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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: **September 30, 2023**

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

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

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

The number of outstanding shares of the registrant's common stock was 44,122,225 as of November 9, 2023.

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**EYENOVIA, INC.**  
**FORM 10-Q**  
**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023**  
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**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**EYENOVIA, INC.**  
**Condensed Balance Sheets**

	<b>September 30, 2023</b>	<b>December 31, 2022</b>
	<b>(unaudited)</b>	
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 20,702,212	\$ 22,863,520
Inventories	50,296	—
Deferred clinical supply costs	3,622,687	2,284,931
License fee and expense reimbursements receivable	397,014	1,183,786
Security deposits, current	—	119,550
Prepaid expenses and other current assets	1,760,824	1,190,719
Total Current Assets	<u>26,533,033</u>	<u>27,642,506</u>
Property and equipment, net	3,531,365	1,295,115
Security deposits, non-current	198,674	80,874
Intangible assets	2,122,945	—
Operating lease right-of-use asset	1,792,667	1,291,592
Equipment deposits	686,753	726,326
Total Assets	<u>\$ 34,865,437</u>	<u>\$ 31,036,413</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 1,426,028	\$ 1,428,283
Accrued compensation	1,375,832	1,747,191
Accrued expenses and other current liabilities	295,703	503,076
Operating lease liabilities - current portion	444,616	484,882
Notes payable - current portion, net of debt discount of \$327,217 and \$33,885 as of September 30, 2023 and December 31, 2022, respectively	3,006,116	174,448
Convertible notes payable - current portion, net of debt discount of \$0 and \$33,885 as of September 30, 2023 and December 31, 2022, respectively	—	174,448
Total Current Liabilities	<u>6,548,295</u>	<u>4,512,328</u>
Operating lease liabilities - non-current portion	1,441,081	907,644
Notes payable - non-current portion, net of debt discount of \$754,919 and \$813,229 as of September 30, 2023 and December 31, 2022, respectively	6,549,248	4,190,938
Convertible notes payable - non-current portion, net of debt discount of \$452,920 and \$813,229 as of September 30, 2023 and December 31, 2022, respectively	4,547,080	4,190,938
Total Liabilities	<u>19,085,704</u>	<u>13,801,848</u>
<b>Commitments and contingencies (Note 8)</b>		
<b>Stockholders' Equity:</b>		
Preferred stock, \$0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value, 90,000,000 shares authorized; 42,898,246 and 36,668,980 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	4,290	3,667
Additional paid-in capital	153,299,865	135,461,361
Accumulated deficit	(137,524,422)	(118,230,463)
Total Stockholders' Equity	<u>15,779,733</u>	<u>17,234,565</u>
Total Liabilities and Stockholders' Equity	<u>\$ 34,865,437</u>	<u>\$ 31,036,413</u>

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

EYENOVIA, INC.

Condensed Statements of Operations  
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
<b>Operating Income</b>				
Revenue	\$ 1,198	\$ —	\$ 1,198	\$ —
Cost of revenue	(1,198)	—	(1,198)	—
Gross Profit	—	—	—	—
<b>Operating Expenses:</b>				
Research and development	3,578,113	3,876,876	8,911,124	11,176,326
General and administrative	2,942,073	3,353,352	9,028,768	10,362,907
Total Operating Expenses	6,520,186	7,230,228	17,939,892	21,539,233
Loss From Operations	(6,520,186)	(7,230,228)	(17,939,892)	(21,539,233)
<b>Other Income (Expense):</b>				
Other (expense) income, net	(348,226)	70,277	(157,783)	96,580
Interest expense	(679,222)	(177,138)	(1,691,228)	(475,811)
Interest income	208,901	28,093	494,944	30,703
Total Other Expense	(818,547)	(78,768)	(1,354,067)	(348,528)
<b>Net Loss</b>	<u>\$ (7,338,733)</u>	<u>\$ (7,308,996)</u>	<u>\$ (19,293,959)</u>	<u>\$ (21,887,761)</u>
Net Loss Per Share - Basic and Diluted	<u>\$ (0.18)</u>	<u>\$ (0.21)</u>	<u>\$ (0.50)</u>	<u>\$ (0.67)</u>
Shares Outstanding - Basic and Diluted	<u>40,139,697</u>	<u>34,631,774</u>	<u>38,563,074</u>	<u>32,778,551</u>

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

EYENOVIA, INC.

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

	For the Three and Nine Months Ended September 30, 2023				Total Stockholders' Equity
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	
	Shares	Amount			
<b>Balance - January 1, 2023</b>	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)
<b>Balance - March 31, 2023</b>	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)
<b>Balance - June 30, 2023</b>	38,169,398	3,817	140,703,819	(130,185,689)	10,521,947
Issuance of common stock and warrants in registered direct offering [3][7]	4,198,633	420	10,885,694	—	10,886,114
Issuance of common stock as consideration for licensing agreement [4]	487,805	49	999,951	—	1,000,000
Issuance of common stock in At the Market offering [5]	42,410	4	97,432	—	97,436
Warrant modification - incremental value (6)	—	—	1,738,700	—	1,738,700
Warrant modification - in issuance costs for registered direct offering (7)	—	—	(1,738,700)	—	(1,738,700)
Stock-based compensation	—	—	612,969	—	612,969
Net loss	—	—	—	(7,338,733)	(7,338,733)
<b>Balance - September 30, 2023</b>	<u>42,898,246</u>	<u>\$ 4,290</u>	<u>\$ 153,299,865</u>	<u>\$ (137,524,422)</u>	<u>\$ 15,779,733</u>

[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.

[3] Includes gross proceeds of \$11,977,468 less total cash issuance costs of \$1,091,354.

[4] Shares issued as partial consideration for License Agreement with Formosa Pharmaceuticals Inc.

[5] Includes gross proceeds of \$100,449 less total issuance costs of \$3,013.

[6] Registered direct offering included modification of warrant originally granted in the March 2022 offering.

[7] Non-cash warrant modification issuance costs related to the registered direct offering of \$1,738,700 are shown on a separate line item.

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

EYENOVIA, INC.

Condensed Statements of Changes in Stockholders' Equity  
(unaudited)

	For the Three and Nine Months Ended September 30, 2022				
	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Stockholders' Equity
<b>Balance - January 1, 2022</b>	28,426,616	\$ 2,844	\$ 110,683,077	\$ (90,219,306)	\$ 20,466,615
Issuance of common stock and warrants in registered direct offering [1]	3,000,000	300	14,897,608	—	14,897,908
Issuance of common stock in At the Market offering [2]	252,449	25	860,340	—	860,365
Stock-based compensation	—	—	908,987	—	908,987
Issuance of common stock related to vested restricted stock units	19,359	2	(2)	—	—
Net loss	—	—	—	(7,339,665)	(7,339,665)
<b>Balance -March 31, 2022</b>	31,698,424	3,171	127,350,010	(97,558,971)	29,794,210
Exercise of stock warrants	1,870,130	187	18,514	—	18,701
Stock-based compensation	—	—	1,036,926	—	1,036,926
Issuance of common stock related to vested restricted stock units	54,499	5	(5)	—	—
Net loss	—	—	—	(7,239,100)	(7,239,100)
<b>Balance - June 30, 2022</b>	33,623,053	3,363	128,405,445	(104,798,071)	23,610,737
Issuance of common stock in At the Market offering [3]	1,876,314	188	3,098,506	—	3,098,694
Stock-based compensation	—	—	928,733	—	928,733
Issuance of common stock related to vested restricted stock units	26,322	2	(2)	—	—
Net loss	—	—	—	(7,308,996)	(7,308,996)
<b>Balance - September 30, 2022</b>	<u>35,525,689</u>	<u>\$ 3,553</u>	<u>\$ 132,432,682</u>	<u>\$ (112,107,067)</u>	<u>\$ 20,329,168</u>

[1] Includes gross proceeds of \$14,981,299 less total issuance costs of \$83,391.

[2] Includes gross proceeds of \$886,974, less total issuance costs of \$26,609.

[3] Includes gross proceeds of \$3,194,530, less total issuance costs of \$95,836.

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

**EYENOVIA, INC.**  
**Condensed Statements of Cash Flows**  
**(unaudited)**

	For the Nine Months Ended	
	September 30,	
	2023	2022
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (19,293,959)	\$ (21,887,761)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,925,665	2,874,646
Depreciation of property and equipment	505,684	228,898
Amortization of debt discount	497,654	78,645
Write-off of property and equipment	—	209,040
Write-down of inventories to net realizable value	12,218	—
Provision for returned deferred clinical supplies	400,000	—
Non-cash rent expense	403,362	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	39,035	(66,250)
License fee and expense reimbursements receivables	786,772	995,635
Deferred clinical supply costs	(1,637,756)	(1,871,096)
Inventories	(62,514)	—
Security and equipment deposits	1,750	(67,614)
Accounts payable	(2,255)	(509,145)
Accrued compensation	(371,359)	(275,609)
Accrued expenses and other current liabilities	(307,373)	539,084
Lease liabilities	(411,266)	50,905
<b>Net Cash Used In Operating Activities</b>	<u>(17,514,342)</u>	<u>(19,700,622)</u>
<b>Cash Flows From Investing Activities</b>		
Purchases of property and equipment	(2,702,361)	(509,370)
Vendor deposits for property and equipment	—	(53,589)
Investment in intangible asset	(1,122,945)	—
<b>Net Cash Used In Investing Activities</b>	<u>(3,825,306)</u>	<u>(562,959)</u>
<b>Cash Flows From Financing Activities</b>		
Proceeds from sale of common stock and warrants in direct offering [1][2]	11,977,468	14,981,299
Payment of offering issuance costs	(1,091,354)	(83,391)
Proceeds from sale of common stock in At the Market offering	4,123,864	4,081,504
Payment of issuance costs for At the Market offering	(123,716)	(122,445)
Proceeds from exercise of stock options	27,200	18,701
Proceeds from note payable to Avenue	5,000,000	—
Payment of issuance costs for notes issued to Avenue	(125,982)	—
Repayments of notes payable	(609,140)	(675,332)
<b>Net Cash Provided By Financing Activities</b>	<u>19,178,340</u>	<u>18,200,336</u>
<b>Net Decrease in Cash and Cash Equivalents</b>	<u>(2,161,308)</u>	<u>(2,063,245)</u>
<b>Cash, cash equivalents and restricted cash - Beginning of Period</b>	22,863,520	27,336,850
<b>Cash, cash equivalents and restricted cash - End of Period</b>	<u>\$ 20,702,212</u>	<u>\$ 25,273,605</u>

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

**EYENOVIA, INC.**  
**Condensed Statements of Cash Flows, continued**  
**(unaudited)**

	For the Nine Months Ended	
	September 30,	
	2023	2022
<b>Cash, cash equivalents and restricted cash consisted of the following:</b>		
Cash and cash equivalents	\$ 20,702,212	\$ 17,398,605
Restricted cash	—	7,875,000
	<u>\$ 20,702,212</u>	<u>\$ 25,273,605</u>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Cash paid during the year for:		
Interest	\$ 1,194,132	\$ 315,550
<b>Supplemental Disclosure of Non-Cash Investing and Financing Activities</b>		
Purchase of insurance policy financed by note payable	\$ 609,140	\$ 675,332
Right-of-use assets and lease liabilities recognized upon lease renewal	\$ 904,437	\$ —
Vendor deposits applied to purchases of property and equipment	\$ 39,573	\$ —
Original issue discount on notes payable	\$ 212,500	\$ —
Warrant modification - incremental value	\$ 1,738,700	\$ —
Issuance of common stock in consideration of licensing agreement	\$ 1,000,000	\$ —
Cashless exercise of stock options	\$ 2	\$ —
Issuance of common stock related to vested restricted stock units	\$ 4	\$ 9

[1] For 2022, includes gross proceeds of \$14,981,299, of which \$5,741,299 is pre-funded warrants.

[2] For 2023, includes gross proceeds of \$11,977,468, of which \$4,168,011 is pre-funded warrants.

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 an ophthalmic technology company developing the Optejet® delivery system for use both in combination with its own drug-device therapeutic programs in mydriasis (pupil dilation), presbyopia and pediatric progressive myopia as well as out-licensing for additional indications. The Company’s investigational products are classified by the Food and Drug Administration (“FDA”) as drug-device combination products with drug primary mode of action, meaning that the Center for Drug Evaluation and Research (“CDER”), is designated as the lead center with primary jurisdictional oversight. Accordingly, the product candidates are submitted to the FDA and CDER for premarket review and approval under new drug applications (“NDAs”).

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 September 30, 2023 and for the three and nine months ended September 30, 2023 and 2022. The results of operations for the nine months ended September 30, 2023 are not necessarily indicative of the operating results for the full year ending December 31, 2023 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, 2022 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, 2022, filed with the Securities and Exchange Commission (“SEC”) on March 31, 2023 (the “2022 Form 10-K”), as amended by Amendment No. 1, filed with the SEC on May 1, 2023 (the “2022 Form 10-K Amendment”).

**Note 2 – Going Concern and Summary of Significant Accounting Policies**

Since the date of the 2022 Form 10-K, there have been no material changes to the Company’s significant accounting policies, except as disclosed below.

Going Concern

As of September 30, 2023, the Company had cash and cash equivalents in the aggregate amount of approximately \$20.7 million. For the nine months ended September 30, 2023 and 2022, the Company incurred net losses of approximately \$19.3 million and \$21.9 million, respectively, and used cash in operations of approximately \$17.5 million and \$19.7 million, respectively. The Company does not have material recurring revenue, has not yet achieved profitability and may never become profitable. The Company expects to continue to incur cash outflows from operations. Research and development and general and administrative expenses will continue to be incurred by the Company and, as a result, the Company 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 were issued. Implementation of the Company’s plans and its ability to continue as a going concern will depend upon the Company’s ability to raise further capital through licensing transactions, the sale of additional equity or debt securities, or otherwise, to support its future operations.

The Company’s operating needs include the planned costs to operate its business, including amounts required to fund working capital and capital expenditures. The Company’s future capital requirements and the adequacy of its available funds 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. If the Company is unable to secure additional capital, it may be required to curtail its research and development initiatives and/or take additional measures to reduce general and administrative and sales and marketing 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 September 30, 2023, the Company had Treasury bills with original maturity dates of three months or less in the amount of \$5,221,319.

## 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 September 30, 2023 and December 31, 2022, the Company had cash balances in excess of FDIC insurance limits of \$15,056,184 and \$22,613,520, respectively.

Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period plus fully vested shares that are subject to issuance for little or no monetary consideration. Diluted earnings 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 September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
<b>Numerator:</b>				
Net loss attributable to common stockholders	\$ (7,338,733)	\$ (7,308,996)	\$ (19,293,959)	\$ (21,887,761)
<b>Denominator (weighted average quantities):</b>				
Common shares issued	39,107,338	34,564,366	38,192,414	32,260,723
Add: Prefunded warrants	926,225	—	305,349	445,269
Add: Undelivered vested restricted shares	106,134	67,408	65,311	72,559
Denominator for basic and diluted net loss per share	40,139,697	34,631,774	38,563,074	32,778,551
Basic and diluted net loss per common share	\$ (0.18)	\$ (0.21)	\$ (0.50)	\$ (0.67)

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

	September 30,	
	2023	2022
Options	5,218,686	5,484,687
Warrants	10,926,554	6,087,845
Convertible notes	2,327,747	—
Restricted stock units	86,205	172,800
Total potentially dilutive shares	18,559,192	11,745,332

Clinical Supply Arrangements

Bausch + Lomb, Inc. (“B+L”) and Arctic Vision (Hong Kong) Limited (“Arctic Vision”) have 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. The Company’s licensing agreements with Bausch + Lomb and Arctic Vision represent collaborative arrangements and they are not customers 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) to report the net income from the clinical supply arrangements as other income.

**EYENOVIA, INC.****NOTES TO CONDENSED FINANCIAL STATEMENTS****(UNAUDITED)**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:

	September 30, 2023
Finished goods	\$ 24,506
Work-in-process	—
Raw materials	25,790
Total inventory	<u>\$ 50,296</u>

Intangible Assets

The application of the guidance in ASC 805 (“Business Combinations”) on accounting for business combinations can differ significantly depending on whether the acquired entity is considered a “business” or an “asset.” A determination of whether the transaction represented an asset acquisition or a business combination must be made. Pursuant to ASC 350 (“Intangibles - Goodwill and Other”), the payment made for the intangible asset will be capitalized and amortized over the useful life of the intangible asset.

On August 15, 2023 (the “Effective Date”), the Company entered into a license agreement (the “License”) with Formosa Pharmaceuticals Inc. (the “Licensor”), whereby the Company acquired the exclusive U.S. rights to commercialize any product related to a novel formulation of clobetasol propionate ophthalmic nanosuspension, 0.05% (the “Licensed Product”), which is currently under review 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 the Licensor the aggregate amount of \$2,000,000 (the “Upfront Payment”), consisting of (a) cash in the amount of \$1,000,000 and (b) 487,805 shares of common stock valued at \$1,000,000, which is included in Intangible Assets on the accompanying condensed balance sheet. In addition to the Upfront Payment, the Company also capitalized \$122,945 of transaction costs, which were primarily legal expenses. In addition, the Company must pay the Licensor up to \$4 million upon the achievement of certain development milestones and up to \$80 million upon the achievement of certain sales milestones. The initial trigger for development milestone payments is FDA approval of the Licensed Product. These contingent payments will be recorded when payment becomes probable and estimable.

It was determined that the transaction represented an asset acquisition, rather than a business combination, because substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset. Consequently, the accounting is pursuant to the cost accumulation model. The Upfront Payment has been capitalized as an intangible asset by the Company, and will be amortized over the useful life of 10 years beginning on the date of the first commercial sale of the Licensed Product.

Recently Adopted Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments - Credit Losses (Topic 326)” and also issued subsequent amendments to the initial guidance under ASU 2018-19, ASU 2019-04 and ASU 2019-05 (collectively, “Topic 326”). Topic 326 requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This replaces the existing incurred loss model with an expected loss model and requires the use of forward-looking information to calculate credit loss estimates. The Company adopted ASU 2016-13 on January 1, 2023. The adoption of ASU 2016-13 did not have a material impact on the Company’s financial position, results of operations or cash flows.

In August 2020, the FASB issued ASU 2020-06, “Debt—Debt with Conversion and Other Options (Subtopic 470-20)” and “Derivatives and Hedging— Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity”, to clarify the accounting for certain financial instruments with characteristics of liabilities and equity. The

**EYENOVIA, INC.****NOTES TO CONDENSED FINANCIAL STATEMENTS****(UNAUDITED)**

amendments in this update reduce the number of accounting models for convertible debt instruments and convertible preferred stock by removing the cash conversion model and the beneficial conversion feature model. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in-capital. In addition, ASU 2020-06 improves disclosure requirements for convertible instruments and earnings-per-share guidance. ASU 2020-06 also revises the derivative scope exception guidance to reduce form-over-substance-based accounting conclusions driven by remote contingent events. The amendments in this update are effective for the Company in fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted. The Company early adopted ASU 2020-06 effective January 1, 2023 which eliminates the need to assess whether a beneficial conversion feature needs to be recognized upon the issuance of new convertible instruments. The adoption of ASU 2020-06 did not have a material impact on the Company's financial position, results of operations or cash flows.

**Note 3 – Prepaid Expenses and Other Current Assets**

As of September 30, 2023 and December 31, 2022, prepaid expenses and other current assets consisted of the following:

	<b>September 30, 2023</b>	<b>December 31, 2022</b>
Payroll tax receivable	\$ 500,684	\$ 660,891
Prepaid insurance expenses	375,961	201,082
Prepaid conference expenses	345,334	97,743
Prepaid professional fees	193,750	—
Prepaid research and development expenses	155,767	2,521
Prepaid general and administrative expenses	110,659	87,982
Prepaid patent expenses	59,919	38,796
Prepaid security deposit	18,750	74,959
Other	—	26,745
Total prepaid expenses and other current assets	<u>\$ 1,760,824</u>	<u>\$ 1,190,719</u>

## EYENOVIA, INC.

## NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

**Note 4 - Property and Equipment, Net**

As of September 30, 2023 and December 31, 2022, property and equipment consisted of the following:

	September 30, 2023	December 31, 2022
Equipment	\$ 3,621,033	\$ 1,271,372
Equipment not yet placed in service	4,430	90,411
Leasehold improvements	1,047,424	569,170
	4,672,887	1,930,953
Less: accumulated depreciation and amortization	(1,141,522)	(635,838)
Property and equipment, net	<u>\$ 3,531,365</u>	<u>\$ 1,295,115</u>

Depreciation expense was \$318,417 and \$82,997 for the three months ended September 30, 2023 and 2022, respectively, of which \$316,673 and \$80,212, respectively, was included within research and development expenses and \$1,744 and \$2,785, respectively, was included in general and administrative expenses in the accompanying statements of operations. Depreciation expense was \$505,684 and \$228,898 for the nine months ended September 30, 2023 and 2022, respectively, of which \$499,535 and \$221,031, respectively, was included within research and development expenses and \$6,149 and \$7,867, respectively, was included in general and administrative expenses in the accompanying statements of operations.

As of September 30, 2023 and December 31, 2022, the Company had \$686,753 and \$726,326, respectively, of outstanding deposits for equipment purchases.

**Note 5 – Accrued Compensation**

As of September 30, 2023 and December 31, 2022, accrued compensation consisted of the following:

	September 30, 2023	December 31, 2022
Accrued bonus expenses	\$ 1,048,249	\$ 1,447,643
Accrued payroll expenses	327,583	299,548
Total accrued compensation	<u>\$ 1,375,832</u>	<u>\$ 1,747,191</u>

**Note 6 – Accrued Expenses and Other Current Liabilities**

As of September 30, 2023 and December 31, 2022, accrued expenses and other current liabilities consisted of the following:

	September 30, 2023	December 31, 2022
Accrued rework of clinical supply returns	\$ 100,000	\$ —
Accrued research and development expenses	45,000	35,524
Credit card payable	53,751	50,639
Accrued consulting and professional services	46,750	320,000
Accrued franchise tax	39,300	—
Accrued leasehold improvements	—	92,528
Accrued travel and entertainment expenses	10,033	—
Other	869	4,385
Total accrued expenses and other current liabilities	<u>\$ 295,703</u>	<u>\$ 503,076</u>

## EYENOVIA, INC.

## NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

**Note 7 – Notes Payable**

As of September 30, 2023 and December 31, 2022, notes payable consisted of the following:

	September 30, 2023			December 31, 2022		
	Notes Payable	Debt Discount	Net	Notes Payable	Debt Discount	Net
<b>Current portion:</b>						
Avenue - Note payable	\$ 3,333,333	\$ (327,217)	\$ 3,006,116	\$ 208,333	\$ (33,885)	\$ 174,448
Avenue - Convertible note payable	—	—	—	208,333	(33,885)	174,448
Total current portion	<u>\$ 3,333,333</u>	<u>\$ (327,217)</u>	<u>\$ 3,006,116</u>	<u>\$ 416,666</u>	<u>\$ (67,770)</u>	<u>\$ 348,896</u>
<b>Non-Current portion:</b>						
Avenue - Note payable	\$ 7,304,167	\$ (754,919)	\$ 6,549,248	\$ 5,004,167	\$ (813,229)	\$ 4,190,938
Avenue - Convertible note payable	5,000,000	(452,920)	4,547,080	5,004,167	(813,229)	4,190,938
Total non-current portion	<u>\$ 12,304,167</u>	<u>\$ (1,207,839)</u>	<u>\$ 11,096,328</u>	<u>\$ 10,008,334</u>	<u>\$ (1,626,458)</u>	<u>\$ 8,381,876</u>

On February 24, 2023, the Company issued a note payable in the amount of \$609,140 for the purchase of a directors and officers' liability insurance policy (the "D&O Loan"). The note accrued interest at a rate of 7.11% per year and matured on August 24, 2023. The D&O Loan was payable in six monthly payments of \$103,639 consisting of principal and interest. During the nine months ended September 30, 2023, the Company fully repaid the \$609,140 of principal owed on the D&O Loan.

On May 22, 2023, pursuant to the Company's Loan and Security Agreement (the "Loan and Security Agreement") with Avenue Capital Management II, L.P., and related entities ("Avenue"), the Company received an additional tranche of non-convertible debt funding in the gross amount of \$5,250,000 (which includes a \$250,000 final payment, or 5% of the debt funding). The Company paid approximately \$126,000 of origination and legal fees connected to this debt funding. The additional funding was made under the provisions of the Loan and Security Agreement, bearing interest at an annual rate equal to the greater of (A) 7.0% and (B) the prime rate as reported in The Wall Street Journal plus 4.45%. The entire outstanding balance due under the Loan and Security Agreement has a maturity date of November 1, 2025. The additional funding triggered the extension of the interest-only period from the original 12 months to 18 months (through May 2024) for the entire outstanding balance due under the Loan and Security Agreement (initial and additional tranches). Following the interest-only period, the Company will make equal monthly payments of principal until the maturity date, plus interest.

During the three months ended September 30, 2023, the Company recorded interest expense of \$679,222, of which \$677,394 (which includes amortization of debt discount of \$184,208) was related to the Loan and Security Agreement with Avenue and \$1,828 was related to the D&O Loan. During the nine months ended September 30, 2023, the Company recorded interest expense of \$1,691,228, of which \$1,678,534 was related to the Loan and Security Agreement (including amortization of debt discount of \$497,654) and \$12,694 was related to the D&O Loan.

**Note 8 – Commitments and Contingencies**Clinical Supply Returns

A certain portion of clinical supply product sold to a licensee has been determined to be defective and will be returned to the Company to be replaced or reworked. The defect occurred with the clinical trial Gen 1.0 device. The Company is still working to determine the exact quantity of the defective clinical supply and the cost to replace or rework the product. The current estimate of the range of the loss is between \$400,000 and \$600,000, with no amount within that range being a more accurate estimate than the others at this time. Accordingly, the Company has recorded a charge equal to the low end of the range or \$400,000, which is included within other income (expense), because the original sales to the licensee were recorded on that line item.

## EYENOVIA, INC.

## NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

Operating Leases

In June 2023, the Company entered into an extension agreement to renew its lease for approximately 3,800 square feet of office space in New York, NY. The lease was due to expire on October 31, 2023. The lease was extended from November 1, 2023 to December 31, 2026.

In February 2023, the Company exercised its options to renew its three leases in Redwood City, California, for a total of approximately 6,700 square feet. The leases were due to expire on August 31, 2023. The leases were extended from September 1, 2023 to August 31, 2025.

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

	<u>For the Nine Months Ended September 30, 2023</u>
<b>Cash paid for amounts included in the measurement of lease liabilities:</b>	
Operating cash flows used in operating activities	\$ 411,266
<b>Right-of-use assets and lease liabilities recognized upon lease renewal</b>	
Operating leases	\$ 904,437
<b>Weighted Average Remaining Lease Term (Years)</b>	
Operating leases	3.28 years
<b>Weighted Average Discount Rate</b>	
Operating leases	10.0 %

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

<u>For the Year Ending December 31,</u>	<u>Minimum Lease Payments</u>
2023	\$ 137,838
2024	660,923
2025	675,400
2026	560,996
2027	214,619
Total future minimum lease payments	2,249,776
Less: amount representing imputed interest	(364,079)
Present value of lease liabilities	1,885,697
Less: current portion	(444,616)
Lease liabilities, non current portion	<u>\$ 1,441,081</u>

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' Equity**Equity Incentive Plan

On June 27, 2023, the Company's stockholders approved an amendment to the Company's Amended and Restated 2018 Omnibus Stock Incentive Plan, as amended, reserving an additional 1,000,000 shares of common stock for further issuance under such plan.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

At-The-Market Offering

During the nine months ended September 30, 2023, the Company received approximately \$4.0 million in net proceeds from the sale of 1,464,346 shares of its common stock pursuant to its Sales Agreement with Leerink Partners, formerly known as SVB Securities LLC (“Leerink Partners”) in an “at-the-market” offering (the “At-the-Market Offering Program”).

Registered Direct Offering

On August 24, 2023, the Company entered into a securities purchase agreement with a certain institutional and accredited investor (the “Purchaser”), pursuant to which the Company agreed to sell, in a registered direct offering by the Company directly to the Purchaser (the “August 2023 Offering”), 4,198,633 shares of common stock, pre-funded warrants to purchase up to 2,252,979 shares of common stock (the “Pre-Funded Warrants”) and warrants to purchase up to 4,838,709 shares of common stock (the “Common Warrants”) and, together with the Pre-Funded Warrants, the “Warrants”). The combined offering price for each share of common stock and accompanying Common Warrant was \$1.86, and the combined offering price for each Pre-Funded Warrant and accompanying Common Warrant was \$1.85.

The Common Warrants will be exercisable beginning six months following the date of issuance and may be exercised for a period of five years from the initial exercisability date at an exercise price of \$2.23 per share. The Pre-Funded Warrants were immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full at an exercise price of \$0.01 per share. The exercise prices and numbers of shares of common stock issuable upon exercise of the Common Warrants and the Pre-Funded Warrants are subject to typical anti-dilution provisions. A holder may not exercise any portion of such holder’s Common Warrants or Pre-Funded Warrants to the extent that the holder would own more than 4.99% of the Company’s outstanding common stock immediately after exercise (unless the holder otherwise elects a limitation of 9.99%). The Company determined that the Warrants met the criteria to be classified as equity.

The net cash proceeds of the August 2023 Offering were approximately \$10.9 million after deducting cash issuance costs in the aggregate amount of approximately \$1.1 million. See Warrant Modification below for details about an additional \$1.7 million of non-cash issuance costs. The August 2023 Offering closed on August 29, 2023.

Warrant Modification

*Original Warrant Issuance - March 2022*

On March 3, 2022, the Company entered into a securities purchase agreement (the “March 2022 Purchase Agreement”) with a holder (the “Holder”) relating to the issuance and sale of 3,000,000 shares of common stock, pre-funded warrants to purchase an aggregate of 1,870,130 shares of common stock and warrants to purchase an aggregate of 4,870,130 shares of common stock (the “March 2022 Investor Warrants”). The March 2022 Investor Warrants became exercisable beginning six months from the date of issuance and initially were exercisable for a period of five years at an exercise price of \$3.54 per share.

*Warrant Amendment*

In connection with the August 2023 Offering (see “Registered Direct Offering” above), the Company entered into a warrant amendment agreement (the “Amendment”) with the Holder, whereby the Company agreed to amend the March 2022 Investor Warrants to (i) reduce the exercise price from \$3.54 per share of common stock to \$2.23 per share of common stock, (ii) extend the term of the March 2022 Investor Warrants until March 1, 2029, (iii) include a stockholder approval requirement in connection with a modification of the beneficial ownership limitation and (iv) prohibit exercise of the March 2022 Investor Warrants for the six-month period following the effective date of the Amendment.

The Company accounted for the modification of the March 2022 Investor Warrants as an exchange of the old warrants for new warrants. The incremental value of the new warrant (resulting from the decrease in exercise price from \$3.54 to \$2.23 per share and the extension of the warrant expiration date to March 1, 2029) was measured as the excess of the fair value of the modified warrants over the fair



EYENOVIA, INC.

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value of the original warrants immediately before modification. The increase in the incremental value of \$1,738,700 was credited to additional paid-in-capital (“APIC”) and debited to APIC as an issuance cost of the August 2023 Offering.

Warrants

A summary of the warrant activity for the nine months ended September 30, 2023 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years
Outstanding January 1, 2023	6,087,845	\$ 3.37	
Granted	7,091,688	1.52	
Repriced - Old (1)	(4,870,130)	3.54	
Repriced - New (1)	4,870,130	2.23	
Outstanding September 30, 2023	<u>13,179,533</u>	<u>\$ 1.89</u>	<u>4.2</u>
Exercisable September 30, 2023	<u>3,470,694</u>	<u>\$ 0.95</u>	<u>0.7</u>

(1) Warrants represent the reset of the exercise price of the March 2022 Investor Warrants to purchase 4,870,130 shares of common stock to a price of \$2.23 per share.

The following table presents information related to warrants as of September 30, 2023:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
\$0.0100 (1)	2,252,979	N/A	2,252,979
\$2.2300 (2)	9,708,839	—	—
\$2.4696	909,451	1.5	909,451
\$2.7240	216,380	1.5	216,380
\$4.7600	91,884	7.6	91,884
	<u>13,179,533</u>	0.7	<u>3,470,694</u>

(1) These are Pre-Funded Warrants that do not expire.

(2) These warrants are not yet exercisable.

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 September 30, 2023 and 2022, the Company recorded expense of \$612,969 (\$235,731 of which was included within research and development expenses and \$377,238 was included within general and administrative expenses on the statements of operations) and \$928,733 (\$420,619 of which was included within research and development expenses and \$508,114 was included within general and administrative expenses on the statements of operations), respectively. For the nine months ended September 30, 2023 and 2022, the Company recorded expense of \$1,925,665 (\$647,058 of which was included within research and development expenses and \$1,278,607 was included within general and administrative expenses on the statements of operations) and \$2,874,646 (\$1,438,469 of which was included within research and development expenses and \$1,436,177 was included within general and administrative expenses on the statements of operations), respectively.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

Restricted Stock Units

A summary of RSU activity during the nine months ended September 30, 2023 is presented below:

	Number of RSUs	Weighted Average Grant Date Value Per Share
RSUs non-vested January 1, 2023	172,800	\$ 1.80
Granted	86,205	2.32
Vested	(150,578)	1.80
Forfeited	(22,222)	1.80
RSUs non-vested September 30, 2023	<u>86,205</u>	<u>\$ 2.32</u>
Vested RSUs undelivered September 30, 2023	<u>135,745</u>	<u>\$ 2.22</u>

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 to defer settlement of such RSUs until the termination of such director's service on the Company's board of directors. On February 28, 2023, the Company delivered 3,289 shares of common stock in respect of RSUs upon the resignation of a director. On June 16, 2023, the Company delivered 44,444 shares of common stock in respect of RSUs based on the prior resignation of two directors.

As of September 30, 2023, there was \$203,055 of unrecognized stock-based compensation expense related to RSUs which will be recognized over a weighted average period of 1.0 years.

Stock Options

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Expected term (years)	N/A	5.41 - 5.85	5.50 - 10.00	0.58 - 10.00
Risk free interest rate	N/A	2.66% - 3.02%	3.44% - 4.18%	0.76% - 3.35%
Expected volatility	N/A	85% - 87%	82% - 95%	82% - 90%
Expected dividends	N/A	0.00%	0.00%	0.00%

The Company has computed the fair value of stock options granted using the Black-Scholes option pricing model. Option forfeitures are accounted for at the time of occurrence. The expected term is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the "simplified" method to develop an estimate of the expected term of "plain vanilla" employee option grants. The Company uses a blended volatility calculation, the components of which are the Company's historical volatility for the period from its initial public offering through the valuation date and the average peer-group data of six comparable entities to supplement the Company's own historical data for the preceding years in computing the expected volatility. Accordingly, the Company is utilizing an expected volatility figure based on a review of the historical volatility of comparable entities over a period of time equivalent to the expected life of the instrument being valued. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued. The Company has not declared dividends, is currently in the development stage and has no plan to declare future dividends at this time.

There were no options granted in the three months ended September 30, 2023. The weighted average estimated grant date fair value of the stock options granted for the three months ended September 30, 2022 was approximately \$1.22 per share. The weighted average estimated grant date fair value of the stock options granted for the nine months ended September 30, 2023 and 2022 was approximately \$1.70 and \$1.61 per share respectively.

EYENOVIA, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

A summary of the option activity during the nine months ended September 30, 2023 is presented below:

	Number of Options	Average Exercise Price	Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2023	5,380,553	\$ 3.55		
Granted	797,190	2.29		
Exercised	(88,999)	1.83		
Forfeited/ Expired	(870,058)	3.86		
Outstanding September 30, 2023	5,218,686	\$ 3.33	7.0	\$ 59,408
Exercisable September 30, 2023	3,835,305	\$ 3.62	6.2	\$ 59,408

The following table presents information related to stock options as of September 30, 2023:

Options Outstanding		Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
\$1.00 - \$1.99	1,493,849	5.3	1,067,990
\$2.00 - \$2.99	1,450,105	6.7	841,000
\$3.00 - \$3.99	898,528	6.7	717,140
\$4.00 - \$4.99	333,000	7.9	224,429
\$5.00 - \$5.99	50,805	4.0	50,638
\$6.00 - \$6.99	843,759	6.3	785,468
\$7.00+	148,640	4.5	148,640
	5,218,686	6.2	3,835,305

As of September 30, 2023, there was \$2,841,102 of unrecognized stock-based compensation expense related to stock options, which will be recognized over a weighted average period of 1.8 years.

**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. For 2023 and 2022, 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 September 30, 2023 and 2022, the Company recorded expense of \$46,636 and \$39,914 associated with its matching contributions, respectively. During the nine months ended September 30, 2023 and 2022, the Company recorded expense of \$171,800 and \$173,896 associated with its matching contributions, respectively.

**EYENOVIA, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 11 - Subsequent Events**

Exercise of Pre-Funded Warrants

On November 2, 2023, the Purchaser exercised a portion of its Pre-Funded Warrants in order to purchase 1,223,979 of the Company's common stock at the exercise price of \$0.01 per share. The total proceeds of the transaction were \$12,240 (see "Registered Direct Offering" in Note 9 – Stockholders' Equity).

## **Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

*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 September 30, 2023 and for the three and nine months ended September 30, 2023 and 2022 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 our 2022 Form 10-K, as amended by our 2022 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 2022 Form 10-K, as amended by our 2022 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.

### **License Agreement With Formosa**

On August 15, 2023, we entered into a license agreement (the “License”) with Formosa Pharmaceuticals Inc. (“Formosa”), whereby we acquired the exclusive U.S. rights to commercialize any product related to a novel formulation of clobetasol propionate ophthalmic nanosuspension, 0.05% (the “Licensed Product”), which is currently under review by the U.S. Food and Drug Administration (“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. We paid Formosa an upfront payment in an aggregate amount of \$2,000,000 which consisted of (a) cash in the amount of \$1,000,000 and (b) 487,805 shares of common stock valued at \$1,000,000. We also capitalized \$122,945 of transaction costs in connection with the License. In addition, we must pay Formosa up to \$4 million upon the achievement of certain development milestones and up to \$80 million upon the achievement of certain sales milestones.

### **FDA Approval of Mydcombi™**

We received notification from the FDA on May 5, 2023 that our NDA for the Mydcombi™ product was approved. It is the only FDA-approved fixed combination of the two leading mydriatic agents in the United States. As an ophthalmic spray, Mydcombi may present a number of benefits for the optometric and ophthalmic offices as well as patients. Those benefits may include better tolerability, 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, and are continuing to expand the manufacturing process in preparation for a broader launch in 2024, when internal manufacturing capabilities are expected to come on-line.

## Overview

We are an ophthalmic technology company commercializing Mydcombi™ (tropicamide and phenylephrine HCL ophthalmic spray) for mydriasis and 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 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 ~ 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 to provide reminders via Bluetooth to smart devices and date and time stamp device use. 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 back-of-the-eye ocular disease associated with pathologic axial elongation 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 application ("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 (the "Bausch License Agreement") with B+L, pursuant to which B+L may 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 we may receive up to a total of \$35.0 million in additional payments, based on the achievement of certain regulatory and launch-based milestones. B+L also will pay royalties to Eyenovio 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, B+L assumed sponsorship of the IND as well as ownership and the costs related to the ongoing CHAPERONE study.

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. As of the date of filing, we are up-to-date supplying clinical product for the CHAPERONE study.

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. Allergan recently launched Vuity™, a pilocarpine drug product for the treatment of presbyopia. Our second Phase III study, VISION-2, used the same drug, delivered with the advantages of our Optejet® device. We released positive top-line results from VISION-2 in the fourth quarter of 2022. We are now manufacturing registration batches for stability testing with the goal of filing a new drug application for MicroLine by the end of 2024.

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Mydcombi is our fixed combination formulation of tropicamide-phenylephrine for inducing mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired. Mydcombi is a novel approach for the over 106 million office-based comprehensive and diabetic eye exams performed every year in the United States. As the only FDA-approved fixed combination of the two leading mydriatic agents in the United States and as an ophthalmic spray, Mydcombi may present a number of benefits for the optometric and ophthalmic offices as well as patients. Those benefits may include better tolerability, more efficient use of office time and resources, and an overall improved doctor-patient experience. As noted above in “FDA Approval of Mydcombi”, we received FDA approval on May 5, 2023, and are commercializing the product starting with a targeted launch and expanding in 2024 when we expect our internal manufacturing capabilities to come on-line.

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, as amended, 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 \$39.7 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 (the “Senju License Agreement”).

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.

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 \$7.3 million and \$19.3 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2023, we had working capital and an accumulated deficit of \$20.0 million and \$137.5 million, respectively.

## **Financial Overview**

### Revenue and Cost of Sales

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.

Cost of sales consisted of the cost of the production of the MydCombi ophthalmic spray that was sold.

### 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 personnel-related 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;

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- 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 the aforementioned initiatives.

### General and Administrative Expenses

General and administrative expenses consist primarily of payroll and related expenses, legal and other professional services, as well as 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.

### 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) interest income earned on treasury bills; and (c) interest expense incurred on our indebtedness.

## **Results of Operations**

### ***Three Months Ended September 30, 2023 Compared with Three Months Ended September 30, 2022***

#### Revenue and Cost of Sales

Revenue for the three months ended September 30, 2023 totaled \$1,198, which was offset by cost of revenues of \$1,198. We expect to generate flat gross margins (after writing inventories down to net realizable value) during the early stages of the commercialization process for Mydcombi until we can roll out our second generation Optejet device and scale up production.

#### Research and Development Expenses

	<b>For the Three Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Personnel-related expenses	\$ 1,716,355	\$ 1,187,195
Direct clinical and non-clinical expenses	269,471	1,619,948
Non-cash stock-based compensation expenses	235,731	420,619
Facilities expenses	333,114	212,584
Supplies and materials	685,698	206,781
Other expenses	337,744	229,749
<b>Total research and development expenses</b>	<b>\$ 3,578,113</b>	<b>\$ 3,876,876</b>

Research and development expenses for the three months ended September 30, 2023 totaled \$3.6 million, a decrease of \$0.3 million, or 8%, as compared to \$3.9 million recorded for the three months ended September 30, 2022. The increase in personnel-related expenses was primarily due to salary increases and new staff additions made throughout 2023, primarily related to the anticipated Mydcombi launch. The decrease in direct clinical and non-clinical expenses was primarily due to the VISION-2 study being concluded in 2022 and the decrease in the use of external consultants. The decrease in non-cash stock-based compensation expenses was primarily due to the change in the allocation percentages applied to research and development expenses and general and administrative expenses beginning in late 2022. This resulted primarily from a change in the role of an individual from a senior executive officer role to an advisory role.



General and Administrative Expenses

	<b>For the Three Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Salaries and benefits	\$ 963,634	\$ 900,506
Professional fees	715,832	793,842
Stock-based compensation	377,238	508,114
Insurance expense	224,645	269,840
Sales and marketing	203,733	407,737
Facilities expense	111,388	120,636
Director fees and expense	96,875	113,542
Other	248,728	239,135
	<u>\$ 2,942,073</u>	<u>\$ 3,353,352</u>

General and administrative expenses for the three months ended September 30, 2023 totaled \$2.9 million, a decrease of \$0.4 million, or 12%, as compared to \$3.4 million recorded for the three months ended September 30, 2022. The decrease was primarily attributable to a decrease in professional fees which resulted from legal and recruiting expenses associated with the addition of new directors in 2022 that were not incurred in the first half of 2023. The decrease in non-cash stock-based compensation expenses was primarily due to the ending of the amortization period for older grants. The decrease in sales and marketing expenses primarily resulted from the decrease in promotional expenses.

Other Income (Expense), Net

Net other expense for the three months ended September 30, 2023 totaled \$0.8 million, an increase of \$0.7 million, or 939%, as compared to \$0.1 million for the three months ended September 30, 2022. The increase was primarily due to a \$0.5 million increase in interest expense and a \$0.4 million increase in the provision for clinical supply returns, partially offset by a \$0.2 million increase in interest income.

***Nine Months Ended September 30, 2023 Compared with Nine Months Ended September 30, 2022***Revenue and Cost of Sales

Revenue for the nine months ended September 30, 2023 totaled \$1,198, which was offset by cost of revenues of \$1,198. We expect to generate flat gross margins (after writing inventories down to net realizable value) during the early stages of the commercialization process for Mydcombi until we can roll out our second generation Optejet device and scale up production.

Research and Development Expenses

	<b>For the Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Personnel-related expenses	\$ 5,078,228	\$ 4,159,905
Direct clinical and non-clinical expenses	547,697	3,494,633
Non-cash stock-based compensation expenses	647,058	1,438,469
Facilities expenses	828,111	720,917
Supplies and materials	1,197,692	898,683
Other expenses	612,338	463,719
Total research and development expenses	<u>\$ 8,911,124</u>	<u>\$ 11,176,326</u>

Research and development expenses for the nine months ended September 30, 2023 totaled \$8.9 million, a decrease of \$2.3 million, or 20%, as compared to \$11.2 million recorded for the nine months ended September 30, 2022. The increase in personnel-related expenses was primarily due to salary increases and costs related to staff additions made throughout 2022 mainly related to the ramp up for the Mydcombi launch. The decrease in direct clinical and non-clinical expenses was primarily due to the VISION-2 study being concluded in 2022 and the decrease in the use of external consultants. In addition, the decrease in direct clinical expenses related to an increase in supplies and materials expenses resulting from the prospective change in the nature of the accounting for the Gen 2.0 device from a clinical expense to a supply expense. The decrease in non-cash stock-based compensation expenses was primarily due to the change in the allocation percentages applied to research and development expenses and general and administrative expenses

beginning in January 2023. This resulted primarily from a change in the role of an individual from a senior executive officer role to an advisory role.

#### General and Administrative Expenses

	<u>For the Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>
Salaries and benefits	\$ 2,960,978	\$ 2,834,306
Professional fees	2,108,656	3,061,990
Stock-based compensation	1,278,607	1,436,177
Insurance expense	708,639	789,629
Sales and marketing	600,869	905,243
Facilities expense	359,057	342,590
Director fees and expense	300,625	294,375
Other	711,337	698,597
	<u>\$ 9,028,768</u>	<u>\$ 10,362,907</u>

General and administrative expenses for the nine months ended September 30, 2023 totaled \$9.0 million, a decrease of \$1.3 million, or 13%, as compared to \$10.4 million recorded for the nine months ended September 30, 2022. The decrease was primarily attributable to a decrease in professional fees which resulted from legal and recruiting expenses associated with the addition of new directors in 2022 that were not incurred in the first half of 2023. The decrease in sales and marketing expense primarily resulted from the decrease in promotional expenses.

#### Other Income (Expense), Net

Net other expense for the nine months ended September 30, 2023 totaled \$1.4 million, an increase of \$1.0 million, or 289%, as compared to \$0.3 million for the nine months ended September 30, 2022. The increase was primarily due to a \$1.2 million increase in interest expense and a \$0.4 million increase in the provision for clinical supply returns, partially offset by a \$0.5 million increase in interest income.

#### **Liquidity and Capital Resources and Going Concern**

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

	<u>September 30,</u>	<u>December 31,</u>
	<u>2023</u>	<u>2022</u>
Cash and cash equivalents	\$ 20,702,212	\$ 22,863,520
Working capital	\$ 19,984,738	\$ 23,130,178
Notes payable (gross)	\$ 15,637,500	\$ 10,425,000

Since inception, we have experienced negative cash flows from operations. As of September 30, 2023, our accumulated deficit since inception was \$137.5 million.

As of September 30, 2023, we had a cash and cash equivalents balance of \$20.7 million, working capital of \$20.0 million and stockholders' equity of \$15.8 million. As of September 30, 2023 and December 31, 2022, we had \$15.6 million and \$10.4 million, respectively, of 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. 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 enhance or complement 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.

During the nine months ended September 30, 2023 and 2022, our sources and uses of cash were as follows:

Net cash used in operating activities for the nine months ended September 30, 2023 was \$17.5 million, which includes cash used to fund a net loss of \$19.3 million, reduced by \$3.7 million of non-cash expenses, plus \$2.0 million of cash used to fund changes in operating assets and liabilities. Net cash used in operating activities for the nine months ended September 30, 2022 was \$19.7 million, which includes cash used to fund a net loss of \$21.9 million, reduced by \$3.4 million of non-cash expenses, plus \$1.2 million of cash used to fund changes in operating assets and liabilities.

Cash used in investing activities for the nine months ended September 30, 2023 was \$3.8 million, which was related to \$2.7 million of purchases of property and equipment and a \$1.1 million cash investment in an intangible asset. Cash used in investing activities for the nine months ended September 30, 2022 was \$0.6 million, which was related to purchases of and vendor deposits for property and equipment.

Net cash provided by financing activities for the nine months ended September 30, 2023 totaled \$19.2 million, which was attributable to \$12.0 million of gross proceeds received from the August 2023 Offering, \$4.1 million of gross proceeds from our At-the-Market Offering Program and \$5.0 million of gross proceeds from the additional tranche under the Loan and Security Agreement. This was slightly offset by the repayment of \$0.6 million of notes payable in connection with the D&O Loan, \$1.1 million of August 2023 Offering cash issuance costs, \$0.1 million of the At-the-Market offering issuance costs and \$0.1 million of issuance costs related to the additional tranche under the Loan and Security Agreement. Net cash provided by financing activities for the nine months ended September 30, 2022 totaled \$18.2 million, which was attributable to \$19.1 million of gross proceeds received from the March 2022 Offering (as defined in our 2022 Form 10-K, as amended by our 2022 Form 10-K Amendment) and the At-the-Market Offering Program. This was slightly offset by the repayment of \$0.7 million of notes payable in connection with the D&O Loan and the \$0.2 million payment of issuance costs related to the March 2022 Offering and the At-the-Market Offering Program.

#### Contractual Obligations and Commitments

During the next twelve months we have commitments to pay: (a) \$3.1 million to settle our September 30, 2023 accounts payable, accrued compensation, and accrued expenses and other current liabilities; (b) \$0.4 million relating to our non-cancelable operating lease commitments; and (c) \$3.3 million of potential payments due under our notes payable. In addition, we would be required to pay an aggregate of \$1.5 million of executive severance pay under the provisions of our executive employment agreements with three executive officers, in the event that their respective employment with us were to be terminated without cause or if there is an involuntary termination (as defined in the agreement).

After twelve months we have commitments to pay an additional \$1.4 million relating to our non-cancelable operating lease commitments and notes payable in the amount of \$12.3 million.

#### 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 Policies and Estimates**

For a description of our critical accounting policies, including critical accounting estimates, see Item 7 – Critical Accounting Policies in our 2022 Form 10-K, as amended by our 2022 Form 10-K Amendment.

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires us to make estimates and judgements that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We base our estimates on historical experience and on various

other assumptions that we believe to be reasonable under the circumstances. Changes in estimates are reflected in reported results for the period in which they become known. Actual results could differ significantly from the estimates made by our management.

There have been no material changes to our critical accounting policies and estimates from those disclosed in our financial statements and the related notes and other financial information included in our 2022 Form 10-K, as amended by our 2022 Form 10-K Amendment, except as disclosed below:

- (a) 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.
- (b) Intangible Assets - The application of the guidance in ASC 805 (“Business Combinations”) on accounting for business combinations can differ significantly depending on whether the acquired entity is considered a “business” or an “asset.” A determination of whether the transaction represented an asset acquisition or a business combination must be made. Pursuant to ASC 350 (“Intangibles – Goodwill and Other”), the payment made for the intangible asset will be capitalized as an intangible asset over the useful life of the intangible asset.

### **Recently Adopted Accounting Standards**

For a description of recently adopted accounting standards, including adoption dates and estimated effects, if any, on our condensed financial statements, see Note 2 – Summary of Significant Accounting Policies in Part 1, Item 1 of this Quarterly Report on Form 10-Q.

### **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 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 Securities Exchange Act of 1934, as amended (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 officer concluded that, as of September 30, 2023, 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 officer, as appropriate, to allow timely decisions regarding required disclosures as of September 30, 2023.

#### **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 September 30, 2023, 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 2022 Form 10-K, as amended by our 2022 Form 10-K Amendment.

### Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

#### Recent Sales of Unregistered Securities

On August 15, 2023, we entered into the License with Formosa whereby we acquired the exclusive U.S. rights to commercialize the Licensed Product 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. Among other consideration, in connection with the License, we issued to Formosa 487,805 shares of the Company's common stock valued at \$1,000,000. The shares issued to Formosa were issued pursuant to Section 4(a)(2) of the Securities Act. The Company did not receive any proceeds from the issuance of common stock to Formosa.

#### 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 three months ended September 30, 2023, 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 Securities Exchange Act of 1934 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	<a href="#">Third Amended and Restated Certificate of Incorporation</a>	8-K	001-38365	3.1	January 29, 2018
3.1.1	<a href="#">Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation</a>	8-K	001-38365	3.1.1	June 14, 2018
3.2	<a href="#">Second Amended and Restated Bylaws</a>	8-K	001-38365	3.1	February 7, 2022
4.1	<a href="#">Form of Warrant</a>	8-K	001-38365	4.1	August 29, 2023
4.2	<a href="#">Form of Pre-Funded Warrant</a>	8-K	001-38365	4.2	August 29, 2023
10.1#	<a href="#">License Agreement, dated August 15, 2023, by and between Eyenovia, Inc. and Formosa Pharmaceuticals, Inc.</a>	—	—	—	Filed herewith
10.2	<a href="#">Securities Purchase Agreement, dated August 24, 2023</a>	8-K	001-38365	10.1	August 29, 2023
10.3	<a href="#">Warrant Amendment Agreement, dated August 24, 2023</a>	8-K	001-38365	10.2	August 29, 2023
31.1	<a href="#">Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>	—	—	—	Filed herewith
31.2	<a href="#">Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>	—	—	—	Filed herewith
32.1*	<a href="#">Certification of the Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>	—	—	—	Filed herewith
32.2*	<a href="#">Certification of the Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>	—	—	—	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,

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as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

# Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets (“[\*\*\*]”) because the identified confidential portions (i) are not material and (ii) is the type of information that the Company treats as private or confidential.

**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: November 13, 2023

By: /s/ John Gandolfo

John Gandolfo

Chief Financial Officer

(Principal Financial Officer)



Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets (“\*\*\*”) because the identified confidential portions (i) are not material and (ii) contain the type of information that the registrant treats as private or confidential.

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**LICENSE AGREEMENT**

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dated

August 15, 2023

by and between

**FORMOSA PHARMACEUTICALS, INC.**

and

**EYENOVIA, INC.**

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#### **Schedules and Exhibits**

Schedule 7.1	Supply Agreement Key Terms
Schedule 10.2(a)	Existing Patents
Schedule 10.2(h)	Existing Agreements
Schedule 12.4	Press Releases
Exhibit A	Form of Subscription Agreement

## License Agreement

This License Agreement (“**Agreement**”) is entered into on August 15, 2023 (“**Effective Date**”)

BY AND BETWEEN

**Formosa Pharmaceuticals Inc.**, a Taiwanese corporation with primary business office at 8F-6 Fuxing North Road, Songshan District, Taipei City, Taiwan 105494 (“**Licensor**”);

AND

**Eyenovia, Inc.**, a Delaware corporation with primary business office at 295 Madison Ave., Suite 2400, New York, New York 10017, U.S. (“**Licensee**”);

Licensor and Licensee each is referred to as a “**Party**” and collectively referred to as the “**Parties**”.

### INTRODUCTION

- A. Licensor is a preclinical and clinical stage biopharmaceutical company with a focus in therapeutic areas of ophthalmology, oncology, and is engaged in the business of developing, manufacturing and supplying related products and services.
- B. Licensor is Developing the Licensed Product and owns or controls an evolving intellectual property portfolio related to the Licensed Product and is willing to grant a license to such intellectual property to Licensee.
- C. Licensee is interested in Commercializing the Licensed Product and wishes to receive such a license.
- D. The Parties intend to negotiate and enter into a separate supply agreement as well as quality and pharmacovigilance agreements following signature of this Agreement.

NOW THEREFORE, in consideration of the foregoing premises and the following mutual covenants and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

#### 1. DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the meanings set forth in this Article 1.

1.1 “**AAA Rules**” has the meaning set forth in Section 14.4(b)(i).

1.2 “**Acquiring Affiliate**” means (a) [\*\*\*] and (b) [\*\*\*], in each case ((a) and (b)), other than [\*\*\*].

- 1.3 “**Affiliate**” means any company, partnership, joint venture or other entity, which directly or indirectly controls, is controlled by or is under common control with a respective named Party. Control shall mean the possession of more than fifty percent (50%) of the voting stock or the power to control the management and policies of the controlled entity, whether through the ownership of voting securities, by contract, or otherwise. Licensor’s Affiliate includes [\*\*\*]. For purposes of this Agreement, [\*\*\*].
- 1.4 “**Agreement**” has the meaning set forth in the preamble hereto.
- 1.5 “**Alliance Manager**” has the meaning set forth in Section 6.7.
- 1.6 “**Arbitrators**” has the meaning set forth in Section 14.4(b)(i).
- 1.7 “**Auditor**” has the meaning set forth in Section 3.8.
- 1.8 “**Business Day**” means a day other than a Saturday, Sunday, or other day on which commercial banks, in Taipei, Taiwan, or the United States, are authorized or required to be closed for business.
- 1.9 “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31.
- 1.10 “**Calendar Year**” means the respective periods of twelve (12) consecutive calendar months ending on December 31, except that (a) the first Calendar Year under this Agreement shall commence on the Effective Date and end on the first December 31 to occur after the Effective Date and (b) the last Calendar Year under this Agreement shall commence on the last January 1 to occur prior to the end of the Term and end on the last day of the Term.
- 1.11 “**Change of Control**” means, with respect to a Party, any of the following events: (a) the sale or other disposition of all or substantially all of Licensee’s assets or business to any Third Party, (b) the sale or other disposition of more than fifty percent (50%) of the securities having ordinary voting power for the election of directors or other governing body of Licensee to any Third Party, or (c) the merger or consolidation of Licensee with or into a Third Party with the effect that a Third Party other than the existing shareholders of Licensee prior to such transaction own or control, directly or indirectly, more than fifty percent (50%) of the securities having ordinary voting power for the election of directors or other governing body of Licensee surviving such merger, or the entity surviving or resulting from such consolidation.
- 1.12 “**Commercialization**” or “**Commercialize**” means any and all activities directed to marketing, promoting, distributing, importing, exporting, offering for sale or selling a Licensed Product.
- 1.13 “**Commercially Reasonable Efforts**” means, with respect to a Party’s obligations under this Agreement, including to Develop or Commercialize the Licensed

Product, those efforts and resources (including expenditures) consistent with the usual practices of such Party in pursuing the Development, Commercialization of its own biologic or pharmaceutical products that are of similar status, such as commercial potential, the proprietary position of the product, the regulatory structure involved, the probable profitability of the applicable product, and other relevant factors including technical, legal, scientific or medical factors. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Party: (a) [\*\*\*]; (b) [\*\*\*]; and (c) [\*\*\*].

- 1.14 “**Common Stock**” has the meaning set forth in Section 3.1.
- 1.15 “**Competing Program**” means [\*\*\*].
- 1.16 “**Development**” or “**Develop**” means all activities related to obtaining Regulatory Approval of a Licensed Product and all non-clinical and clinical research, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, clinical studies (including pre- and post-approval studies and investigator sponsored clinical studies), regulatory affairs, and Regulatory Approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).
- 1.17 “**Dollars**” or “**\$**” means United States Dollars.
- 1.18 “**Effective Date**” has the meaning set forth at the beginning of this Agreement.
- 1.19 “**Existing Agreements**” has the meaning set forth in Section 10.2(h).
- 1.20 “**Existing Patents**” has the meaning set forth in Section 10.2(a).
- 1.21 “**FDA**” means the United States Food and Drug Administration or any successor entity thereto.
- 1.22 “**FDA Approval**” has the meaning set forth in Section 4.2(a).
- 1.23 “**FFDCA**” means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).
- 1.24 “**Field**” means for ophthalmic use for inflammation and pain after ocular surgery and supplemental ophthalmic disease indications (i.e., uveitis or dry eye disease), if any, associated with NDA No. [\*\*\*].
- 1.25 “**First Commercial Sale**” means the first arm’s length commercial sale for monetary value by Licensee or its Affiliates or Sublicensee to a Third Party of a Licensed Product in the Field in the Territory following the receipt of Regulatory Approval for such Licensed Product. For clarity, any first arm’s length commercial



sale of a Licensed Product by Licensee or its Affiliate or its Sublicensee to a distributor or wholesaler would be a First Commercial Sale.

- 1.26 “**Force Majeure**” has the meaning set forth in Section 13.1.
- 1.27 “**Generic Product**” means, with respect to a Licensed Product, any pharmaceutical or biological product that (a) is distributed by a Third Party under a Regulatory Filing approved by a Regulatory Authority in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Licensed Product, including any product authorized for sale in the U.S. pursuant to Section 505(j) of the Act (21 U.S.C. 355(j)) or (b) is otherwise substitutable under applicable law for such Licensed Product when dispensed without the intervention of a physician or other health care provider with prescribing authority.
- 1.28 “**IND**” means an Investigational New Drug Application as defined in the FDCA.
- 1.29 “**Indemnification Claim Notice**” has the meaning set forth in Section 11.3(a).
- 1.30 “**Indemnified Party**” has the meaning set forth in Section 11.3(a).
- 1.31 “**Infringement Claim**” has the meaning set forth in Section 8.3(a).
- 1.32 “**Information**” means all Know-How and other proprietary information and data of a financial, commercial, regulatory, research and development or technical nature which the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs, formulae or strategy in relation to this Agreement.
- 1.33 “**Initial Presentation**” has the meaning set forth in the definition of “Licensed Product.”
- 1.34 “**Insolvency Event**” means with respect to a Party, the occurrence of any of the following: (a) the Party is deemed to be or is declared to be unable to pay its debts as they fall due or admits inability to pay its debts; (b) a petition is filed or a notice is given by a Party, or a resolution is passed, or an order is made, for or in connection with the winding-up of the Party; (c) an application is made to court, or an order is made, for the appointment of an administrator, or if an administrator is appointed over the Party; (d) a person becomes entitled to appoint a receiver over the assets of the Party or a receiver is appointed over the assets of the Party; (e) the holder of a qualifying floating charge over the assets of a Party has become entitled to appoint or has appointed an administrative receiver; (f) a creditor or encumbrancer of the Party attaches or takes possession of, or a distress, execution, sequestration or other such process is levied or enforced on or sued against, the whole or a material portion of its assets and such attachment or process is not discharged within [\*\*\*]; (g) if the other Party shall make an assignment for the

benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganization, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, whether now or hereafter in effect; (h) that the sum of such Party's debts is greater than all of such Party's property, at a fair valuation; or (i) any event occurs, or proceeding is taken, with respect to the Party in any jurisdiction in which it has assets and to which it is subject, that has an effect equivalent or similar to any of the events mentioned in (a) to (h) above.

- 1.35 “**Joint Steering Committee**” or “**JSC**” has the meaning set forth in Section 6.1.
- 1.36 “**JSC Deadlock**” has the meaning set forth in Section 6.5.
- 1.37 “**Know-How**” means all technical information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to compounds, formulations, compositions, products or to their manufacture, development, registration, use or commercialization or methods of assaying or testing them or processes for their manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, regulatory strategy, expertise and information, Regulatory Filings and copies thereof, relevant to the development, manufacture, use or commercialization of or which may be useful in studying, testing, development, production or formulation of products, or intermediates for the synthesis thereof.
- 1.38 “**Late Payment Notice**” has the meaning set forth in Section 3.5.
- 1.39 “**Licensed Product**” means any product sold, offered for sale or distributed pursuant to NDA No. [\*\*\*], including APP13007, a novel formulation of Clobetasol Propionate (Clobetasol Propionate Ophthalmic Nanosuspension, 0.05%) as 3.5 mL of a preserved eye drop in a 5 mL multidose eyedropper bottle (the “**Initial Presentation**”).
- 1.40 “**Licensee**” has the meaning set forth in the preamble hereto.
- 1.41 “**Licensee Regulatory Data**” has the meaning set forth in Section 4.2(d).
- 1.42 “**Licensor**” has the meaning set forth in the preamble hereto.
- 1.43 “**Licensor Know-How**” means all information, data and other Know-How owned or controlled by Licensor or any of its Affiliates prior to or on the Effective Date or at any time during the Term that is necessary or reasonably useful for the Commercialization of the Licensed Product in the Field in the Territory.

- 1.44 “**Licensee Marks**” means trademarks owned or controlled by Licensee or its Affiliates or Sublicensee and any associated logos, graphic designs or trade dress to be used with the Licensed Product, excluding any trademarks of Licensee’s corporate name, other than Licensor Marks.
- 1.45 “**Licensor Marks**” means trademarks owned or controlled by Licensor or its Affiliates and any associated logos, graphic designs or trade dress, [\*\*\*].
- 1.46 “**Licensor Patents**” means all Patents owned or controlled by Licensor or any of its Affiliates prior to or on the Effective Date or at any time during the Term that are necessary or reasonably useful for the Commercialization of the Licensed Product in the Field in the Territory, including any Patents owned or controlled by Licensor or any of its Affiliates prior to or on the Effective Date or at any time during the Term that claim the Licensed Product or a component thereof.
- 1.47 “**Licensor Regulatory Data**” has the meaning set forth in Section 4.2(d).
- 1.48 “**Licensor Technology**” means all Licensor Know-How and Licensor Patents.
- 1.49 “**Losses**” has the meaning set forth in Section 11.1.
- 1.50 “**Manufacture**” or “**Manufacturing**” means all activities related to producing, making, having made, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping or storage of a Licensed Product, or any intermediate thereof, including process development, process improvement, process qualification and validation, scale-up, non-clinical, clinical and commercial manufacturing and analytic development, product characterization, stability testing, quality assurance and quality control.
- 1.51 “**Milestone Event**” has the meaning set for in Section 3.2.
- 1.52 “**Milestone Payment**” has the meaning set for in Section 3.2.
- 1.53 “**Minimum Supply Price**” means, (a) with respect to the Initial Presentation, a price equal to [\*\*\*] per unit (*provided, however*, if a Generic Product is available, the price shall be the lower of the then-current Minimum Supply Price or [\*\*\*] or (b) with respect to any other presentation of Licensed Product, the price per unit negotiated by the Parties pursuant to Section 7.5, and in the case of both (a) and (b) as may be adjusted in accordance with Section 7.5(a).
- 1.54 “**NDA**” means a New Drug Application as defined in the FFDCA.
- 1.55 “**Net Sales**” means, with respect to each Licensed Product for any period, the gross amounts received by Licensee or its Affiliates or its Sublicensee for sales of such Licensed Product in such period, less the following deductions:
- (a) normal and customary trade, quantity and cash discounts and sales returns and allowances;

- (b) sales and other taxes directly related to the sale or delivery of Licensed Product;
- (c) amounts repaid or credits taken by reason of damaged goods, rejections, defects, expired dating, recalls, returns or because of retroactive price changes;
- (d) charge back payments and rebates granted to (i) managed healthcare organizations, (ii) federal, state and/or provincial and/or local governments or other agencies, (iii) purchasers and reimbursors, or (iv) trade customers, including wholesalers and chain and pharmacy buying groups, to the extent permitted by applicable law and regulations; and
- (e) distribution costs and expenses;
- (f) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) and reasonably allocable to sales of the Licensed Product as agreed by the Parties;
- (g) any other customary deductions that are consistent with GAAP, but which may not be duplicative of the deductions specified in (a)-(f).

In no event will any particular amount identified above be deducted more than once in calculating Net Sales (i.e., no “double counting” of the reductions). For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when invoiced and a “sale” shall not include transfers or dispositions of such Licensed Product for pre-clinical or clinical purposes or as samples, in each case, without charge. Licensee’s or its Affiliate’s transfer of any Licensed Product to an Affiliate shall not result in any Net Sales, unless such Licensed Product is consumed or administered by such Affiliate in the course of commercial activities.

- 1.56 “**Net Sales Price**” means for a given Calendar Quarter, total Net Sales in the Territory in such Calendar Quarter divided by total units of the Licensed Product sold in the Territory in that Calendar Quarter.
- 1.57 “**Net Sales Price Reconciliation Payment**” means, with respect to a Calendar Quarter, (a) [\*\*\*] multiplied by (b) [\*\*\*]. For clarity, the Net Sales Price Reconciliation Payment may be positive or negative.
- 1.58 “**Net Sales Report**” has the meaning set forth in Section 3.3.
- 1.59 “**Party**” and “**Parties**” have the meanings set forth in the preamble hereto.
- 1.60 “**Patents**” means (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or

from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention; and (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)).

- 1.61 **“Regulatory Approval”** means, with respect to the Licensed Product in any country or jurisdiction, any and all approvals, licenses, registrations, or authorizations from a Regulatory Authority required to Commercialize the Licensed Product in such country or region.
- 1.62 **“Regulatory Authority”** means any governmental agency or authority responsible for granting Regulatory Approvals for the Licensed Product, including the FDA, with responsibility for granting licenses or approvals necessary for the marketing and sale of the Licensed Product.
- 1.63 **“Regulatory Filings”** means, with respect to the Licensed Product, all (a) applications (including all INDs and NDAs), registrations, licenses, authorizations and approvals (including Regulatory Approvals), (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files and (c) clinical and other data, datasets, and databases contained, referenced or relied upon in any of the foregoing, in each case ((a), (b) and (c)), relating to the Licensed Product in the Field.
- 1.64 **“Regulatory Maintenance”** means all interactions with Regulatory Authorities with respect to the Licensed Product in the Territory, including communications and filings with the Regulatory Authorities and preparations of such communications and filings.
- 1.65 **“Remedial Action”** has the meaning set forth in Section 4.3(c).
- 1.66 **“Senior Officers”** means, with respect to Licensor, Chairman of the Board of Directors or Chief Executive Officer of Licensor, or either of their designee, and, with respect to Licensee, [\*\*\*].
- 1.67 **“Subscription Agreement”** has the meaning set forth in Section 14.14.
- 1.68 **“Sublicensee”** has the meaning set forth in Section 2.2.
- 1.69 **“Sublicenses”** has the meaning set forth in Section 2.2.

- 1.70 “**Supply Agreement**” has the meaning set forth in Section 7.1.
- 1.71 “**Term**” has the meaning set forth in Section 9.1.
- 1.72 “**Territory**” means the United States and its territories and possessions (including the District of Columbia and Puerto Rico).
- 1.73 “**Third Party**” means any individual or entity other than the Parties and their respective Affiliates.
- 1.74 “**Third Party Claims**” has the meaning set forth in Section 11.1.
- 1.75 “**United States**” or “**U.S.**” means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

## 2. GRANT OF LICENSE; SUBLICENSING

- 2.1 **Grant.** Licensor (on behalf of itself and its Affiliates) hereby grants to Licensee (a) an exclusive (including with regard to Licensor and its Affiliates) license, with the right to grant sublicenses through multiple tiers, under the Licensor Technology to Commercialize the Licensed Product in the Field and in the Territory, (b) a non-exclusive license, with the right to grant sublicenses through multiple tiers, to use the Licensor Marks solely to Commercialize the Licensed Product in the Field and in the Territory, (c) an exclusive (including with regard to Licensor and its Affiliates) license and right of reference and use, with the right to grant sublicenses through multiple tiers, under the Regulatory Filings owned or controlled by Licensor or its Affiliates to Commercialize the Licensed Product in the Field in the Territory and (d) only as expressly provided in this Agreement or the Supply Agreement, a non-exclusive license to Manufacture the Licensed Product for Commercialization in the Field and in the Territory. For avoidance of doubt, this Agreement does not grant Licensee Development rights to the Licensed Product either stand-alone or in combination with any device (including but not limited to Optejet® or any other current or future Licensee owned or developed device).
- 2.2 **Sublicensee.** Licensee shall have the right to grant sublicenses under the licenses and rights of reference granted to Licensee in Section 2.1 to Third Parties (such Third Parties, the “**Sublicensees**”) or its Affiliates to Commercialize the Licensed Product within the Field and Territory; *provided* that (a) any such sublicense or further rights of reference (each “**Sublicense**”) shall be consistent with the terms and conditions of this Agreement, (b) Licensee shall remain responsible for the Sublicensees’ compliance with the applicable terms and conditions of this Agreement, (c) Licensee shall notify Licensor of each Sublicense no later than [\*\*\*] before the execution of such Sublicense and (d) copies of Sublicense agreement (which may be redacted to prevent disclosure of competitively sensitive information) will be provided to Licensor within [\*\*\*] of signing by any Sublicensee and Licensee.

- 2.3 **Reservation of Rights.** All worldwide rights of Licensor in and to the Licensor Technology that are not expressly granted to Licensee by this Agreement are reserved to Licensor. No rights are granted under this Agreement by implication, estoppel or statute. By way of example and without limitation, Licensor retains the rights to Develop, use, Manufacture, make, have made the Licensed Product anywhere in the world inside or outside the Field (but not Commercialize in the Territory), and sell, offer for sale, export and import Licensed Product anywhere outside of the Field or outside the Territory. This Agreement does not prevent or restrict in any respect Licensor’s ability to, or to grant a license to any third party to, Develop, use, Manufacture, make, have made, sell, offer for sale, export, or import any product other than the Licensed Product.
- 2.4 **No Impairment.** Parties shall not, and shall cause their respective Affiliates not to, grant to any Third Party any (sub)licenses or other rights that conflict with any of the (sub)licenses or other rights granted to Licensee under this Article 2.

**3. PAYMENTS**

- 3.1 **Upfront Payment.** In partial consideration for the licenses and rights granted to Licensee hereunder, no later than forty-five (45) days following the Effective Date, Licensee shall pay to Licensor a non-refundable, non-creditable payment in the amount of Two Million Dollars (\$2,000,000), payable as One Million Dollars (\$1,000,000) in cash and One Million Dollars (\$1,000,000) in EYENOVIA common stock, \$0.0001 par value per share (the “**Common Stock**”) (NASDAQ: EYEN), with EYEN share value calculated using [\*\*\*]. If EYENOVIA Common Stock (NASDAQ: EYEN) cannot be issued to Licensor within forty-five (45) days after the Effective Date, Licensee shall pay to Licensor One Million Dollars (\$1,000,000) in cash in lieu of such Common Stock.
- 3.2 **Milestone Payments.** In partial consideration for the licenses and rights granted to Licensee hereunder, and on the terms and subject to the conditions set forth herein, Licensee shall pay to Licensor the non-refundable, non-creditable one-time milestone payments set out below (each, a “**Milestone Payment**”) following the first achievement of the corresponding milestone events by Licensee, its Affiliates or Sublicensees (each, a “**Milestone Event**”).
- (a) **Development Milestone Payments.** Milestone Payments set forth in this Section 3.2(a) will be paid no later than [\*\*\*] following achievement of each corresponding Milestone Event.

Milestone Event	Milestone Payment
Upon (a) the FDA Approval of the Licensed Product in the Territory and (b) the effective date of the acceptance by Licensee of the transfer and assignment of the FDA Approval from Licensor to Licensee	[***]

The date that is the earlier of (a) [***] after the FDA Approval of the Licensed Product in the Territory and (b) [***] following the First Commercial Sale of the Licensed Product in the Territory	[***]
<u>Maximum Potential Milestone Payments</u>	Four Million Dollars (\$4,000,000)

- (b) **Sales Milestone Payments.** Commencing from the First Commercial Sale, Licensee will pay to Licensor a one-time sales milestone payment based on the first achievement by in total the Licensee or its Affiliates or Sublicensee of the corresponding Milestone Event. Milestone Payments set forth in this Section 3.2(b) shall be paid [\*\*\*]. If multiple sales Milestone Events are achieved in the same Calendar Year, Licensee will pay the Milestone Payment with respect to the first such Milestone Event [\*\*\*] and may elect to pay any additional Milestone Payment(s) with respect to such additional Milestone Event(s) [\*\*\*].

<b>Milestone Event</b>	<b>Milestone Payment</b>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
<u>Maximum Potential Sales Milestones</u>	Eighty Million Dollars (\$80,000,000)

Each Milestone Payment under this Section 3.2 shall be payable only once, upon the first achievement of the applicable Milestone Event in a given Calendar Year by the first Licensed Product, and no amounts shall be due for subsequent or repeated achievements of such milestone event in any subsequent Calendar Years or for achievements of such milestone event by other Licensed Product, unless otherwise agreed by the Parties in writing for future products.

- 3.3 **Reporting; Transfer Pricing and Invoicing.** Licensee shall submit to Licensor within [\*\*\*] in which Licensee, its Affiliates or its Sublicensee books sales of Licensed Product, an accurate, complete, itemized report (the “**Net Sales Report**”) setting forth for such Calendar Quarter or cumulative year to date the following information:

- (a) the quantity of Net Sales for the applicable Calendar Quarter for the Territory; and



- (b) the amount of sales Milestone Payment, Net Sales Price and Net Sales Price Reconciliation Payment due thereon, or, if no Sales Milestone Payment or Net Sales Price Reconciliation Payment are due to Licensor for such reporting period, a statement that no Sales Milestone Payment or Net Sales Price Reconciliation Payment is due.

Pricing and invoicing for the sale of Licensed Product under the Supply Agreement, including invoicing of the Net Sales Price Reconciliation Payment, if applicable, are set forth in Section 7.4.

- 3.4 **Payments; Payment Method.** All payments due to Licensor hereunder will be made in Dollars and shall be remitted to the following bank account:

[\*\*\*]

Licensee shall have the right to offset any payment that is owed by Licensor to Licensee or its Affiliates against any payments owed by Licensee, if any, under this Agreement.

- 3.5 **Interest on Late Payments.** If Licensee fails to make a timely payment pursuant to the terms of this Agreement, Licensor shall provide a written notice of such failure to Licensee (a “**Late Payment Notice**”), and interest shall accrue on the past due amount starting on the date of the Late Payment Notice at [\*\*\*].

- 3.6 **Taxes.** Each Party will pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are required to be withheld by the Party who makes the payment, the paying Party will: (a) deduct such taxes from the payment made to the other Party; (b) timely pay the taxes to the relevant tax authority; (c) send proof of payment to the other Party within [\*\*\*]; and (d) reasonably assist the other Party in its efforts to obtain a credit for such tax payment. Each Party agrees to reasonably assist the other Party in lawfully claiming exemptions from or minimizing such deductions or withholdings under double taxation laws, treaties or similar circumstances. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use their reasonable efforts to cooperate and coordinate with each other to achieve such objective.

- 3.7 **Records.** Licensee shall keep, and require its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable to Licensor pursuant to this Agreement. Such books and records shall be kept for such period of time required by applicable laws, but no less than [\*\*\*]. Such records shall be subject to inspection in accordance with Section 3.8.

- 3.8 **Audits.** Upon not less than [\*\*\*] prior written notice, Licensee shall, and cause its Affiliates to, permit an independent, certified public accountant selected by Licensor and reasonably acceptable to Licensee (for the purposes of this Section

3.8, the “**Auditor**”), to audit or inspect such books or records of Licensee and its Affiliates that relate to Net Sales for the sole purpose of verifying the: (a) Milestone Payments payable hereunder in respect of Net Sales; (b) Net Sales Price; (c) Net Sales Report; (d) Net Sales Price Reconciliation Payment and (e) withholding taxes, if any, required by applicable laws to be deducted as a payment by Licensee in respect of such Net Sales. The Auditor will send a copy of the report to Licensor at the same time it is sent to Licensee; *provided* that the Auditor shall disclose only whether the reports are correct or not and the specific details concerning any discrepancies. No other information (including pricing information) shall be shared. Such inspections may be made no more than once each Calendar Year and during normal business hours. The Auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. With respect to Licensee’s Sublicensees, upon not less than [\*\*\*] prior written notice, Licensee shall, or shall request an auditor agreed upon by the Sublicensee to, conduct such audit and inspection of books or records of its Sublicensees that relate to such purpose. Should such inspection lead to the discovery of a discrepancy to Licensor’s detriment, Licensee shall pay to Licensor such discrepancy within [\*\*\*] after its receipt from the Auditor of the report. Any overpayment by Licensee revealed by an audit shall, at Licensee’s election, be reimbursed to Licensee within [\*\*\*] after its receipt from the Auditor of the report or fully credited against future payments to be made to Licensor hereunder. Inspections conducted under this Section 3.8 shall be at the expense of [\*\*\*].

#### 4. DEVELOPMENT AND REGULATORY OBLIGATIONS

##### 4.1 Development

- (a) **Development Activities for FDA Approval.** After the Effective Date, Licensor will continue to use Commercially Reasonable Efforts at its own cost to carry out the Development needed to obtain Regulatory Approval of the Licensed Product in the Field and in the Territory.

##### 4.2 Regulatory

- (a) **Regulatory Approval.** Licensor will be responsible for applying for the Regulatory Approval from FDA for the application under NDA No. [\*\*\*] (the “**FDA Approval**”) with respect to Commercialization of the Initial Presentation of the Licensed Product, and Licensor shall use Commercially Reasonable Efforts to obtain such FDA Approval by [\*\*\*].
- (b) **Transfer and Assignment of FDA Approval.** To the extent permitted by applicable laws, after the Initial Presentation of the Licensed Product receives FDA Approval, Licensor shall, at its own cost, convey, assign, transfer and deliver to Licensee, and Licensee shall accept, all of Licensor’s right, title and interest in and to the FDA Approval for the Licensed Product as well as any associated post-approval regulatory obligations received from FDA related to the Licensed Product under NDA No. [\*\*\*]. The

Parties shall take all actions necessary to accomplish the foregoing as soon as reasonably practical, including promptly notifying the FDA of such transfer and assignment of the FDA Approval in accordance with the provision of 21 C.F.R. 314.72.

- (c) **Regulatory Fees.** Licensor will bear all regulatory fees charged by the Regulatory Authorities for submission of the Regulatory Filing for FDA Approval of the NDA for the Initial Presentation of the Licensed Product in the Field in the Territory and any cost associated with the transfer and assignment of FDA Approval to Licensee pursuant to Section 4.2(b).
- (d) **Regulatory Data.** To the extent required by Licensee to Commercialize or maintain Regulatory Approval of the Licensed Product in the Field in the Territory or to the extent necessary for Licensee (i) to have FDA Approval transferred and assigned from Licensor in accordance with Section 4.2(b) and (ii) thereafter to maintain the FDA Approval and to conduct all communications and interactions with the FDA in accordance with Section 4.2(e), Licensor shall, to the extent permitted by applicable law, provide to Licensee copy of or access to all non-clinical data and clinical data, NDA packages and other information, results and analyses that are available or generated at any time within a reasonable time (the “**Licensor Regulatory Data**”). Licensee shall, upon request by Licensor and to the extent permitted by applicable law, provide to Licensor copies of or access to all non-clinical data and clinical data, regulatory packages and other information, results and analyses that are generated at any time with respect to the Licensed Product within a reasonable time (a “**Licensee Regulatory Data**”).
- (e) **Disclosure of Licensor Know-How.** At any time upon the reasonable request of Licensee, Licensor shall promptly disclose to Licensee any Licensor Know-How in its or its Affiliates possession, to the extent (i) not previously disclosed or transferred to Licensee in connection with the transfer of Licensor Regulatory Data pursuant to Section 4.2(d) and (ii) reasonably necessary for Licensee to exercise its rights or perform its obligations under this Agreement.
- (f) **Maintenance of Regulatory Approvals.** Licensee will at its own cost and effort be responsible for Regulatory Maintenance in the Territory, including providing all relevant information and documentation needed as well as payment of any required fees, including for avoidance of doubt the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended), and any other like fees as a result of the sale of Licensed Product in the Territory. Licensor will provide reasonable support as required in a timely manner.
- (g) **Communications and Filings with Regulatory Authorities.** To the extent permitted under applicable law, for obtaining Regulatory Approvals of the

Licensed Product in the Territory, each Party shall provide the other Party with copies of material submissions to or communications with a Regulatory Authority (in the original language) relating to the Licensed Product in a reasonable amount of time prior to the anticipated date for the submission or communication to allow the other Party a reasonable opportunity to review and comment on submission or communication, and in such event each Party shall consider all comments and proposed revisions from the other Party in good faith in connection with effecting such submission or communication. In the event that an exigent action prevents a Party from allowing the other Party the time set forth above, such first Party shall make all efforts to provide the other Party with as much time as possible to review and comment as the timeline permits. Each Party shall consult with the other Party regarding, and keep the other Party informed of, the status of the preparation of all material submissions and communications it has with the applicable Regulatory Authority relating to each Licensed Product in the Territory.

(h) **Post FDA Approval of Licensed Product in the Field and in the Territory Changes; Variations.**

Licensor will bear all actual related costs resulting from:

- (i) Changes requested by Licensor (on its own or on behalf of any approved subcontractor);
- (ii) Changes required under applicable laws or regulations or requested or required by a Regulatory Authority relating to Manufacturing of the Licensed Product or any component of the Licensed Product; and
- (iii) Changes in the materials or suppliers of the Licensed Product or components of the Licensed Product.

Licensee will bear all actual and related costs resulting from:

- (i) Changes requested by Licensee, which are approved by Licensor in writing, which approval shall not be unreasonably withheld, conditioned or delayed; and
- (ii) Changes required under applicable laws or regulations or changes requested or required by FDA relating to the Development or Commercialization, or marketing of the Licensed Product in the Field in the Territory; and
- (iii) Changes in the text of prescribing information (package insert), labeling and trade dress.

- (i) **Right of Reference.** Licensee hereby grants Licensor and its Affiliates and Licensors' sublicensees a right of full access, a right of reference and the right to use and incorporate by reference all of its and its Affiliates' and its Sublicensees' Regulatory Approvals and Licensee Regulatory Data contained therein for use outside the Territory. Upon request from Licensor for right of reference, the Licensee shall without delay request, or require its Sublicensee or Affiliate or Acquiring Affiliate to request without delay from Regulatory Authority any required documents or provide any signed documentations or statements as required by Licensor as to meet the requirements of the relevant Regulatory Authority.

#### 4.3 **Pharmacovigilance and Post Marketing Surveillance**

- (a) **Pharmacovigilance Agreement.** Following the Effective Date and no later than [\*\*\*] prior to the First Commercial Sale of the Licensed Product by Licensee or any of its Affiliates in the Field and in the Territory, the Parties shall enter into a separate written pharmacovigilance agreement providing details related to managing and reporting adverse events, adverse drug experiences and similar events or experiences in respect of the Licensed Product (including those of such events or experiences as occur during clinical studies worldwide) and other safety and reporting practices and procedures in respect to the Licensed Product in compliance with all applicable law.
- (b) **Global Safety Database.** Licensor shall establish, hold and maintain the global safety database for the Licensed Product. Each Party shall provide the other Party with information in such Party's possession or control as necessary for such other Party to comply with its pharmacovigilance or other post-marketing regulatory responsibilities and reporting in respect to the Licensed Product, including, as applicable, any adverse events, adverse drug experiences or similar events or experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding applicable law outside the United States) from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies and commercial experiences with the Licensed Product, in each case, in the form reasonably requested by such other Party.
- (c) **Remedial Actions.** Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Licensed Product may be subject to any recall, corrective action or other regulatory action by any Regulatory Authority (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Licensee shall have sole discretion, except as required by applicable law, with respect to any matters relating to any Remedial Action in or for the Territory, including the decision to commence such

Remedial Action and the control over such Remedial Action, and Licensor shall, and shall cause its Affiliates to, cooperate fully with Licensee's reasonable requests in respect of such matters. Unless otherwise provided in any applicable supply agreement between the Parties or their Affiliates, the costs and expenses of any Remedial Action in or for the Territory shall be borne solely by Licensee, and the costs and expenses of any Remedial Action outside the Territory shall be borne solely by Licensor. Each Party shall maintain, and shall ensure that its Affiliates shall maintain, adequate records to permit the Parties to trace the manufacture, distribution and use of the Licensed Product in their respective territories.

## 5. COMMERCIALIZATION

- 5.1 **Commercialization in Territory.** Subject to the terms and conditions of this Agreement, Licensor hereby appoints Licensee as Licensor's exclusive distributor of the Licensed Product in the Territory during the Term, and Licensee hereby accept such appointment. Licensee will have the sole right and responsibility, at its sole cost and expense, for all aspects of Commercialization of the Licensed Product in the Field in the Territory, including planning and implementation, distribution, marketing, salesbooking of sales, pricing and reimbursement and including import and export unless otherwise agreed in the Supply Agreement. Licensee shall have the right, in its sole discretion, to appoint its Affiliates, and Licensee and its Affiliates shall have the right, in their sole discretion, to appoint any other distributors, in the Territory, to distribute, market, and sell the Licensed Product.
- 5.2 **Licensee Diligence.** At all times during the Term, Licensee shall, directly or through its Affiliates, use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Territory. Licensee will use Commercially Reasonable Efforts to launch the Licensed Product in the United States within [\*\*\*] of FDA Approval. Without further limiting any other obligations set forth in this Agreement, at all times during the Term, Licensee shall keep Licensor through the JSC reasonably and timely informed as to the Commercialization efforts and results thereof relating to the Licensed Product in the Territory.
- 5.3 **Licensed Product Branding.**
- (a) Licensee shall have the sole right to determine the trademarks to be used with respect to the Commercialization of the Licensed Product for its Initial Presentation in the Field in the Territory, including whether to use any Licensor Mark or Licensee Mark used or held for use with the Licensed Product. Licensor shall not, and shall not permit its Affiliates to, (i) use in their respective businesses, any trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Licensed Product trademarks or (ii) do any act which endangers, destroys or similarly affects, in any material respect, the value of the goodwill pertaining to the Licensed Product trademarks. Licensor shall not, and shall not permit its Affiliates to, attack, dispute or contest the validity

of or ownership of such Licensed Product trademark anywhere in the Territory or any registrations issued or issuing with respect thereto.

- (b) Licensee acknowledges the standards and reputation for quality symbolized by the Licensor Marks as of the Effective Date and, if applicable, Licensee shall use the Licensor Marks in a manner consistent with such quality standards and reputation. Licensor shall have the right to inspect and audit, from time to time, any Licensed Product Commercialized by Licensee using a Licensor Mark, and all packaging, product inserts and marketing materials therefor, in order to monitor and ensure the quality of all products and services being marketed with or bearing any Licensor Mark.
- (c) Upon Licensor's request to use Licensee Marks for the Licensed Product in the Field outside the Territory, the Parties shall promptly notify JSC and JSC shall determine whether such Licensee Mark may be licensed to Licensor for such use with the Licensed Product in the Field outside the Territory.

5.4 **Reporting by Licensee.** Prior to Licensee or its Affiliates achieving aggregate Net Sales of [\*\*\*] in the Territory, Licensee shall update Licensor via the JSC no less than [\*\*\*] during the Term regarding its Commercialization activities (including to the extent material, pre-marketing activities, market research, health economic and outcome research, plans and publications) and Commercialization strategy (including to the extent material, launch plans, pricing and reimbursement strategy and twelve (12)-month sales forecasts). From and after achievement of aggregate Net Sales of [\*\*\*] in the Territory, Licensee shall provide such updates no less than [\*\*\*].

## 6. JOINT STEERING COMMITTEE

6.1 **General Provisions.** Within [\*\*\*] after the Effective Date, the Parties shall establish a Joint Steering Committee (the "**Joint Steering Committee**" or "**JSC**"), which shall consist of two (2) representatives from each of the Parties, each with the requisite experience and seniority to enable such individuals to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JSC. From time to time, each Party may substitute one or more of its representatives to the JSC on written notice to the other Party. Each Party shall designate one of its representatives to serve as co-chairpersons. The JSC shall: (a) provide a forum to update on Licensor Development, Manufacture and regulatory activity and Licensee Commercialization progress; (b) discuss any Licensee sponsored Development activity for the Licensed Product in the Territory; (c) upon Licensor's request, determine whether Licensee Marks of the Licensed Product may be licensed to Licensor for use with the Licensed Product outside the Territory; (d) in the event that Licensee decides to abandon a Licensee Mark of the Licensed Product, determine whether Licensor may have the right to request assignment of such Licensee Mark; (e) attempt to resolve any dispute with respect to matters

within the JSC's jurisdiction; and (f) perform such other functions as expressly set forth in this Agreement or allocated to it by the Parties' written agreement.

- 6.2 **Meetings and Minutes.** The JSC shall meet [\*\*\*]; *provided* that from and after Licensee or its Affiliates achieves aggregate Net Sales of [\*\*\*] in the Territory, Licensee shall have the option to reduce the frequency of such meetings to [\*\*\*]. The co-chairpersons of the JSC shall be responsible for calling meetings on no less than [\*\*\*] notice unless exigent circumstances require shorter notice. Each Party shall make all proposals for agenda items at least [\*\*\*] in advance of the applicable meeting and shall provide all appropriate information with respect to such proposed items at least [\*\*\*] in advance of the applicable meeting; *provided* that under exigent circumstances requiring input by the JSC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (which consent shall not be unreasonably withheld, conditioned or delayed). The JSC shall prepare and circulate for review and approval of the Parties minutes of each meeting within [\*\*\*] after the meeting. The Parties shall alternate the responsibility for keeping such meeting minutes. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JSC.
- 6.3 **Procedural Rules.** The JSC shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the JSC shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Representatives of the Parties on the JSC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants; *provided* that if one Party designated a location for an in-person meeting, the location for the next in-person meeting shall be designated by the other Party. The location for the first in-person meeting shall be designated by Licensor. Other employees or consultants of a Party who are not representatives of the Parties on the JSC may attend meetings of the JSC; *provided, however*, that such attendees (a) shall not vote or otherwise participate in the decision-making process of the JSC and (b) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 12.
- 6.4 **Limitations on Authority.** Without limitation to the foregoing, the Parties hereby agree that matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and authority of the JSC, including (a) amendment, modification or waiver of compliance with this Agreement; (b) such other matters as are reserved to the consent, approval, agreement or other decision-making authority of either or both Parties in this Agreement that are not required by this Agreement to be considered by the JSC prior to the exercise of such consent,



approval or other decision-making authority; and (c) any determination as to whether a Party is in breach of this Agreement.

- 6.5 **Decision Making within JSC.** Decisions of the JSC shall be made by consensus of the representatives present at a meeting at which a quorum exists, with each Party having one (1) vote; in order to make any decision, the JSC must have present (in person or via telephone or videoconference) and voting at least one representative of each Party, unless the meeting has been reconvened on not less than [\*\*\*] notice because the prior meeting was not quorate. If the JSC cannot resolve a material matter within its responsibilities by consensus (a “**JSC Deadlock**”), then either Party may escalate such JSC Deadlock to the Senior Officers for further consideration. Either Party shall have the right to select a Third Party who has experience of issues that are relevant to the disputed issue to present their views to the Senior Officer of the other Party who shall in good faith listen and consider such views. If the Senior Officers are unable to resolve a JSC Deadlock related to [\*\*\*] (a) [\*\*\*] shall have final decision-making authority with regard to [\*\*\*], and (b) [\*\*\*] shall have final decision-making authority for [\*\*\*]. Neither Party shall exercise its final decision-making authority to (i) require acts or omissions by or on behalf of the other Party in violation of applicable law, (ii) expand the non-decision-making Party’s obligations or reduce the non-decision-making Party’s rights under this Agreement or (iii) expand the decision-making Party’s rights or reduce the decision-making Party’s obligations under this Agreement.
- 6.6 **Disbanding.** The JSC shall continue to exist until the Parties mutually agree to disband the JSC. If the JSC is disbanded, the JSC shall be terminated and shall have no further rights or obligations under this Agreement, and thereafter any requirement of either Party to provide information or other materials to the JSC shall be deemed a requirement to provide such information or other materials to the other Party upon such other Party’s reasonable request in order to facilitate the carrying out of such other Party’s obligations under this Agreement.
- 6.7 **Alliance Managers.** Promptly following the Effective Date, each Party shall designate an individual to act as the primary business contact for such Party for matters related to this Agreement (such Party’s “**Alliance Manager**”), unless another contact is expressly specified in the Agreement or designated by the Parties for a particular purpose. The Alliance Managers shall facilitate communication and collaboration between the Parties and assist in the resolution of potential and pending issues and potential non-technical disputes in a timely manner to enable the Parties to reach consensus and avert escalation of such issues or potential disputes. The Alliance Managers may attend all meetings of the JSC contemplated herein as non-voting participants and will be responsible for assisting such committees and teams in performing their informational and review responsibilities. Either Party may replace its Alliance Manager at any time by notifying the other Party’s Alliance Manager in writing (which may be by email).

## 7. SUPPLY

- 7.1 **Supply Agreement.** Licensor will be the sole supplier of Licensed Product to the Licensee or its Affiliates or its Sublicensee in the Territory. The Parties will negotiate in good faith and in no later than [\*\*\*] prior to the First Commercial Sale of the Licensed Product by Licensee or any of its Affiliates in the Field and in the Territory to enter into a Supply Agreement (a “**Supply Agreement**”), which Supply Agreement shall be consistent with this Article 7 and shall contain the material terms set forth in Schedule 7.1 and a Quality Agreement (“**Quality Agreement**”). If the Parties are unable to agree on the terms and conditions of the Supply Agreement by such time, either Party may submit such dispute for arbitration in accordance with Section 14.4(b) to establish a commercially reasonable Supply Agreement that incorporates all the material terms set forth in Schedule 7.1. The Parties acknowledge that Licensee will be unable to Commercialize the Licensed Product without an executed Supply Agreement between the Parties.
- 7.2 **Product Warranty.** With respect to Licensed Product Manufactured and supplied by or on behalf of Licensor, (a) the Licensed Product shall be in conformity with the specifications for the Licensed Product, (b) the Licensed Product shall, at the time of delivery, have a remaining shelf life [\*\*\*], (c) the Licensed Product shall have been Manufactured in conformance in all material respects with all applicable law, this Agreement and any quality agreement, if applicable, (d) the Licensed Product shall have been Manufactured in facilities that are in compliance with applicable law at the time of such Manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities), (e) the Licensed Product shall not be adulterated or misbranded under the FFDCa or similar provisions of any other applicable law and (f) the Licensed Product may be introduced into interstate commerce pursuant to the FFDCa.
- 7.3 **Delivery.** Licensor shall deliver all quantities of Licensed Product ordered by Licensee CIP (Incoterms 2020) Licensee’s warehouse in [\*\*\*].
- 7.4 **Transfer Pricing and Invoicing.**
- (a) **Invoicing for Product on Delivery.** Licensor shall invoice Licensee for each unit of Licensed Product ordered by and delivered to Licensee at the Minimum Supply Price. Licensee shall pay the undisputed portion of such invoices within [\*\*\*] of receipt of such invoice by Licensee.
- (b) **Net Sales Price Reconciliation.** After the end of each Calendar Quarter, within [\*\*\*] after Licensor’s receipt of the Net Sales Report, if the Net Sales Price Reconciliation Payment is positive, Licensor shall issue to Licensee an invoice for the amount of the Net Sales Price Reconciliation Payment. Licensee shall pay the undisputed portion of any such invoice within [\*\*\*] of receipt of such invoice by Licensee. For clarity, if the Net Sales Price Reconciliation Payment is negative, Licensor shall not invoice Licensee for, and Licensee shall have no obligation to pay Licensor, such amount.
- 7.5 **Minimum Supply Price.**

- (a) **Adjustment.** If with respect to any Calendar Year there is no Net Sales Price Reconciliation Payment, the Minimum Supply Price of the Licensed Product will increase by [\*\*\*] from the then-current Minimum Supply Price for the following Calendar Year; *provided, however*, that in no event shall the Minimum Supply Price of the Licensed Product exceed [\*\*\*]. If the Minimum Supply Price of the Licensed Product has exceeded [\*\*\*], the Minimum Supply Price will remain at the last set Minimum Supply Price.
- (b) **Additional Presentations.** If during the Term Licensor Develops and seeks Regulatory Approval for a presentation of the Licensed Product in the Field in the Territory other than the Initial Presentation, the Parties will negotiate in good faith a Minimum Supply Price with respect to such Licensed Product.

## 8. INTELLECTUAL PROPERTY

### 8.1 Ownership of Intellectual Property.

- (a) **Licensor Know How, Licensor Patents.** Licensor has and shall retain, all right, title and interest in and to, the Licensor Know How and Licensor Patents.

### 8.2 Prosecution and Maintenance of Patents.

- (a) **Prosecution of Licensor Patents.** Licensor shall have sole right to obtain, prosecute and maintain at its own cost the Licensor Patents in and outside the Territory. Licensor shall also have the exclusive right to seek patent term extensions or supplemental patent protection under the Licensor Patents, if available, including supplementary protection certificates, in the Field and in the Territory in relation to the Licensed Product.

### 8.3 Third Party Infringement.

- (a) **Notice.** Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the Licensor Patents, or (ii) unauthorized use or misappropriation of any of the Licensor Know-How, in the case of either clause (i) or clause (ii), that could reasonably be expected to impact the (A) Commercialization of any Licensed Product in the Field in the Territory by or on behalf of Licensee or its Affiliates, or (B) scope of the rights licensed to Licensee under Section 2.1 (an “**Infringement Claim**”), of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such Infringement Claim.
- (b) **Enforcement Rights.** Licensee shall have the right, but not the obligation, after consultation with Licensor, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (i.e., prevent or abate actual or threatened infringement or misappropriation of) or otherwise

enforce the Licensor Patents, Licensor Know-How, with respect to an Infringement Claim in the Territory and shall consider in good faith the reasonable interests of Licensor in so doing. For this purpose, Licensor shall execute such legal papers and cooperate in the prosecution of such suit as may be reasonably required for Licensee to take such action; *provided* that Licensee shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Licensor in connection with such cooperation.

- (c) **Conduct of Certain Actions; Costs.** Licensee shall have the sole and exclusive right to select counsel for, and otherwise control, any suit initiated by it pursuant to Section 8.3(b) and will pay its own costs and expenses in connection with such suit.
- (d) **Recoveries.** Any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party by the Licensee over enforcing any Infringement Claim in the Territory shall be allocated first to reimburse each Party's out-of-pocket costs and expenses in connection with such enforcement and then shared equally between the Parties.

8.4 **Patent Invalidity Claim.** Each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a Licensor Patent in the Field or in the Territory of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. To the extent permitted by applicable law, Licensee shall have the first right, but not the obligation, to defend against any such action involving a Licensor Patent in its own name, and the costs of any such defense shall be at Licensee's expense. Licensor, upon request of Licensee, agrees to join in any such action and to cooperate reasonably with Licensee at its own cost. If Licensee does not defend against any such action involving a Licensor Patent, then Licensor shall have the right, but not the obligation, to defend such action and any such defense shall be at Licensor's expense.

8.5 **Claimed Infringement.** Each of the Parties shall promptly notify the other in the event a Party becomes aware that the Commercialization of any Licensed Product in the Field in the Territory infringes or misappropriates the intellectual property rights of any Third Party, and shall promptly provide the other Party with any notice it receives or has received from a Third Party related to such suspected infringement or misappropriation. Licensee shall have in the Territory the first right, but not the obligation, to defend and control the defense of any such claim, suit, or proceeding at its own expense, using counsel of its own choice. Licensor may participate in any such claim, suit, or proceeding with counsel of its choice at its own expense if Licensee give up the first right. Without limitation of the foregoing, if each Party finds it necessary or desirable to join the other Party as a party to any such action, such other Party shall execute all papers and perform such acts as shall be reasonably required. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit, or proceeding.

- 8.6 **Procedure and Settlement.** To the extent Licensee takes a lead role to enforce or defend a Licensor Patent or the Licensor Know-How in a suit, legal or administrative proceeding or action in pursuance with this Article 8, Licensee shall keep Licensor reasonably informed of the status of the suit, proceeding or action. Licensee (a) shall consult with Licensor, provide relevant documents to Licensor with a reasonable amount of time prior to each deadline set by a court or other venue or authority of competent jurisdiction and consider Licensor's comments in good faith and (b) without Licensor's prior written consent, shall not offer or enter into any settlement or compromise, admit or concede that any aspect of any such Patents or Know-How is invalid or unenforceable or may adversely affect the scope of the Licensor Patents or the Licensor Know-How, or admit any wrongdoing or misconduct on the part of Licensor. Licensor shall have the right, but not the obligation, to join Licensee in such proceedings to the extent permissible under applicable law at Licensor's sole cost and expense. Licensee will take the lead in the control and conduct of any such suit or action under this Article 8 in close coordination with Licensor.
- 8.7 **Licensor Marks.** Licensor shall own the Licensor Marks and will be primarily responsible for registering, defending and maintaining the same in the Territory to the extent necessary for Commercialization of Licensed Product at its sole cost and expense, using counsel of its choice. Licensee shall have the sole right, but not the obligation to register, defend and maintain all trademarks used for Commercialization of the Licensed Product other than the Licensor Marks, using counsel of its choice. In the event that Licensor decides to abandon a Licensor Mark being used in connection with the Commercialization of the Licensed Product in the Territory, it shall promptly notify Licensee of such intention and Licensee shall have the right to request assignment of the applicable Licensor Mark. Upon receipt of the notice requesting assignment, Licensor shall, at Licensee's costs, take all reasonable steps to assign the applicable Licensor Mark to Licensee before abandonment of the applicable Licensor Mark, and shall provide applicable correspondence with the relevant trademark office and other documents reasonably related to such Licensor Mark to assist in transition of prosecution and maintenance of the applicable Licensor Mark.
- 8.8 **Licensee Marks.** Licensee shall own the Licensee Marks and will be primarily responsible for registering, defending and maintaining the same in the Territory to the extent necessary for Commercialization of Licensed Product at its sole cost and expense, using counsel of its choice. Licensee shall have the sole right, but not the obligation to register, defend and maintain all trademarks used for Commercialization of the Licensed Product, using counsel of its choice. In the event that Licensee decides to abandon a Licensee Mark being used in connection with the Commercialization of the Licensed Product in the Territory, it shall promptly notify JSC and based on the determination by JSC Licensor may have the right to request assignment of the applicable Licensee Mark.

## 9. TERM AND TERMINATION

- 9.1 **Term.** The term of this Agreement shall commence on the Effective Date and, unless sooner terminated by a Party pursuant to this Article 9, shall continue in full force for ten (10) years from the First Commercial Sale (the “**Term**”). The Agreement may be renewed subject to the Parties’ mutual agreement and other terms to be agreed by the Parties.
- 9.2 **Termination by Either Party.** This Agreement may be terminated by either Party:
- (a) at any time with immediate effect if the other Party is in material breach of this Agreement and where such breach is capable of being cured but has not been cured within [\*\*\*]; *provided* that if the breaching Party disputes that it has materially breached one or more of its obligations under this Agreement, the non-breaching Party shall not be entitled to terminate the Agreement unless and until (i) a final and non-appealable judgment has been issued pursuant to which the breaching Party is determined to have been in material breach of one or more of its obligations under this Agreement and (ii) where such breach is capable of being cured, such breach has not been cured within [\*\*\*];
  - (b) upon mutual agreement of the Parties; or
  - (c) at any time with immediate effect if an Insolvency Event occurs with respect to the other Party.
- 9.3 **Termination by Licensor.** Licensor may terminate this Agreement on written notice to Licensee if:
- (a) during the Term, Licensee undergoes a Change of Control and the Acquiring Affiliate is then engaged in a Competing Program, with such termination to become effective one hundred and twenty (120) days after notice is given or at any time after the Change of Control has occurred and Commercialization has ceased on the Licensed Product;
  - (b) during [\*\*\*] after the First Commercial Sale, Net Sales has not attained [\*\*\*] or annual unit sales of [\*\*\*], with such termination to become effective one hundred and twenty (120) days after notice is given;
  - (c) at any time after [\*\*\*] following the First Commercial Sale, annual Net Sales is less than [\*\*\*], with such termination to become effective one hundred and twenty (120) days after notice is given; or
  - (d) the Supply Agreement is terminated, with such termination to become effective on the date on which the Supply Agreement is terminated.
- 9.4 **Termination by Licensee.** Licensee may terminate this Agreement:
- (a) on written notice to Licensor if a material unexpected or new safety concern is reported in compliance with Section 4.3, and the JSC determines such

safety concern is not curable within [\*\*\*], or if such safety concern remains uncured after [\*\*\*]; or

- (b) on written notice to Licensor if the FDA Approval is rejected or revoked after issuance, and the JSC determines that such FDA Approval would not be reasonably expected to issue or re-issue, as applicable, following use of further Commercially Reasonable Efforts for [\*\*\*] by Licensee and Licensor.

#### 9.5 **Effect of Termination or Expiration.**

- (a) **Expiration of Agreement or Termination by Either Party.** If this Agreement expires under Section 9.1 or is terminated by either Party under Section 9.2 to Section 9.4, then:
  - (i) the effects of termination in this Section 9.5(a) are without prejudice to the rights of either Party accrued at the date of the termination and to any right and remedy of either Party in respect of the event(s) leading to the termination;
  - (ii) all rights and licenses granted by either Party hereunder shall terminate;
  - (iii) each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Information of the other Party; *provided* that such Party may keep one (1) copy for archival purposes only subject to a continuing confidentiality obligations;
  - (iv) to the extent permitted by applicable law, Licensee shall promptly assign and transfer to Licensor or such persons as Licensor may designate all of its right, title and interest in (and shall cause its Affiliates and Sublicensees to assign all of their right, title and interest in) the Regulatory Filings and Regulatory Approvals (including the FDA Approval) and Licensee Regulatory Data related to the Licensed Product in the Territory, Licensee Marks for the Licensed Product as of the effective date of the termination and shall take any actions reasonably requested by Licensor to give full effect of such assignment, including making any necessary filings with Regulatory Authorities and transferring to Licensor or its designee any copies of such items in the possession or under control of Licensee or its Affiliates or Sublicensees, *provided* that if any such Regulatory Filings, Regulatory Approval, or Licensee Regulatory Data is not immediately transferrable, Licensee will grant Licensor a non-exclusive and royalty-free right of reference under all other Regulatory Filings and Regulatory Approvals (including the FDA

Approval) or Licensee Regulatory Data, if any, that relate to the Licensed Product in the Territory; and

- (v) Licensee shall be permitted to sell off inventory of the Licensed Product to the extent permitted by applicable laws and the expiration date(s) of such inventory.

9.6 **Survival.** The rights and obligations set forth in this Agreement shall extend beyond the Term or termination of this Agreement only to the extent expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of this Section 9.6 and of Sections 3.4 (for final accounting), 3.5 (for final accounting), 3.6 (for final accounting), 7.2 (with respect to Licensed Product delivered prior to termination), 8.1, 8.2, 8.3 (with respect to Infringement Claims arising during the Term), 8.5 (with respect to claims of infringement or misappropriation occurring during the Term), 8.6 (for the duration of the survival of Sections 8.3 and 8.5) and 9.5, and of Article 1 and the Schedules (to the extent required to give effect to the provisions set forth in this Section 9.6), Article 11, Article 12 (for the period set forth therein), Article 13 and Article 14 shall survive expiration or termination of this Agreement.

## 10. REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 **Mutual Representations, Warranties and Covenants.** Licensor and Licensee each represents and warrants to the other, as of the Effective Date, that:

- (a) **Good Standing.** It is validly existing and in good standing under the applicable laws of the jurisdiction of its incorporation and has the full right, power and authority to enter into this Agreement.
- (b) **No Conflicts.** It is not a party to or otherwise bound by any oral or written contract or agreement that will result in any individual or entity obtaining any interest in, or that would give to any individual or entity any right to assert any claim in or with respect to, any of such Party's rights granted under this Agreement.
- (c) **Authorization.** It has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of such Party. Assuming due authorization, execution and delivery on the part of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.
- (d) **Debarment.** Neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity in connection with the activities to be performed under this Agreement, any individual or entity who has been debarred pursuant to



section 306 of the FDCA or who is the subject of a conviction described in such section.

It will inform the other Party in writing promptly if it or any such individual or entity who is performing activities hereunder is debarred or is the subject of a conviction described in section 306 or if any action, suit, claims, investigation or legal or administrative proceeding is pending or, to its knowledge, is threatened, relating to the debarment or conviction of it or any such individual or entity performing activities hereunder.

10.2 **Representations and Warranties of Licensor.** Licensor represents and warrants to Licensee the following as of the Effective Date:

- (a) All Licensor Patents existing as of the Effective Date (the “**Existing Patents**”) are set forth on Schedule 10.2(a) and are solely and exclusively owned by Licensor. All Existing Patents are subsisting and are not invalid or unenforceable, in whole or in part;
- (b) Licensor is entitled to grant to Licensee the licenses herein and for the purposes set forth in this Agreement herein and to the best of Licensor’s knowledge the Licensor Patents and the Licensor Know-How are valid and enforceable, and are not known to be infringed by any Third Party;
- (c) To Licensor’s knowledge, the exercise of the licenses and rights granted hereunder to Licensee does not infringe on any intellectual property rights of any Third Party;
- (d) Licensor has not received any written claim or demand alleging that (i) the Existing Patents, the Licensor Know-How, the Licensor Marks or any intellectual property right granted by the Third Party under an Existing Agreement that is reasonably necessary or useful for the Licensed Product in the Field in the Territory are invalid or unenforceable in the Territory or (ii) the Development or Commercialization of the Licensed Product as contemplated herein infringes any Patent owned by any Third Party;.
- (e) Licensor and its Affiliates have generated, prepared, maintained and retained all Regulatory Filings that is required to be maintained or retained pursuant to and in accordance with applicable law;
- (f) Licensor, its Affiliates, and its and their respective contractors and consultants have conducted, and with respect to Development occurring after the Effective Date, will conduct, all Development of the Licensed Product in accordance with good laboratory and clinical practice as applicable and applicable laws, including compliance with 21 C.F.R. 50, 54, 56, 58, 812 and similar regulatory or legal obligations outside the United States;
- (g) True, complete and correct (as of the Effective Date) copies of all material adverse information with respect to the safety and efficacy of the Licensed

Product known to Licensor have been provided to Licensee prior to the Effective Date;

- (h) True, complete and correct copies (as of the Effective Date) of (i) the file wrappers and other documents and materials relating to the prosecution, defense, maintenance, validity and enforceability of the Existing Patents and (ii) all license and other agreements regarding any intellectual property rights licensed in the Field hereunder, including the Existing Patents, as amended to the date hereof (the “**Existing Agreements**”), in each case ((i) and (ii)) have been provided to Licensee prior to the Effective Date. All of the Existing Agreements are listed on Schedule 10.2(h);
- (i) The Existing Patents represent all Patents that Licensor or its Affiliates own, Control or otherwise have rights to relating to the Licensed Product or the Commercialization thereof, as of the Effective Date. There is no Information owned by or otherwise in the possession or control of Licensor or any of its Affiliates as of the Effective Date that relates to the Licensed Product in the Field that is not within the Licensor Know-How. All intellectual property rights relating to the Licensed Product or the Commercialization in the Field thereof licensed to Licensor or its Affiliates pursuant to the Existing Agreements are Controlled by Licensor and the rights and obligations of the Parties hereunder are fully consistent with and are not limited by the Existing Agreements, including such that the rights granted to Licensee hereunder to intellectual property licensed pursuant to an Existing Agreement are no more restricted than the analogous rights granted to Licensee hereunder with respect to intellectual property rights wholly owned by Licensor or its Affiliates. No rights or licenses are required under the Existing Patents or Licensor Know-How for Licensee to Commercialize the Licensed Product as contemplated herein other than those granted under Section 2.1;
- (j) Neither Licensor nor any of its Affiliates has previously entered into any agreement, whether written or oral, with respect to or otherwise assigned, transferred, licensed, conveyed or otherwise encumbered its right, title or interest in or to the Existing Patents, Licensor Know-How, Regulatory Filings, or the Licensed Product in the Field (including by granting any covenant not to sue with respect thereto) or any Patent or other intellectual property or proprietary right or Information that would be Existing Patents, Licensor Know-How or Regulatory Filings but for such assignment, transfer, license, conveyance or encumbrance and it will not enter into any such agreements, grant any such right, title or interest to any person during the Term that is inconsistent with or otherwise diminish the rights and licenses granted to Licensee under this Agreement. Without limiting the foregoing, during the Term, Licensor will not (i) commit any acts or permit the occurrence of any omissions that would cause breach or termination of any Existing Agreement or (ii) amend or otherwise modify or permit to be amended or modified, any Existing Agreement; and

- (k) The Commercialization of the Licensed Product as contemplated herein will not be subject to any other license or agreement to which Licensor or any of its Affiliates is a party, other than the Existing Agreements.

10.3 **Representations and Warranties of Licensee.** Licensee represents and warrants to Licensor the following as of the Effective Date (except for any representations and warranties that are expressly stated to have been made as of a specified date, which shall have been true and correct as of such specified date):

- (a) Licensee has the financial resources, and Licensee has itself or through its Affiliates the capabilities and expertise, to (i) Commercialize the Licensed Product and (ii) perform such other obligations assigned to Licensee under this Agreement in compliance with all applicable laws, and Licensee further covenants that it shall continue to maintain such capabilities during the Term; and
- (b) During the Term, Licensee shall continue to use Commercially Reasonable Efforts following receipt of the FDA Approval for the Licensed Product, to Commercialize and launch in the Territory. Licensee shall keep Licensor reasonably and timely informed as to the foregoing efforts and results thereof relating to the Licensed Product in the Territory.

## 11. INDEMNIFICATION; LIMITATION OF LIABILITY

11.1 **Indemnification by Licensee.** Licensee agrees to defend, indemnify and hold Licensor, its Affiliates and their respective officers, directors, employees, consultants, agents, successors and assigns harmless from and against any and all claims, demands, actions, causes of action, judgments, losses, damages, costs and expenses (including attorneys' and expert witness fees and expenses) (collectively "**Losses**") to the extent resulting from any claim, action, suit, proceeding, liability or obligation asserted by a Third Party (collectively, "**Third Party Claims**") arising out of, relating to or resulting from:

- (a) any breach of any representation, warranty, covenant or agreement made by Licensee in this Agreement;
- (b) the gross negligence or willful misconduct of Licensee in connection with Licensee's performance of this Agreement; or
- (c) the post-approval Development activities (to the extent agreed by the Parties) or Commercialization of Licensed Product by or on behalf of Licensee, its Affiliates or Sublicensees in or for the Territory,

except, in each case ((a)-(c)) for those Losses for which Licensor has an obligation to indemnify Licensee pursuant to Section 11.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

11.2 **Indemnification by Licensor.** Licensor agrees to defend, indemnify and hold Licensee and its Affiliates and their respective officers, directors, employees, agents, successors and assigns harmless from and against any and all Losses to the extent resulting from any Third Party Claim arising out of or relating to or resulting from:

- (a) any breach of any representation, warranty, covenant or agreement made by Licensor in this Agreement;
- (b) the gross negligence or willful misconduct of Licensor in connection with Licensor's performance of this Agreement; or
- (c) the Development or Manufacture of Licensed Product by or on behalf of Licensor, its Affiliates, or their respective sublicensees and collaborators or the Commercialization of Licensed Product by or on behalf of Licensor, its Affiliates, or their respective sublicensees and collaborators outside the Field or outside the Territory,

except, in each case ((a)-(c)) for those Losses for which Licensee has an obligation to indemnify Licensor pursuant to Section 11.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

11.3 **Indemnification Procedures.**

- (a) **Notice of Claim.** All indemnification claims in respect of a Party, its Affiliates, or its or their sublicensees or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 11; *provided* that no failure or delay in providing such notice shall relieve the indemnifying Party of any liability it may have to the Indemnified Party, except to the extent that such failure or delay materially prejudices the indemnifying Party with respect to such claim. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.
- (b) **Control of Defense.** The indemnifying Party shall have the right to assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [\*\*\*] after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an

acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification.

Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 11.3(c), the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify the Indemnified Party from and against such Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all reasonable and verifiable costs and expenses (including attorney's fees and costs of suit) and any Losses incurred by the indemnifying Party in accordance with this Section 11.3(b) in its defense of the Third Party Claim.

- (c) **Right to Participate in Defense.** Any Indemnified Party shall be entitled to participate in the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided, however*, that such employment shall be at the Indemnified Party's sole cost and expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing (in which case, the defense shall be controlled as provided in Section 11.3(b)), (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 11.3(b) (in which case the Indemnified Party shall control the defense), or (iii) the interests of the indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under applicable law, ethical rules or equitable principles (in which case, the Indemnified Party shall control its defense).
- (d) **Settlement.** With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the applicable indemnitee(s) becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in

connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 11.3(b), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; *provided* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

- (e) **Cooperation.** Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided.
- (f) **Expenses.** Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed [\*\*\*] by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

11.4 **Insurance Recovery.** Any indemnification hereunder shall be made net of any insurance proceeds actually recovered by the Indemnified Party from unaffiliated Third Parties; *provided, however*, that if, following the payment to the Indemnified Party of any amount under this Article 11, such Indemnified Party recovers any such insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such net indemnification payment) to the indemnifying Party.

11.5 **LIMITATION OF LIABILITY.** EXCEPT AS EXPRESSLY SET OUT IN THIS AGREEMENT OR THE SUPPLY AGREEMENT, NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE BEACH OF STATUTORY DUTY OR OTHERWISE FOR ANY

SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY CURRENT OR FUTURE POTENTIAL ECONOMIC LOSS, OR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT (A) IN THE EVENT OF THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY OR (B) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 11.

## 12. CONFIDENTIALITY

- 12.1 **Duty of Confidence.** Subject to the other provisions of this Article 12, all Information disclosed by a Party or its Affiliates under or in connection with this Agreement, whether prior to, on or after the Effective Date, shall be maintained in confidence and otherwise safeguarded by the recipient Party. The recipient Party may only use Information of the other Party for the purposes of this Agreement and pursuant to the rights granted to the recipient Party under this Agreement. Subject to the other provisions of this Article 12, each Party will hold as confidential such Information of the other Party or its Affiliates in the same manner and with the same protection as such recipient Party maintains its own confidential information. A recipient Party may disclose Information of the other Party to employees, agents, contractors, consultants and advisor of the Party, its Affiliates and sublicensees to the extent reasonably necessary for the purposes of this Agreement, *provided* that such persons are bound to maintain the confidentiality of the Information in a manner consistent with the confidentiality provisions of this Agreement. Notwithstanding the foregoing, (a) the terms of this Agreement and (b) Licensor Know-How related to the Licensed Product in the Field in the Territory that is exclusively licensed to Licensee hereunder shall in each case ((a) and (b)) be deemed to be the Information of both Parties (and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto); *provided* that in the case of clause (b), (i) Licensor shall have the right to use and disclose (subject to customary confidentiality obligations) such Information outside the Territory or outside the Field consistent with its customary practices, and (ii) Licensee shall have the right to use and disclose such Information solely to the extent required for Licensee's exercise and performance of its rights and obligations under this Agreement or the Supply Agreement.
- 12.2 **Exclusions.** Information does not include information that (a) was known to the receiving Party prior to receipt from the disclosing Party as evidenced by the receiving Party's records; (b) is or becomes (at time of disclosure) part of the public domain through no breach of this Agreement by the receiving Party; (c) is lawfully received by the receiving Party from a Third Party that is not bound by any obligations of confidentiality with respect to such information; or (d) comprises identical subject matter to that which had been originally and independently developed by or for the receiving Party without knowledge or use of any Information as evidenced by written records.

- 12.3 **Permitted Disclosures.** Notwithstanding the foregoing, the receiving Party may disclose the Information of the disclosing Party (a) as and to the extent required by the order of any governmental authority of competent jurisdiction; *provided* that the receiving Party shall, to the extent permitted by applicable law, use reasonable efforts to notify the disclosing Party of such proposed disclosure in such a manner and on such a schedule as will afford the disclosing Party a reasonable opportunity to seek a protective order or similar restriction on disclosure of the disclosing Party's Information proposed to be disclosed by the receiving Party, (b) as required by applicable law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make a disclosure that describes or refers to the terms and conditions of this Agreement or any related agreements between the Parties, (c) to the extent that such disclosure is made to Regulatory Authorities as deemed reasonably necessary by the receiving Party in connection with any filing, application, or request for Regulatory Approval, response to any requests or inquiries from a Regulatory Authority, or other communication with a Regulatory Authority, and (d) to prospective acquirers, lenders, investors, collaboration partners, and sublicensees that agree to be bound by non-use and non-disclosure obligations no less onerous than those under this Agreement in respect of such Information.
- 12.4 **Press Releases and Other Announcements.** The Parties have agreed upon the content of press releases which shall be issued substantially in the form attached hereto as Schedule 12.4, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Neither Party shall issue any other press release or otherwise make a public announcement concerning the subject matter of this Agreement without the prior review and written approval of the text of any such press release or other public announcement by the other Party. The other Party shall not unreasonably withhold or delay such review and approval.
- 12.5 **Publications.** The Parties recognize the desirability of publishing and publicly disclosing the results of and information regarding, activities under this Agreement. Accordingly, Parties shall be free to publicly disclose the results of and information regarding, activities under this Agreement, subject to prior review and consent by the other Party of any disclosure of the other Party's Information. Accordingly, prior to publishing or disclosing any of the other Party's Information, Parties shall provide the other Party with drafts of proposed abstracts, manuscripts or summaries of presentations that cover such Information for the other Party's approval. Parties shall respond promptly through its designated representative and in any event no later than [\*\*\*] after receipt of such proposed publication or presentation.
- 12.6 **Duration.** Except as otherwise provided herein, the restrictions and covenants set forth in this Article 12 shall survive until [\*\*\*]; *provided, however*, that with respect to Information that constitutes a trade secret under applicable law, the receiving Party's obligations pursuant to this Article 12 shall survive so long as such Information remains a trade secret under applicable law.



### 13. FORCE MAJEURE

13.1 **Force Majeure Event.** In the event that either Party is prevented from performing its obligations under this Agreement as a result of any contingency beyond its reasonable control and without fault or negligence of such Party (“**Force Majeure**”), including but not limited to, acts of God, natural disasters, energy shortages, fire, flood, severe storm, earthquake, pandemic, civil disturbance, lockout, riot, order of any court or administrative body, embargo, acts of government, war (whether or not declared), acts of terrorism, or other similar causes, the Party immediately affected thereby will give prompt written notice to the other Party specifying the Force Majeure event complained of, and such affected Party shall not be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement to the extent caused by an even of Force Majeure, *provided* that such Party will use reasonable efforts to resume performance of its obligations. Under no circumstance will an event of Force Majeure excuse a Party’s obligations to make payments when due under this Agreement, unless such Force Majeure event results in a failure of the banking system that deprives a Party’s access to available funds. The Parties shall use their reasonable endeavors to:

- (a) overcome the effects of the Force Majeure;
- (b) mitigate the effect of any delay occasioned by any Force Majeure, including by recourse to alternative mutually acceptable (which acceptance shall not be unreasonably withheld by either Party) sources of services, equipment and materials; and
- (c) ensure resumption of normal performance of this Agreement as soon as reasonably practicable and shall perform their obligations to the maximum extent practicable, *provided* that neither Party shall be obliged to settle any strike, lock out, work stoppage, labor dispute or such other industrial action by its employees.

### 14. MISCELLANEOUS

14.1 **Assignment.** Neither Party shall assign any of its rights or delegate any of its obligations hereunder without the prior written consent of the other Party; *provided, however*, that either Party may assign its rights or delegate its obligations, in whole or in part, without such consent (but with written notice to the other Party), to one (1) or more of its Affiliates or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to or acquisition of all or substantially all of the business to which the Agreement relates; *provided* that such successor in interest does not have a Competing Program. The assigning Party will remain responsible for the performance by its assignee of any obligation hereunder so assigned. Any purported assignment or transfer in violation of this Section 14.1 will be void and of no force and effect.

- 14.2 **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of any applicable bankruptcy or insolvency law in the Territory or where a Party is situated (collectively, the “**Bankruptcy Laws**”), licenses of rights to “**Intellectual Property**” as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee), shall provide to the other Party copies of all Information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party’s written request therefor. All rights, powers and remedies of the non-bankrupt or non-insolvent Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.
- 14.3 **Governing Law and Venue.** This Agreement will be governed by and construed under the laws of State of Delaware without regard to conflicts or choice of law rules or principles that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.
- 14.4 **Dispute Resolution.**
- (a) **Dispute Resolution.** Except for disputes to be resolved by the procedures set forth in Section 6.5, in the event of a dispute arising out of or relating to this Agreement, either Party may provide written notice of the dispute to the other, in which event the dispute shall be referred to the Senior Officers of each Party for attempted resolution by good faith negotiations within [\*\*\*] after such notice is received. In the event the Senior Officers do not resolve such dispute within the allotted [\*\*\*], either Party may, after the expiration of the [\*\*\*] period, seek to resolve the dispute through arbitration in accordance with Section 14.4(b).
- (b) **Claims.**
- (i) **Arbitration.** Any unresolved disputes between the Parties relating to, arising out of or in any way connected with this Agreement or any term or condition hereof, or the performance by either Party of

its obligation hereunder, whether before or after termination of this Agreement, will be resolved by final and binding arbitration. Disputes shall be resolved by final and binding arbitration by a panel of experts with relevant industry experience (the “**Arbitrators**”). The arbitration process will be conducted expeditiously in accordance with the Commercial Arbitration Rules then in force (the “**AAA Rules**”) of the American Arbitration Association or any successor entity (the AAA). Arbitration will take place in New York City.

- (ii) **Arbitrators’ Award.** The Arbitrators shall endeavor, within [\*\*\*] after the conclusion of the arbitration hearing, to issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and binding, and judgment may be entered upon it in accordance with applicable law in any court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.
- (iii) **Compliance with this Agreement.** Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding.
- (iv) **Injunctive or Other Equity Relief.** Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.
- (v) **Confidentiality.** All arbitration proceedings and decisions of the Arbitrators under this Section 14.4(b) shall be deemed the Information of both Parties.

14.5 **Waiver; Amendments; Non-Exclusion of Remedies.** The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver will be effective unless it has been given in writing and signed by the Party giving such waiver. This Agreement may not be modified or amended except in a writing signed by a duly authorized officer or representative of each Party. The

rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable law or otherwise available except as expressly set forth herein.

- 14.6 **Severability.** If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.
- 14.7 **Relationship of the Parties.** It is expressly agreed that Licensor, on the one hand, and Licensee, on the other hand, shall be independent contractors and that the relationship between the Parties shall not constitute or give rise to an employer-employee, partnership, joint venture or agency relationship. Neither Licensor, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other Party without the prior written consent of the other Party to do so and each Party's performance hereunder is that of a separate, independent entity.
- 14.8 **Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, or sent by email, addressed as follows:

(a) if to Licensor, addressed to:

Attention: [\*\*\*]

Address: 8F-6, No. 57, Fuxing N. Rd., Songshan Dist., Taipei City 105, Taiwan

Email: [\*\*\*]

with copy to: Tsar & Tsai Law Firm

Address: 11F., No. 100, Songren Rd., XinyiDist., Taipei City 11073, Taiwan (R.O.C.)

Attention: Lynn Lin

Email: [\*\*\*]

(b) if to Licensee, addressed to:

Attention: [\*\*\*]

Address: 295 Madison Ave., Suite 2400, New York, NY 10017

Email: [\*\*\*]

With copy to: Covington & Burling LLP

Address: The One International Place, Suite 1020, Boston, MA 02110-2627

Attention: Megan Gates

Email: [\*\*\*]

Or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (i) on the date of delivery if delivered in person, (ii) on the Business Day after dispatch if sent by nationally-recognized overnight courier, (iii) on the [\*\*\*] following the date of mailing, if sent by mail, or (iv) [\*\*\*] after the time sent (as recorded on the device from which the sender sent the email), unless the sender receives an automated message that the email has not been delivered.

- 14.9 **Further Assurance.** Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.
- 14.10 **Counterparts.** This Agreement may be executed in any number of counterparts, by original or electronic (including “pdf”) signature, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.
- 14.11 **Change of Control.** Licensee may not undertake a Change of Control without the prior written consent of Licensor. Licensor shall have the right to request adjustment to terms and conditions under this Agreement including terms of Article 3 and Article 7 as a condition to give consent to the proposed Change of Control of Licensee. Licensee shall enter into good-faith negotiations with Licensor without undue delay on Licensor’s proposed adjustments upon Licensor’s request. In the

case of a permitted Change of Control, Licensee shall ensure continued performance of its obligations under this Agreement in accordance with its terms and conditions (as adjusted if requested by Licensor hereunder) by the applicable purchaser or surviving entity after the Change of Control.

- 14.12 **Language.** The language of this Agreement and all activities to be pursued under this Agreement is English. Any and all documents proffered by one Party to the other in fulfillment of any provision of this Agreement shall only be in compliance if in English. Any translation of this Agreement in another language shall be deemed for convenience only and shall never prevail over the original English version. This Agreement is established in the English language.
- 14.13 **Third Parties.** None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party which shall be a Third Party beneficiary to this Agreement.
- 14.14 **Subscription Agreement.** As a condition to the issuance of the Common Stock pursuant to Article 3 hereof, Licensee and Licensor shall enter into the subscription agreement attached hereto as Exhibit A (the “**Subscription Agreement**”).
- 14.15 **Entire Agreement.** This Agreement, the Supply Agreement, Quality Agreement and Pharmacovigilance Agreement and the Subscription Agreement, together with their Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including [\*\*\*]. In the event of any conflict between a substantive provision of this Agreement and any Schedule hereto, the substantive provisions of this Agreement will prevail.
- 14.16 **Interpretation.** The captions to the several Articles and Sections of this Agreement are not a part of this Agreement but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) the word “or” means “and/or” unless the context dictates otherwise because the subject of the conjunction are mutually exclusive; (c) the words “herein,” “hereof” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Article or Section or other subdivision; (d) references in this Agreement to “days” shall mean calendar days; (e) the singular shall include the plural and vice versa; and (f) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP consistently applied, but only to the extent consistent with its usage and the other definitions in this Agreement.
- 14.17 **Costs.** Except as is otherwise expressly set forth herein, each Party shall bear its own expenses in connection with the activities contemplated and performed hereunder.

**[Signature Page Follows]**

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

Formosa Pharmaceuticals Inc.

By: /s/ Erick Co

Name: Erick Co

Title: President and Chief Executive Officer

Eyenovia, Inc.

By: /s/ Michael Rowe

Name: Michael Rowe

Title: Chief Executive Officer

SIGNATURE PAGE TO LICENSE AGREEMENT

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

Date: November 13, 2023

/s/ Michael Rowe

Name: Michael Rowe

Title: Chief Executive Officer

(Principal Executive Officer)

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

Date: November 13, 2023

/s/ John Gandolfo

Name: John Gandolfo

Title: Chief Financial Officer

(Principal Financial Officer)

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

In connection with this Quarterly Report of Eyenovia, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2023, 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: November 13, 2023

/s/ Michael Rowe

\_\_\_\_\_  
Name: Michael Rowe

Title: Chief Executive Officer  
(Principal Executive Officer)

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

In connection with this Quarterly Report of Eynovia, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2023, 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: November 13, 2023

/s/ John Gandolfo

Name: John Gandolfo

Title: Chief Financial Officer  
(Principal Financial Officer)

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