June 30, 2024 is presented below:

	Number of RSUs	Weighted Average Exercise Price
RSUs non-vested January 1, 2024	106,019	$ 2.12
Granted	368,886	0.65
Vested	(106,019)	2.12
Forfeited	—	—
RSUs non-vested June 30, 2024	368,886	$ 0.65
Vested RSUs undelivered June 30, 2024	241,764	$ 2.17

To date, RSUs have only been granted to directors in accordance with the Company's Amended and Restated 2018 Omnibus Stock Incentive Plan. The Company's policy is not to deliver shares underlying the RSUs until the termination of service.

As of June 30, 2024, there was $ 237,405 of unrecognized stock-based compensation expense related to RSUs which will be recognized over a weighted average period of 0.9 years.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

Stock Options

A summary of the option activity during the six months ended June 30, 2024 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2024	5,306,377	$ 3.31		
Granted	1,926,136	1.18		
Exercised	—	—		
Forfeited	(633,124)	3.27		
Outstanding, June 30, 2024	6,599,389	$ 2.91	7.3	$ 26,325
Exercisable, June 30, 2024	4,053,359	$ 3.48	6.0	$ —

The following table presents information related to stock options as of June 30, 2024:

Options Outstanding			Options Exercisable	
Exercise Price	Number of Options	Weighted Average Remaining Life In Years	Number of Options	
$0.01 - $0.99	1,053,136	—	—	
$1.00 - $1.99	2,263,037	5.6	1,145,297	
$2.00 - $2.99	1,279,099	6.8	1,014,401	
$3.00 - $3.99	819,018	6.1	733,022	
$4.00 - $4.99	303,027	7.2	278,567	
$5.00 - $5.99	35,805	2.9	35,805	
$6.00 - $6.99	695,627	5.5	695,627	
$7.00+	150,640	3.8	150,640	
	6,599,389	6.0	4,053,359	

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following approximate assumptions:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Expected term (years)	5.50 - 5.85	5.50 - 10.00	5.50 - 10.00	5.50 - 10.00
Risk free interest rate	4.32% - 4.72%	3.44% - 4.02%	4.04% - 4.72%	3.44% - 4.18%
Expected volatility	83% - 86%	82% - 94%	80% - 86%	82% - 95%
Expected dividends	0.00%	0.00%	0.00%	0.00%

As of June 30, 2024, there was $2,358,546 of unrecognized stock-based compensation expense related to stock options which will be recognized over a weighted average period of 1.8 years.

The weighted average estimated grant date fair value of the stock options granted for the three months ended June 30, 2024 and 2023 was approximately $0.44 and $2.04 per share, respectively. The weighted average estimated grant date fair value of the stock options granted for the six months ended June 30, 2024 and 2023 was approximately $0.84 and $1.78 per share, respectively.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

Note 10 – Employee Benefit Plans

401(k) Plan

In April 2019, the Company adopted the Eyenovia 401(k) Plan (the "Plan"), which went into effect in May 2019. All Company employees are able to participate in the Plan, subject to eligibility requirements as outlined in the Plan documents. Under the terms of the Plan, eligible employees are able to defer a percentage of their pay every pay period up to annual limitations set by Congress and the Internal Revenue Service under Section 401(k) of the Internal Revenue Code. The Company's Board of Directors approved a matching contribution equal to 100% of elective deferrals up to 4% of eligible earnings with the matching contribution subject to certain vesting requirements as outlined in the Plan documents.

During the three months ended June 30, 2024 and 2023, the Company recorded expense of $61,706 ($43,875 which was included within research and development expenses and $17,831 was included within general and administrative expenses on the statements of operations) and $46,196 ($35,178 of which was included within research and development expenses and $11,018 of which was included within general and administrative expenses on the statements of operations), respectively, associated with its matching contributions. During the six months ended June 30, 2024 and 2023, the Company recorded expense of $164,189 ($95,412 of which was included within research and development expenses and $68,777 of which was included within general and administrative expenses on the statements of operations) and $125,164 ($78,176 of which was included within research and development expenses and $46,988 of which was included within general and administrative expenses on the statements of operations) associated with its matching contributions, respectively.

Note 11 - Subsequent Events

Registered Direct Offering

On July 1, 2024, the Company closed on a registered direct offering (the "July Offering") with certain institutional and accredited investors (the "Investors"), pursuant to which the Company sold 7,575,757 shares of common stock and warrants to purchase up to 7,575,757 shares of common stock. The combined offering price for each share of common stock and accompanying warrant was $0.66. The Company also agreed to issue warrants to purchase an additional 1,749,780 shares of common stock to one of the Investors at an exercise price of $0.69 per share. All of the new warrants become exercisable six months following their issuance, and may be exercised until January 2, 2030.

In connection with the July Offering, the Company entered into warrant amendment agreements (the "Amendments") with the holders of previously issued warrants (the "Prior Warrants") to purchase up to an aggregate of 10,386,269 shares of common stock, whereby the Company agreed to amend the Prior Warrants to reduce the exercise price of the Prior Warrants from $2.23 or $2.21 per share of common stock to $0.69 per share of common stock, extend the term of the Prior Warrants until January 2, 2030 and prohibit exercise of the Prior Warrants for the six-month period following the effective date of the Amendments.

The aggregate gross proceeds from the July Offering were approximately $5.0 million. Total estimated issuance costs are approximately $0.7 million.

At-The-Market Offering

Subsequent to June 30, 2024, the Company received approximately $0.8 million in gross proceeds from the sale of 665,762 shares of its common stock pursuant to its Sales Agreement with Leerink Partners in its "at-the-market" offering.

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

The following discussion and analysis of the results of operations and financial condition of Eyenovia, Inc. ("Eyenovia," the "Company," "we," "us" and "our") as of June 30, 2024 and for the three and six months ended June 30, 2024 and 2023 should be read in conjunction with our unaudited condensed financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements and the notes thereto included in the 2023 Form 10-K, as amended by the 2023 Form 10-K Amendment.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such forward-looking statements include our estimates regarding expenses, future revenue, capital requirements and our need for additional financing and other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements about the advantages of our product candidates and platform technology; estimates regarding the potential market opportunity for our product candidates and platform technology; statements regarding our clinical trials; factors that may affect our operating results; statements about our ability to establish and maintain intellectual property rights; statements about our ability to retain key personnel and hire necessary employees and appropriately staff our operations; statements related to future capital expenditures; statements related to future economic conditions or performance; and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "might," "will," "plan," "project," "seek," "should," "target," "would," and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward – looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the sections titled "Summary Risk Factors" and "Risk Factors" included in Item 1A of Part I of our Form 10-K, as filed with the SEC on March 18, 2024, as amended by our 2023 Form 10-K Amendment, and the risks discussed in our other SEC filings. Furthermore, such forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are an ophthalmic technology company focused on the late-stage development of MicroPine in the multi-billion dollar pediatric progressive myopia market while commercializing Mydcombi™ (tropicamide and phenylephrine HCL ophthalmic spray) for inducing mydriasis for routine diagnostic procedures and in conditions where short term pupil dilation is desired, and clobetasol propionate ophthalmic suspension, for the treatment of post-operative pain and inflammation following ocular surgery. We are also developing the Optejet® delivery system both for use in combination with our own drug-device therapeutic programs and for out-licensing for use in combination with therapeutics for additional indications. Our aim is to improve the delivery of topical ophthalmic medication through the ergonomic design of the Optejet which facilitates ease-of-use and delivery of more physiologically appropriate medication volume, with the goal to reduce side effects and improve tolerability, and introduce digital health technology to improve therapy compliance and ultimately medical outcomes.

The ergonomic and functional design of the Optejet allows for horizontal drug delivery and eliminates the need to tilt the head back or the manual dexterity to squeeze a bottle, to administer medications. Drug is delivered in a microscopic array of droplets faster than the blink reflex to help ensure instillation success. The precise delivery of a low-volume columnar spray by the Optejet device minimizes contamination risk with a non-protruding nozzle and self-closing shutter. In clinical trials, the Optejet has demonstrated that its targeted delivery achieves a high rate of successful administration, with 98% of sprays being accurately delivered upon first attempt compared to the established rate reported with traditional eye drops of approximately 50%.

A more physiologically appropriate volume of medication in the range of seven to nine microliters is delivered by the Optejet, which is approximately one-fifth of the 35 to 50 microliter dose typically delivered in a single eye drop. Lower volume of medication exposes the ocular surface to less active ingredient and preservatives, potentially reducing ocular stress and surface damage and improving tolerability. The lower volume also minimizes the potential for drug to enter systemic circulation, with the goal of avoiding some common side effects that are related to overdosing of the eye.

We are developing versions of the Optejet with on-board digital technology that records the date and time of each use. These data may be used to provide reminders via Bluetooth to smart devices and to allow healthcare practitioners to monitor usage. This information can then be used by practitioners and health care systems to measure treatment compliance and improve medical decision making. In this way, the Optejet could serve as an extension of the physician's office by providing information that is not currently possible to collect except through the use of diaries.

Our drug-device product line includes Mydcombi (tropicamide and phenylephrine HCL ophthalmic spray) and therapeutic programs MicroPine (atropine ophthalmic spray) and MicroLine (pilocarpine ophthalmic spray). MicroPine is our first-in-class topical therapy for the treatment of progressive myopia, a disease associated with pathologic axial elongation of the eye and sclero-retinal stretching. In the United States, myopia is estimated to affect approximately 25 million children, with up to five million considered to be at high risk for progressive myopia. In February 2019, the FDA accepted our Investigational New Drug ("IND") to initiate the CHAPERONE study to reduce the progression of myopia in children. The first patient was enrolled in the CHAPERONE study in June 2019.

On October 9, 2020, we entered into a license agreement with Bausch + Lomb, pursuant to which Bausch + Lomb had the rights to develop and commercialize MicroPine in the United States and Canada. Under the terms of the Bausch License Agreement, we received an upfront payment of $10.0 million and were eligible to receive up to a total of $35.0 million in additional payments, based on the achievement of certain regulatory and launch-based milestones. Bausch + Lomb also agreed to pay royalties to Eyenovia on a tiered basis (ranging from mid-single digit to mid-teen percentages) on gross profits from sales of MicroPine in the United States and Canada, subject to certain adjustments. Under the terms of the Bausch License Agreement, Bausch + Lomb assumed sponsorship of the IND as well as ownership and the costs related to the ongoing CHAPERONE study.

On January 12, 2024, we entered into an agreement with Bausch + Lomb to reacquire our rights to MicroPine and take control of the CHAPERONE study. In this agreement, we agreed to pay Bausch + Lomb $2.0 million in cash up front. Upon transfer of the regulatory documents and study elements to us on April 11, 2024, we issued 2,299,397 shares to Bausch + Lomb on May 3, 2024 (calculated pursuant to the Letter Agreement at $3.0 million using a thirty-day volume-weighted average price on April 11, 2024, but valued at $2.3 million on the May 3, 2024 settlement date). We also agreed to pay Bausch + Lomb a low single-digit royalty on net sales once MicroPine is commercialized in the United States, assuming receipt of regulatory approvals. We believe that this new arrangement is in our and our shareholders' best interests, as it may substantially increase the value of the asset through potential improvements in the conduct of the study, including a planned interim analysis of the data in late 2024. On April 23, 2024, the Company and Bausch + Lomb entered into the Side Letter, pursuant to which the Company agreed to pay approximately $0.5 million to Bausch + Lomb related to defective clinical supply. It was also agreed that the Company will receive approximately $0.25 million from Bausch + Lomb related to amounts previously held back from vendors that will be due upon completion of the CHAPERONE study. In addition, the Company purchased $0.5 million of clinical supplies from Bausch + Lomb in April 2024.

We have also successfully expanded our manufacturing capabilities through a partnership with Coastline International, Inc. located in Tijuana, Mexico, as well as the construction of our new manufacturing facility in Reno, Nevada and the construction of our own fill and finish facility in Redwood City, California. The FDA approved the use of both Coastline International and our Redwood City facility for the production of Mydcombi cartridges, and the use of our Reno facility for the production of technical elements such as the base unit for the Optejet device.

MicroLine is our investigational pharmacologic treatment for presbyopia, a non-preventable, age-related hardening of the lens, which causes the gradual loss of the eye's ability to focus on near objects and impairs near visual acuity. There are two FDA-approved treatments for presbyopia which use pilocarpine, the same drug used in our investigational product. We have completed two Phase III studies using our Optejet device. In these studies, patients reported high satisfaction with using the device and a strong preference over using an eye dropper bottle. We released positive top-line results from VISION-2 in the fourth quarter of 2022.

Mydcombi is the only FDA-approved fixed combination of the two leading mydriatic agents, tropicamide and phenylephrine in the United States and our first FDA-approved product. As an ophthalmic spray delivered with Optejet technology, Mydcombi may present a number of benefits for ophthalmic surgical centers, optometric and ophthalmic offices and patients. Those benefits may include improved cost-effectiveness in centers that employ single-use bottles for mydriasis, more efficient use of office time and resources, and an overall improved doctor-patient experience. We have begun the commercialization of Mydcombi, with the first commercial sale of the product occurring on August 3, 2023 as part of a targeted launch, expanded our launch with the hiring and onboarding of nine sales representatives through August 1, 2024. We received FDA approval for our primary Mydcombi manufacturing facility in February 2024, which we believe will allow us to expand and continue to build our manufacturing operations. On July 24, 2024, we received written comments from the FDA outlining the design of a clinical bridging study to transition Mydcombi into our new Gen-2 Optejet device, which has a significantly lower cost to manufacture than the currently approved product.

On August 10, 2020, we entered into a license agreement with Arctic Vision (as amended on September 14, 2021, the "Arctic Vision License Agreement") pursuant to which Arctic Vision may develop and commercialize MicroPine, MicroLine and Mydcombi in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea. Under the terms of the Arctic Vision License Agreement, we received an upfront payment of $4.25 million before any payments to Senju Pharmaceutical Co.,Ltd. ("Senju"). In addition, we may receive up to a total of $37.7 million in additional payments, based on various development and regulatory milestones, including the initiation of clinical research and approvals in Greater China and South Korea, and development costs. Arctic Vision also will purchase its supply of MicroPine, MicroLine and Mydcombi from Eyenovia or, for such products not supplied by Eyenovia, pay a mid-single digit percentage royalty on net sales of such products, subject to certain adjustments. We will pay between 30 and 40 percent of such payments, royalties, or net proceeds of such supply to Senju pursuant to an exclusive license agreement with Senju dated March 8, 2015, as amended.

We are in active discussions with manufacturers of existing and late-stage ophthalmic medications to explore whether development with the Optejet technology can solve unmet medical and business needs. Some of those business needs could include extension of exclusivity under the Optejet patents, improvement in a drug's tolerability profile, or potential improvement in treatment compliance.

On August 15, 2023, we entered into a license agreement with Formosa, whereby we acquired the exclusive U.S. rights to commercialize any product related to a novel formulation of clobetasol propionate ophthalmic suspension 0.05% (the "Licensed Product"), which was approved by the FDA, for post-operative inflammation and pain after ocular surgery, on March 4, 2024. The License will remain in effect for ten years from the date of the first commercial sale of a Licensed Product, unless earlier terminated.

We paid Formosa an upfront payment in an aggregate amount of $2.0 million which consisted of (a) cash in the amount of $1.0 million and (b) 487,805 shares of common stock valued pursuant to the License Agreement at $1.0 million. We also capitalized $122,945 of transaction costs in connection with the License. In addition, we agreed to pay Formosa up to $4.0 million upon the achievement of certain development milestones and up to $80 million upon the achievement of certain sales milestones. The trigger for the initial $2.0 million development milestone payment was FDA approval of the Licensed Product and the effective date of the acceptance by the Company of the transfer and assignment of the FDA approval, which occurred on March 14, 2024. Based on the achievement of this milestone, we paid Formosa (a) cash in the amount of $1.0 million on April 26, 2024 and (b) 613,496 shares of common stock (calculated pursuant to the License Agreement at $1.0 million using a five-day volume-weighted average price on March 14, 2024, but valued at $0.4 million on the April 29, 2024 settlement date). The remaining $2.0 million development milestone (to be fully paid in cash) was earned and accrued upon FDA approval, but payment will be triggered on the earlier of twelve months after FDA approval of the Licensed Product or six months following the first commercial sale of the Licensed Product.

On July 23, 2024, we entered into a collaboration agreement with Senju, under which the companies intend to work to develop EYEN-520, a combination of Senju's corneal epithelial wound healing candidate with our Optejet dispensing technology, as a potential treatment for chronic dry eye disease. The companies anticipate a meeting with the FDA in late 2024, to be followed by execution of a definitive agreement related to the further development of the product and anticipated completion of a Phase 2b study in 2025. If successful, the collaboration agreement could be expanded to bring the product into two Phase 3 studies by 2026.

On July 26, 2024, we received notice from the staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") providing notification that the Company had regained compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Listing Rule 5550(a)(2). Previously, Nasdaq had notified us on July 2, 2024 that, for the preceding 30 consecutive business days, the closing bid price of our common stock had been below the minimum requirement of $1.00 per share. The notification letter stated that we would be provided 180 calendar days to regain compliance. In order to regain compliance, the closing bid price of our common stock had to be at least $1.00 for a minimum of 10 consecutive business days at any time before December 30, 2024. Subsequently, the Staff determined that, from July 12 to July 25, 2024, the closing bid price of our common stock had been at $1.00 per share or greater. Accordingly, the Company had regained compliance with Listing Rule 5550(a)(2).

Historically, we have financed our operations principally through equity offerings. We have also generated cash through licensing arrangements and our credit facilities with Leerink Partners and Avenue. However, based upon our current operating plan, there is substantial doubt about our ability to continue as a going concern for at least one year from the date that our financial statements were issued. Our ability to continue as a going concern depends on our ability to complete additional licensing or business development transactions or raise additional capital through the sale of equity or debt securities to support our future operations. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and/or take additional measures to reduce costs.

Our net losses were $11.1 million and $6.2 million for the three months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had a working capital deficit and an accumulated deficit of approximately $8.6 million and $167.5 million, respectively.

Financial Overview

Revenue and Cost of Revenue

Revenue is earned from the sale of our product, Mydcombi. The first commercial sale of the product occurred on August 3, 2023 as part of a targeted launch and we expanded our launch with the onboarding of nine sales representatives through July 15, 2024.

Cost of sales consisted of the cost of the production of the Mydcombi ophthalmic spray that was sold and the write-down of inventories to net realizable value.

Research and Development Expenses

Research and development expenses are incurred in connection with the research and development of our microdose therapeutics and consist primarily of contract service expenses. Given where we are in our life cycle, we do not separately track research and development expenses by project. Our research and development expenses consist of:

- direct clinical and non-clinical expenses, which include expenses incurred under agreements with contract research organizations, contract manufacturing organizations, and costs associated with preclinical activities, development activities and regulatory activities;

- personnel-related expenses, which include expenses related to consulting agreements with individuals that have since entered into employment agreements with us as well as salaries and other compensation of employees that is attributable to research and development activities; and

- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, marketing, insurance and other supplies used in research and development activities.

We expense research and development costs as incurred. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or other information our vendors provide to us.

We expect that our research and development expenses will increase with the continuation of these initiatives.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll and related expenses, legal and other professional services, insurance expense, and non-cash stock-based compensation expense. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and the potential commercialization of our product candidates.

Reacquisition of License Rights

Reacquisition of license rights consists of the expense related to the payments that we are required to pay Bausch + Lomb in connection to the reacquisition of the license.

Other Income (Expense), Net

Other income (expense), net consists of (a) other income (expense) related to our sales of clinical supply to our licensees; (b) changes in fair value of equity consideration (the equity payable for the Baush + Lomb and Formosa transactions); (c) interest income earned on Treasury bills; and (d) interest expense incurred on our indebtedness.

Results of Operations

Three Months Ended June 30, 2024 Compared with Three Months Ended June 30, 2023

Revenue and Cost of Revenue

Revenue for the three months ended June 30, 2024 totaled $22,625, which was offset by cost of revenues of ($490,361). Write-down of inventories to net realizable value for the three months ended June 30, 2024 totaled approximately $0.5 million, compared to no expense for the three months ended June 30, 2023. The $0.5 million represented the write-down of short-dated inventory to net realizable value. The negative gross loss was primarily due to write-downs of commercial inventory that were still on the balance sheet at June 30, 2024.

No revenue was earned or recognized during the three months ended June 30, 2023.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2024 totaled $4.6 million, an increase of $1.8 million, or 64%, compared to $2.8 million recorded for the three months ended June 30, 2023. Research and development expenses consisted of the following:

	For the Three Months Ended June 30,	
	2024	2023
Personnel-related expenses	$ 1,752,197	$ 1,747,020
Supplies and materials	1,249,597	153,063
Non-cash stock-based compensation expenses	232,154	36,197
Direct clinical and non-clinical expenses	722,126	452,026
Facilities expenses	278,134	267,952
Depreciation expense	293,710	121,967
Other expenses	69,255	32,836
Total research and development expenses	$ 4,597,173	$ 2,811,061

The increase in supplies and materials expense was primarily due to (a) the expensing of Gen-1 MicroPine vials and cartridges that will now be used in Eyenovia-led clinical trials rather than being sold to Bausch as a result of the reacquisition of the Bausch license rights; (b) drug formulation engineering batches; and (c) the purchase of parts for the Gen-2 device that are intended to be used for Eyenovia-led clinical trials. The increase in non-cash stock-based compensation expenses was primarily due to new grants in the second quarter of 2024. The increase in direct clinical and non-clinical expenses was primarily due to increased costs related to Gen-2 R&D, Mydcombi stability testing and clinical regulatory expenses. The decrease in facilities expenses was due to costs incurred in 2023 related to getting the new Reno facility online that were not incurred in 2024. The increase in depreciation expense was primarily due to increased equipment purchases and equipment placed in service during the last two quarters of 2023 and the first and second quarters of 2024. The increase in other expenses was primarily due to increased IT expenses related to data tracking and cybersecurity.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2024 totaled $3.8 million, an increase of $0.7 million, or 19%, compared to $3.1 million recorded for the three months ended June 30, 2023. General and administrative expenses consisted of the following:

	For the Three Months Ended June 30,	
	2024	2023
Salaries and benefits	$ 1,497,747	$ 975,393
Professional fees	637,619	779,788
Stock-based compensation	308,902	457,435
Insurance expense	210,582	227,257
Sales and marketing	263,340	201,516
Travel, lodging and meals	150,476	78,110
Investor relations	115,983	125,640
Facilities expense	122,307	126,251
Director fees and expense	101,875	106,250
Other	350,004	72,169
Total general and administrative expenses	$ 3,758,835	$ 3,149,809

The increase in personnel-related expenses was mainly due to new staff additions made to support commercialization during the last two quarters of 2023 and the first quarter of 2024. The decrease in stock-based compensation expenses was primarily due to the ending of the amortization period for older equity grants. The increase in travel, lodging and meals was primarily due to increased travel between our New York, Nevada and California locations, an increase in the number of investor conferences attended and increased travel by the sales team to promote Mycombi. The increase in other expenses is primarily due to commercial regulatory costs for Mydcombi.

Reacquisition of License Rights

Reacquisition of license rights for the three months ended June 30, 2024 totaled approximately $2.9 million, compared to no expense for the three months ended June 30, 2023. The $2.9 million amount is comprised of the $3.0 million settled in common stock to Bausch + Lomb in the second quarter 2024 in connection with the reacquisition of the license (which we are recording as an operating expense), offset by $0.1 million of the purchase price allocated to the repurchase of equipment.

Other Income (Expense)

Other income (expense) for the three months ended June 30, 2024 totaled approximately $0.6 million of net other income, a decrease of $0.9 million, compared to ($0.3 million) of net other expense for the three months ended June 30, 2023. Net other expense for the three months ended June 30, 2024 primarily consisted of approximately $0.7 million of interest expense related to the Avenue loan, partially offset by $1.2 million of changes in fair value of equity consideration (the equity payable for the Baush + Lomb and Formosa transactions) and $0.1 million of interest income primarily from Treasury bills.

Results of Operations

Six Months Ended June 30, 2024 Compared with Six Months Ended June 30, 2023

Revenue and Cost of Revenue

Revenue for the six months ended June 30, 2024 totaled $27,618, which was offset by cost of revenues of ($693,388). Write-down of inventories to net realizable value for the six months ended June 30, 2024 totaled approximately $0.7 million, compared to no expense for the six months ended June 30, 2023. The $0.7 million was comprised of the adjustment to bring the inventory to list price for the first quarter of 2024 and the write-down of short-dated inventory to net realizable value for the second quarter of 2024. The negative gross loss was primarily due to write-downs of commercial inventory that were still on the balance sheet at June 30, 2024.

No revenue was earned or recognized during the six months ended June 30, 2023.

Research and Development Expenses

Research and development expenses for the six months ended June 30, 2024 totaled $9.0 million, an increase of $3.7 million, or 69%, compared to $5.3 million recorded for the six months ended June 30, 2023. Research and development expenses consisted of the following:

	For the Six Months Ended June 30,	
	2024	2023
Personnel-related expenses	$ 3,757,798	$ 3,361,872
Supplies and materials	2,309,784	511,994
Non-cash stock-based compensation expenses	438,740	411,327
Direct clinical and non-clinical expenses	1,336,305	278,225
Facilities expenses	446,573	494,999
Depreciation expense	625,169	220,854
Other expenses	114,405	53,740
Total research and development expenses	$ 9,028,774	$ 5,333,011

The increase in personnel-related expenses was primarily due to new staff additions made to support commercialization during the last two quarters of 2023 and the first quarter of 2024. The increase in supplies and materials expense was primarily due to (a) the expensing of Gen-1 MicroPine vials and cartridges that will now be used in Eyenovia-led clinical trials rather than being sold to Bausch + Lomb as a result of the reacquisition of the Bausch license rights; (b) drug formulation engineering batches; and (c) the purchase of parts for the Gen-2 device that are intended to be used in Eyenovia-led clinical trials. The increase in direct clinical and non-clinical expenses was primarily due to increased costs related to Gen-2 R&D, Mydcombi stability testing and clinical regulatory expenses. The increase in depreciation expense was primarily due to increased equipment purchases and equipment placed in service during the last two quarters of 2023 and the first and second quarters of 2024. The increase in other expenses was primarily due to increased IT expenses related to data tracking and cybersecurity.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2024 totaled $7.4 million, an increase of $1.3 million, or 22%, compared to $6.1 million recorded for the six months ended June 30, 2023. General and administrative expenses consisted of the following:

	For the Six Months Ended June 30,	
	2024	2023
Salaries and benefits	$ 2,983,915	$ 1,997,344
Professional fees	1,529,661	1,392,823
Stock-based compensation	648,548	901,369
Insurance expense	429,716	483,993
Sales and marketing	449,568	397,136
Travel, lodging and meals	237,483	121,908
Investor relations	228,624	206,675
Facilities expense	248,954	247,669
Director fees and expense	213,750	203,750
Other	425,805	134,028
Total general and administrative expenses	$ 7,396,024	$ 6,086,695

The increase in personnel-related expenses was mainly due to new staff additions related to commercialization efforts made during the last two quarters of 2023 and the first quarter of 2024. The increase in professional fees was primarily due to the short-term need for temporary staff while in the process of hiring permanent employees. The decrease in stock-based compensation expenses was primarily due to the ending of the amortization period for older equity grants. The increase in travel, lodging and meals was primarily due to increased travel between our New York, Nevada and California locations, an increase in the number of investor conferences attended and increased travel by the sales team to promote Mycombi. The increase in other expenses was primarily due to commercial regulatory costs for Mydcombi.

Reacquisition of License Rights

Reacquisition of license rights for the six months ended June 30, 2024 totaled $4.9 million, compared to no expense for the six months ended June 30, 2023. The $4.9 million in the account is comprised of the aggregate $5.0 million of payments ($2.0 million of cash and $3.0 million settled in common stock) to Bausch + Lomb in connection with the reacquisition of the license (which we are recording as an operating expense), offset by $0.1 million related to the repurchase of equipment.

Other Income (Expense)

Other income (expense) for the six months ended June 30, 2024 totaled approximately ($20,632) of net other expense, a decrease of $0.5 million, compared to $0.5 million of net other expense for the six months ended June 30, 2023. Net other expense for the six months ended June 30, 2024 primarily consisted of approximately $1.4 million of interest expense related to the Avenue loan and $0.1 million related to the charge for the defective clinical supply settlement (see Note 8 – Commitments and Contingencies – Defective Clinical Supply), partially offset by $1.2 million of changes in fair value of equity consideration (the equity payable for the Baush + Lomb and Formosa transactions) and $0.2 million of interest income primarily from Treasury bills.

Liquidity and Going Concern

We measure our liquidity in a number of ways, including the following:

	June 30, 2024	December 31, 2023
Cash and Cash Equivalents	$ 2,300,852	$ 14,849,057
Working Capital (Deficit)	$ (8,564,989)	$ 11,176,336
Notes Payable (Gross)	$ 15,060,110	$ 15,637,500

Cash Flow

Since inception, we have experienced negative cash flows from operations and our operations have primarily been funded by proceeds from equity and debt financings.

Our net losses were $22.0 million and $12.0 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of approximately $167.5 million. As of June 30, 2024, we had a cash and cash equivalents balance of $2.3 million, a working capital deficit of $8.6 million and stockholders' deficiency of $2.4 million. As of June 30, 2024 and December 31, 2023, we had $15.1 million and $15.6 million, respectively, of gross debt outstanding.

These conditions raise substantial doubt about our ability to continue as a going concern for at least one year from the date that the financial statements included elsewhere in this Quarterly Report on Form 10-Q were issued. Our financial statements do not include adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise additional capital through the sale of equity or debt securities to support our future operations and the potential for entering into collaborations with other companies to enhance or complement our product and service offerings. Our operating needs include the planned costs to operate our business, including amounts required to fund research and development activities including clinical studies, working capital and capital expenditures. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products and services, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to further improve the marketability of our product and service offerings. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce general and administrative and sales and marketing costs in order to conserve our cash.

On July 1, 2024, the Company raised $5.0 million of gross proceeds from a registered direct offering of equity securities. Also, subsequent to June 30, 2024, the Company raised $0.8 million of gross proceeds from its ongoing "at-the-market" offering.

During the six months ended June 30, 2024 and 2023, our sources and uses of cash were as follows:

Net cash used in operating activities for the six months ended June 30, 2024 was approximately $18.1 million, which includes cash used to fund a net loss of $22.0 million, reduced by $4.6 million of net non-cash expenses, plus $0.7 million of net cash used by changes in the levels of operating assets and liabilities. Net cash used in operating activities for the six months ended June 30, 2023 was $11.7 million, which includes cash used to fund a net loss of $12.0 million, reduced by $2.1 million of non-cash expenses, plus $1.8 million of cash used to fund changes in operating assets and liabilities.

Net cash used in investing activities for the six months ended June 30, 2024 was approximately $0.2 million, which was primarily related to the purchase of property and equipment. Cash used in investing activities for the six months ended June 30, 2023 was $2.1 million, which was related to purchases of property and equipment.

Net cash provided by financing activities for the six months ended June 30, 2024 totaled approximately $5.7 million, which was primarily attributable to $1.9 million of net proceeds from the sale of common stock and warrants in a registered direct offering, $4.9 million of net proceeds from the sale of common stock in our "at-the-market" offering pursuant to the Sales Agreement with Leerink Partners, partially offset by $1.1 million from the repayment of notes payable. Net cash provided by financing activities for the six months ended June 30, 2023 totaled $8.4 million, which was attributable to $3.9 million of net proceeds received from sales under our "at-the-market" offering and $4.9 million of net proceeds from the additional tranche under the Loan and Security Agreement with Avenue. This was partially offset by the repayment of $0.4 million of notes payable in connection with the D&O Loan.

Contractual Obligations and Commitments

During the next twelve months we have commitments to pay (a) $5.7 million to settle our June 30, 2024 accounts payable, accrued expenses and other current liabilities, (b) $0.6 million relating to our non-cancelable operating lease commitments, and (c) $10.3 million of gross payments due under our notes payable, convertible notes payable (if not previously converted) and D&O Loan.

After the next twelve months we have commitments to pay (a) an additional $1.0 million relating to our non-cancelable operating lease commitments, and (b) $4.8 million of gross payments due in connection with notes payable and convertible notes payable (if not previously converted).

Risks and Uncertainties

The continuing worldwide implications of the war between Russia and Ukraine and the conflict in the Middle East remain difficult to predict at this time. The imposition of sanctions on Russia by the United States and other countries and counter sanctions by Russia, and the resulting economic impacts on oil prices and other materials and goods, could affect the price of materials used in the manufacture of our product candidates. If the price of materials used in the manufacturing of our product candidates increase, that would adversely affect our business and the results of our operations.

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements between us and any other entity that have, or are reasonably likely to have, a current or future effect on financial conditions, changes in financial conditions, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Critical Accounting Estimates

As described in Item 7 – Critical Accounting Estimates in our 2023 Form 10-K, as amended by our 2023 Form 10-K Amendment, we prepare our financial statements in accordance with U.S. GAAP, which require our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. There are items within our financial statements that require estimation but are not deemed critical, as defined above.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Smaller reporting companies such as Eyenovia are not required to provide the information required by this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act.

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on their evaluation, our principal executive officer and principal financial and accounting officer concluded that, as of June 30, 2024, our disclosure controls and procedures were designed to, and were effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosures as of June 30, 2024.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the quarter ended June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors.

There have been no material changes to the risk factors set forth in Part I, Item 1A of our 2023 Form 10-K, as amended by our 2023 Form 10-K Amendment.

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

Recent Sales of Unregistered Securities

The following issuances of common stock occurred in the second quarter:

Pursuant to the License with Formosa, we issued 613,496 shares of the Company's common stock on April 29, 2024.

Pursuant to the agreement for the reacquisition of the Bausch + Lomb license, we issued 2,299,397 shares of the Company's common stock on May 3, 2024.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Securities Trading Plans of Directors and Executive Officers

During the six months ended June 30, 2024, none of our directors or officers, or the Company, adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) promulgated under the Exchange Act or any "non-Rule 10b5-1 trading arrangement."

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference from Filings as Noted Below (Unless Otherwise Indicated)			
		Form	File No.	Exhibit	Filing Date
3.1	Third Amended and Restated Certificate of Incorporation	8-K	001-38365	3.1	January 29, 2018
3.1.1	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation	8-K	001-38365	3.1.1	June 14, 2018
3.2	Second Amended and Restated Bylaws	8-K	001-38365	3.1	February 7, 2022
3.3	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation	8-K	001-38365	3.1	June 14, 2024
4.1	Form of Warrant	8-K	001-38365	4.1	July 1, 2024
10.1	Form of Securities Purchase Agreement, dated June 27, 2024	8-K	001-38365	10.1	July 1, 2024
10.2	Warrant Amendment Agreement, dated June 27, 2024	8-K	001-38365	10.2	July 1, 2024
10.3	Warrant Amendment Agreement, dated June 28, 2024	8-K	001-38365	10.3	July 1, 2024
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.1*	Certification of the Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.2*	Certification of the Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document contained in Exhibit 101	—	—	—	Filed herewith

* This certification is deemed not filed for purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933.

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.

EYENOVIA, INC.

Date: August 14, 2024

By: /s/ John Gandolfo
John Gandolfo
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Rowe, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Eyenovia, Inc. for the quarterly period ended June 30, 2024;

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: August 14, 2024

/s/ Michael Rowe
Name: Michael Rowe
Title Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Gandolfo, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Eyenovia, Inc. for the quarterly period ended June 30, 2024;

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: August 14, 2024

/s/ John Gandolfo
Name: John Gandolfo
Title Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the quarterly report of Eyenovia, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Rowe, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2024

/s/ Michael Rowe
Name: Michael Rowe
Title Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Eyenovia, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Gandolfo, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2024

/s/ John Gandolfo
Name: John Gandolfo
Title Chief Financial Officer
(Principal Financial and Accounting Officer)